

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

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

**REVISED SUPPORTING STATEMENT-PART A**

LTCH CARE DATA SET  
FOR THE COLLECTION OF DATA  
PERTAINING TO THE RATE OF  
PRESSURE ULCERS THAT ARE NEW OR WORSENERD IN PATIENTS IN  
LONG TERM CARE HOSPITALS (LTCHs)

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**TABLE OF CONTENTS**

1. Background & Justification.....	1
2. Information Users.....	2
3. Use of Information Technology.....	2
4. Duplication of Efforts.....	2
5. Small Businesses.....	2
6. Less Frequent Collection.....	3
7. Special Circumstances.....	3
8. Federal Register/Outside Consultation.....	3
9. Payment/Gifts to Respondents.....	3
10. Confidentiality.....	3
11. Sensitive Questions.....	4
12. Burden Estimates (Hours & Wages).....	4
13. Capital Costs.....	5
14. Cost to Federal Government.....	5
15. Changes to Burden.....	6
16. Publication/Tabulation Dates.....	6
17. Expiration Date.....	6
18. Certification Statement.....	7
APPENDIX A Master List of LTCH CARE Data Set Items.....	8
APPENDIX B Master List of Changes to LTCH CARE Data Set Items since September 2, 2011.....	9

**Revised Supporting Statement for Paperwork Reduction Act Submissions**  
**PART A**

***LTCH CARE Data Set For the Collection of Data Pertaining To the Rate of Pressure Ulcers  
That Are New or Worsened In Patients in Long Term Care Hospitals***

**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). Beginning in FY 2014, LTCHs that fail to submit quality measures data to CMS 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. One of the quality measures LTCHs are to collect and submit data on for this new quality reporting program is the Percent of Residents with Pressure Ulcers That Are New or Have Worsened.

A new pressure ulcer data set has been developed specifically for use in LTCHs. This pressure ulcer data set incorporates data items contained in other, well know and clinically established pressure ulcer data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and Continuity Assessment Record & Evaluation (CARE).

Beginning on October 1, 2012, LTCHs will begin to collect a newly created set of pressure ulcer measure data elements for the LTCH quality reporting program. This data set consists of the following components:

- (1) pressure ulcer documentation;
- (2) selected covariates related to pressure ulcers;
- (3) patient demographic information; and;
- (4) a provider attestation section

The use of the newly created 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 pressure ulcer data in LTCHs.

## **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 pressure ulcer measure records.

CMS will require that the collected data be transmitted to CMS electronically, in a manner similar to the process 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 is 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 pressure ulcer data item will meet the Federal 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 2014 reporting requirements.

## **4. Duplication of Efforts**

This information collection does not duplicate any other effort and the standardized information regarding pressure ulcers 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 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 LTCH CARE Data Set will be used in LTCHs to collect quality measure data about pressure ulcers that are new or that have worsened since admission. Collection of pressure ulcer 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 Notice was published on Friday, September 2, 2011 (Volume 76, Issues 171). The 60 day public comment period began on Friday, September 2, 2011, and continued until Tuesday, November 1, 2011. Two public comments were received during this time. Comment responses are included in Exhibit A.

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

## **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 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 ID number 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 considered to be confidential personal health information. This individual 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 thru the use of other CMS instruments in other post-acute care settings. The items on the 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)**

### **Burden Estimate For Pressure Ulcer Submissions (Total Hours and Wages)**

To estimate the total time and cost burdens associated with pressure ulcer quality measure data reporting using the LTCH CARE Data Set, CMS performed the following calculations (*Note: all values rounded to whole numbers*):

Total number of LTCHs= **435**

Total Number of LTCH discharges per year = **131,500<sup>1</sup>**

**Number of LTCH CARE Data Set responses for each patient per LTCH stay = 2**  
(Completed on admission and discharge)

**Average Number of LTCH CARE Data Set responses by all LTCHs per year = 263,000**  
(131,500 discharges per year x 2 submissions per patient = 263,000 submissions/all LTCHs/year)

**Average Number of LTCH CARE Data Set responses by each LTCH per year = 604**  
(131,500 discharges per year x 2 submissions per patient = 263,000 submissions per all LTCHs per year)  
(263,000 submissions per all LTCHs per year / 435 LTCHs in U.S. = 604 submissions/each LTCH per year)

**Average Number LTCH CARE Data Set responses by each LTCH per month = 50**  
(604 pressure ulcer submissions per each LTCH per year/12 months/year = 50)

Average time spent to perform data entry per LTCH CARE Data Set = **10 minutes**

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<sup>1</sup> [http://www.medpac.gov/chapters/Mar11\\_Ch10.pdf](http://www.medpac.gov/chapters/Mar11_Ch10.pdf)

**Average time spent to perform LTCH CARE Data Set responses per patient per LTCH stay = 20 minutes**  
(10 minutes x 2 LTCH Data Sets per patient per each LTCH stay = 20 minutes)

**Estimated Hour Burden Associated with LTCH CARE Data Set Responses**

Estimated **Monthly** Hour Burden per **each** LTCH = **8.33** hour/month

Estimated **Annual** Hour Burden per **each** LTCH = **100**

Estimated **Annual** Hour Burden for **all** LTCHs = **43,500** hour/year

**Estimated Cost Burden Associated with LTCH CARE Data Set Responses**

Average Cost per **each** submission = **\$5.57**

Average Cost per **each** LTCH/year = **\$1,683**

Average Cost per **each** LTCH/month = **\$140.25**

Average Cost per **all** LTCHs/year = **\$732,105**

To estimate the total hour and cost burden, CMS consulted the following sources:

- Data Source – MedPAC Report To Congress: March 2011  
([http://www.medpac.gov/chapters/Mar11\\_Ch10.pdf](http://www.medpac.gov/chapters/Mar11_Ch10.pdf))
- Data Source – U.S. Bureau of Labor wage statistics ([www.bls.gov](http://www.bls.gov))

### **13. Capital Costs**

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

### **14. Cost to Federal Government**

HHS/CMS will incur costs associated with the collection and handling of the data through use of the LTCH CARE Data Set in LTCHs. It is anticipated that this data will be transmitted by the LTCHs to DNS. This data will be processed by DNS and the list of eligible LTCHs will be generated.

The estimated cost to the federal government for the handling of this quality measures data is estimated to be **\$760,500**.

## **15. Changes to Burden**

The LTCH CARE Data Set will be newly introduced to LTCHs. However, the contents of the LTCH CARE Data Set will elicit information that LTCHs should already be collecting in the normal course of business and as part of safe and effective patient care. As LTCHs should already be collecting information regarding pressure ulcers in the normal course of patient care, there should be little, if any, additional burden placed upon LTCH providers to complete the LTCH CARE Data Set.

We acknowledge that the administrative burden to LTCH providers will be somewhat greater at the outset, because of the establishment of this new quality reporting program. However, the burden that is associated with the LTCH quality reporting program will be necessary in order for CMS to meet the requirements set forth in section 3004 of the Affordable Care Act. We anticipate that after the initial year of the LTCH quality reporting program, the burden to the provider should diminish as providers will have had time to acclimate themselves to the program and become more familiar with its requirements.

The 60 day Federal Notice was published on Friday, September 2, 2011 (Volume 76, Issues 171). The 60 day public comment ran from September 2, 2011 until November 1, 2011. Since September 2, 2011, CMS has worked on the operational aspects of the LTCH Quality Reporting Program. While performing this work, CMS determined that several non-material changes were needed on the LTCH CARE Data Set. These changes have been made merely to correct minor errors and **do not** increase the burden to the provider.

Changes that have been made to the LTCH CARE Data Set, since September 2, 2011 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 Items**

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**APPENDIX B**

**Master List of  
Changes to LTCH CARE Data Set Items since September 2, 2011**