

**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 V1.01
FOR THE COLLECTION OF DATA
PERTAINING TO
LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM

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Revised Supporting Statement for Paperwork Reduction Act Submissions
PART A

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

1. Background & Justification

Section 3004 of The Affordable Care Act authorizes the establishment of a new quality reporting program for Long Term Care Hospitals (LTCHs). The LTCH Quality Reporting Program (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 Patient Protection and Affordable Care Act of 2010.² 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 update to the standard Federal rate for discharges occurring during a rate year. In the FY 2013 IPPS/LTCH PPS final rule (76 FR 51743 through 51756), CMS retained three measures and adopted two new measures (NQF #0680 and NQF #0431) for the FY 2016 payment determination, as listed in the **Table 1-1**³:

Table 1-1. Quality Measures for Fiscal Years 2014, 2015, and 2016 Payment Update Determination

NQF Number	Measure Name	Fiscal Year Payment Update Determination	Data Collection Start Date
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay)	Starting FY 2014	October 1 , 2012
NQF #0138	National Health Safety Network (NHSN) Catheter - associated Urinary Tract Infection (CAUTI) Outcome Measure	Starting FY 2014	October 1 , 2012
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream 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	January 1, 2014
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel	Starting FY 2016	January 1, 2014

The Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set (LTCH CARE Data Set) was developed specifically for use in LTCHs for data collection of NQF #0678 Pressure Ulcer measure 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 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 & Evaluation (CARE), were incorporated into the LTCH CARE Data Set V1.01⁴. The Office of

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 The LTCH CARE Data Set, the data collection instrument for the submission of the pressure ulcer measure, was approved on April 24, 2012 by the Office of Management and Budget in accordance with the Paperwork Reduction Act. The OMB Control

Management and Budget (OMB) approved the LTCH CARE Data Set for use in the LTCH QRP on April 24, 2012 (OMB Control number: 201202-0938-003). OMB approved the LTCH CARE Data Set V1.01 for one year conditional upon the expansion of the measure, *Pressure Ulcers That are New or Have Worsened* (NQF #0678), to the LTCH setting. This measure was subsequently fully endorsed and approved for expansion to the post-acute care settings (LTCHs and IRFs). This decision was board ratified by NQF on August 1, 2012. Evidence of endorsement and expansion in the form of a letter from the Vice President of NQF Performance Measures is attached to this document as Appendix C. The CMS Division of Chronic and Post-Acute Care is requesting that approval for the current version of the LTCH CARE Data Set V1.01 (OMB Control number 201202-0938-003), be extended through December 31, 2013.

Beginning January 1, 2014, the following changes will be made to the LTCH CARE Data Set V1.01 to create LTCH CARE Data Set V2.00:

- The addition of Section O: Major Treatments, Procedures, and Clinical Data to discharge responses to collect data elements for NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.

The use of this newly created section in LTCH CARE Data Set is necessary in order to allow CMS to collect LTCH quality measure data in compliance with Section 3004 of the Affordable Care Act. There are no other reasonable alternatives available to CMS for use in the collection of seasonal influenza vaccine data in LTCHs.

- The addition of A2500: Program Interruptions, A2510: Number of program interruptions during this stay in this LTCH, and A2520 A1 – C2: Program Interruption Dates.

Item will allow CMS to evaluate effect of program interruptions on quality measures and will allow providers to skip next two items if response to A2500 is 00.

- Removal of the covariate items related to data collection for NQF #0678 Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) from discharge data sets.
- Removal of items related to date of oldest pressure ulcer, dimensions of unhealed pressure ulcer, and most severe tissue type.
- Removal of the administrative items related to education, lifetime occupations, primary diagnosis, correction number, discharge delay, discharge return status.

The removal of these items will decrease burden and still allow the provision of sufficient information for the implementation of the Long-Term Care Hospital Quality Reporting Program.

- We have also made a minor editorial change to the term “non-removable” and have changed the item number for A2100 to A2110.

2. Information Users

- Data Submitters: All LTCHs
- Data Users:
 - CMS - as required under Section 3004 of the Affordable Care Act
 - Public - the measure calculated from the data obtained will be made available at a later date for public use on CMS' website.

3. Use of Information Technology

LTCHs will 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 will 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) for transmitting required seasonal influenza vaccine measure records. LTCHs will soon begin using the QIES ASAP system for transmitting other measure records, such as pressure ulcer measure records.

CMS will require that the collected data be transmitted to CMS electronically, in a manner similar to the process soon to be used by LTCHs submitting 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.

Each data item will meet the Federal Commission for Healthcare Information Technology (CHIT) requirements for interoperability. Data specifications will be made available for LTCHs to submit the specified data items in an interoperable manner for meeting the 2015 reporting requirements for 2017 payment update determination.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the standardized information regarding seasonal influenza vaccination 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 information. Provider participation in the submission of quality data is mandated by Section 3004 of the Affordable Care 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 quality data, this provider shall be subject to a 2% reduction in their payment update for the standard Federal rate for discharges from that LTCH during that rate year.

6. Less Frequent Collection

The updated LTCH CARE Data Set will be used in LTCHs to collect quality measure data about the seasonal influenza vaccine during the patient's stay. Collection of seasonal influenza vaccine data will be performed upon admission and discharge of every patient. LTCHs will be required to submit this data to CMS on a regular periodic basis.

7. Special Circumstances

None.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on February 1, 2013 (78 FR 7433). There were no comments received.

The updated LTCH CARE Data Set was developed in consultation with the CMS Division of Chronic and Post Acute Care measure development contractor, Research Triangle Institute, International (RTI), the CMS Division of National Systems (DNS) and its contractors, Telligen, Stepwise and Buccaneer.

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 by use of 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 use in the LTCH quality reporting program, which has been established pursuant to Section 3004 of the Affordable Care Act.

12. Burden Estimates (Hours & Wages)

A. Burden Estimate from the Prior PRA Package

(Filed in August 2011, with notices published in the Federal Register on September 2, 2011 December 28, 2011)

Average Number of Reports Submitted By Each LTCH per Month = 25

131,500 discharges per all LTCHs per year

131,500 discharges per all LTCHs per year / 435 LTCHs in US = 302 discharges per each LTCH per year

302 discharges per each LTCH per year / 12 months/year = 25 discharges per each LTCH per month

Average Number of Reports Submitted By Each LTCH Each Year = 604

131,500 discharges per all LTCH per year / 435 LTCHs in US = 302 discharges per each LTCH per year

(302 discharges per each LTCH per year x 2 reports per patient per stay = 604 reports submitted per each LTCH per year)

Average Number of Reports Submitted By All LTCHs in the U.S. Each Year = 263,000

302 reports submitted per each LTCH per year x 435 LTCHs in U.S. = 131,370 reports submitted by all LTCHs in the U.S. each year)

131,370 submissions per all LTCHs per year x 2 submissions per each pt per admission = 262,740 submissions per all LTCHs per year)

Average Time per Pressure Ulcer Submission / TOTAL = 20 minutes per patient

10 minutes spent to collate data and perform data entry for **admission report**)

10 minutes spent to collate data and perform data entry for **discharge report**)

Estimated Annual Hourly Burden for each LTCH = 50 hours/LTCH/year

25 reports submitted by each LTCH per month x 20 min per patient to collate and submit report of pressure ulcer data = 500 min per each LTCH per month

500 min per each LTCH per month / 60 minutes/hour = 8.33 hours spent by each LTCH per month

8.33 hours spent by each LTCH per month x 12 months/year = 100 hours spent by each LTCH per year

Estimated Annual Hourly Burden for all LTCHs in the U.S = 43,500 hours/LTCH/year

100 hours per each LTCH per year x 435 LTCHs = 43,500 hours per all LTCHs per year

Cost/Wage Calculation

Average time spent to report PU data on each patient per stay = 20 minutes

20 minutes clerical time spent to input clinical data related to pressure ulcers into computer– paid @ **\$16.83** per hour

Wage Calculation:

20 minutes per patient per stay x 25 reports by each LTCH per month = 500 minutes/LTCH/month

500 minutes by each LTCH per month / 60 minutes/hour = **8.33** hours/each LTCH/month

8.33 hours per LTCH per month x 12 months/year = **100** hours spent by each LTCH per year

Estimated Annual Cost Burden per each LTCH = \$1,683

100 hours per each LTCH per year x \$16.83 per hour = **\$1,683** wages/per each LTCH/year

Estimated Annual Cost Burden per All LTCHs = \$732,105

\$1,683 wages per each LTCH per year x 435 LTCH providers in U.S. = \$732,105 Total wages expended by all LTCHs in the U.S. per year

Average Monthly costs to All LTCHs:

\$732,105 annual cost burden to all LTCHs each year/12 months per year = **\$61,009**

Average Monthly costs to Each LTCH:

\$732,105 annual cost burden to all LTCHs each year /12 months per year/435 LTCHs = **\$140.25**

Cost To Each LTCH Per Pressure Ulcer Submission Per Patient:

\$732,105 annual cost burden to all LTCHs each year /131,370 patient treated per year by all LTCHs in the U.S. = **\$5.57**

Cost To Each LTCH Per Each Individual Pressure Ulcer Submission:

\$732,105 annual cost burden to all LTCHs per year / 262,740 individual pressure ulcer reports per year = **\$2.78**

B. Current Burden Estimate

Below is an updated burden estimate for the LTCH CARE Data Set. This updated burden estimate contains the following new information: (a) an updated number of yearly LTCH discharges; (b) updated time estimates based on new measures that have been added to the LTCH Quality Reporting Program.

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

Total Number of LTCH in U.S. = **442**

Total Number of Discharges from all LTCHs per year: 202,050

134,700 - Medicare Beneficiaries

67,350 – Non Medicare Beneficiaries

202,050⁵ – Total LTCH D/C's

Estimated Number of Discharges from each LTCH per year = 457

202,050 D/Cs from all LTCHs / **442** LTCHs in U.S.

Estimated Number of Discharges from each LTCH per month = 38

202,050 D/Cs from all LTCHs / **442** LTCHs in U.S. / **12** months per year = **38**

Estimated Number of LCDS's submitted by all LTCHs per year = 403,988

457 estimated # of D/C's in each LTCH per year x **442** LTCHs in US = **201,994** D/C's per all LTCHs per year

201,994 D/C'S per all LTCH per year x **2** LCDS forms per patient = **403,988** LCDS per all LTCHs per year

Estimated Average Number of LCSD's submitted by each LTCH per year = 914

403,988 LCDS per all LTCHs in U.S. / **442** LTCHs in US = **914** LCDS per each LTCH

Estimated Average Number of LCSD's submitted by each LTCH per year = 914

(Alternate Method of Calculation)

202,050 D/C'S per all LTCH per year x **2** LCDS forms per patient = **404,100** LCDS per all LTCHs per year

404,100 LCDS per all LTCHs per year / **442** LTCHs in U.S. = **914** LCDS per each LTCH

Estimated Average Number of LCSD's submitted by each LTCH per month = 76

403,988 LCDS per all LTCHs in U.S. per mo. / **442** LTCHs in US = **914** LCDS per each LTCH per year

914 LCDS per each LTCH per year / **12** months per year = **76** LCDS per each LTCH per month

Estimated Average Number of LCSD's submitted by All LTCHs per month = 33,666

403,988 LCDS per all LTCHs in U.S. per year / **12** months per year

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

⁵ MedPAC Report To Congress, March 2012, page 261

(http://www.medpac.gov/documents/Mar12_EntireReport.pdfhttp://www.medpac.gov/documents/Mar12_EntireReport.pdf)

Time Required to Complete Each LTCH CARE Data Set Assessment = 32 minutes

- 11 minutes for Admission assessment – nursing/clinical staff time to collect clinical data;
- 11 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
- 32 minutes⁶** – Total time burden to complete LTCH CARE Data Set per patient

Estimated Annual Time Burden per each LTCHs = 480 hrs/each LTCH/year

Estimated Annual Time Burden all LTCHs = 201,552 hrs/all LTCH's/year

- 32 minutes/form x 76 forms/each LTCH/month = 2,432 minutes/each LTCH/month
- 2,432 minutes / 60 minutes/ hour = 40 hours per LTCH per month
- 40 hours per LTCH per month x 12 months/year = 480 hours per each LTCH/year
- 480 hours/each LTCH/year x 442 LTCHs in U.S. = 212,160 hrs/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

11 minutes for Admission assessment - nursing time to collect clinical data @ \$33.23/hour⁷

11 minutes for Discharge assessment - nursing time to collect clinical data;@ \$33.23/hour

- 22 minutes x 914 LCDS forms/ each LTCH / yr = 20,108 minutes /each LTCH / year
- 20,108 minutes per LTCH per yr / 60 minutes = 335 hours per year
- 335 hours per year x \$33.23 per hour = \$11,132 nursing wages /per each LTCH / year
- \$11,132 x 442 LTCH providers = \$4,920,344 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/hour

- 10 minutes x 914 LCDS forms/ LTCH/yr = 9,140 minutes/LTCH/year
- 9,140 minutes per LTCH per yr / 60 minutes = 152 hours per year
- 152 hours per year x \$15.59⁸ per hour = \$2,370 admin assistant wages/per LTCH/year
- \$2,370 x 442 LTCHs = \$1,047,540 per all LTCH providers/year

4. Combined Calculations:

\$11,132 Nursing wages/per LTCH /year (LTCH CARE Data Set)

\$ 2,370 Admin assistant wages/per LTCH /year (LTCH CARE Data Set)

⁶ This time estimate includes the time required to complete both the required and voluntary questions on the LTCH CARE Data Set.

⁷ The mean hourly wage of \$33.23 for a Registered Nurse was obtained from the U.S. Bureau of Labor Statistics. See <http://www.bls.gov/oes/current/oes291111.htm>)

⁸ The mean hourly wage of \$15.59 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics. See <http://www.bls.gov/oes/current/oes436013.htm>

\$13,502 Total Annualized Cost to Each LTCH Provider

\$ 4,920,344 Nursing wages/per ALL LTCHs /year (**LTCH CARE Data Set**)

\$ 1,047,540 Admin assistant wages/per ALL LTCHs /year (**LTCH CARE Data Set**)

\$5,967,884 Total Annualized Cost For All LTCH Providers

5. Additional Calculations:

Total Yearly Cost To All LTCH Providers for Reporting Data using the LCDS = \$5,967,884

- **\$13,502 x 442 LTCHs in U.S. = \$5,967,884**

Total Yearly Cost To Each LTCH Provider for Reporting Quality Data = \$13,502

- **\$5,967,884 yearly cost for all LTCHS / 442 LTCHs in U.S. = \$13,502**

Estimated Average Monthly Cost To Each LTCH Provider for Reporting Quality Data = \$1,125

- **\$5,967,884 Total yearly cost for all LTCHS/ 442 LTCHs in U.S./ 12 months per year = \$1,125**

Estimated Average Cost per each LCDS Submission = \$14.77

- **\$5,967,884 yearly cost of LCDS submissions for ALL LTCHs / 403,998 LCDS submissions per all LTCHs/year = \$14.77; OR**
 - **\$13,502 yearly cost of LCDS submissions per each LTCH / 914 LCDS submissions per LTCHs/year = \$14.77**
-

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

- The LTCH CARE Date Set consists of 4 different assessment forms.
- All of these forms consist of some data items (questions) that are required, and some that are voluntary (LTCH may chose not to answer the voluntary questions without affecting quality reporting compliance)
- An LTCH is required to perform and submit an admission assessment within 3 days after the patient is admitted.
- An LTCH must also perform a discharge assessment on each patient,(but only one of the three discharge assessment forms is used)
- There are 3 different types of Discharge Assessment forms:
 - o Planned Discharge Assessment
 - o Unplanned Discharge Assessment
 - o Expired (Death) Assessment
- The type of discharge assessment form used is based on the circumstances of the discharge.

Admission Assessment

Number of Required Questions:	25	@0.3 minutes each = 7.5 minutes
Number of Voluntary Questions:	11	@0.3 minutes each = 3.3 minutes
Total Number of Questions:	36	@0.3 minutes each =10.8 minutes

Planned Discharge Assessment

Number of Required Questions:	25	@0.3 minutes each = 7.5 minutes
Number of Voluntary Questions:	11	@0.3 minutes each = 3.3 minutes
Total Number of Questions:	36	@0.3 minutes each =10.8 minutes

Unplanned Discharge Assessment

Number of Required Questions:	25	@0.3 minutes each = 7.5 minutes
Number of Voluntary Questions:	11	@0.3 minutes each = 3.3 minutes
Total Number of Questions:	36	@0.3 minutes each = 10.8 minutes

Expired Assessment

Number of Required Questions:	13	@ 0.3 minutes each = 3.9 minutes
Number of Voluntary Questions:	4	@0.3 minutes each = 1.2 minutes
Total Number of Questions:	17	@0.3 minutes each = 5.1 minutes

Supporting Statement for Administering the LTCH CARE Data Set

The following are cost estimates for several combinations of the LTCH CARE Data Set Admission and Discharge forms:

Planned Discharge / Required and Voluntary Data Given By Provider

Admission Assessment – Nursing Wages (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Admission Assessment – Nursing Wages (Voluntary)	3.3 minutes	@33.23 per hour = \$ 1.83
Admission Assessment – (Admin Assistant)	10.0 minutes	@15.59 per hour = \$ 2.60
Planned Discharge Assessment (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Planned Discharge Assessment (Voluntary)	3.3 minutes	@33.23 per hour = \$ 1.83
	21.6 minutes	@33.23 per hour = \$11.98
	10.0 minutes	@15.59 per hour = \$ 2.60
	31.6 minutes	= \$14.58

Unplanned Discharge / Required and Voluntary Data Given By Provider

Admission Assessment – Nursing Wages (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Admission Assessment – Nursing Wages (Voluntary)	3.3 minutes	@33.23 per hour = \$ 1.83
Admission Assessment – (Admin Assistant)	10.0 minutes	@15.59 per hour = \$ 2.60
Unplanned Discharge Assessment (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Unplanned Discharge Assessment (Voluntary)	3.3 minutes	@33.23 per hour = \$ 1.83
	21.6 minutes	@33.23 per hour = \$11.98
	10.0 minutes	@15.59 per hour = \$ 2.60
	31.6 minutes	= \$14.58

Planned or Unplanned Discharge / Required Only Data Given By Provider

Admission Assessment – Nursing Wages (Required Data Only)	7.5 minutes	@33.23 per hour = \$ 4.16
Admission Assessment – (Admin Assistant)	10.0 minutes	@15.59 per hour = \$ 2.60
Planned Discharge Assessment (Required Data Only)	7.5 minutes	@33.23 per hour = \$ 4.16
	15 minutes	@33.23 per hour = \$ 8.32
	10 minutes	@15.59 per hour = \$ 2.60
	25 minutes	= \$10.92

Expired Discharge / Required and Voluntary Data Given By Provider

Admission Assessment – Nursing Wages (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Admission Assessment – Nursing Wages (Voluntary)	3.3 minutes	@33.23 per hour = \$ 1.83
Admission Assessment – (Admin Assistant)	10.0 minutes	@15.59 per hour = \$ 2.60
Expired Discharge Assessment - (Required)	3.9 minutes	@33.23 per hour = \$ 2.16
Expired Discharge Assessment - (Voluntary)	1.2 minutes	@33.23 per hour = \$ 0.66
	15.9 minutes	@33.23 per hour = \$ 8.81
	10.0 minutes	@15.59 per hour = \$ 2.60
	25.9 minutes	= \$11.41

Expired Discharge / Required Only Data Given By Provider

Admission Assessment – Nursing Wages (Required)	7.5 minutes	@33.23 per hour = \$ 4.16
Admission Assessment – (Admin Assistant)	10.0 minutes	@15.59 per hour = \$ 2.60
Expired Discharge Assessment - (Required)	3.9 minutes	@33.23 per hour = \$ 2.16
	11.4 minutes	@33.23 per hour = \$ 6.32
	3.9 minutes	@15.59 per hour = \$ 2.60
	15.3 minutes	= \$8.92

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 quality reporting program including costs associated with the IT system used to process LTCH submissions to CMS and analysis of the data received.

CMS has 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 quality measure data to CMS.

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

DCPAC has retained the services of a third contractor to assist us 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 \$239,592.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or \$111,102.

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)	\$ 293,592
<u>GS-14 Federal Employee (33% X 3 years)</u>	<u>\$ 111,102</u>
Total cost to Federal Government:	\$3,154,694

15. Changes to Burden

In section 12 above, we have provided the burden estimate that was submitted with our initial PRA package. We have also provided a new, updated burden estimate. A comparison of these two burden estimates will show that adjustments have been made to the time and cost estimates for several reasons. First, we have received updated information from the Center For Medicare regarding the current number of Medicare-certified LTCHS in the U.S., as well as the total number of yearly LTCH discharges. We use this information to inform our burden calculations. Both of the above figures have increased since the previous PRA submission and thus have increased the burden calculation included in this package.

We have determined that it was necessary to add a time estimate for a clinician such as a Registered Nurse to either review, complete, or verify the LTCH CARE Data Set Admission and Discharge Assessment on each patient. The added estimate of clinical time is in addition to the estimate of administrative time to aggregate and submit the quality data to CMS. Use of these updated statistics has contributed to an increase in the burden cost estimates.

Our previous burden estimate was completed in August, 2011, and before the start of the LTCH Quality Reporting Program, thus we had no real-time experience upon which to base our burden estimates. In the original burden calculation,⁹ we estimated that it would take a total of 10 minutes of administrative staff time to aggregate and transmit the LTCH CARE Data Set on each patient. We did not include any clinical staff time in the original burden calculation because we expected that data related to pressure ulcers would be collected and documented by an LTCH as a normal part of patient care.

The LTCH QRP went live on October 1, 2012. Given that the LTCH QRP is nearing the end of the first quarter of reporting, we have become more familiar with the burden of this program. We have now received feedback from LTCH providers about the time burden associated with the completion of the LTCH CARE Data Set. We have considered feedback from LTCH providers in the form of public comments to the most recent LTCH proposed rule, questions during Open Door forums, and LTCH helpdesk inquiries. LTCH providers have stated that CMS has grossly underestimated the amount of time that is required of the LTCH staff to complete the LTCH CARE Data Set on each LTCH patient.

In response to the feedback received, we have significantly revised our burden estimates. For example, in our previous PRA package burden estimate, we estimated that it would take approximately 15

⁹ OMB control number CMS-10409. The 30 day PRA notice was published in the Federal Register on September 2, 2011. The 60 day PRA notice was published on December 28, 2011.

minutes of administrative staff time to complete the admission assessment and another 10 minutes of administrative staff time to complete the discharge assessment. We did not include any clinical staff time in this burden estimate for the completion of the LTCH CARE Data Set. In our current burden estimate, we have increased our time estimate to **11** minutes of clinical staff time for the admission assessment and another **11** minutes for the discharge assessment. We also included **10** minutes of administrative time per patient in addition to the clinical time. This burden estimate includes the time required to complete the new data items added for the patient influenza measure. This measure was proposed and finalized in the LTCH final rule that was published in the Federal Register on August 31, 2012, Vol. 77, No. 170.

While the burden calculation for this PRA submission has increased significantly compared to CMS' original calculation, we believe that providers will react positively, as the calculation now more accurately reflects the required burden associated with implementing collection of the CMS-specified quality measures, as mandated by Section 3004 of the Patient Protection and Affordable Care Act.

All changes that have been made to the LTCH CARE Data Set, since April 30, 2012 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. The date and method for publication of this data has not yet been established. At this time, there are no publications or tabulations associated with data collection not associated with Section 3004 of the Affordable Care Act.

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 V2.00 Items

APPENDIX B

**Master List of Changes to LTCH CARE Data Set Version 1.01 to prepare LTCH CARE Data Set
Version 2.00**