

**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 V3.00
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

1. Background and Justification

Section 3004 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) authorizes the establishment of a new quality reporting program for Long Term Care Hospitals (LTCHs). The LTCH Quality Reporting Program (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 on three quality measures (NQF #0678, NQF #0138, NQF #0139), as listed in the **Table 1-1**, may be subject to a 2 percentage point reduction in their annual payment update.

In the FY 2013 IPPS/LTCH PPS final rule (76 FR 53614 through 53637 and 53667 through 53672), CMS retained three measures and adopted two new measures (NQF #0680 and NQF #0431) for the FY 2016 LTCH QRP, as listed in the Table 1-1³.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853 through 50887 and 50959 through 50964)⁴, CMS retained five measures and adopted two additional measures (NQF #1716 and NQF #1717) for the FY 2017 LTCH QRP.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50318 and 50348 through 50349)⁵, CMS retained seven measures and adopted one additional measure (NQF #2512) for the FY 2017 LTCH QRP and four additional measures (application of NQF #0674, NQF #2631, NQF #2632, and non-NQF endorsed NHSN VAE) for the FY 2018 LTCH QRP.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49756 and 49764 through 49766)⁶, CMS retained twelve measures and adopted three measures to meet the requirements of the IMPACT Act (NQF #0678, application of NQF #2631, and application of NQF #0674) for FY 2018 LTCH QRP and one measure (NQF #2512) to reflect NQF endorsement status for FY 2018 LTCH QRP.

¹ 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>.

² 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>.

³ Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Final Rule, Federal Register/Vol. 77, No. 170, August 31, 2011. <http://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/2012-19079.pdf>.

⁴ 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 Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status; Final Rule, Federal Register/Vol. 78, No. 160, August 19, 2013. <http://www.gpo.gov/fdsys/pkg/FR-2013-08-19/pdf/2013-18956.pdf>.

⁵ 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 Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program; Final Rule, Federal Register/Vol. 79, No. 163, August 22, 2014 <http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-18545.pdf>.

⁶ 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 Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Extensions of the Medicare-Dependent, Small Rural Hospital Program and the Low-Volume Payment Adjustment for Hospitals; Final Rule, Federal Register/Vol. 80, No. 158, August 17, 2015 <http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-19049.pdf>.

In the FY 2017 IPPS/LTCH PPS final rule⁷, CMS retained thirteen measures and adopted four measures to meet the requirements of the IMPACT Act. Three of those measures (Medicare Spending per Beneficiary-PAC LTCH QRP, Discharge to Community-PAC LTCH QRP, and Potentially Preventable 30-Day Post Discharge Readmission Measure) were adopted for the FY 2018 LTCH QRP and one measure (Drug Regimen Review) for the FY 2020 LTCH QRP.

In the FY 2018 IPPS/LTCH PPS proposed rule (81 FR 20086 through 20120), CMS is proposing to adopt three measures beginning with the FY 2020 LTCH QRP and remove two measures. The proposed measures are Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay, and Ventilator Liberation Rate. The proposed measures for removal are Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512). We are also proposing to characterize the data elements, as described in section IX.C.10 of the FY 2018 IPPS/LTCH PPS proposed rule, as standardized patient assessment data under section 1899B(b)(1)(B) of the Act, that must be reported by LTCHs under the LTCH QRP through the LTCH CARE Data Set.

While the reporting of data on quality measures and standardized patient assessment data elements involves collecting information, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in the FY 2018 IPPS/LTCH PPS proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the LTCH CARE Data Set or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

Table 1-1. Quality Measures Currently Adopted and Proposed for the LTCH QRP

NQF Number	Measure Name	Fiscal Year [year] LTCH QRP*	Data Collection Start Date	Notes
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay)	Starting FY 2014	October 1, 2012	Proposed removal in FY 2018 IPPS/LTCH PPS proposed rule
NQF #0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	Starting FY 2014	October 1, 2012	
NQF #0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure	Starting FY 2014	October 1, 2012	
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)	Starting FY 2016	October 1, 2014	
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel	Starting FY 2016	October 1, 2014	
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia Outcome Measure	Starting FY 2017	January 1, 2015	

⁷ Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals; Final Rule, Federal Register/Vol. 81, No. 162, August 22, 2016 <https://www.gpo.gov/fdsys/pkg/FR-2016-08-22/pdf/2016-18476.pdf>.

NQF Number	Measure Name	Fiscal Year [year] LTCH QRP*	Data Collection Start Date	Notes
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure	Starting FY 2017	January 1, 2015	
NQF #2512	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals	Starting FY 2018	N/A – Medicare FFS Claims Data	Proposed removal in FY 2018 IPPS/LTCH PPS proposed rule
Application of NQF #0674	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)	Starting FY 2018	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	Starting FY 2018	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	Starting FY 2018	April 1, 2016	
NQF #2632	Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support	Starting FY 2018	April 1, 2016	
Not endorsed	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure	Starting FY 2018	January 1, 2016	
Not endorsed	Medicare Spending Per Beneficiary-Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	Starting FY 2018	N/A – Medicare FFS Claims Data	
Not endorsed	Discharge to Community-Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	Starting FY 2018	N/A – Medicare FFS Claims Data	
Not endorsed	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	Starting FY 2018	N/A – Medicare FFS Claims Data	
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)	Starting FY 2020	April 1, 2018	
Not endorsed	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	Starting FY 2020	April 1, 2018	Proposed in FY 2018 IPPS/LTCH PPS proposed rule
Not endorsed	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	Starting FY 2020	April 1, 2018	Proposed removal in FY 2018 IPPS/LTCH PPS proposed rule
Not endorsed	Ventilator Liberation Rate	Starting FY 2020	April 1, 2018	Proposed removal in FY 2018 IPPS/LTCH PPS proposed rule

* Please note that term “FY [year] LTCH QRP” refers to the fiscal year for which the LTCH QRP requirements applicable to that fiscal year must be met for an LTCH to receive the full annual update when calculating the payment rates applicable to it for that fiscal year.

The Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LTCH CARE Data Set or LCDS) was developed to implement the LTCH QRP and for data collection. The Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) was one of the first quality measures implemented beginning October 1, 2012, with the understanding that the data set would expand in future rule-making years with the adoption of additional quality measures and standardized patient assessment data elements for the LTCH QRP. Relevant data elements contained in other well-known and clinically established data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and Continuity Assessment Record and Evaluation (CARE), were incorporated into the LTCH CARE Data Set V1.01,⁸ V2.00⁹ and V2.01, V3.00¹⁰ each of which has been approved by the Office of Management and Budget (OMB).

Section 1886(m)(5)(F)(ii) of the Act requires that for fiscal years beginning on or after October 1, 2018, LTCHs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1886(m)(5)(F)(iii) of the Act allows an LTCH to submit the patient assessment data required under section 1899B(b)(1) of the Act using the standard instrument in a time, form, and manner specified by the Secretary.

The changes from the LTCH CARE Data Set V 3.00 were made to develop LTCH CARE Data Set V 4.00 which will be implemented April 1, 2018 and are detailed in Appendix A.

2. Information Users

- Data Submitters: All LTCHs
- Data Users:
 - CMS: as required under Section 3004 of the Affordable Care Act and the IMPACT Act
 - Public: the measures calculated from the data obtained will be made available for public use 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, which is currently used by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs). LTCHs also use the QIES ASAP system for transmitting other measure records, such as pressure ulcer, function, falls, and influenza measure records.

CMS requires that the collected data be transmitted to CMS electronically, in a manner similar to the process used by LTCHs submitting, for example, pressure ulcer data, and currently used by HHAs for the Outcome and Assessment Information Set, Version C (OASIS-C), SNFs for the Minimum Data Set (MDS 3.0), and IRFs for Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). Attestation as to the accuracy of the data collected remains required of the provider upon completion of the LTCH CARE Data Set. However, if electronic signatures were to be required at a future date, CMS could accommodate this as well.

⁸ The LTCH CARE Data Set V1.01 was approved on August 13, 2012 by the Office of Management and Budget in accordance with the Paperwork Reduction Act. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013.

⁹ The LTCH CARE Data Set V2.00 was approved on June 10, 2013 by the Office of Management and Budget in accordance with the Paperwork Reduction Act. The OMB Control Number is 0938-1163. Expiration Date June 30, 2016.

¹⁰ The LTCH CARE Data Set V3.00 was approved on March 31, 2017 by the Office of Management and Budget in accordance with the Paperwork Reduction Act. The OMB Control Number is 0938-1163. Expiration Date March 31, 2020.

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

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 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% reduction in their annual payment update.

6. Less Frequent Collection

The updated LTCH CARE Data Set will be used in LTCHs to collect quality measure data on ventilator weaning and drug regimen review as well as standardized patient assessment data. Collection of this data will be performed at admission and upon discharge of every patient. LTCHs will be required to submit this data to CMS on a quarterly basis.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

We are soliciting comments on the proposed modifications to the LTCH QRP through the FY 2018 IPPS/LTCH PPS Proposed Rule which was published April 28, 2017 (82 FR 19796). We will respond to those comments in the corresponding final rule.

The updated LTCH CARE Data Set was developed in consultation with the CMS Division of Chronic and Post Acute Care measure development contractor, RTI International (RTI), the CMS Division of Quality Systems for Assessments and Surveys and its contractors, Telligen and GDIT.

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. This 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(a) of the Affordable Care Act.

12. Burden Estimates (Hours & Wages)

A. Burden Estimate from Prior PRA Package

(Based on V3.00 for OMB Control Number: 0938-1163)

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

Total Number of LTCH in U.S. = **432**

Total Number of Discharges from all LTCHs per year: **202,635**

Estimate Number of Discharges from each LTCH per year = 469

(202,635 D/Cs from all LTCHs / 432 LTCHs in U.S. = **469**)

Estimated Number of Discharges from each LTCH per month = 39

(202,635 D/Cs from all LTCHs / 432 LTCHs in U.S. / 12 months per year = **39**)

Estimated Number of LCDS's submitted by all LTCHs per year = 405,270

(469 estimated # of D/C's in each LTCH per year x 432 LTCHs in US ≈ **202,635** D/C's per all LTCHs per year

202,635 D/C'S per all LTCH per year x 2 LCDS forms per patient = **405,270** LCDS per all LTCHs per year)

Estimated Average Number of LCDS's submitted by each LTCH per year = 938

(405,270 LCDS per all LTCHs in U.S. / 432 LTCHs in US = **938** LCDS per each LTCH)

OR

(202,635 D/C'S per all LTCH per year x 2 LCDS forms per patient = 405,270 LCDS per all LTCHs per year

405,270 LCDS per all LTCHs per year / 432 LTCHs in U.S. = **938** LCDS per each LTCH)

Estimated Average Number of LCDS's submitted by each LTCH per month = 78

(405,270 LCDS per all LTCHs in U.S. per mo. / 432 LTCHs in US = 938 LCDS per each LTCH per year

938 LCDS per each LTCH per year / 12 months per year = **78** LCDS per each LTCH per month)

Estimated Average Number of LCDS's submitted by All LTCHs per month = 33,773

(405,270 LCDS per all LTCHs in U.S. per year / 12 months per year = **33,773**)

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

Time Required to Complete Each LTCH CARE Data Set Assessment = 58.3 minutes

22.2 minutes for Admission assessment – nursing/clinical staff time to collect clinical data;

26.1 minutes for Discharge assessment – nursing/clinical staff time to collect clinical data;

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

58.3 minutes¹¹ – Total time burden to complete LTCH CARE Data Set per patient

An arithmetic error in the calculations for Estimated Annual Time Burden below was discovered. The previous PRA package based the Estimated Annual Time Burden on 78 forms per each LTCH which resulted in 909.4 hours per each LTCH or 392,861 hours for all LTCHs. However, the actual number of forms was 39 per LTCH. As a result, the Estimated Annual Time burden changed to 454.8 hours per each LTCH or 196,474 hours for all LTCHs.

Estimated Annual Time Burden per each LTCH = **454.8 hours/each LTCH/year**

Estimated Annual Time Burden all LTCHs = 196,474 hours/all LTCH's/year

58.3 minutes/form x 39 forms/each LTCH/month = 2,274 minutes/each LTCH/month

¹¹ This time estimate includes the time required to complete both the required and voluntary questions on the LTCH CARE Data Set.

2,274 minutes / 60 minutes / hour = 37.90 hours per LTCH per month
 37.90 hours per LTCH per month x 12 months/year = **454.8 hours per each LTCH/year**
 454.8 hours/each LTCH/year x 432 LTCHs in U.S. = **196,474 hours/all LTCH's/year**

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

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

22.2 minutes for Admission assessment – nursing time to collect clinical data at \$33.23/hour¹²
 26.1 minutes for Discharge assessment – nursing time to collect clinical data at \$33.23/hour

48.3 minutes x 469 LCDS forms¹³ / each LTCH / year = 22,653 minutes / each LTCH / year
 22,653 minutes per LTCH per year / 60 minutes = 377.6 hours per year

377.6 hours per year x \$33.55 per hour = **\$12,668.48** nursing wages /per each LTCH / year
 \$12,668.48 x 432 LTCH providers = **\$5,472,783** 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 \$15.59/hour¹⁴)

10 minutes x 469 LCDS forms / LTCH/year = 4,690 minutes/LTCH/year
 4,690 minutes per LTCH per year / 60 minutes = 78.17 hours per year

78.17 hours per year x \$16.12 per hour = **\$1,260.10** admin assistant wages/per LTCH/year
 \$1,260.10 x 432 LTCHs = **\$544,363** per all LTCH providers/year

4. Combined Calculations

\$12,668.48 – Nursing wages/per LTCH /year (LTCH CARE Data Set)
 \$1,260.10 – Admin assistant wages/per LTCH /year (LTCH CARE Data Set)
\$13,928.58 – Total Annualized Cost to Each LTCH Provider

\$5,472,783 – Nursing wages/per ALL LTCHs /year (LTCH CARE Data Set)
 \$544,363 – Admin assistant wages/per ALL LTCHs /year (LTCH CARE Data Set)
\$6,017,146 – Total Annualized Cost For All LTCH Providers

5. Additional Calculations

Total Yearly Cost to All LTCH Providers for Reporting Data using the LCDS = **\$6,017,146**
 \$13,928.58 x 432 LTCHs in U.S. = **\$6,017,146**)

Total Yearly Cost to Each LTCH Provider for Reporting Quality Data = **\$13,928.58**
 (\$6,017,146 yearly cost for all LTCHs / 432 LTCHs in U.S. = **\$13,928.58**)

Estimated Average Monthly Cost to Each LTCH Provider for Reporting Quality Data = **\$1,160.71**
 (\$6,017,146 Total yearly cost for all LTCHs / 432 LTCHs in U.S. / 12 months per year = **\$1,160.71**)

Estimated Average Cost per each LCDS Submission = **\$29.69**
 (\$6,017,146 yearly cost of LCDS submissions for ALL LTCHs / 202,635 LCDS submissions per all LTCHs/year = **\$29.69**)

¹² The mean hourly wage of \$33.55 for a Registered Nurse was obtained from the U.S. Bureau of Labor Statistics at the time of developing the previous PRA package.

¹³ LCDS forms include 1 admission and 1 discharge assessment (2 total)

¹⁴ The mean hourly wage of \$16.12 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics at the time of developing the previous PRA package.

OR

(\$13,928.58 yearly cost of LCDS submissions per each LTCH / 469 LCDS submissions per LTCHs/year = **\$29.69**)

B. Current Burden Estimate

(Based on V4.00 for OMB Control Number: 0938-1163)

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

Total Number of LTCH in U.S. = **426**

Total Number of Discharges from all LTCHs per year: **146,592**

Estimate Number of Discharges from each LTCH per year = 344

(146,592 D/Cs from all LTCHs / 426 LTCHs in U.S. = **344**)

Estimated Number of Discharges from each LTCH per month ≈ 29

(146,592 D/Cs from all LTCHs / 426 LTCHs in U.S. / 12 months per year ≈ **29**)

Estimated Number of LCDS's submitted by all LTCHs per year = 293,184

(344 estimated # of D/C's in each LTCH per year x 426 LTCHs in US ≈ **146,592** D/C's per all LTCHs per year

146,592 D/C's per all LTCH per year x 2 LCDS forms per patient = **293,184** LCDS per all LTCHs per year)

Estimated Average Number of LCDS's submitted by each LTCH per year = 688

(293,184 LCDS per all LTCHs in U.S. / 426 LTCHs in US = **688** LCDS per each LTCH)

OR

(146,592 D/C'S per all LTCH per year x 2 LCDS forms per patient = 293,184 LCDS per all LTCHs per year

293,184 LCDS per all LTCHs per year / 426 LTCHs in U.S. = **688** LCDS per each LTCH)

Estimated Average Number of LCDS's submitted by each LTCH per month ≈ 57

(293,184 LCDS per all LTCHs in U.S. per mo. / 426 LTCHs in US = 688 LCDS per each LTCH per year

688 LCDS per each LTCH per year / 12 months per year ≈ **57** LCDS per each LTCH per month)

Estimated Average Number of LCDS's submitted by All LTCHs per month = 24,432

(293,184 LCDS per all LTCHs in U.S. per year / 12 months per year = **24,432**)

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

Time Required to Complete Each LTCH CARE Data Set Assessment = 67.9 minutes

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

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

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

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

Estimated Annual Time Burden per each LTCH = **389.4 hours/each LTCH/year**

Estimated Annual Time Burden all LTCHs = 165,884 hours/all LTCH's/year

67.9 minutes/form x 28.68 LCDS forms¹⁵/each LTCH/month = 1,947.37 minutes/each LTCH/month

1,947.37 minutes / 60 minutes / hour = 32.456 hours per LTCH per month

32.456 hours per LTCH per month x 12 months/year = **389.4 hours per each LTCH/year**

389.4 hours/each LTCH/year x 426 LTCHs in U.S. = **165,884 hours/all LTCH's/year**

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

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

¹⁵ LCDS forms include 1 admission and 1 discharge assessment (2 total)

Registered nurses: 47.6 minutes for Admission & Discharge assessment at \$69.40/hour¹⁶
Licensed vocational nurses: 7.7 minutes for Admission & Discharge assessment at \$43.12/hour¹⁷
Respiratory therapists: 2.6 minutes for Admission & Discharge assessment at \$58.30/hour¹⁸
Average wages for clinical staff based on completion time: **\$65.14/hour**

57.9 minutes x 344 LCDS forms¹⁹ / each LTCH / year = 19,917.6 minutes / each LTCH / year
19,917.6 minutes per LTCH per year / 60 minutes = 332.0 hours per year

332.0 hours per year x \$65.14 per hour ≈ **\$21,719.61** clinical staff wages /per each LTCH / year
\$21,719.61 x 426 LTCH providers ≈ \$9,252,556 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 \$33.70/hour²⁰)

10 minutes x 344 LCDS forms²¹ / LTCH/year = 3,440 minutes/LTCH/year
3,440 minutes per LTCH per year / 60 minutes = 57.33 hours per year
57.33 hours per year x \$33.70 per hour ≈ **\$1,932.77** admin assistant wages/per LTCH/year
\$1,932.77 x 426 LTCHs ≈ \$823,358 per all LTCH providers/year

4. Combined Calculations

\$21,719.61 – Clinical staff wages/per LTCH /year (LTCH CARE Data Set)
\$1,932.77 – Admin assistant wages/per LTCH /year (LTCH CARE Data Set)
\$23,652.38 – Total Annualized Cost to Each LTCH Provider

\$9,252,556 – Clinical staff wages/per ALL LTCHs /year (LTCH CARE Data Set)
\$711,046 – Admin assistant wages/per ALL LTCHs /year (LTCH CARE Data Set)
\$10,075,914 – Total Annualized Cost For All LTCH Providers

5. Additional Calculations

Total Yearly Cost to All LTCH Providers for Reporting Data using the LCDS = \$10,075,914
\$23,652.38 x 426 LTCHs in U.S. = \$10,075,914)

Total Yearly Cost to Each LTCH Provider for Reporting Quality Data = \$23,652.38
(\$10,075,914 yearly cost for all LTCHs / 426 LTCHs in U.S. = \$23,652.38)

Estimated Average Monthly Cost to Each LTCH Provider for Reporting Quality Data = \$1,809.97
(\$10,075,914 Total yearly cost for all LTCHs / 426 LTCHs in U.S. / 12 months per year = \$1,809.97)

Estimated Average Cost per each LCDS Submission = \$68.73
(\$10,075,914 yearly cost of LCDS submissions for ALL LTCHs / 146,592 LCDS submissions per all LTCHs/year = \$68.73)

OR

¹⁶ The mean hourly wage of \$34.70 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>

¹⁷ The mean hourly wage of \$21.56 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>

¹⁸ The mean hourly wage of \$29.15 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>

¹⁹ LCDS forms include 1 admission and 1 discharge assessment (2 total)

²⁰ The mean hourly wage of \$16.85 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>

²¹ LCDS forms include 1 admission and 1 discharge assessment (2 total)

(\$23,652.38 yearly cost of LCDS submissions per each LTCH / 344 LCDS submissions per LTCHs/year ≈ \$68.73)

C. 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): 197

Number of Required Questions for Assessment Completion Time: 109 @ 0.3 minutes each = 32.7 minutes

Planned Discharge Assessment

Number of Required Questions (including subitems): 124

Number of Required Questions for Assessment Completion Time: 84 @ 0.3 minutes each = 25.2 minutes

Unplanned Discharge Assessment

Number of Required Questions (including subitems): 71

Number of Required Questions for Assessment Completion Time: 48 @ 0.3 minutes each = 14.4 minutes

Expired Assessment

Number of Required Questions (including subitems): 46

Number of Required Questions for Assessment Completion Time: 27 @ 0.3 minutes each = 8.1 minutes

13. Capital Costs

There are no additional capital costs to respondents or to record keepers.

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 helpdesk 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 \$284,389.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or \$112,021.

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).....	\$284,389
GS-14 Federal Employee (33% X 3 years).....	\$112,021
Total cost to Federal Government.....	\$3,146,409

15. Changes to Burden

In section 12 above, we have provided the burden estimate that was submitted with our previous PRA package for the LTCH CARE Data Set V 3.00 that was approved on March 31, 2017. Subsequently, we have provided a new burden estimate for the LTCH CARE Data Set V 4.00. A comparison of these two burden estimates will show that adjustments have been made to the time and cost estimates. We note that an arithmetic error in the previous PRA package inflated the annual burden hours to 392,474 from 196,474 hours. The details on the corrected burden hours are on step 2 of section 12A in this document.

The transition from LTCH CARE Data Set V 3.00 to LTCH CARE Data Set V 4.00 decreased the annual burden hours from 196,474 to 165,884. This decrease is due to 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 have declined from 432 to 426 and discharges have significantly decreased from 202,635 in calendar year 2015 to 146,592 in fiscal year 2016.

The number of questions increased from V 3.00 to V 4.00 due to the addition of new measures and standardized patient assessment data elements. We have increased our time estimate from 22.2 to 32.7 minutes for the admission assessment, but decreased our time estimate from 26.1 to 25.2 minutes for the discharge assessment. Overall, the time estimate to complete the admission and discharge assessment including the 10 minute estimate to submit the assessment increased from 58.3 to 67.9 minutes.

Wages have been updated to the most recent figures. It is important to note that we have doubled the wages to account for fringe benefits which has not been accounted for in previously approved PRA packages. Consequently, the wage for a registered nurse to complete the LTCH CARE Data Set assessment increased from \$33.55 to \$69.40 per hour (\$34.70 without fringe benefits), and the wage for an administrative assistant to aggregate and submit data to CMS increased from \$16.12 to \$33.70 per hour (\$16.85 without fringe benefits). In addition, we have added wages for licensed vocational nurses (\$43.12 per hour; \$21.56 without fringe benefits) and respiratory therapists (\$58.30 per hour; \$29.15 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 was \$65.41.

Overall, the estimated average cost per each LTCH CARE Data Set V 4.00 submission was \$63.12 which is an increase from the cost of completing V 3.00 (\$29.69). Subsequently, the total yearly cost to each LTCH provider for reporting quality data increased from \$13,928.58 for V 3.00 to \$21,719.61 for V 4.00, and the total yearly cost to all LTCH providers for reporting data using the LTCH CARE Data Set increased from \$6,017,146 for V 3.00 to \$10,075,914 for V 4.00. As previously stated, the significant increase in cost burden is due to accounting for the fringe benefits which doubled the wages.

All changes that have been made to the LTCH CARE Data Set are listed in Appendix B. The justification for each change is also included in Appendix B.

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 Long-Term Care Hospital Compare (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. 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.

Appendix A – Master List of LTCH CARE Data Set Version 4.00 Items

See attached Excel: Appendix A - Master List of LTCH CARE Data Set Version 4.00 Items

Appendix B – Master List of Changes from LTCH CARE Data Set Version 3.00 to LTCH CARE Data Set Version 4.00

See attached PDF: Appendix B - Proposed LTCH CARE Data Set Version 4.00 Change Table - Effective April 1, 2018

Appendix C – Proposed LTCH CARE Data Set V 4.00

See attached zip file: Proposed LTCH CARE Data Set V 4.00 - Effective April 1, 2018