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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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TABLE OF CONTENTS

A.	Background.....	1
B.	Justification.....	1
1.	<u>Need and Legal Basis</u>	1
2.	<u>Information Users</u>	3
3.	<u>Use of Information Technology</u>	3
4.	<u>Duplication of Efforts</u>	3
5.	<u>Small Businesses</u>	3
6.	<u>Less Frequent Collection</u>	4
7.	<u>Special Circumstances</u>	4
8.	<u>Federal Register/Outside Consultation</u>	4
9.	<u>Payment/Gifts to Respondents</u>	4
10.	<u>Confidentiality</u>	4
11.	<u>Sensitive Questions</u>	4
12.	<u>Burden Estimates (Hours & Wages)</u>	4
13.	<u>Capital Costs</u>	7
14.	<u>Cost to Federal Government</u>	7
15.	<u>Changes to Burden</u>	8
16.	<u>Publication/Tabulation Dates</u>	8
17.	<u>Expiration Date</u>	8
18.	<u>Certification Statement</u>	8

Appendices:.....8
Appendix A – LTCH CARE Data Set V 5.00 Item Mockups and Change Table.....8

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 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 December 31, 2021. 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** lists the quality measures currently collected via the LTCH CARE Data Set.

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

NQF Number	Measure Name	Data Collection Start Date
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
Not endorsed	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	July 1, 2018
Not endorsed	Ventilator Liberation Rate	July 1, 2018

The burden associated with this requirement is staff time required to complete the LTCH CARE Data Set. The burden associated with transmitting the data is unaffected by the revisions 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 fiscal year (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 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 2020 IPPS/LTCH PPS final rule, we adopted two Transfer of Health Information measures as well as standardized patient assessment data elements (SPADEs) beginning with the FY 2022 LTCH QRP. We estimate the data elements for the Transfer of Health Information quality measures will take 1.5 minutes of clinical staff time to report data on discharge. We believe that the additional LTCH CARE Data Set data elements will be completed by registered nurses and licensed vocational nurses. Individual LTCHs determine the staffing resources necessary. We estimate 102,468 discharges from 415 LTCHs annually. This equates to an increase of 2,562 hours in burden for all LTCHs (0.025 hours × 102,468 discharges). Given 0.8 minutes of registered nurse time at \$72.60 per hour and 0.7 minutes of licensed vocational nurse time at \$45.24 per hour to complete an average of 247 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by \$367.08 per LTCH annually, or \$152,337 for all LTCHs annually.

We estimate the SPADEs will take 11.3 minutes of clinical staff time to report data on admission and 10.4 minutes of clinical staff time to report data on discharge, for a total of 21.7 minutes. We believe that the additional LTCH CARE Data Set data elements will be completed by registered nurses and licensed vocational nurses. Individual LTCHs determine the staffing resources necessary. We estimate 102,468 discharges from 415 LTCHs annually. This equates to an increase of 37,093 hours in burden for all LTCHs (0.362 hours × 102,468 discharges). Given 11.4 minutes of registered nurse time at \$72.60 per hour and 10.2 minutes of licensed vocational nurse time at \$45.24 per hour to complete an average of 247 sets of LTCH CARE Data Set assessments per provider per year, we estimated the total cost will be increased by \$5,308.21 per LTCH annually, or \$2,202,906 for all LTCHs annually.

a) Transfer of Health Information Measures

- Transfer of Health Information from LTCH to Provider–Post-Acute Care (PAC)
- Transfer of Health Information from LTCH to Patient–Post-Acute Care (PAC)

b) Standardized Patient Assessment Data Elements

- Brief Interview for Mental Status (BIMS)
- Confusion Assessment Method (CAM)
- Patient Health Questionnaire-2 to 9
- Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)
- Ability to Hear
- Ability to See
- Nutritional Approaches: Parenteral/IV Feeding, Feeding Tube, Mechanically Altered Diet, Therapeutic Diet
- Cancer Treatments: Chemotherapy, Radiation

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>.

- Respiratory Treatments: Oxygen Therapy, Suctioning, Tracheostomy Care, Invasive Mechanical Ventilator, Non-invasive Mechanical Ventilator
- Other Treatments: IV Medications, Transfusions, Dialysis, IV Access
- High-Risk Drug Classes and Indications
- Mobility [Car transfer, Walking 10 feet on uneven surfaces, 1 step (curb), 4 steps, 12 steps, Picking up object]
- Transportation
- Preferred Language and Interpreter Services
- Health Literacy
- Social Isolation
- Race
- Ethnicity

See **Appendix A** for the LTCH CARE Data Set V5.00 Item Mockups and Change Table (effective October 1, 2020).

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 (the 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. All of the data that must be reported in accordance with section 1899B(a)(1)(A) must be standardized and interoperable so as to allow for the exchange of the information among PAC providers and other providers and the use of such data in order to enable access to longitudinal information and to facilitate coordinated care.

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. LTCHs recently transitioned from transmitting the data from the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system to the Internet Quality Improvement and Evaluation System (iQIES), which is a modernized, cloud-based solution that was developed through user-centered design.

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 415 LTCHs, approximately 89 are considered small LTCHs. The average number of assessment sets completed yearly is 247, and is the same across all respondents based on the number of actual assessment sets completed by LTCHs in FY 2018.

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

The FY 2019 IPPS/LTCH PPS final rule (84 FR 42524 through 42590) was published to the Federal Register on August 16, 2019 and available at: <https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-16762.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. = **415**

Total Number of Discharges from all LTCHs per year: **102,468**

Estimate Number of Discharges from each LTCH per year = 247
(102,468 D/Cs from all LTCHs / 415 LTCHs in U.S. = 247)

Estimated Number of LCDS's submitted by all LTCHs per year = 204,936
(247 estimated # of D/C's in each LTCH per year x 415 LTCHs in U.S. ≈ 102,468 D/C's per all LTCHs per year
102,468 D/C'S per all LTCHs per year x 2 LCDS forms per patient = 204,936 LCDS per all LTCHs per year)

Estimated Average Number of LCDS's submitted by each LTCH per year = 494
(204,936 LCDS per all LTCHs in U.S. / 415 LTCHs in U.S. = 494 LCDS per each LTCH)
OR

(102,468 D/C'S per all LTCHs per year x 2 LCDS forms per patient = 204,936 per all LTCHs per year
204,936 LCDS per all LTCHs per year / 415 LTCHs in U.S. = 494 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 = 85.4 minutes

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

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

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

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

Estimated Annual Time Burden per each LTCH = 351.4 hours/each LTCH/year

Estimated Annual Time Burden all LTCHs = 145,831 hours/all LTCHs/year

29.333 hours per LTCH per month x 12 months/year = 351 hours per each LTCH/year

351.4 hours/each LTCH/year x 415 LTCHs in U.S. = 145,831 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: 62.3 minutes for Admission & Discharge assessment at \$72.60/hour³

Licensed vocational nurses: 12.2 minutes for Admission & Discharge assessment at \$45.24/hour⁴

Respiratory therapists: 0.9 minutes for Admission & Discharge assessment at \$60.10/hour⁵

Average wages for clinical staff based on completion time: **\$68.04/hour**

75.4 minutes x 247 LCDS forms⁶ / each LTCH / year ≈ 18,624 minutes / each LTCH / year

18,624 minutes per LTCH per year / 60 minutes ≈ 310.4 hours per year

310.4 hours per year x \$68.04 per hour ≈ **\$21,119.62** clinical staff wages /per each LTCH / year

\$21,119.62 x 415 LTCHs ≈ **\$ 8,764,642** 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 \$35.66/hour⁷)

10 minutes x 247 LCDS forms⁸ /per LTCH/year = 2,470 minutes/LTCH/year

³ The mean hourly wage of \$36.30 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 <https://www.bls.gov/oes/current/oes291141.htm>

⁴ The mean hourly wage of \$22.62 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 \$30.05 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 \$17.83 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)

2,470 minutes per LTCH per year / 60 minutes = 41.15 hours per year
41.15 hours per year x \$34.50 per hour ≈ **\$1,467.47** admin assistant wages/per LTCH/year
 $\$1,467.47 \times 415 \text{ LTCHs} \approx \mathbf{\$609,001}$ per all LTCHs/year

4. Combined Calculations

\$21,112.38 – Clinical staff wages/per LTCH /year (LTCH CARE Data Set)
\$1,467.47 – Admin assistant wages/per LTCH /year (LTCH CARE Data Set)
\$22,579.86 – Total Annualized Cost to Each LTCH

\$8,761,640 – Clinical staff wages/per all LTCHs /year (LTCH CARE Data Set)
\$609,001 – Admin assistant wages/per all LTCHs /year (LTCH CARE Data Set)
\$9,370,641 – Total Annualized Cost for All LTCHs

5. Additional Calculations

Total Yearly Cost to All LTCHs for Reporting Quality Data = **\$9,370,641**
\$22,579.86 x 415 LTCHs in U.S. = **\$9,370,641**)

Total Yearly Cost to Each LTCHs for Reporting Quality Data = **\$22,579.86**
(\$9,370,641 yearly cost for all LTCHs / 415 LTCHs in U.S. = **\$22,579.86**)

Estimated Average Cost per each LCDS Submission = **\$91.45**
(\$9,370,641 yearly cost of LCDS submissions for all LTCHs / 102,468 LCDS submissions per all LTCHs/year ≈ **\$91.45**)
OR
(\$22,579.86 yearly cost of LCDS submissions per each LTCH / 247 LCDS submissions per LTCHs/year ≈ **\$91.45**)

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 patient 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): 253
Number of Required Questions for Assessment Completion Time: 134

Planned Discharge Assessment

Number of Required Questions (including subitems): 175
Number of Required Questions for Assessment Completion Time: 132

Unplanned Discharge Assessment

Number of Required Questions (including subitems): 105

Number of Required Questions for Assessment Completion Time: 68

Expired Assessment

Number of Required Questions (including subitems): 36

Number of Required Questions for Assessment Completion Time: 15

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 software to collect and submit the LTCH CARE Data Set. Information regarding the free software, including instructions for installing and using the software, is located at:

<https://qtso.cms.gov/providers/long-term-care-hospital-ltch-providers>.

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 CARE Data Set 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 LTCHs 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 software that is made available to LTCHs 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 & help desk 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 LTCH CARE Data Set V5.00 in the FY 2020 IPPS/LTCH PPS proposed rule and the revised PRA package submission for LTCH CARE Data Set V5.00 finalized in the FY 2020 IPPS/LTCH PPS final rule.

The total annual burden hours increased from 145,665 to 145,831. We have decreased our time estimate from 39.2 to 39.15 minutes for completing the admission assessment and increased our time estimate from 36.1 to 36.25 minutes for completing the discharge assessment. Overall, the combined time estimate increased from 75.3 to 75.4 minutes for the revised LTCH CARE Data Set.

The wages for a registered nurse and administrative assistant have been updated. In addition, we have added wages for licensed vocational nurses (\$45.24 per hour; \$22.62 without fringe benefits) and respiratory therapists (\$60.10 per hour; \$30.05 without fringe benefits) since they have been assigned to some of the new items added to the LTCH CARE Data Set. Overall, the average wage based on time to complete the assessment for each clinical staff increased from 65.94 to \$68.04.

The estimated average cost per each LTCH CARE Data Set V5.00 submission increased from \$88.46 to \$91.45. Subsequently, the total yearly cost to each LTCH for reporting quality data increased from \$21,840.54 to \$22,579.86, and the total yearly cost to all LTCHs for reporting data using the LTCH CARE Data Set increased from \$9,063,824 to \$9,370,641.

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 5.00 Item Mockups and Change Table