

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES**

**OFFICE OF MANAGEMENT AND BUDGET
PAPERWORK REDUCTION ACT
CLEARANCE PACKAGE**

SUPPORTING STATEMENT-PART A

REVISIONS TO THE LTCH CARE DATA SET
FOR THE COLLECTION OF DATA
PERTAINING TO
LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM

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Supporting Statement Part A

LTCH CARE Data Set For the Collection of Data Pertaining to the Long-Term Care Hospital Quality Reporting Program

A. Background

We are requesting approval for future revisions to the Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS). The current PRA approval expiration date is March 31, 2020. The LTCH CARE Data Set is used to collect, submit, and report quality data to CMS for compliance with the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

Regarding the LTCH QRP, **Table 1-1** lists the quality measures collected via the LTCH CARE Data Set.

Table 1-1. Quality Measures Currently Collected via the LTCH CARE Data Set

NQF Number	Measure Name	Data Collection Start Date	Notes
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay)*	October 1, 2012	Finalized for removal in the FY 2018 IPPS/LTCH PPS final rule
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)	October 1, 2014	Finalized for removal in the FY 2019 IPPS/LTCH PPS final rule
Application of NQF #0674	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)	April 1, 2016	
NQF #2631	Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function	April 1, 2016	
Application of NQF #2631	Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function	April 1, 2016	
NQF #2632	Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support	April 1, 2016	
Not endorsed	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	July 1, 2018	
Not endorsed	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	July 1, 2018	Finalized in FY 2018 IPPS/LTCH PPS final rule
Not endorsed	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	July 1, 2018	Finalized in FY 2018 IPPS/LTCH PPS final rule
Not endorsed	Ventilator Liberation Rate	July 1, 2018	Finalized in FY 2018 IPPS/LTCH PPS final rule

*Note: This measure was removed effective July 1, 2018 and replaced with Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. This burden change was finalized in the previous PRA update.

The burden associated with this requirement is staff time required to complete and encode the data from the LTCH CARE Data Set. The burden associated with transmitting the data is unaffected by the finalized future revision to the assessment instrument.

B. Justification

1. Need and Legal Basis

Section 3004 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) authorizes the establishment of the LTCH QRP. The LTCH QRP was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756)¹ pursuant to Section 3004 of the Affordable Care Act.² Beginning in FY 2014, LTCHs that fail to submit quality measures data to CMS were subject to a 2 percentage point reduction in their annual payment update.

Section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185, enacted on Oct. 6, 2014), requires that the Secretary specify not later than the applicable specified application date, as defined in section 1899B(a)(2)(E), quality measures on which LTCH providers are required to submit standardized patient assessment data described in section 1899B(b)(1) and other necessary data specified by the Secretary. Section 1899B(c)(2)(A) requires, to the extent possible, the submission of the such quality measure data through the use of a PAC assessment instrument and the modification of such instrument as necessary to enable such use; for LTCHs, this requirement refers to the LTCH CARE Data Set.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 20514 through 20515) we finalized to remove the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP. LTCHs will no longer be required to submit data on this measure beginning with October 1, 2018 patient admissions and discharges. Beginning with October 1, 2018 admissions and discharges, LTCHs should enter a dash (-) for O0250A, O0250B, and O0250C until the next LTCH CARE Data Set is released. We plan to remove the data elements from the LTCH CARE Data Set as soon as feasible.

As a result, the estimated burden and cost for LTCHs for complying with requirements of the LTCH QRP will be reduced. Specifically, we believe that there will be a 1.8 minute reduction in clinical staff time to report data per patient stay. We estimate 136,476 discharges from 420 LTCHs annually. This equates to a decrease of 4,094 hours in burden for all LTCHs (0.03 hours per assessment × 136,476 discharges). Given 1.8 minutes of registered nurse time at \$70.72 per hour completing an average of 325 sets of LTCH CARE Data Set assessments per LTCH per year, we estimate that the total cost will be reduced by \$689.40 per LTCH annually, or \$289,547 for all LTCHs annually.

See **Appendix A** for the LTCH CARE Data Set V4.00 (effective July 1, 2018). Again, please note the removal of the influenza vaccine data elements will be removed in the next release of the LTCH CARE Data Set, implementation date to be determined.

2. Information Users

The LTCH CARE Data Set is used to collect data for the LTCH QRP. The LTCH QRP is authorized by section 1886(m)(5) of the Social Security Act, and it applies to all hospitals certified by Medicare as LTCHs. Under the LTCH QRP, the Secretary reduces the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year by 2 percentage points if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. The IMPACT Act enacted new data reporting requirements for LTCHs. The collection of standardized patient assessment data is critical to our efforts to drive improvement in health care quality across the four PAC settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among health care providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation and identifying comorbidities that might increase the medical complexity of a particular admission.

¹ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, Federal Register/Vol. 76, No. 160, August 18, 2011. <http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-19719.pdf>.

² Patient Protection and Affordable Care Act. Pub. L. 111-148. Stat. 124-119. 23 March 2010. Web. <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>.

In addition, the public/consumer is a data user, as CMS is required to make LTCH QRP data available to the public after ensuring that an LTCH has the opportunity to review its data prior to public display. Measure data is currently displayed on Long-Term Care Hospital Compare (LTCH Compare): <https://www.medicare.gov/longtermcarehospitalcompare/>

3. Use of Information Technology

LTCHs have the option of recording the required data on a printed form and later transferring the data to electronic format or they can choose to directly enter the required data electronically. The LTCHs transmit the submission to the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

CMS developed the LTCH Assessment Submission Entry and Reporting (LASER) tool, which is a free Java-based application that provides an option for LTCHs to collect and maintain facility, patient, and LTCH CARE Data Set assessment information for subsequent submission to CMS. LASER displays the LTCH CARE Data Set assessment instrument similar to the paper version of the form. Information regarding LASER, including instructions for installing and using the software, is located at: <https://www.qtso.com/laser.html>.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the standardized information cannot be obtained from any other source. There are no other data sets that will provide comparable information on patients admitted to LTCHs.

5. Small Businesses

As part of our PRA analysis for an update of our existing approval, we considered whether the change impacts a significant number of small entities. Out of a total of 420 LTCHs, approximately 112 or 27% are considered small LTCHs. The average number of assessment sets completed yearly is 325, and is the same across all respondents based on the number of actual assessment sets completed by LTCHs in fiscal year 2017.

CMS requests authorization for LTCHs to use the updated LTCH CARE Data Set for the submission of quality measure and standardized patient assessment data information. Provider participation in the submission of quality measure and standardized patient assessment data is mandated by Section 3004 of the Affordable Care Act and Section 1899B(c)(2)(A) of the IMPACT Act. Small business providers viewing the data collection as a burden can elect not to participate. However, if an LTCH does not submit the required data, this provider shall be subject to a 2 percentage point reduction in their annual payment update.

6. Less Frequent Collection

Standardized patient assessment data and quality measure data will be collected for every patient at admission and upon discharge. According to the LTCH QRP requirements, LTCHs are required to submit this data to CMS on a quarterly basis so that data can be updated more frequently in their confidential feedback reports and on the LTCH Compare website.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

For future changes related to the LTCH CARE Data Set, we published a 60-day Federal Register notice on May 7, 2018 (83 FR 20164) for this information collection requirement. We responded to those comments in the corresponding final rule, which was published to the Federal Register on August 17, 2018 (83 FR 41144), and available at <https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-16766.pdf>.

9. Payment/Gifts to Respondents

There will be no payments/gifts to respondents for the use of the LTCH CARE Data Set.

10. Confidentiality

The data collected using the updated LTCH CARE Data Set will be kept confidential by CMS. Data will be stored in a secure format meeting all federal privacy guidelines. Data will be collected using a secure platform for electronic data entry and secure data transmission. The electronic system will be password protected with access limited to CMS and project staff. To protect beneficiary confidentiality, the subject's name will not be linked to his/her individual data. For identification purposes, a unique identifier will be assigned to each sample member.

All patient-level data is protected from public dissemination in accordance with the Privacy Act of 1974, as amended. The information collected is protected and held confidential in accordance with 20 CFR 401.3. Data will be treated in a confidential manner, unless otherwise compelled by law.

11. Sensitive Questions

The information collected in the LTCH CARE Data Set is still considered to be confidential personal health information. Some patient level data is considered sensitive and all necessary protections will be employed to keep the data secure and confidential. Though this information is considered to be personal health information, similar information is currently collected through the use of other CMS instruments in other post-acute care settings. The items on the updated LTCH CARE Data Set are being collected for the LTCH QRP, which has been established pursuant to Section 3004 of the Affordable Care Act.

12. Burden Estimates (Hours & Wages)

A. Current Burden Estimate

1. Estimate Number of Yearly LTCH Discharges and LTCH CARE Data Sets (LCDS) Submissions

Total Number of LTCHs in U.S. = **420**

Total Number of Discharges from all LTCHs per year: **136,476**

Estimate Number of Discharges from each LTCH per year = 325

(136,476 D/Cs from all LTCHs / 420 LTCHs in U.S. = **325**)

Estimated Number of LCDS's submitted by all LTCHs per year = 272,952

(325 estimated # of D/C's in each LTCH per year x 420 LTCHs in U.S. ≈ **136,476** D/C's per all LTCHs per year
136,476 D/C'S per all LTCH per year x 2 LCDS forms per patient = **272,952** LCDS per all LTCHs per year)

Estimated Average Number of LCDS's submitted by each LTCH per year = 650

(272,952 LCDS per all LTCHs in U.S. / 420 LTCHs in U.S. = **650** LCDS per each LTCH)

OR

(136,476 D/C'S per all LTCH per year x 2 LCDS forms per patient = 272,952 LCDS per all LTCHs per year

272,952 LCDS per all LTCHs per year / 420 LTCHs in U.S. = **650** LCDS per each LTCH)

2. Estimate of Financial (Wage) Burdens for Submission of LTCH CARE Data Set

Time Required to Complete Each LTCH CARE Data Set Assessment = 53.5 minutes

23.4 minutes for Admission assessment – clinical staff time to collect clinical data;

20.1 minutes for Discharge assessment – clinical staff time to collect clinical data;

10 minutes administrative data entry time to aggregate and submit data to CMS

53.5 minutes – Total time burden to complete LTCH CARE Data Set per patient

Estimated Annual Time Burden per each LTCH = **289.7 hours/each LTCH/year**

Estimated Annual Time Burden all LTCHs = 121,674 hours/all LTCHs/year

24.142 hours per LTCH per month x 12 months/year = **289.7 hours per each LTCH/year**

289.7 hours/each LTCH/year x 420 LTCHs in U.S. = **121,674 hours/all LTCHs/year**

3. Cost/Wage Calculation for Completion of the LTCH CARE Data Set

a. Wages for Clinical Staff Completing the LTCH CARE Data Set

Registered nurses: 40.3 minutes for Admission & Discharge assessment at \$70.72/hour³

Licensed vocational nurses: 1.9 minutes for Admission & Discharge assessment at \$43.96/hour⁴

Respiratory therapists: 1.3 minutes for Admission & Discharge assessment at \$59.44/hour⁵

Average wages for clinical staff based on completion time: **\$69.22/hour**

43.5 minutes x 325 LCDS forms⁶ / each LTCH / year = 14,137.5 minutes / each LTCH / year

14,137.5 minutes per LTCH per year / 60 minutes = 235.6 hours per year

235.6 hours per year x \$69.22 per hour ≈ **\$16,305.93** clinical staff wages /per each LTCH / year

\$16,305.93 x 420 LTCH providers ≈ **\$6,848,489** per all LTCHs / year

b. Wages for Admin Assistant/ Clerical Staff who gather and transmit LTCH CARE Data Set

(NOTE: Administrative data entry time calculated at an hourly wage of \$34.50/hour⁷)

10 minutes x 325 LCDS forms⁸ / LTCH/year = 3,250 minutes/LTCH/year

3,250 minutes per LTCH per year / 60 minutes = 54.17 hours per year

54.17 hours per year x \$34.50 per hour ≈ **\$1,868.42** admin assistant wages/per LTCH/year

\$1,868.42 x 420 LTCHs ≈ **\$784,737** per all LTCH providers/year

4. Combined Calculations

\$16,305.93 – Clinical staff wages/per LTCH /year (LTCH CARE Data Set)

\$1,868.42 – Admin assistant wages/per LTCH /year (LTCH CARE Data Set)

\$18,174.35 – Total Annualized Cost to Each LTCH Provider

\$6,848,489 – Clinical staff wages/per ALL LTCHs /year (LTCH CARE Data Set)

\$784,737 – Admin assistant wages/per ALL LTCHs /year (LTCH CARE Data Set)

\$7,633,226 – Total Annualized Cost For All LTCH Providers

5. Additional Calculations

Total Yearly Cost to All LTCH Providers for Reporting Data using the LCDS = \$7,636,226

\$18,174.35 x 420 LTCHs in U.S. = **\$7,636,226**)

Total Yearly Cost to Each LTCH Provider for Reporting Quality Data = \$18,174.35

(\$7,636,226 yearly cost for all LTCHs / 420 LTCHs in U.S. = **\$18,174.35**)

³ The mean hourly wage of \$35.36 for a Registered Nurse was obtained from the U.S. Bureau of Labor Statistics, and the wage was multiplied by 2 to account for fringe benefits. See <http://www.bls.gov/oes/current/oes291111.htm>

⁴ The mean hourly wage of \$21.98 for a Licensed Vocational Nurse was obtained from the U.S. Bureau of Labor Statistics, and the wage was multiplied by 2 to account for fringe benefits. See <https://www.bls.gov/oes/current/oes292061.htm>

⁵ The mean hourly wage of \$29.72 for a Respiratory Therapist was obtained from the U.S. Bureau of Labor Statistics, and the wage was multiplied by 2 to account for fringe benefits. See <https://www.bls.gov/oes/current/oes291126.htm>

⁶ LCDS forms include 1 admission and 1 discharge assessment (2 total)

⁷ The mean hourly wage of \$17.25 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics, and the wage was multiplied by 2 to account for fringe benefits. See <https://www.bls.gov/oes/current/oes436013.htm>

⁸ LCDS forms include 1 admission and 1 discharge assessment (2 total)

Estimated Average Cost per each LCDS Submission = \$50.18

(\$7,636,226 yearly cost of LCDS submissions for ALL LTCHs / 136,476 LCDS submissions per all LTCHs/year = \$50.18)

OR

(\$18,174.35 yearly cost of LCDS submissions per each LTCH / 325 LCDS submissions per LTCHs/year ≈ \$50.18)

B. Itemized Time and Wage/Cost Burden Estimate for the LTCH CARE Data Set Assessments

- The LTCH CARE Data Set consists of 4 different assessment forms in which 2 (an admission and discharge assessment) are required per stay.
- All of these forms consist of required items (questions) that contribute to the assessment completion time, and required items if information is available.
 - Some of these items have subitems. These subitems are not counted towards the assessment completion time since the time to complete the subitems is included in the time to complete the parent item.
- An LTCH is required to perform an admission assessment within 3 days after the patient is admitted.
- An LTCH must also perform a discharge assessment on each patient.
- There are 3 different types of Discharge Assessment forms:
 - Planned Discharge Assessment
 - Unplanned Discharge Assessment
 - Expired (Death) Assessment
- The type of discharge assessment used is based on the circumstances of the discharge.

Admission Assessment

Number of Required Questions (including subitems): 148

Number of Required Questions for Assessment Completion Time: 78 @ 0.3 minutes each = 23.4 minutes

Planned Discharge Assessment

Number of Required Questions (including subitems): 87

Number of Required Questions for Assessment Completion Time: 67 @ 0.3 minutes each = 20.1 minutes

Unplanned Discharge Assessment

Number of Required Questions (including subitems): 65

Number of Required Questions for Assessment Completion Time: 45 @ 0.3 minutes each = 13.5 minutes

Expired Assessment

Number of Required Questions (including subitems): 43

Number of Required Questions for Assessment Completion Time: 24 @ 0.3 minutes each = 7.2 minutes

13. Capital Costs

There are no additional capital costs to respondents or to record keepers. LTCHs do not need to acquire any additional equipment to collect data. LTCHs can use the free LASER tool for record submission. Information regarding LASER, including instructions for installing and using the software, is located at: <https://www.qtso.com/laser.html>.

14. Cost to Federal Government

The Department of Health & Human Services (DHHS) will incur costs associated with the administration of the LTCH QRP including costs associated with the IT system used to process LTCH submissions to CMS and analysis of the data received.

CMS engaged the services of an in-house CMS contractor to create and manage an online reporting/IT platform for the LTCH CARE Data Set. This contractor works with the CMS Center for Clinical Standards and Quality, Division of Post-Acute and Chronic Care (DCPAC) in order to support the IT needs of multiple quality reporting programs. When LTCH

providers transmit the data contained within the LTCH CARE Data Set to CMS it is received by this contractor. Upon receipt of all data sets for each quarter the contractor performs some basic analysis which helps to determine each provider’s compliance with the reporting requirements of the LTCH QRP. The findings are communicated to the LTCH QRP lead in a report. Contractor costs include the development, testing, roll-out, and maintenance of the LTCH Assessment Submission Entry and Reporting (LASER) software that is made available to LTCH providers free of charge providing a means by which LTCHs can submit the required data to CMS.

DCPAC retains the services of a separate contractor for the purpose of performing a more in-depth analysis of the LTCH data, as well as the calculation of the quality measures, and for future public reporting of the LTCH data. Said contractor is responsible for obtaining the LTCH quality reporting data from the in-house CMS contractor. They perform statistical analysis on this data and prepare reports of their findings, which will be submitted to the LTCH QRP lead.

DCPAC retains the services of a third contractor to assist with provider training and help desk support services related to the LTCH QRP.

In addition to the contractor costs, the total includes the cost of the following Federal employees:

- GS-13 (locality pay area of Washington-Baltimore-Northern Virginia) at 100% effort for 3 years, or \$290,910.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or \$114,590.

The estimated cost to the federal government for the contractor is as follows:

CMS in-house contractor – Maintenance and support of IT platform that Supports the LTCH CARE Data Set.....	\$750,000
Data analysis contractor.....	\$1,000,000
Provider training & helpdesk contractor.....	\$1,000,000
GS-13 Federal Employee (100% X 3 years).....	\$290,910
GS-14 Federal Employee (33% X 3 years).....	\$114,590
Total cost to Federal Government.....	\$3,155,500

15. Changes to Burden

This section compares the burden of the previously approved PRA package for LTCH CARE Data Set V4.00 and the revised PRA package submission for LTCH CARE Data Set V4.00 because of LTCH QRP proposals finalized in the FY 2019 IPPS/LTCH PPS final rule. As previously mentioned, LTCHs will no longer be required to report the 3 data elements (O0250A, O0250B, and O0250C) necessary to calculate this measure beginning with October 1, 2018 admissions and discharges. Beginning with October 1, 2018 admissions and discharges, LTCHs should enter a dash (-) for O0250A, O0250B, and O0250C until the next LTCH CARE Data Set is released. Implementation date is to be determined. We plan to remove the data elements from the LTCH CARE Data Set as soon as feasible.

We have updated information regarding the current number of Medicare-certified LTCHs in the U.S., as well as the total number of yearly LTCH discharges. The number of Medicare-certified LTCHs has declined from 426 to 420 and discharges declined from 146,592 to 136,476. As a result, the total annual burden hours decreased from 135,128 to 121,674. We have decreased our time estimate from 24.3 to 23.4 minutes for completing the admission assessment and decreased our time estimate from 21.0 to 20.1 minutes for completing the discharge assessment. Overall, the combined time estimate decreased from 45.3 minutes to 43.5 minutes for the revised LTCH CARE Data Set.

Wages have been updated to the most recent figures. The wage for a registered nurse to complete the LTCH CARE Data Set assessment increased from \$69.40 to \$70.72 per hour (\$35.36 without fringe benefits), and the wage for an administrative assistant to aggregate and submit data to CMS increased from \$33.70 to \$34.50 per hour (\$17.25 without fringe benefits). In addition, we have added wages for licensed vocational nurses (\$43.96 per hour; \$21.98 without fringe benefits) and respiratory therapists (\$59.44 per hour; \$29.72 without fringe benefits) since they also contribute to completing the assessments. Overall, the average wage based on time to complete the assessment for each clinical staff increased from \$65.41 to \$69.22.

The estimated average cost per each LTCH CARE Data Set V4.00 submission decreased from \$51.32 to \$50.18. Subsequently, the total yearly cost to each LTCH provider for reporting quality data decreased from \$19,594.34 to \$18,174.35, and the total yearly cost to all LTCH providers for reporting data using the LTCH CARE Data Set decreased from \$8,347,190 to \$7,633,226.

16. Publication/Tabulation Dates

CMS is mandated to publish quality measure data collected pursuant to Section 3004 of the Affordable Care Act. Measure data is currently displayed on the LTCH Compare website, which is an interactive web tool that assists individuals by providing information on LTCH quality of care including those who need to select an LTCH. The IMPACT Act mandates that measures that are standardized across post-acute care settings be published within two years from the implementation date. The information on the LTCH Compare website is refreshed quarterly. For more information on LTCH Compare, we refer readers to: <https://www.medicare.gov/longtermcarehospitalcompare/>.

17. Expiration Date

The OMB expiration date will be displayed on all disseminated data collection materials.

18. Certification Statement

There are no exceptions to the certifications statement.

Appendices:

Appendix A – LTCH CARE Data Set V 4.00

See attached: Appendix A