Supporting Statement – Part A

Reform of Requirements for Long-Term Care Facilities
(OMB Control Number 0938-1363) CMS-10573

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of this updated collection of information requirements for the requirements of participation for Long-Term Care (LTC) facilities that must be met to participate in the Medicare and Medicaid Programs.

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

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

The ICRs covered in this package do not require a standard form or survey instrument, except for §483.80(d)(3)(iv). 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 (ICRs) 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 this OMB submission, we are revising the information collection request to add information collection requirements for the nursing services requirements at §483.35 and revise the existing information collection requirements for the facility assessment requirements at §483.70(e) (new §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). In this final rule, we revised the LTC requirements for participation to establish minimum nurse staffing requirements for LTC facilities. This rule also finalized new requirements for LTC facilities to incorporate the input of facility staff and their representatives into their facility assessments and to develop and maintain a plan to maximize recruitment and retention of direct care staff.

B. Justification

1. Need and Legal Basis

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

2. Information Users

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

3. Use of Information Technology

LTC facilities may use health information technologies (HIT) to store and manage records, consistent with statutory and regulatory requirements for record keeping and confidentiality. Use of certified HIT technology is encouraged but not required, as some facilities, particularly small or rural facilities, may not have electronic capacity at this time. Facilities are free to take advantage of any technology advances they find appropriate for their needs.

4. Duplication of Efforts

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

5. Small Businesses

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

6. Less Frequent Collection

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

7. Special Circumstances

There are no special circumstances for collecting this information.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice of the Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting proposed rule (CMS-3442-P) published on September 6, 2023 (88 FR 61352). We received a few comments regarding the Collection of Information section. Those comments were addressed in the final rule (CMS-3442-F) that was published on May 10, 2024 (89 FR 40876, 40935- 40939).

The 60-day Federal Register notice published on April 16, 2024 (89 FR 26892). There were two public comments received. One comment was from a therapist that expressed concerns regarding LTCFs being more concerned about making profits than providing the care their residents need. While profits rise, negative outcomes for residents, such as falls, pressure ulcers, and urinary tract infections (UTIs) increase. The other comment was from a professional organization for individuals in the fields of infection control and epidemiology concerned about burden and staffing. They wanted infection preventionists (IPs) included in the estimated burden and an estimate for the opportunity cost of not having a full-time IP in each LTC facility.
The comments were addressed in the attached response to comments document and did not result in changes to the information collection.

The 30-day Federal Register notice published July 26, 2024 (89 FR 60427).

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents.

10. Confidentiality

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

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

In analyzing information collection costs, we rely heavily 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/current/oes_nat.htm. Furthermore, where applicable, the wage information for each occupation was pulled from the BLS industry category "nursing care facilities (skilled nursing facilities)." Based on this information, we have

calculated the estimated adjusted hourly rates for the LTC requirements 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 those rules issued prior to 2023 (as outlined in Table 3). 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 the rules issued in 2023 and after (as outlined in Table 2). 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.

Table 1 - Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages for Those Rules Issued prior to 2023

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
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	Social Worker	$26.69	$53

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
	Workers (Nursing Facilities/Skilled Nursing Facilities)			
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 - Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages for Those Rules Issued in 2023 and After

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1229	Physicians, All Others (Specialty (except Psychiatric and Substance Abuse)	Medical Director,	$135.86	$272
29-1141	Registered Nurses (Nursing Facilities/Skilled	Registered Nurse (RN), Infection Preventionist (IP)	$37.11	$74

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
	Nursing Facilities)			
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 Facilities)	Nurse Aide/Certified Nursing Assistant (CAN)	$16.90	$34
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

This PRA package covers all rulemaking that created ICRs for LTC facilities up to and including those in effect as of May 2024. Table 3 below indicates the specific ICRs and proposed rule, final rule, or interim final rule with comment (IFC) that created the ICRs with the rule's Federal Register (FR) citation. Table 5 below indicates the burden hours and costs of the ICRs created in the rules indicated in Table 3.

Table 3 - ICRs and Estimated Costs Associated with Each Rule

Rule Name	FR Citation	ICR
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Final rule (CMS-3260-F) (2016 Final Rule) Published October 4, 2016	81 FR 68688	All ICRs, except as noted below.
Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; IFC (CMS-3401-IFC) (September 2020 Testing IFC) Published September 2, 2020	85 FR 54820	Section 483.80(h) – COVID-19 Testing
Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff; IFC (CMS-3414-IFC) (May 2021 Vaccination IFC) Published May 13, 2021	86 FR 26306	Sections 483.80(d)(3) – COVID-19 immunizations
Medicare and Medicaid Programs: CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities (86 FR 62240) (CMS -1747—F and	86 FR 62240	Section 483.80(g)

Rule Name	FR Citation	ICR
CMS-5531-F). Published November 9, 2021		
Medicare and Medicaid Programs; Minimum Staffing Standards for Long Term Care Facilities and Medicaid Institutional Payment Transparency Reporting	89 FR 40876	Section 483.35- Nursing Services, §483.70(e)-Administration, which is the new §483.71 Facility Assessment

In the last approved 2023 PRA package, we used 15,372 LTC facilities and 1,290,290 residents to inform our burden assumptions and estimates. Since the number of LTC facilities and residents varies yearly, for the purposes of this package update for those new ICRs discussed in §483.35, 483.70(e), and §483.71, we utilize the estimate of 14,688 for LTC facilities, which aligns with the assumptions used in the most recent proposed rule (CMS-3244-P) that this update is based on.

A. §483.10 Resident Rights

§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 per resident, to obtain a resident signature. We estimate that this may occur up to four times per year per resident. Based on an estimated 1.3 million residents per year, the resulting burden hours are 173,333 (1,300,000 X .1333 ((2 ÷ 60 or 0.03333) x 4)). The cost is $11,959,977 (173,333 x $69).

§483.10(f)(4)(v) through 483.10(f)(4)(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.[1] 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).

§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 (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 per resident of a social worker's time to provide the notice and communicate with the resident. Hence, for each notification, it would require 5 minutes or 0.0833 hours at a cost of $4 (0.0833 x $53). The annual burden for all 15,600 facilities would be 21,658 burden hours (0.0833 x 260,000 residents) at a cost $1,147,874 (21,658 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

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1 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.

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).

B. §483.15 Admission, Transfer, and Discharge Rights

§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 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 cost of $94 would prepare the notice and this would require 10 minutes or 0.1667 hours. 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 or 0.0833 hours to forward a copy of the notice to the OSLTCO. 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 burden for these notices for all 15,600 LTC facilities is 107,250 hours (0.25 (0.1667 + 0.0833) hours x 429,000) at a cost of $8,151,000 (0.1667 x $94 or $16) + (0.0833 x $38 or $3) = $19 x 429,000).

C. §483.21 Comprehensive Resident-Centered Care Planning

§483.21(a) Baseline care plan

Section 483.21(a) 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.[2] Of that number, approximately 60 percent of those admissions or 2,909,827 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 15,600 LTC facilities would be 2,909,827 hours at a cost of $200,778,063 (2,909,827 x $69).

§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

2 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.

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 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 hour, 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 hours x 4 meetings) annually at a cost of $1,752 (4 x $438). The burden for all 1,300,000 residents in the 15,600 LTC facilities would be 20,800,000 hours (1,300,000 x 16) at a cost of $2,277,600,000 (1,300,000 x $1,752).

§483.21(c) Discharge Planning Process

We note that the Discharge Planning Final rule (84 FR 51836) does not cover LTC Facilities. 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.

Regarding the discharge planning, §483.21(c)(1)(ix) requires that the resident's medical record be documented with the IDT's evaluation of the resident's discharge needs and discharge plan. 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.

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 about one-third of the estimated 1,300,000 or 429,000 residents would require a discharge summary annually. Thus, the burden for all 15,600 LTC facilities would be 429,000 hours (1,300,000 x .33) at an estimated cost of $29,601,000 (429,000 x $69).

D. §483.25 Quality of Care

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 at a cost of about $12 ($69 x .1667) to discuss this information with the new resident or resident representative. As noted above, we have estimated that there are 2,909,827 new residents admitted annually to LTC facilities. Hence, the total burden for all 15,600 LTC facilities is 485,068 hours (2,909,827 x 0.1667) at a cost of $33,469,692 (485,068 x $69).

E. §483.35 Nursing Services

At § 483.35(b), each LTC facility must have to provide services by sufficient numbers of each of the following types of personnel identified in this section on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans. Except when exempted in accordance with the criteria outlined at §483.35(h), licensed nurses, including but not limited to 0.55 hours per resident day of registered nurses; and other nursing personnel, including but not limited to 2.45 hours per resident day of NAs. Except when waived in accordance with sections 483.35(f), (g), and (h), each LTC facility must also have a RN on site 24 hours per day, for 7 days a week that is available to provide direct resident care. These requirements require each LTC facility to review and modify, as necessary, its policies and procedures regarding nurse staffing. We believe the review and modifications to the necessary policies and procedures would require activities by the DON, an administrator, and an administrative assistant. The DON and the administrator need to review the requirements, as well as the facility assessment, to determine if any changes are necessary to the policies and procedures and, if so, make those necessary changes. The DON would then need to work with a medical administrative assistant to ensure that those changes were made to the appropriate documents and ensure that all appropriate individuals in the facility were made aware of the changes. We estimate that these activities require 8 burden hours for an administrator at a cost of $800 ($100 × 8), 7 hours for the DON at a cost of $700 ($100 × 7), and 4 hour for the administrative assistant at a cost of $164 ($41 × 4). Hence, for each LTC facility the burden estimate would be 19 hours (8 + 7 + 4) at a cost of $ 1,664 ($800 + $700 + $164). There are currently 14,688 LTC facilities. Thus, the burden for all LTC facilities is 279,072 (14,688 × 19) hours at a cost of $24,440,832 ($1,664 × 14,688 LTC facilities).

F. §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).t.

G. §483.60 Food and Nutrition Services

Under the food safety requirements at CFR 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.

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 x $62). For all 15,600 LTC facilities, the burden would be 31,200 hours (2 x 15,600) at a cost of $1,934,400 (31,200 x $62).

H. §483.70 Administration

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.

Section 483.70(e) 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.

I. §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.

In the previous PRA package, we included a one-time burden for developing the initial facility assessment. We also indicated LTC facilities would be required to review and update their facility assessment as necessary and 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).

We relocated current § 483.70(e)(1) (i) through (v) to § 483.71(a)(1)(i) through (v). This section 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.

We relocated the current requirements at § 483.70(e)(2)(i) through (vi) to § 483.71(a)(2)(i) through (vi). 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.

We propose to add a new requirement at § 483.71(a)(4) for LTC facilities to incorporate the input of facility staff and their representatives into their facility assessment. These staff categories include, but are not limited to, nursing home leadership, management, direct care staff and representatives and other service workers. 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.

A new section, §483.71(b) 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 of the nursing categories, an RN, LPN/LVN, and 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 administrator at a cost of $1,000 ($100 × 10); 10 hours for the DON at a cost of $1,000 ($100 × 10); 8 hours for a registered nurse at a cost of $592 ($74 × 8); 4 hours for a LPN/LVN at a cost of $224 ($56 × 4); 5 hours for a nursing assistant at a cost of $170 ($34 × 5); and, 3 hours for an administrative assistant $123 ($41 x 3). Thus, the burden for each LTC facility is 40 (10 + 10 + 8 + 4 + 5 + 3) hours 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 (14,688 LTC facilities x 40) at an estimated cost of $45,664,992 ($3,109 × 14,688 LTC facilities).

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 a 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 administrator 1 hour at $100 per hour ($100 × 1 hour = $100) to draft the text of the communication and then an administrative assistant 2 hours at $41 per hour ($41 × 2 hours = $82) 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 (1 + 2 = 3) at an estimate cost of $182 ($100 + $82). For all 14,688 LTC facilities, the total estimated burden is 44,064 hours (14,688 LTCFs × 3 hours) at a cost of $2,673,216 ($182 × 14,688 LTCFs).

J. §483.75 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 adjusted hourly costs: the DON at $94; the Medical Director at $276; the IP at $69; an administrator at $94; a staff nurse at $69; and a nursing aide at $31. The burden for each LTC facility would be 48 burden hours (2 x 6 x 4) at an estimated cost of $5,064 (2 x ($94 + $276 + 69 + 94 + 69 + 31 = $633)) x 4). The burden for all 15,600 LTC facilities would be 748,800 hours (15,600 x 48) at an estimated cost of $78,998,400 (15,600 x $5,064).

K. 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.

A. Section 483.80(a) Infection Prevention and Control Program.

Section 483.80 requires a facility to establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment with the goal of preventing and controlling 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. 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 3 hours annually to document the IPCP program. Based upon our experience with LTC facilities, we are revising that estimate.

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). They should have at least one IP who is responsible for the LTC facility's IPCP, which must be maintained, and works at least part-time at the facility. Upon review, we believe that 3 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. We estimate that this would require an average of 10 hours a month or 120 hours annually for the IP to perform all of the documentation for the LTC facility's IPCP. According to Table 1 above, the adjusted hourly wage for an IP is $69. Thus, for each LTC facility the annual burden would be 120 hours (10 hours x 12 months) at an estimated cost of $8,280 (120 hours x $69). For all 15,600 LTC facilities, the annual burden would be 1,872,000 hours (120 hours x 15,600 facilities) at an estimated cost of $ 129,168,000 (15,600 facilities x $8,280).

1. ICRs regarding the development of policies and procedures for § 483.80(d)(3).

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 on 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. These facilities also need to review the policies and procedures to ensure they are up-to-date and make any necessary changes. We believe these activities would be performed by the infection preventionist (IP), director of nursing (DON), and medical director in the first year and the IP in subsequent years as analyzed below.

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. For the IP, we estimate that this would require 10 hours initially to develop the policies and procedures, and one hour a month thereafter to review and

make changes or updates as needed, for a total of 21 hours (10 hours initially and 1 hour for the 11 months thereafter). According to Table 1 above, the IP's adjusted hourly cost is $69. Thus, for each LTC facility the burden for the IP would be 21 hours at a cost of $1,449 (21 hours x $69). For the IPs in all 15,600 LTC facilities, the burden would be 327,600 hours (21 hours x 15,600 facilities) at an estimated cost of $22,604,400 ($1,449 x 15,600). For subsequent years, the IP would need to review the policies and procedures and make any updates or changes to them. Hence, we estimate that the IP would need 12 hours annually (1-hour x 12 months) at a cost of $828 (12 hours x $69). For all LTC facilities, the annual burden would be 187,200 hours (12 x 15,600) at a cost of $12,916,800 (15,600 x $828).

As discussed above, the development and approval of these policies and procedures would also require activities by the medical director and the DON. Both the medical director and the DON would need to have meetings with the IP to discuss the development, evaluation, and approval of the policies and procedures. We estimate that this would require 4 hours for both the medical director and DON. According to Table 1 above, the adjusted hourly cost for a medical director is $276. For each LTC facility, this would require 4 hours for the medical director during the first year at an estimated cost of $1,104 (4 hours x $276). For the first year, the burden would be 62,400 (4 x 15,600) at an estimated cost of $17,222,400 ($1,104 x 15,600). For subsequent years, the medical director might need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the medical director associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

For the DON, we have estimated that the development of policies and procedures would also require 4 hours. According to the chart above, the total hourly cost for the DON is $94. The burden in the first year for the DON in each LTC facility would be 4 hours at an estimated cost of $376 (4 hours x $94). The first-year burden would be 62,400 hours (4 x 15,600) at an estimated cost of $5,865,600($376 x 15,600). For subsequent years, the DON would likely need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the DON associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Therefore, for each LTC facility the burden for the first year would be 29 (21 + 4 + 4) hours at a cost of $2,929 ((21 x $69 = $1,449) + (4 x $276 = $1,104) + (4 x $4 = $376)). For all 15,600 LTC facilities in the first year, the estimated burden for this ICR would be 452,400 hours ((21 x 15,600 = 327,600) + (4 x 15,600 = 62,400) + (4 x 15,600 = 62,400)) at a cost of $45,692,400 ($2929 x 15,600).

The annual burden for this ICR would require that IP to review the policies and procedures to ensure they are up-to-date and make any changes, if necessary. Hence, we estimate that the IP would need 12 hours annually (1-hour x 12 months) at a cost of $828 (12 hours x $69). For all LTC facilities, the annual burden would be 187,200 hours (12 x 15,600) at a cost of $12,916,800 (15,600 x $828).

2. ICRs regarding LTC Facilities offering the COVID-19 vaccine and obtaining and documenting consent for § 483.80(d)(3)(ii) to (iv).

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.

As indicated in the next section, the facility must also ensure that the provision of the education and the resident's decision must be documented in the resident's medical record. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's chart. Documentation regarding a resident's medical care is a 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).

3. ICRs regarding staff education requirements in § 483.80(d)(3)(ii) through (iv).

At § 483.80(d)(3)(ii), we require that the LTC facility provide all of its staff with education regarding the benefits and potential risks of the COVID-19 vaccine. This would require that the LTC facility develop or choose educational materials for this staff training. We expect that most if not all LTC facilities will use resources developed by other entities as there is a considerable amount of free information on COVID-19 and vaccines available online. The CMS Nursing Home COVID-19 training program has five modules designed for the frontline clinical staff and ten modules for nursing home management staff (building maintenance staff and other support staff would not take these particular courses). The training is online, at http://QSEP.cms.gov, and is summarized in a CMS press release that can be found at https://www.cms.gov/newsroom/press-releases/cms-releases-nursing-home-covid-19-training-data-urgent-call-action. In addition, both CDC and FDA provide information on the COVID-19 vaccines online.[3, 4] Finally, we expect that trade publications and other public sources would provide training materials that might complement or substitute for the CMS materials. We believe this educational material would likely be selected by the IP. The IP would need to review the information available on the vaccines, determine what information needs to be presented to staff, and gather that information as appropriate for their facility's staff. We estimate that it would take an average of 4 hours for the IP to accomplish these tasks. Thus, for each LTC facility to meet this requirement would require 4 burden hours at an estimated cost of $276 (4 x $69). For all 15,600 LTC facilities, the burden would be 62,400 burden hours (4 x 15,600) at an estimated cost of $4,305,600 (15,600 facilities x $276).

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3 CDC. Communication Resources for COVID-19 Vaccines. Access at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html. Updated March 16, 2021. Accessed on March 23, 2021.
4 FDA. COVID-19 Vaccines. Access at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines. Updated March 18, 2021. Accessed on March 23, 2021.

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.

At § 483.80(d)(3)(iv), we require that the LTC facility must provide to the staff, resident, or the resident representative, in situations where the vaccination process requires one or more doses of vaccine, 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, before requesting consent for administration of each additional vaccinations. 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 this would require 6 hours of an IP's time annually. Thus, for each LTC facility to meet this requirement would require 6 burden hours at an estimated cost of $414 (6 x $69). For all LTC facilities, the annual burden would be 93,600 (6 hours x 15,600 facilities) hours at an estimated cost of $6,458,400 (15,600 x $414). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities.

4. ICRs regarding the documentation requirements in § 483.80(d)(3)(vi) and (vii).

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. 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 but estimate no burden as maintaining a medical record is a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

The LTC facility would also be required to document that the required education was provided to its staff that must include the benefits and potential risks associated with of the COVID-19 vaccine as set forth in § 483.80(d)(3)(ii). Section 483.80(d)(3)(vii) sets forth that the LTC facility must maintain documentation on its staff regarding the education provided; that the staff person was offered the COVID-19 vaccine or information on obtaining the vaccine; and his or her vaccine status and related information as indicated by the NSHN. This would require that a staff person document the required information in the staff person's record. We estimate that this would require one half-hour per month per facility. According to Table 1 above, the total hourly cost of an administrative assistant is $38. For each LTC facility, we estimate that the annual burden for this activity would be 6 hours at an estimated cost of $228 (6 x $38). For all LTC facilities, this would require 93,600 (6 x 15,600) burden hours at an estimated cost of $3,556,800(15,600 x $228). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities.

5. ICRs regarding the reporting requirements to CMS and CDC (NHSN) § 483.80(g).

The ICRs in § 483.80(g) were finalized on November 9, 2021 in a final rule entitled, "Medicare and Medicaid Programs: CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements;, Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities (86 FR 62240) (CMS-1747—F and CMS-5531-F) (November 2021 FR). Section 483.80(g)(1) – (3) requires LTC facilities to electronically report the following information about COVID-19 in a standardized format to the NHSN weekly, unless otherwise specified by the Secretary: the suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies in the facility; resident beds and census; access to COVID-19 testing while a resident is in the facility; staffing shortages; and the COVID-19 vaccine status of residents and staff, including the total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events. Section 483.80(g)(3) requires that the LTC facility must also inform its residents, their representatives, and the families of those residing at the facility by 5 p.m. the next calendar day following the occurrence of either a single confirmed COVID-19 infection or three or more residents or staff with new-onset respiratory symptoms within 72 hours of each other. The information must not include personally identifiable information; include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified or whenever three or more resident or staff with new onset of respiratory symptoms occur within 72 hours of each other.

This section also includes a sunset date of December 31, 2024 for all requirements, except for (g)(1)(viii) that requires the LTC facility to report the COVID-19 vaccine status of residents and staff.

The ICRs in this section require that the IP update the policies and procedures for the LTC facility's IPCP to comply with the requirements in this section. The IP earns an adjusted hourly wage of $69. We estimate that it would require 1 hour of the IP's time to update the required policies and procedures to comply with the changes in this rule. For each LTC facility, the burden would be 1 hour at an estimated cost of $69. According to CMS, there are currently 15,600 LTC facilities. Hence, the total burden for this requirement would be 15,600 hours (1 × 15,600) at an estimated cost of $1,076,400 (15,600 × $69).

The ICRs in this section also require that a staff member, probably the IP, to locate the appropriate information and electronically report the required information weekly to the NHSN. In addition, the IP would need to identify and inform the residents, their representatives, and the families of those residing at the facility of the information required in § 483.80(g)(3). Depending upon the degree of respiratory illnesses and COVID-19 infections in each LTC facility, the burden required by these ICRs would vary substantially between LTC facilities. For purposes of this analysis, we estimate that these ICRs would require the IP 60 minutes or 1 hour each week. According to Table 1 above, an IP's adjusted hourly wage is $69. Hence, for each LTC facility the annual burden would be 52 hours (1-hour x 52 weeks) at an estimated cost of $3,588 (52 x $69). For all 15,600 LTC facilities, the annual burden would be 811,200 hours (15,600 x 52) at an estimated cost of $55,972,800 (15,600 x $3,588).

Hence, the total annual burden for the ICRs in the first year for each LTC facility is 53 hours (1 + 52) at an estimated cost of $3,657 ($69 + $3,588). For all 15,600 LTC facilities in the first year of these requirements, the total annual burden would be 826,800 (53 x 15,600) at an estimated cost of $57,049,200 ($1,076,400 + $55,972,800).

For subsequent years, the total annual burden for all 15,600 LTC facilities would be 811,200 hours (52 x 15,600) at an estimated cost of $55,972.800. After the sunset date of December 31, 2024, we anticipate that the burden for the ICRs in this section would decrease substantially. Since that reduction in burden will occur after December 31, 2024, it will be accounted for in 2025 PRA package for the LTC requirements.

6. ICRs regarding the documentation requirements in §483.80(h).

The September 2020 Testing IFC finalized § 483.80(h) requires LTC facilities to test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. Each LTC facility would be required to modify its IPCP with the policies and procedures necessary to require the testing. 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. This would require that the LTC facility develop or modify its policies and procedures as necessary to comply with the necessary testing and documentation requirements and perform the required documentation. We believe that developing the necessary policies and procedures in the LTC facility's IPCP would

require 2 hours for an IP at an adjusted hourly wage of $69 to develop the necessary policies and procedures. We also believe that the development of these policies and procedures would require 0.5 hours from the DON and 0.5 hours from an administrator both at an adjusted hourly wage of $94 to assist, review and approve the policies and procedures. Hence, the estimated burden for the development of these policies and procedures for each LTC facility is 3 hours (2 + .5 + .5) at an estimated cost of $232 ((2 x $69) or $138 + (1 x $94). For all 15,600 LTC facilities, the burden would be 46,800 hours (15,600 x 3) at an estimated cost of $3,619,200 (15,600 x $232).

In Section I.A. above, we estimated that the documentation activities required under the LTC facility's IPCP would require 10 hours monthly or 120 hours annually for an IP. We believe that estimate is sufficient to account for the burden for the documentation under this requirement also.

Table 4 - Burden Table for §483.80(d)(3), (g), and (h)

COI Requirements	**First Year Burden Hours**	**First Year Costs**	**Subsequent Years Burden Hours**	**Subsequent Years Costs**
§483.80(d)(3) Developing Policies and Procedures	452,400	$45,692,400	187,200	$12,916,800
§483.80(d)(3)(ii) & (iii) Developing education materials for staff members and residents and residents' representatives	62,400	$4,305,600	N/A	N/A
§483.80(d)(3)(iv) Keeping vaccine information up-to-date and making necessary changes	93,600	$6,458,400	93,600	$6,458,400
§483.80(d)(3)(vi) and (vii) Documentation requirements	93,600	$3,556,800	93,600	$3,556,800
§483.80(g) NHSN Reporting	826,800	$57,049,200	811,200	$55,972,800
§483.80(h)	46,800	$3,619,200	N/A	N/A

COI Requirements	First Year Burden Hours	First Year Costs	Subsequent Years Burden Hours	Subsequent Years Costs
Documentation of testing requirements				
Totals	1,575,600	$120,681,600	1,185,600	$78,904,800

L. §483.85 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 CDP. 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 6140 operating organizations (466 + 5,674), we believe it would require an administrator at an adjusted hourly cost of $94 and a DON at an adjusted hourly cost of $94 about 10 hours each to review and update the operating organization's CEP. In addition, we believe that it would require 1 hour for an administrative assistant to make the changes and finalize the revised CEP. Hence, the annual burden for each of

these operating organizations would be 21 hours (10 + 10 + 1) at an estimated cost of $1,918 ((10 x $94) + (10 x $94) + (1 x 38)). The burden for all 6,140 operating organizations with fewer than 5 facilities would be 128,940 hours (21 x 6,140) at a cost of $11,776,520 (6,140 x $1,918).

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. For the purpose of this analysis, we believe the reviewing and updating of the CEP would require 6 hours from an administrator at an hourly cost of $94; 6 hours from a DON at an hourly cost of $94; 10 hours from the compliance officer at an hourly cost of $94; 6 hours from a compliance liaison at an adjusted hourly cost of $69; and one hour from an administrative assistant to compile the revisions and finalize the CEP at an adjusted hourly cost of $38. The burden for each of these 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 of these operating organizations, the burden would be 13,514 hours (466 organizations x 29 hours) at a cost of $1,174,320 (466 x $2,520).

Thus, for all 15,600 LTC facilities the burden for this section would be 142,454 (128,940 + 13,514) at a cost of $12,950,840 ($11,776,520 + $1,174,320).

M. §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.

N. §483.95 Training Requirements

General Training Topics (§483.95(a) through 483.95(e))

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; 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.

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

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.

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

Each facility is already required to complete a performance review of every nurse aide (NA) at least once every 12 months and must provide in-service education based on the outcome of these reviews. Section 483.95(g) requires a facility to include dementia management and abuse prevention in their regular in-service education for all NAs.

Existing regulation at §483.95 already requires that NAs who provide services to individuals with cognitive impairments receive in-service training to address the care of the cognitively impaired. Based on the existing requirements, facilities already conduct training for some NAs on caring for residents who are cognitively impaired. Additionally, existing regulations at §483.95 state that NAs must receive in-service training that addresses areas of weakness as determined in their performance reviews and may address the special needs of residents, as determined by the facility staff. Thus, NAs receive annual training in dementia management and abuse prevention only if the training is indicated by their performance reviews.

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.

We are not adding additional burden for the staff to train the NAs, since the existing requirements for facilities require them to provide in-service training to all NAs at least once every 12 months. We estimate that the burden associated with complying with this requirement would be a one-time burden due to the resources required to review and, if necessary, modify the existing training materials to apply to all NAs, regardless of identified performance weaknesses. 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.

The table below summarizes the estimated annual reporting and recordkeeping burden.

Table 5 - Annual Reporting and Recordkeeping Burdens

Regulation Section(s) (§)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Annual Cost ($)
483.10(c)(2)	1,300,000	5,320,000	0.0333	173,333	11,959,977
483.10(g)(17)	260,000	260,000	0.08333	21,658	1,147,874
483.15(c)(4)	15,600	429,000	0.25	107,250	8,151,000
483.21(a)	15,600	2,909,827	1	2,909,827	200,778,063
483.21(b)(2)	15,600	5,200,000	4	20,800,000	2,277,600,000
483.21(c)(2)	15,600	429,000	1	429,000	29,601,000
483.25(n)(2)	15,600	2,909,827	0.1666	485,068	33,469,692
483.35(b)	14,688	14,688	19	279,072	24,440,832
483.60(c)(4)	15,600	15,600	2	31,200	1,934,400
483.71(Recruitment and retention plan)	14,688	14,688	40	587,520	45,664,992
483.71(b) (Soliciting Input)	14,688	14,688	3	44064	2,673,216
483.75	15,600	62,400	12	748,800	78,998,400
483.80(a)	15,600	15,600	120	1,872,000	129,168,000
483.80(d)(3)	15,600	15,600	29	452,400	45,692,400
483.80(d)(3)(ii) & (iii)	15,600	15,600	4	62,400	4,305,600
483.80(d)(3)(iv)	15,600	15,600	6	93,600	6,458,400

Regulation Section(s) (§)	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Annual Cost ($)
483.80(d)(3) (vi) & (vii)	15,600	187,200	0.5	93,600	3,556,800
483.80(g)	15,600	826,800	2	826,800	57,049,200
483.80(h)	15,600	15,600	3	46,800	3,619,200
483.85(e)	15,600	15,600	24/32	142,454	12,950,840
Totals	**1,838,064**	**18,687,318**	**271/279**	**30,206,846**	**2,979,219,886**

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

There are minimal changes between the 2023 PRA package that was approved and this current package update. Those changes are explained below.

A. Changes related to estimates of burden hours and costs.

(1) Differences in the estimate for LTC facilities.

In the 2023 PRA package, we used 15,600 as the number of LTC facilities. These numbers are taken from CMS internal data based on the data available at the time. As such, the numbers can fluctuate yearly. For this current update to the PRA package, based on the assumptions used in the 2023 LTC staffing proposed rule, we have updated the ICR burden estimates for 483.70(e) and incorporated the new ICR burden estimates for §483.35 and §483.71 based on a total of 14,688 LTC facilities.

(2) Differences in cost estimates due to BLS data.

In the 2023 PRA package, we used the BLS salary data that was current at the time the package was updated. That data was from May 2020. The BLS salary data is updated each year. The BLS salary data used for the new ICRs in §483.35 and §483.71 in this package update is from May 2022. Specifically, the mean hourly wage for most occupations discussed in the updated

and new ICRs for §483.35, §483.70(e), and §483.71 has increased and therefore, the adjusted hourly wage also increased.

(3) Differences in cost estimates due to new requirements.

The 2024 rule finalized new requirements for LTCFs in §§483.35 Nursing services and 483.71 (formerly 483.70(e)) Facility assessment. Based upon our analysis of the public comments received on the proposed rule, we revised our burden estimates by adding a burden estimate for LTC facilities to solicit and consider any input received by residents, resident representatives, and family members.

16. Publication/Tabulation Dates

There are no plans to publish the information collected, except for those required in §483.80(g)(1)(viii). That section requires LTC facilities to electronically report information about COVID-19 in a standardized format to the NHSN about the COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events. The LTC facility must also report the therapeutics administered to residents for treatment of COVID-19. LTC facilities will report the required information weekly, and it will be published in the NHSN.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number. The expiration date will also be published on www.cms.gov at https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC.

18. Certification Statement

We have not identified any exceptions.