THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

March 9, 2011

The Honorable Joseph R. Biden, Jr.
President of the Senate
Washington, DC 20510

Dear Mr. President:

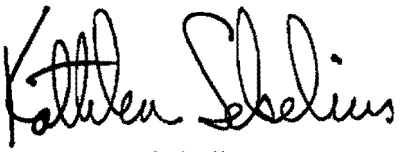
Section 114(b) of the Medicare, Medicaid and SCHIP Extension Act of 2007 (P.L. 110-173) requires that the Secretary of Health and Human Services provide a report to Congress on the establishment of national facility and patient criteria for determining medical necessity, appropriateness of admission, continued stay and discharge from long-term care hospitals (LTCHs) together with recommendations for legislative and administrative action. The Centers for Medicare & Medicaid Services (CMS) contracted with Kennell and Associates with a subcontract to Research Triangle International (RTI) to conduct this study. The Report to Congress includes CMS' recommendations for legislative and administrative actions and its consideration of recommendations contained in the MedPAC June 2004 Report to Congress on long-term care facility and patient criteria. This Report to Congress predates the passage of the Affordable Care Act and thus does not discuss possible effects of the Affordable Care Act on LTCHs. I respectfully submit this letter and the enclosed Report to Congress to satisfy this requirement.

This study provides a review of past studies by MedPAC, the LTCH industry and RTI (under contract to CMS) examining patient and facility characteristics of LTCHs and past examinations of LTCH payment adequacy and patient appropriateness. This is followed by an examination of the clinical characteristics of the LTCH population focused on defining medical complexity, identifying critically complex patients, predicting outcomes for these patients using severity scoring systems, and evaluating their quality of care. The final chapter presents an agenda for research to define a critically complex patient population. This study is enclosed with this Report to Congress as Appendix I.

Based on research reported in the above study, I currently have no actions to recommend. In a subsequent letter from MedPAC to CMS of March 24, 2008, MedPAC stated that "...The types of cases treated by LTCHs can be (and are) treated in other settings, particularly in step-down units of many acute-care hospitals. Therefore, it is not possible (nor desirable) to develop criteria defining patients who can be cared for exclusively in LTCHs. Rather, CMS should seek to define the **level of care** typically furnished in LTCHs, step-down units of many acute-care hospitals, and some specialized skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs)."

Please accept the enclosed report as the Department of Health and Human Services' Report to Congress. I am also sending a copy of this report to the Speaker of the House of Representatives.

Sincerely,



Kathleen Sebelius

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

March 9, 2011

The Honorable John A. Boehner
Speaker of the House of Representatives
Washington, DC 20515

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Please accept the enclosed report as the Department of Health and Human Services' Report to Congress. I am also sending a copy of this report to President of the Senate.

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Kathleen Sebelius

Enclosure

CMS Report

Determining Medical Necessity and Appropriateness of Care for Medicare Long Term Care Hospitals

March 2011

INTRODUCTION

This Report to Congress is the Secretary's response to Section 114(b) (2) of the Medicare, Medicaid and SCHIP Extension Act (MMSEA) of 2007 (PL 110-173). The statute requires that the Secretary of Health and Human Services at (b)(1) conduct a study on the establishment of national long-term care hospital (LTCH) facility and patient criteria for determining medical necessity, appropriateness of admission, continued stay and discharge from long-term care hospitals (LTCHs) and at (b)(2) provide a report on the results of this study to Congress together with recommendations for legislation and administrative action, including timelines for implementation of criteria or other appropriate action. The statute further specifies that in conducting the study and preparing the report, the Secretary "shall consider recommendations contained in a report to Congress by the Medicare Payment Advisory Commission in June 2004 for long-term care hospital-specific facility and patient criteria to ensure that patients admitted to long-term care hospitals are medically complex and appropriate to receive long-term care hospital services; and ongoing work by the Secretary to evaluate and determine the feasibility of such recommendations."

The mandated study includes a summary of past research, a discussion of MedPAC's recommendations and recommendations regarding ongoing research that are included as Appendix I. Based on research presented in the mandated study, the Secretary does not recommend the development of additional patient and facility level criteria for LTCHs at this time. Regarding MedPAC's recommendation in 2004 for the development of such criteria, in a subsequent letter to the Centers for Medicare & Medicaid Services (CMS) (dated March 24, 2008), MedPAC stated that "...The types of cases treated by LTCHs can be (and are) treated in other settings, particularly in step-down units of many acute-care hospitals. Therefore, it is not

possible (nor desirable) to develop criteria defining patients who can be cared for exclusively in LTCHs. Rather, CMS should seek to define the **level of care** typically furnished in LTCHs, step-down units of many acute-care hospitals, and some specialized skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs)."

SUMMARY OF THE KENNELL/RTI STUDY (APPENDIX I)

Section I of the Kennell/RTI study contains background information on characteristics of LTCHs and how they have been paid under Medicare. LTCHs represent a relatively small number of hospitals (approximately 400) treating specialized patient groups. They have average Medicare lengths of stay of 25 days or more. About 90 percent of LTCH Medicare cases are admitted directly from an acute care hospital where they have been stabilized medically. Over 80 percent of LTCH patients are Medicare beneficiaries. Over 60 percent of LTCHs are located in the same facilities (co-located) with acute care hospitals, although under separate ownership. The number of LTCHs has increased rapidly during the past 12 years. Only 7 states and Puerto Rico did not have LTCHs in operation by the end of 2007, but, LTCHs are more heavily concentrated in some states than others. The case-mix treated by LTCHs has evolved over time to become centered on the treatment of patients with complex medical conditions.

From 1983 to 2003, LTCHs were paid under a cost based system. LTCHs were moved to a prospective payment system (LTCH-PPS) in Fiscal Year (FY) 2003. Payments are much higher, however, for the same DRG admitted to LTCHs compared to payments received by acute hospitals for the same DRG. CMS payment policy treats cases that are discharged from an acute care hospital directly into an LTCH as two separate stays, eligible for both an IPPS payment for

the initial hospitalization plus a second, often larger LTCH-PPS payment. The following payment policy issues are of potential concern:

- The medical conditions treated in LTCHs are also treated in acute care hospitals and other facilities, especially in areas where no LTCHs operate. Nevertheless, payment amounts differ by type of provider.
- Many patients treated in LTCHs may not require hospital level care and may be more appropriately treated in a less intensive setting.
- The ability to generate two Medicare payments may provide an opportunity to split a predictably long inpatient hospital stay into two PPS payments, especially when LTCHs and acute care hospitals are co-located.

Section II of this study reviews the findings from the Medicare Payment Advisory Commission (MedPAC), studies commissioned by the LTCH industry, and RTI studies under contract to CMS. This section also summarizes recent legislative and regulatory changes affecting LTCHs.

Research Findings from MedPAC

The 2003 MedPAC report documented rapid growth in the number of LTCHs and total Medicare spending on LTCH services, high concentrations of LTCHs in a few states, higher payments and lack of evidence for better clinical outcomes for LTCH users.

MedPAC's 2004 analysis used multivariate modeling on a full sample of LTCH claims and found that, for very complex patients, LTCH use was associated with similar or improved outcomes at similar or lower Medicare payments, compared to patients receiving other (or no) post acute care. Similar results were not found for other, less complex, types of patients. MedPAC recommended in the 2004 report that LTCHs should be defined by facility and patient criteria that ensure that patients admitted to LTCHs are medically complex and have a good

chance of improvement. MedPAC in their March, 2008 letter to CMS stated that while it was not possible to develop criteria defining patients who could be cared for *exclusively* in an LTCH setting, it was still important to define the level of care that is typically furnished in LTCHs.

Industry Sponsored Studies

In response to the findings presented in the 2004 MedPAC report, the National Association of Long Term Hospitals (NALTH), an LTCH industry trade association, sponsored two sets of research studies. These studies found that LTCHs treat a critically ill population with complex needs and poor outcomes, and that LTCH users had lower average costs and better clinical outcomes compared with similar patients in non-LTCH settings. The NALTH-commissioned Barlow studies offered a wealth of information regarding the characteristics of LTCHs and the critical-care prolonged mechanical ventilation (PMV) patients they treat, they provided little insight into MedPAC's concerns regarding the high cost of LTCH treatment compared to similar treatment in other facilities that were found in other studies. However, by providing greater clinical detail on the severity of illness and co-morbidities of LTCH PMV patients, the Barlow studies demonstrated the difficulty of finding an appropriate comparison group for patients admitted to an LTCH, and highlighted the need for additional clinical data to describe LTCH patients and to identify similar patients who receive care in other settings.

Research Findings from RTI

With the recommendations of MedPAC's June 2004 Report to Congress as a point of departure, CMS awarded a contract to RTI at the start of FY 2005 for a comprehensive evaluation of the feasibility of developing patient and facility level characteristics for LTCHs that could distinguish LTCH patients from those treated in other hospitals. The highlights of RTI's findings are listed below:

- An examination of Medicare quality review contractors indicated that patients who are more appropriate for treatment at LTCHs than at other post-acute facilities have multiple co-morbidities and require an intense level of care with frequent physician and nurse visits.

- The two most important factors in predicting LTCH admission are: 1) proximity to an LTCH; that is, whether the beneficiary lived in a state where many LTCHs were available; and 2) severity of illness.

- There were no differences in average outcomes between episodes from areas that have high LTCH use and those that do not.

- For the most medically complex ventilator patients, Medicare payments were the same or lower, mortality was lower, and the chance of being discharged to home was higher than those remaining in acute care settings. However, among the least complex ventilator patients, Medicare payments were much higher, hospital stays were longer, and all other outcome measures were the same or worse for those referred to LTCHs versus those remaining in acute care settings. This finding supports previous research by MedPAC that LTCHs may provide beneficial and cost-effective services for a subset of complex patients, but not for all types of patients admitted to these hospitals.

- An LTCH admission was associated with a shorter length of stay in the general acute care hospital, on average, and controlling for a number of factors, including age, gender, number of co-morbid conditions, and critical care use. This indicates, at least for some patients, that LTCH care may be substituting for what would normally be provided in the later days of an acute care hospital stay.

- Between 40 to 45 percent of all LTCH admissions qualify for a payment reduction as a "short-stay outlier". This means that payments for these cases are reduced if the length of stay is substantially less than the average length of stay for a given LTCH-DRG. A high percentage of short-staying cases in a payment system designed for long-stay patients highlight the complexity in discerning which patients are appropriate for admissions to LTCHs.

- The RTI Technical Expert Panel (TEP) reached a consensus that LTCHs provide a service that is comparable to general acute step-down units and is not unique to LTCHs. Discussions with LTCH physicians and acute care hospital physicians practicing in areas that lack LTCHs confirmed that there is an overlap in the patient populations treated in LTCHs and in acute care. Critical care post-ICU patients whom LTCHs describe as their targeted population are treated throughout most of the country in acute care hospital step-down units.

- The TEP acknowledged that Medicare patients with respiratory conditions requiring mechanical ventilation comprise less than 15 percent of all LTCH patients. Thus, these patients insufficiently define which critically ill patients with complex medical

conditions should be treated at LTCHs. It was not clear that any criteria can be developed which identifies patients who belong in a LTCH exclusively.

While there were important differences in the findings from MedPAC, RTI and the LTCH industry, several consistent themes emerge from the studies reviewed in the Kennell/RTI report:

- With the exception of complex ventilator cases, LTCH use has been associated with higher Medicare payments and higher mortality compared to patients with similar DRGs and similar APR-DRG severity levels that remain in general acute care hospitals. How much these findings reflect differences in LTCH care and how much they reflect unmeasured case-mix differences, however, is still not well understood.

- Not all LTCH cases are medically complex or critically ill. Research studies that look only at the population of mechanical ventilator patients discharged from the acute hospitals suggest that for the more complex cases (those on mechanical ventilators for at least 96 hours, or with tracheotomies) LTCHs may produce better outcomes than other care settings, and in a cost-effective manner. For the other less complex ventilator patients, Medicare program costs appear to be higher and outcome differences are estimated to be the same or in some cases worse in LTCHs compared to other settings. For the much larger group of non-ventilator patients transferred into LTCHs, there is conflicting statistical evidence on the impact of LTCH care. More research is needed on which types of cases are more cost-effective when treated in a LTCH.

- LTCH services are not unique to LTCH facilities. Quality LTCH-type care can be provided in more than one type of hospital and in specialized nursing facilities if these providers have adequate nursing, physician supervision and multi-disciplinary teams. This raises questions of payment equity and quality control. Research is needed to determine whether certain patients can be treated by more than one type of provider, whether certain safeguards are needed to ensure quality of care, and whether payment rates reflect expected costs.

Recent Legislative Changes

Section II also describes regulatory and legislative changes that have affected the LTCH industry in the last few years. The two principal changes include CMS' "25 Percent Rule," the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007, and the American Recovery and Reinvestment Act (ARRA) of 2009. This is followed by recent findings by MedPAC in March, 2008, which indicated that

> "[T]he types of cases treated by LTCHs can be (and are) treated in other settings, particularly in step-down units of many acute care hospitals. Therefore, it is not possible (nor desirable) to develop criteria defining patients who can be cared for exclusively in LTCHs. Rather, CMS should seek to define the level of care typically furnished in LTCHs, step-down units of many acute-care hospitals, and some specialized skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs)."

Identifying Medically Complex Patients

Section IIIa provides an examination of the clinical characteristics of the LTCH population focusing on defining medical complexity, identifying critically ill complex patients, predicting outcomes for these patients using severity scoring systems, and evaluating quality of care for these patients. This section reviews research that attempts to define patients who are critically ill with complex conditions. A consensus definition of the chronic critically ill patient that can be observed in claims or clinical data has yet to be developed. While there appears to be a suitable base of research for documenting the complexity of ventilator patients, little is known about patients with multiple co-morbidities that are not associated with ventilator use or respiratory conditions. Determining the prognosis for improvement is also very difficult for patients with complex conditions.

Ongoing Research

The themes emerging from research sponsored by CMS, MedPAC and the LTCH industry underscore our incomplete understanding of the medically complex patient, derived in part from the need to improve and expand statistical modeling to identify these patients from national databases, but in even larger part from the need to gather more complete clinical data on these patients. Section IIIb describes research CMS is sponsoring over the next 18 months that is intended to update and refine our understanding of Medicare LTCH patients and payments to answer some unresolved questions described below. This effort is currently collecting

standardized patient assessment information using the Continuity Assessment Record and Evaluation (CARE) tool, which is designed to be administered to patients in all acute and post-acute settings with the goal of developing consistent measures for case-mix adjustment. These data will improve the ability to (1) identify medically complex patients, (2) understand differences in care needs across facility settings, and (3) translate this understanding into more equitable Medicare payments. Some of the unresolved questions to be addressed include:

- Which types of patients are appropriately treated in LTCHs from the standpoints of medical outcomes and cost effectiveness for the Medicare program? Past research has shown that LTCHs provide an important service for the more complex, critically ill patients although these patients may also be effectively treated in general acute hospitals.

- Do the longer stays associated with LTCH patients correspond to a case-mix with greater medical complexity? If not, what differentiates appropriate referrals to LTCHs from referrals to specialized nursing facilities or rehabilitation centers?

- Is Medicare paying for complex long-stay patients appropriately under separate IPPS and LTCH-PPS systems when patients use both settings? If so, is Medicare paying for similar patients appropriately when they remain in their initial IPPS hospital?

- Are the LTCH payments inappropriately higher than IPPS, inpatient rehabilitation facility (IRF), or SNF payments, relative to expected patient care costs? Past research suggests LTCH margins are high for some of the more commonly admitted respiratory populations and low for the longer-stay, less medically intensive cases.

POLICY CONSIDERATIONS ON ESTABLISHING FACILITY AND PATIENT LEVEL CRITERIA FOR LTCHS

In the following section CMS presents several policy considerations regarding the desirability of establishing facility and patient level criteria for LTCHs.

Facility Criteria

Establishing facility level standards for LTCH case-mix may not be effective for ensuring that LTCH admissions are appropriate. There is substantial overlap in the patient populations of general acute care hospitals and LTCHs. Thus, several types of patients may receive appropriate care in either setting.

The MMSEA of 2007 extends the definition of a LTCH beyond the requirement that the facility has a provider agreement with Medicare to participate as a hospital and an average length of stay for Medicare patients of greater than 25 days to state that "[t]he term 'long-term care hospital' means a hospital which is primarily engaged in providing inpatient services, by or under the supervision of a physician to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital..."

Also included in MMSEA's definition of LTCHs are requirements for facility level criteria which were established following input from MedPAC and the LTCH industry:

- **A patient review process** that 1) is documented in medical record, 2) screens patients prior to admission for LTCH appropriateness, 3) validates within 48 hours that patients meet LTCH admission criteria, 4) regularly evaluates patients throughout

their stay for continuation of LTCH care, and 5) assesses available discharge options when patients no longer meet continued stay criteria.

- **Active physician involvement** with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time.

- **Interdisciplinary treatment teams** for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

CMS believes that these facility-level standards should improve the quality of care at LTCHs and has no plans for additional facility level standards. CMS acknowledges that while these new requirements represent new standards for care provision, facility-level standards will be of very limited value in determining the appropriateness of patients for LTCH care.

Patient Criteria

The Kennell/RTI report has identified the following issues regarding the case-mix of LTCHs:

- The medical conditions treated in the approximately 400 LTCHs are also treated in over 3,000 general acute care hospitals (particularly in areas where there are no LTCHs). Many of these conditions are also treated in IRFs and some are treated in SNFs or Inpatient Psychiatric Facilities (IPFs). Although a high percentage of patients treated in LTCHs are medically complex, far more of these patients are treated in general acute care hospitals nationwide.

- A significant percentage of LTCH patients (particularly those on long-term mechanical ventilation, but who are not co-morbid) may not require hospital-level treatment but could otherwise be appropriately cared for in a SNF.

Following the direction of MedPAC and the RTI TEP panels, CMS concurs with the view that LTCHs are appropriate providers for treating severely ill, **but medically stable**, patients with complex medical conditions. However, additional analysis of Medicare data across

provider types is key in helping to formulate a clinically-based description of critically ill, medically complex patients.

Ongoing CMS research using the CARE tool (described in Section IIIB of the Kennell/RTI report (Appendix I)) should facilitate CMS' efforts to empirically define the types of chronic, complex medical conditions (described in Section IIIA of the Kennell/RTI report) that currently receive treatment in both general acute care hospitals and LTCHs. This is the first step to developing policies to appropriately pay for these types of patients regardless of site of care.

Empirically defining these patients using clinical information is essential for classifying them, determining the resources they use, and providing appropriate payment. Prior research efforts using DRGs as a common patient classification method have not been successful. In addition, outcomes and quality of care provided at LTCHs have had limited evaluation. The research findings on quality of care at LTCHs produced by MedPAC, NALTH, and RTI have yielded inconsistent results.

At present, CMS is proceeding with data collection using the CARE tool in order to obtain patient level clinical data that may be used to identify types of chronically ill patients with complex medical conditions, regardless of provider setting. RTI's current research using the CARE tool should provide the clinical patient level data to measure outcomes, quality of care and performance at LTCHs and other providers treating similar conditions. The data collection on both patient level clinical data and outcomes is a necessary step toward refining patient classification to achieve more appropriate site-neutral payment under Medicare.

CONCLUSIONS

Facility level criteria such as those mandated under MMSEA may improve staffing and quality of care at LTCHs by defining standards for adequate care. However, facility level criteria based on programs of care available or services provided do not address the problem of targeting types of patients that are medically stable, have complex medical conditions and, thus, can receive appropriate treatment in LTCHs.

With respect to establishing patient-level criteria, current research has not clearly demonstrated a significant or consistent difference between patients treated in LTCHs compared to patients treated in general acute care hospitals. Thus, CMS believes that establishing criteria identifying patients exclusively suitable for LTCHs is not desirable at this time.

In fact, there may be several distinct disadvantages to establishing a list of conditions best treated in LTCHs. Such a list would effectively be interpreted as identifying LTCHs as the most appropriate setting for treating the conditions listed and would likely have the unintended consequences of increasing the LTCH industry's rate of expansion and therefore significantly increasing Medicare Part A payments. Further, designating a list of appropriate conditions for treatment at LTCHs would imply new standards of care for these conditions and may increase the risk of malpractice liability.

Although we do not believe that establishing patient-level criteria is appropriate at this time, we do believe that identifying critically ill, medically complex patients is the necessary first step in determining how Medicare should appropriately pay for such patients, regardless of whether patients are treated at a general acute care hospital, a LTCH, an IRF or any other setting. While it is possible to identify patients that "are not inappropriate" for treatment at a

LTCH based on the MMSEA criterion that LTCHs treat beneficiaries whose"...medically complex conditions require a long hospital stay...", patients fitting this description are currently being treated at general acute care hospitals (often as high cost outlier cases), IRFs, and for patients at the lower end of the acuity continuum, at SNFs across the nation, particularly in areas without LTCHs or without referral patterns that extensively utilize LTCHs.

To this end, CMS is currently funding contract research to use the CARE tool to collect suitable patient level clinical data to better identify chronic, critically ill patients. CMS is also currently funding research to develop payment models that would pay for these patients' care reasonably and appropriately in LTCHs or any other site of care.

The broader payment policy revisions that would be made possible because of the CARE tool research will more effectively deal with appropriateness of care and payment equity across sites of care for medically complex (but medically stable) patients treated not only in LTCHs but by several other types of Medicare providers.

ENCLOSURE

Appendix I

Determining Medical Necessity and Appropriateness of Care for Medicare Long Term Care Hospitals

Prepared for:
Centers for Medicare and Medicaid Services (CMS)

Prepared by
Kennell and Associates, Inc.
and its subcontractor:
Research Triangle International (RTI)

January 4, 2010

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This study is prepared in response to Section 114 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (PL 110-173). The Secretary of Health and Human Services was required to conduct a study on the establishment of national long-term care hospital (LTCH) facility and patient criteria for determining medical necessity, appropriateness of admission, continued stay and discharge from long-term care hospitals (LTCHs) and provide a report on the results of this study to Congress together with recommendations for legislation and administrative action, including timelines for implementation of criteria or other appropriate action.. This study was prepared by Kennell and Associates and its subcontractor Research Triangle Institute, International (RTI).

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From 1983 to 2003, LTCHs were paid under a cost based system. LTCHs were moved to a prospective payment system (LTCH-PPS) in Fiscal Year (FY) 2003. Payments are much higher, however, for the same DRG admitted to LTCHs compared to payments received by acute hospitals for the same DRG. CMS payment policy treats cases that are discharged from an acute care hospital directly into an LTCH as two separate stays, eligible for both an IPPS payment for the initial hospitalization plus a second, often larger LTCH-PPS payment. CMS is concerned about the following issues regarding LTCHs:

- The medical conditions treated in LTCHs are also treated in acute care hospitals and other facilities, especially in areas where no LTCHs operate. Nevertheless, payment amounts differ by type of provider.
- Many patients treated in LTCHs may not require hospital level care and may be more appropriately treated in a less intensive setting.
- The ability to generate two Medicare payments may provide an opportunity to split a predictably long inpatient hospital stay into two PPS payments, especially when LTCHs and acute care hospitals are co-located.

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Industry Sponsored Studies

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- The two most important factors in predicting LTCH admission are: 1) proximity to an LTCH; that is, whether the beneficiary lived in a state where many LTCHs were available; and 2) severity of illness.

- There were no differences in average outcomes between episodes from areas that have high LTCH use and those that do not.

- For the most medically complex ventilator patients, Medicare payments were the same or lower, mortality was lower, and the chance of being discharged to home was higher than those remaining in acute care settings. However, among the least complex ventilator patients, Medicare payments were much higher, hospital stays were longer, and all other outcome measures were the same or worse for those referred to LTCHs versus those remaining in acute care settings. This finding supports previous research by MedPAC that LTCHs may provide beneficial and cost-effective services for a subset of complex patients, but not for all types of patients admitted to these hospitals.

- An LTCH admission was associated with a shorter length of stay in the general acute care hospital, on average, and controlling for a number of factors, including age, gender, number of co-morbid conditions, and critical care use. This indicates, at least

for some patients, that LTCH care may be substituting for what would normally be provided in the later days of an acute care hospital stay.

- Between 40 to 45 percent of all LTCH admissions qualify for a payment reduction as a "short-stay outlier". This means that payments for these cases are reduced if the length of stay is substantially less than the average length of stay for a given LTCH-DRG. A high percentage of short-staying cases in a payment system designed for long-stay patients highlights the complexity in discerning which patients are appropriate for admissions to LTCHs.

- The RTI Technical Expert Panel (TEP) reached a consensus that LTCHs provide a service that is comparable to general acute step-down units and is not unique to LTCHs. Discussions with LTCH physicians and acute care hospital physicians practicing in areas that lack LTCHs confirmed that there is an overlap in the patient populations treated in LTCHs and in acute care. Critical care post-ICU patients whom LTCHs describe as their targeted population are treated throughout most of the country in acute care hospital step-down units.

- The TEP acknowledged that Medicare patients with respiratory conditions requiring mechanical ventilation comprise less than 15 percent of all LTCH patients. Thus, these patients insufficiently define which critically ill patients with complex medical conditions should be treated at LTCHs. It was not clear that any criteria can be developed which identifies patients who belong in a LTCH exclusively.

While there were important differences in the findings from MedPAC, RTI and the LTCH industry, several consistent themes emerge from the studies reviewed:

- With the exception of complex ventilator cases, LTCH use has been associated with higher Medicare payments and higher mortality compared to patients in with similar DRGs and similar APR-DRG severity levels that remain in general acute care hospitals. How much these findings reflect differences in LTCH care and how much they reflect unmeasured case-mix differences, however, is still not well understood.

- Not all LTCH cases are medically complex or critically ill. Research studies that look only at the population of mechanical ventilator patients discharged from the acute hospitals suggest that for the more complex cases (those on mechanical ventilators for at least 96 hours, or with tracheotomies) LTCHs may produce better outcomes than other care settings, and in a cost-effective manner. For the other less complex ventilator patients, Medicare program costs appear to be higher and outcome differences are estimated to be the same or in some cases worse in LTCHs compared to other settings. For the much larger group of non-ventilator patients transferred into LTCHs, there is conflicting statistical evidence on the impact of LTCH care. More research is needed on which types of cases are more cost-effective when treated in a LTCH.

- LTCH services are not unique to LTCH facilities. Quality LTCH-type care can be provided in more than one type of hospital and in specialized nursing facilities if these providers have adequate nursing, physician supervision and multi-disciplinary teams. This raises questions of payment equity and quality control. Research is needed to determine whether certain patients can be treated by more than one type of provider, whether certain safeguards are needed to ensure quality of care, and whether payment rates reflect expected costs.

Section II also describes regulatory and legislative changes that have affected the LTCH industry in the last few years. The two principal changes include CMS' "25 Percent Rule," the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007, and the American Recovery and Reinvestment Act (ARRA) of 2009. This is followed by recent findings by MedPAC in March, 2008, which indicated that

> "[T]he types of cases treated by LTCHs can be (and are) treated in other settings, particularly in step-down units of many acute care hospitals. Therefore, it is not possible (nor desirable) to develop criteria defining patients who can be cared for exclusively in LTCHs. Rather, CMS should seek to define the level of care typically furnished in LTCHs, step-down units of many acute-care hospitals, and some specialized skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs)."

Section IIIa provides an examination of the clinical characteristics of the LTCH population focusing on defining medical complexity, identifying critically complex patients, predicting outcomes for these patients using severity scoring systems, and evaluating quality of care for these patients. This section reviews research that attempts to define patients who are

critically ill with complex conditions. A consensus definition of the chronic critically ill patient that can be observed in claims or clinical data has yet to be developed. While there appears to be a suitable base of research for documenting the complexity of ventilator patients, little is known about patients with multiple co-morbidities that are not associated with ventilator use or respiratory conditions. Determining the prognosis for improvement is also very difficult for patients with complex conditions.

The themes emerging from research sponsored by CMS, MedPAC and the LTCH industry underscore our incomplete understanding of the medically complex patient, derived in part from the need to improve and expand statistical modeling to identify these patients from national databases, but in even larger part from the need to gather more complete clinical data on these patients. Section IIIb describes research CMS is sponsoring over the next 18 months that is intended to update and refine our understanding of Medicare LTCH patients and payments to answer some unresolved questions described below. This effort will collect standardized patient assessment information using the Continuity Assessment Record and Evaluation (CARE) tool, which is designed to be administered to patients in all acute and post-acute settings with the goal of developing consistent measures for case-mix adjustment. These data will improve the ability to (1) identify medically complex patients, (2) understand differences in care needs across facility settings, and (3) translate this understanding into more equitable Medicare payments. Some of the unresolved questions to be addressed include:

- Which types of patients are appropriately treated in LTCHs from the standpoints of medical outcomes and cost effectiveness for the Medicare program? Past research has shown that LTCHs provide an important service for the more complex, critically ill patients although these patients may also be effectively treated in other acute hospitals.

- Do the longer stays associated with LTCH patients correspond to a case-mix with greater medical complexity? If not, what differentiates appropriate referrals to LTCHs from referrals to specialized nursing facilities or rehabilitation centers?

- Is Medicare paying for complex long-stay patients appropriately under separate IPPS and LTCH-PPS systems when patients use both settings? If so, is Medicare paying for similar patients appropriately when they remain in their initial IPPS hospital?

- Are the LTCH payments inappropriately higher than IPPS, inpatient rehabilitation facility (IRF), or SNF payments, relative to expected patient care costs? Past research suggests LTCH margins are high for some of the more commonly admitted respiratory populations and low for the longer-stay, less medically intensive cases.

I. BACKGROUND

LTCHs represent a relatively small number of hospitals (approximately 400) treating specialized patient groups. They have average Medicare lengths of stay of greater than 25 days. Although LTCHs are licensed as hospitals by states and must meet Medicare hospital conditions of participation, they do not necessarily provide the full range of surgical, diagnostic and emergency services and may not have the same level of staffing provided in a typical acute care hospital. About 90 percent of LTCH Medicare cases are admitted directly from an acute care hospital, and over 80 percent of LTCH patients are Medicare beneficiaries. Over 60 percent of LTCHs are located in the same facilities (co-located)[1] with acute care hospitals, although under separate ownership. The number of LTCHs has increased rapidly during the past 12 years. In 1983, only 33 LTCHs were in operation. By 1993, there were 105 LTCHs and when the LTCH PPS began in 2003, 318 LTCHs were in operation. By the end of 2007 the LTCH population had grown to 400 facilities. Only 7 states and Puerto Rico did not have LTCHs in operation by the end of 2007, although LTCHs are more heavily concentrated in some states than others. LTCH costs to the Medicare program in 1993 were $398 million and for 2009 are projected by CMS to be $3.63 billion.

The mix of patients treated in LTCHs has undergone major change since implementation of the inpatient prospective payment system (IPPS) in 1983. In 1987, Health and Human Services Secretary Otis R. Bowen noted that the 33 long-term hospitals recognized at the start of the IPPS ". . . are a heterogeneous set of institutions located on the Eastern Seaboard, whose mission is the treatment of patients who are seriously or terminally ill with multiple diseases. In

[1] Co-located LTCHs may be either independent providers located within a hospital (Hospital-within Hospital (HwH)) or branches of LTCHs which have their main facility located elsewhere (satellites). Co-located facilities must meet Medicare rules ensuring separateness of control between the LTCH and the host hospital.

other regions of the country, these same patients would be treated in hospitals or skilled nursing facilities" (Bowen 1987). The average length of stay for almost all of these facilities exceeded 60 days then (DHHS 1987). LTCH lengths of stay currently average approximately 27 days.

The case-mix treated by LTCHs has evolved over time to become centered on the treatment of patients with complex medical conditions, although there is still substantial variation in patient mix across facilities. Since LTCH facilities are defined by their average Medicare length-of-stay rather than types or severity of medical conditions treated, the mix of cases admitted to LTCHs varies widely. The most common admissions in 2004 were for complex respiratory diagnoses, with patients requiring mechanical ventilation making up the single most frequent (15 percent) and most expensive DRG. Other common conditions admitted to LTCHs are complicated skin conditions including ulcers and skin grafts, post-surgical aftercare, and medically complex patients with multiple system failure or septicemia (Gage, et al. 2007).

From 1983 to 2003, LTCHs were paid under a modified cost based system. In 1983, the new Inpatient Prospective Payment System (IPPS) exempted the few LTCHs in operation from payments based on Diagnosis-Related Groups (DRGs). The DRG system was developed for short-term acute care general hospitals and did not adequately take into account special circumstances of conditions requiring long stays. Instead, LTCHs were exempted from the IPPS (along with specialty rehabilitation and psychiatric facilities), and were allowed to receive payments based on their own updated historical average cost per case subject to national limits based on maximum allowable annual increases.[2]

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[2] These were the payment rules applicable under the Tax Equity and Fiscal Responsibility Act of 1981 and were in effect for all hospitals during 1982. They were replaced by the IPPS rules for general acute care hospitals in

In Fiscal Year (FY) 2003, LTCHs moved to an Inpatient Prospective Payment System (IPPS) of their own (LTCH-PPS), based on a variant of the IPPS Diagnosis-Related Groups (DRG) that pays a fixed amount per discharge. Although the LTCH-PPS was based on the same version of DRGs used in the IPPS, the payment weights for each LTCH DRG are set to reflect the relative resource use across LTCH discharges. Because of the longer stays in LTCHs, the LTCH base rate was nearly seven times the IPPS base rate (Gage, Bartosch, and Osber, 2005). However, LTCHs have a lower average Medicare payment *per day* than acute hospitals which is consistent with a lower average intensity of service in LTCHs compared to hospitals paid under the IPPS, where the costs of surgical services, intensive care units and more extensive diagnostic testing are averaged across all days in the stay.

The establishment of LTCH-PPS was intended to be budget neutral relative to total TEFRA payments in FY 2003. In other words, although payment dollars were redistributed across DRGs and across facilities, forecasted aggregate LTCH DRG payments would equal forecasted aggregate TEFRA payments for 2003. Although Medicare LTCH PPS payments should approximate the payments that would have been made in the absence of the LTCH PPS, RTI's analysis of Medicare margins indicated that LTCH DRG payments were higher than previous TEFRA payments, and were significantly greater than LTCH costs. LTCH PPS margins in 2003 were 8.3 percent, increasing to 12.8 percent in 2004 (Gage, et al. 2007). By comparison, IPPS margins were slightly negative during 2004 (MedPAC June 2008).

Both the IPPS and LTCH-PPS make provisions for stop-loss payments for cases with unusually high costs. Such cases are referred to as "outlier" cases or "high cost outliers",

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1983. Hospitals and subprovider units that were exempted from the IPPS were referred to as "TEFRA" or "exempt" providers.

respectively. LTCH cases are also subject to payment reductions if a stay is substantially less than the average length of stay for a given LTCH-DRG. These cases are known as "short-stay outliers." By design, between 40 and 45 percent of all LTCH discharges could be expected to qualify. [3] In 2004, 39 percent of discharges were short stay outliers and 33 percent of discharges were short stay outliers in 2006. Short-stay payment reductions are intended to discourage reimbursement gaming through inappropriate transfers. However, the prevalence of short-stay outliers in a payment system designed for long-stay patients highlights the difficulty of determining which patients are appropriate for LTCH admission and which patients should remain in an acute care hospital.

For most patients, CMS payment policy treats a LTCH admission following an IPPS discharge as two separate stays, eligible for both an IPPS payment for the initial hospitalization plus a second, often larger LTCH-PPS payment for the same episode of care.

CMS is concerned about the following issues regarding LTCHs.

- The medical conditions treated in LTCHs are also treated in acute care hospitals and other facilities, especially in areas where no LTCHs operate. Nevertheless, payment amounts differ by type of provider.
- Many patients treated in LTCHs may not require hospital level care and may be more appropriately treated in a less intensive setting.
- The ability to generate two Medicare payments may provide an opportunity to split a predictably long inpatient hospital stay into two PPS payments, especially when LTCHs and acute care hospitals are co-located.

Medically complex patients can be treated in multiple types of settings. Yet, Medicare payments for similar levels of care vary widely by type of facility. Levels of care can be defined on the basis of medical resource intensity, such as physician availability, nursing hours, staff

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[3] Short-stay outliers are defined empirically as cases with a length of stay that is less than five-sixths of the geometric mean stay for that LTCH DRG.

composition, available equipment and other resources that demarcate between intensive, routine or skilled nursing care. The need for different levels of care varies by the patient's severity and complexity of illness. The level of care provided in LTCHs is thought to be most comparable to the level of care in a step-down unit (an intermediate level between an intensive care unit (ICU) bed and a routine bed). Yet not enough is known about the clinical characteristics of patients who move from a step-down unit to an LTCH, or about the differences between patients who remain in the step-down units of larger IPPS hospitals compared to those who transfer to an LTCH (or other post-acute care) setting.

Only 14 percent of LTCH referrals from IPPS facilities qualify for an IPPS outlier payment. It may be possible that some Medicare patients are discharged from IPPS hospitals to LTCHs to reduce IPPS costs rather than to obtain appropriate care – thus generating a second Medicare payment for what should have been part of the initial hospitalization. This scenario raises questions about the role of LTCHs in the health care system. Are LTCHs treating cases that require a specialized set of services, or are they providing an opportunity to game the reimbursement systems by splitting a predictably long IPPS stay into two PPS payments? Are IPPS hospitals discharging cases that really only need another week or so of ward-level hospital care, and if so, do these cases subsequently become LTCH short-stay outliers?

Such concerns point to the need for additional analysis to answer several questions about the case-mix, services provided, payments, and outcomes associated with LTCH care:

- How do LTCH patients vary in terms of primary conditions and medical complexity?
- Who are the patients transferred from other providers and how do their characteristics differ based on the type of referring provider?

- Do patients with longer stays often associated with referrals from acute care hospitals represent patients with greater medical complexity? If not, what differentiates acute care hospital referrals from skilled nursing facility (SNF) referrals?

- Do referrals from acute care hospitals require special treatment protocols not provided in IPPS hospitals? If not, what differentiates them from patients that remain in the IPPS facilities?

- Is Medicare paying for these patients appropriately under separate IPPS and LTCH-PPS systems?

- Are the LTCH payments inappropriately higher than IPPS, inpatient rehabilitation facility (IRF), or SNF payments, relative to expected patient care costs?

These issues need to be taken into account when evaluating the desirability or feasibility of establishing facility or patient level criteria for LTCHs. Over the past few years the MedPAC, LTCH industry representatives, and CMS have actively pursued answers to these questions. Shortly after the implementation of LTCH PPS, MedPAC raised many of these questions in a chapter of its June 2003 Report to the Congress (MedPAC 2003). The LTCH industry responded to MedPAC's 2003 report by contracting for two new sets of studies. The first provided previously unavailable clinical detail on LTCH ventilator patients across multiple LTCHs (Scheinhorn et al. 2007(a); Scheinhorn et al. 2007(b)). The second analyzed older Medicare claims data using more sophisticated statistical methods to control for the higher average severity of illness among those admitted to LTCHs (Dobson, et al. 2004). The largest research effort following the MedPAC reports came from a multi-year contract awarded by CMS to RTI International. Under this contract a variety of LTCH PPS issues were examined by combining analysis of claims data with input from the medical, quality review, insurance and provider communities. Section II of this Report reviews the findings from MedPAC, the LTCH industry, and the CMS contract studies, to summarize the present state of research with respect to CMS policy questions.

II. REVIEW OF PAST RESEARCH STUDIES AND POLICY RECOMMENDATIONS

II.A. ISSUES IDENTIFIED BY THE MEDICARE PAYMENT ADVISORY COMMISSION

The Medicare Payment Advisory Commission (MedPAC) devoted chapters to LTCH policy and payment issues in two of its annual Reports to the Congress, first in June of 2003 (MedPAC 2003, Chapter 5 "Monitoring Post-Acute Care") and again in June of 2004 (MedPAC 2004, Chapter 5 "Defining Long-term Care Hospitals"). In these chapters, MedPAC addressed the changing role of long-term care hospitals within post-acute care. Both reports studied trends in facility growth, and both analyzed episodes of care constructed from Medicare claims in 2001, comparing Medicare payments and clinical outcomes for patients using LTCHs to outcomes for patients using other types of post-acute care or no post-acute care. The 2003 study had only modest control for differences in patient complexity. The 2004 report expanded the earlier work by providing better control for the expected differences in outcome due to greater illness severity in LTCH patients, and also by including qualitative results from field interviews at LTCH facilities. Each of these reports is discussed in the following sections.

II.A.1 The 2003 MedPAC Report

The 2003 MedPAC report documented substantial changes in the LTCH industry over time and raised several issues of concern to the Medicare program. These included the rapid growth in the number of LTCH facilities and total Medicare LTCH spending; high concentrations of LTCHs in certain regions with very uneven geographic distribution in others; higher total payments for LTCH users; and lack of evidence for improved clinical outcomes for LTCH users.

Rapid growth: The number of LTCHs had tripled from 105 facilities in 1993 to 318 in 2003. Not surprisingly, Medicare spending for LTCHs also grew, at a rate of 15 percent per year, with total payments rising from $398 million in 1993 to $1.9 billion in 2001.

Uneven geographic distribution: Parts of the country (the Midwest and the South) had large numbers of LTCHs, whereas others had few (the Northwest) or none (Mountain and Western states).[4] The 2003 report found no length-of-stay differences between short-stay acute facilities located in high-LTCH areas and those located in low-LTCH areas, but it also showed that patients in low-LTCH areas were more likely to use SNF post-acute care. Based on average length of stay and transfer patterns, the 2003 report concluded that LTCHs were substituting for SNF care.

Medicare payments: To compare payments and outcomes across PAC settings, the 2003 study examined care episodes for the top 11 conditions that generate LTCH transfers. The study design controlled for patient severity differences only through the use of All Patient Refined Diagnostic Related Group (APR-DRG) assignments, grouping each of the 11 DRGs into 4 possible levels of severity. MedPAC concluded that for these conditions, LTCHs appeared to be an expensive substitute for SNF care, did not reduce stays in initial acute admissions, and did not appear to reduce mortality. Yet the report cautioned that some of these findings could be due to unmeasured differences in case-mix.

Clinical Outcomes: For Medicare episodes built around the 11 most common LTCH referral DRGs in 2001, MedPAC reported that LTCH users had higher mortality rates than non-LTCH users as well as higher acute readmission rates. As with the payment findings, however,

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[4] As of March 2008, Massachusetts, Louisiana, Rhode Island, Connecticut, and Texas contained 40 percent of all LTCH beds, yet only 12 percent of Medicare beneficiaries reside in these five states (MedPAC 2008).

the report cautioned that these differences could reflect unmeasured differences in case mix. It also noted that length of stay for the initial acute hospitalizations were no shorter for episodes discharged into LTCHs than for episodes discharged to other post-acute settings such as IRFs, SNFs, or home health agencies (HHAs).

II.A.2 The 2004 MedPAC Report

The 2004 MedPAC report attempted to clarify a number of research and policy questions that had been raised by the 2003 report, including these:

- What is the role of LTCHs in providing care?
- What are alternatives to LTCH care?
- How do Medicare payments and outcomes compare for LTCH patients versus those in other settings?
- What criteria would improve the definition of a long-term acute facility and better identify the patients most appropriate for this type of care?

The report also included results from reanalyzed claims data from the first half of 2001, with study designs that provided better control for selection of sicker patients into LTCH settings. The 2004 report described its model to identify factors that predict LTCH use. The strongest predictor of LTCH use was having had a tracheostomy procedure in the acute setting, but other significant predicting conditions included DRGs for respiratory system diagnosis with ventilator support, acute and subacute endocarditis, amputation, skin graft and wound debridement, and osteomyelitis. Having an APR-DRG severity level of 3 or 4 in the acute admission was also independently associated with greater likelihood of subsequent LTCH use. Geographic proximity to an LTCH raised the probability of an LTCH admission by 4 times. In geographic areas without LTCHs, MedPAC's findings indicated that the use of freestanding

SNFs was higher, particularly for tracheostomy patients and those with the highest probability of LTCH referral.

MedPAC identified two subsets of cases representing the most complex patients: those scoring above the 95th percentile in a model of the probability of LTCH use and those with a tracheostomy and long-term ventilator support. Restricting analysis to these two groups allowed MedPAC to compare episode outcomes across PAC settings for only the most medically complex cases. Their study also applied "instrumental variables" regression approaches, which used distance from the patient to the nearest LTCH as an instrument to provide statistical control for adverse selection into LTCHs that is not captured using APR-DRGs.

Among tracheostomy patients only, episode payments were found to be *lower* for episodes using LTCH than for others, and the difference was statistically significant. Among patients within the top 5 percent probability of using LTCH care, LTCH users and non-users had statistically similar episode payments. The report found *fewer* acute readmissions among those discharged into LTCHs compared to those discharged into other post-acute settings. Further, it found a reduction in acute hospital length of stay associated with LTCH use—7 fewer days in the full sample and 9 fewer days in the most clinically complex group. Shorter acute stays for LTCH users suggest that LTCH care is not simply an alternative site for post-acute care, but a substitute for latter parts of acute stays, specifically the days in step-down or intermediate care units that provide nursing levels most similar to the care in LTCHs. Differences in 120-day mortality between LTCH users and non-users were studied using a variety of statistical techniques to control for adverse patient selection into LTCHs, with one approach showing similar death rates, one showing higher rates, and a third showing lower rates. As a consequence MedPAC was not willing to draw conclusions on the effect of LTCH care on mortality.

Findings from the empirical analyses in the 2004 MedPAC report present a very different picture than descriptive findings in the 2003 report, which showed higher payments and poorer outcomes for patients using LTCHs. The 2004 report found that, for the most complex patients, LTCH use was associated with similar or improved outcomes at similar or lower Medicare payments, compared to other (or no) post acute care use. These results held only for the most complex LTCH admission, not for other LTCH admissions. The difference between the 2003 and 2004 conclusions underscores the importance of identifying clinically appropriate comparison groups for the chronically critically ill patients seen in LTCHs.

II.A.3 Key Unresolved Questions and Recommendations

The key unresolved policy questions from the 2004 report were these (1) What criteria would improve the definition of a long-term acute care facility and (2) What criteria could better identify the patients most appropriate for this type of care? In light of the evidence suggesting that benefits for LTCH care accrued only for the most complex patients, MedPAC recommended that LTCH facilities be defined by stricter criteria than simply their status as acute hospitals with an average length of stay longer than 25 days. The report recommended that CMS develop more precise clinical criteria to determine which patients were suitable for admission to an LTCH. The text of the final recommendations as submitted to Congress was as follows (MedPAC 2004, pages 130, 131):

> **"Recommendation 5A:** The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.
>
> - Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.
> - Patient-level criteria should identify specific clinical characteristics and treatment modalities."

"**Recommendation 5B:** The Secretary should require the Quality Improvement Organizations to review long-term care hospital admissions for medical necessity and monitor that these facilities are in compliance with defining criteria."

II.B. RESEARCH IN RESPONSE TO MEDPAC'S REPORTS

II.B.1. Introduction

The National Association of Long Term Hospitals (NALTH) responded to MedPAC's criticism of the industry by sponsoring two sets of studies. The first study set– commonly referred to as the "Barlow Studies" – examined patients consecutively admitted to 23 LTCHs over a one-year period (Scheinhorn, et al. 2007(a); Scheinhorn, et al. 2007(b)). The purpose of this research was to characterize the post-ICU respiratory ventilator weaning population receiving LTCH care, to characterize the LTCH facilities providing weaning services, and to determine the outcomes and costs of LTCH treatment. The second set, sponsored by NALTH and completed by the Lewin Group, used Medicare claims data to examine the clinical and economic impacts of LTCHs (Dobson, et al. 2004). The Lewin studies were primarily designed to address MedPAC's concerns that LTCHs may be an expensive alternative to other post-acute care with little or no clinical benefit; their research showed that the outcomes for LTCH patients were more favorable when the adverse selection into LTCH care was taken into account. This section reviews the findings of the Barlow and Lewin studies.

II.B.2. The Barlow Studies

NALTH commissioned a multicenter study of patients entering 23 LTCH facilities that offered weaning from prolonged mechanical ventilation (PMV). The primary research site and data-coordinating center was Barlow Respiratory Hospital in Los Angeles, CA.[5] The first of the

[5] The Barlow Hospital was originally opened in 1927 as a tuberculosis sanatorium and has evolved into a LTCH that specializes in respiratory therapies including ventilator weaning and inpatient pulmonary rehabilitation.

two Barlow studies was undertaken to characterize the population of 1,419 ventilator-dependent patients admitted to the 23 LTCHs nationwide and the LTCHs where they were treated. The second study was undertaken to report treatments, outcomes, and estimated cost comparisons for this same population. The hospitals in the Barlow study population are a heterogeneous group of institutions and the patients served were equally diverse (see Table II.B.1).

The primary outcomes considered in the second of the Barlow studies were ventilator weaning success, length of time required for weaning, LTCH discharge destination, and death within 12 months of LTCH admission. Overall, more than half of the PMV patients were weaned from the ventilator at the time of LTCH discharge, with 15 days being the median time to wean. Twenty-five percent of the sample patients died in the LTCH. Of patients discharged alive, 20 percent were re-admitted to a short-stay acute hospital, 50 percent were discharged to another care setting, and 30 percent went home. At least half of the PMV patients had died within 12 months of their LTCH admission. Given the age and severity of illness of this patient population, the high mortality rates and other poor outcomes are not surprising. These LTCH outcomes were not compared to those of similar patients in other acute or post-acute settings.

Table II.B.1.
Facility and Patient Characteristics and Outcomes of Barlow Studies of PMV Patients

	Value	Range
	Facility Characteristics	
Median Number of Beds	50	15-311
Median Patients Per Bedside Nurse	4	3-6
Median Patients Per Respiratory Therapist	7	2-20
Number of Hospitals With Weaning Protocols	9 (47%)	NA
Number of Hospitals Within Hospitals	12 (52%)	NA
Median Cost of Care Per Patient	$47,217	$949-$553,485
	Patients at LTCH Intake	
Median Age	71.8	18-97.7
Percent Female	49.9%	NA
Percent With Smoking History	59%	NA
Diagnosis Resulting in PMV (Medical/Surgical)	60.8%/39.2%	NA
Median Transfer Hospital Length of Stay	27	0-563
APACHE III APS	35	4-115
	Outcome at Discharge	

Median PMV Weaning Rate Across LTCHs	54.1%	41.9%-83.3%
Median Time to Wean in Days	15	7-30
Death Rates at Discharge	25%	0-47.9%
Death Rate at One Year	63%	N/A

Source: Scheinhorn, et al. 2007(a) and Scheinhorn, et al. 2007(b)

Among the patient population in the Barlow studies, almost two thirds had Medicare as the primary payer. The mean cost of care for PMV patients with available cost data was $63,672 (2002 dollars). Scheinhorn et al. (2007b) compared this amount to the approximate costs if those patients had continued care in the ICU of a short-stay acute. Using acute ICU cost figures cited from other research, the authors estimated that costs for the same length of stay in an ICU would have been $210,304 per patient. While this amount is significantly higher than the LTCH costs, it is not clear why they chose ICU-level care for the comparison. The costs of other potential alternatives to LTCH care, such as a step-down unit in an acute hospital or a SNF, were not considered.

Although the Barlow studies offered a wealth of information regarding the characteristics of LTCHs and the critical-care PMV patients they treat, they provided little insight into MedPAC's concerns regarding the high cost of LTCH treatment compared to similar treatment in other facilities. The Barlow studies did not examine outcomes across alternative care settings for PMV patients; and the costs of LTCH care were only compared to the (very high) costs of ICU care, when more realistic comparisons might have included step-down or routine care units in acute care hospitals or specialized skilled nursing facilities (SNFs). However, by providing greater clinical detail on the severity of illness and co-morbidities of LTCH PMV patients, the Barlow studies demonstrated the difficulty of finding an appropriate comparison group for patients admitted to an LTCH, and highlighted the need for additional clinical data to describe LTCH patients and to identify similar patients who receive care in other settings.

II.B.3. The Lewin Studies

In response to MedPAC's June 2003 Report to Congress, the Lewin Group conducted three studies for the National Association of Long Term Hospitals (NALTH) to examine the clinical and economic impacts of long-term hospital care. The Lewin Group studies (Dobson et al., 2004) suggested that there were two possible explanations for MedPAC's conclusions:

- LTCHs are an expensive alternative to other post-acute care and offer little or no clinical benefit; or
- MedPAC's study failed to fully control for the clinical severity of patients treated in LTCHs, which could be the actual cause for the higher Medicare payments and poorer outcomes observed among LTCH patients.

The goal of the Lewin research was to determine which of these two competing hypotheses were correct. To answer this question, the Lewin report includes the three following individual studies:

1. Study 1 – LTCH Admission Process and Criteria
2. Study 2 – LTCH Clinical and Economic Impacts Assessment
3. Study 3 – The Impact of Co-Location on Host Hospitals

II.B.3.1. Lewin 1: LTCH Admission Process and Criteria

The first Lewin study was a qualitative analysis of the clinical factors that differentiate LTCH users from those who receive care in other settings. Lewin conducted a one-day meeting with 12 admissions directors from different LTCHs across the country and 2 representatives from NALTH with knowledge of admission criteria used by LTCHs. According to the panel, the admissions process for LTCHs is more rigorous than that of short-term acute care hospitals. LTCH admissions require a referral from at least one physician and a great deal of the decision for medical necessity rests with that initial physician referral.

Another conclusion of the Lewin panel was that information regarding the need for, use of, and frequency of services provided in LTCHs is not easily obtained from administrative claims data. Lewin further stated that the differences between medically complex LTCH patients and those treated in other post-acute settings such as SNFs are difficult to observe and may not be fully captured in APR-DRGs and severity of illness scores obtained from claims data alone. If so, patient-level criteria for eligible LTCH admissions could not be defined based only on coded diagnoses and procedures, but would have to include additional clinical measures.

II.B.3.2. Lewin 2: LTCH Clinical and Economic Impacts Assessment

Lewin's second study was designed to quantify the value and effectiveness of LTCH treatment for Medicare patients from a five percent random sample of Medicare claims between 1998 and 2000. This analysis compared Medicare payments and other outcomes between patients with similar acute hospital diagnoses who were or were not admitted to LTCH care, noting how the study results differed according to the levels of statistical control for the selection of more severely ill patients into an LTCH.

The Lewin report examined five outcome measures, each measured over the 180 day episode of care: 1) number of days spent in the community, 2) mortality rate, 3) outpatient Emergency Department (ED) visits, 4) two or more readmissions to acute inpatient care, and 5) total Medicare payments. Three analytical approaches were used to analyze these five outcomes:

"Simplified" Approach. Lewin compared treatment and control groups adjusting only for differences in patient APR-DRG levels. In comparison to others with the same APR-DRG levels, an average LTCH patient fared poorly. The average LTCH patient spends 44.0 fewer days in the community, is 11.1 percent more likely to die, is 2.5 percent more likely to have two or more returns to an acute hospital, and costs Medicare nearly $30,000 more (see first column in

Table II.B.2 below). These results in the Lewin report are similar to those found in the 2003 MedPAC report, which also controlled only for APR-DRG level. As both MedPAC and Lewin acknowledge, the poor outcomes observed for LTCH patients are likely due to unobserved levels of complexity and severity in their medical conditions, providing further evidence that APR-DRGs are not likely to fully capture the differences between patients admitted to LTCHs and those receiving treatment in other acute or PAC settings.

"Single Equation" Regression Approach. In a second approach, Lewin used a traditional multivariate regression technique to compare outcomes, controlling for differences between LTCH patients and others simply by including multiple clinical measures such as APR-DRG severity scores, APR-DRG mortality risk scores, plus other patient characteristics available in the Medicare claims data. Some results from this approach are also similar to the 2003 MedPAC report and indicate larger payments and less desirable clinical outcomes for patients treated in LTCHs compared to the other settings (second column in Table II.B.2). While LTCH patients experience fewer days in the community and higher mortality rates than non-LTCH patients, controlling for additional patient characteristics has lessened the negative effect of LTCH use seen from the earlier simplified approach.

"Two-Equation" Approach. Qualitative discussions with LTCH admissions directors led Lewin to a hypothesize that characteristics from Medicare claims data (referred to as the "observed" characteristics because they are included in the data files and therefore observed by the researchers) do not adequately describe the patients' needs and case severity that determine the selection of patients who are treated in an LTCH. Outcome differences between the *treatment group* (LTCH users) and *comparison group* (non-LTCH users) will reflect the impact of the LTCH on patient outcomes as well as the impact of observed and unobserved patient differences – where "unobserved" differences are those known to clinicians at the time of

treatment, but not observed in the data available to the researcher. For example, if LTCH patients were actually sicker for a given APR-DRG, one would expect worse outcomes. Outcome comparisons must be able to control for all patient differences in order to correctly identify the impact of the LTCH facility. To correct for this problem of adverse selection into LTCH care, Lewin used a statistical approach known as a Heckman choice model (Heckman

1979 and Heckman 1976).[6] Using the Heckman model, Lewin found that, across all APR-DRG classifications, LTCH treatment improves clinical outcomes and reduces payments compared with treatment in any other settings (Column 3 in Table II.B.2). Lewin also tested their model on episodes sub-divided by individual DRGs, with mixed results. Many of the DRG level findings were not statistically significant due to the smaller sample sizes.

Table II.B.2
Lewin Study Results:
Comparison of Estimated Impacts of LTCH Treatment on 180 Day Patient Outcomes

	(1) Matched Only by APR-DRG	(2) Single-Equation Regression [a]	(3) Two-Equation Regression With Selection Equation [b]
Days Alive and in the Community	-44.0*	-30.4*	+28.3*
Probability of Mortality	+11.1%*	+4.5%*	-10.3%*
Probability of 1+ ED Visit	-1.9%	-0.9%	-4.6%
Probability of 2+ Returns to an ACH	+2.5*	+1.0%	-7.4%*
Medicare Payments	+$29,757*	+$34,622*	-$10,979*

* Indicates statistically significant from zero at the 95-percent confidence level.
[a/] Ordinary least squares (OLS) was used to estimate the models for days and (log) payments. Probit models were used to estimate probabilities of mortality, an ED visit, and return to an ACH..
[b/] The outcome and the probit selection equations were estimated simultaneously with cross-equation error correlation.
Source: Dobson et al., "The Clinical and Economic Impacts of Long-term Hospitals," March 2004, p. 28, Figure IV.5.

Though the claims data (1998-2000) used by Lewin pre-dated the implementation of LTCH-PPS, the dollar amounts used in the Medicare payment analysis were estimated based on 2003 LTCH-PPS rates. However, this approach cannot account for possible behavioral changes on the part of LTCH providers to the incentives and disincentives imbedded in PPS. In particular, short-stay outlier penalties have been shown to affect discharge patterns, and variation

6 The Heckman model is a two equation statistical approach in which one equation is the selection equation that determines the chances of using an LTCH and the second equation determines outcome (e.g., Medicare payments). To be effective, a Heckman model must include variables in the first equation that affect the selection of LTCH use but are not related to patient's condition and that are not correlated with the outcome measures in the second equation. In the literature these are known as "instrumental variables". In using the Heckman approach, Lewin was attempting to control for unobserved factors that affect both the chances of LTCH use (selection bias) and outcomes.

in profitability by LTCH-DRG may have altered admission patterns (Gage et al., 2007). Without accounting for changes in provider behavior, Lewin's estimate of PPS-equivalent Medicare payments for LTCHs may be understated. Further, while this study updated the results of MedPAC's 2003 study with a different method to control for adverse selection into LTCHs, the main findings were computed as an average effect of LTCHs across the full study sample. The 2004 MedPAC analyses demonstrated clearly, however, that the "treatment effect" of LTCH use is different for the most complex patients than for others. This implies that models derived on *average* treatment effects across the sample may not be appropriate for this purpose. The Heckman approach used in the Lewin models to control for selection could be modified to account for the expected variation in the impact of LTCH care across low and high complexity patients.[7] The Lewin study did present findings from separate analyses by DRG, but due to the small LTCH case numbers in the five percent sample, these did not appear to produce reliable estimates.

II.B.3.3. Lewin 3: The Impact of Co-Location on Host Hospitals

Lewin also examined the effects of a LTCH co-locating with a short-term acute care hospital (i.e. a "hosting" hospital). LTCHs can be stand-alone facilities or co-located within or on the grounds of a hosting short-term acute care hospital facility (the LTCH is then known as a "hospital-within-hospital" or HWH).[8] The Lewin Group investigated whether HWHs increase the likelihood of LTCH treatment and might create strategic transfers of higher-cost cases for the purpose of minimizing losses on short-term acute Medicare cases.

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[7] Other statistical approaches – most notably propensity scores – can also be used to control for selection bias while incorporating theses type of expected differences across sub-groups in the magnitude of the "treatment effect."

[8] In 2006 there were 392 LTCHs nationwide. Of these 227 (58 percent) had hospital-within-hospital arrangements, up from 159 in 2002 (MedPAC 2008).

Lewin found that patients treated at acute care hospitals with HWHs had one percent lower outlier payments than the same patients at other hospitals. These savings were due to the fact that patients at IPPS hospitals with HWHs had lower outlier payments and that the Medicare patients were 11 percent less likely to receive any outlier payment. They found no statistically significant difference in average length of stay (see Table II.B.3 below). Medicare therefore realized some (modest) savings through reduced IPPS payments.

Table II.B.3
Lewin Study Results:
Estimated Effect of LTCH Co-Location on Host Hospitals

Outcome	Effect of Hosting an LTCH
Cost Per Case (Log)	-1%*
Probability of Outlier Payment (Logistic Model)	-11%*
Outlier Payments (as a percent of cost)	-1%*
Length of Stay	-0.016

* indicates statistically significant from zero at the 95-percent confidence level.
Source: Dobson et al., "The Clinical and Economic Impacts of Long-term Hospitals," March 2004, p. 37, Figure V.1.

This final Lewin study did not address whether total Medicare payments for the entire episode of care (combined treatment in both acute and PAC settings) are affected by the presence of an LTCH HWH in the acute hospital, nor did it compare the costs of HWHs to freestanding LTCHs. Further, the study compared all Medicare patients discharged from acute facilities with HWHs to all Medicare patients discharged from those without HWHs. However, this may not be the appropriate comparison, given that more than 99.5 percent of patients discharged from facilities without HWHs were not admitted to an LTCH.

II.B.4. Summary

The National Association of Long Term Hospitals (NALTH) sponsored two individual industry studies that responded to the 2003 MedPAC report. The Barlow studies found that

LTCHs are treating a critically ill population with complex needs and poor outcomes, and pointed to the need for additional clinical data to better describe the LTCH patient population, but provided no outcome comparisons between LTCH patients and patients in other settings. The Lewin studies updated the results of MedPAC's 2003 study with different methodology to control for adverse selection into LTCHs, finding that across the sample of all episodes, LTCH users had lower average payments and better clinical outcomes compared with non-LTCH patients. The sample size could not support estimates for particular types of episodes. Subsequent MedPAC analysis demonstrated clearly that LTCH outcomes are different for the most complex patients than for others. This implies that models based on average treatment effects across the sample are not appropriate for this purpose. Lewin's approach to control for selection should be modified to account for the expected variation in the impact of LTCH care across low and high complexity patients.

II.C. OTHER RECENT STUDIES

Under contract to CMS, RTI International has completed two subsequent studies of the LTCH industry (Gage et al. 2005 and Gage et al. 2007). CMS also contracted with RTI to organize a recent Technical Expert Panel (TEP) to determine outcome differences between LTCHs and other acute and post-acute facilities and to discuss criteria for both LTCH facilities and patients admitted to LTCHs.

II.C.1 Facility and Patient Criteria for LTCHs

The June 2004 MedPAC report recommended that CMS develop both facility-level and patient-level criteria to ensure that LTCH patients are medically "complex" and have a good chance of improvement. To address this issue, CMS' contract with RTI included an evaluation of

how Quality Improvement Organizations (QIOs) review LTCH cases to determine medical appropriateness, as well as a claims analysis of Medicare admissions during 2004 using the calendar year (CY) 2004 MedPAR files.

QIO Patient Reviews. With the establishment of the LTCH-PPS, CMS required QIO reviews for all LTCHs (42 CFR 412.508).[9] CMS selected a nationwide sample of 1,400 cases, focusing on higher-weighted LTCH DRGs and non-covered cases. The QIO reviews were to determine:

- whether services rendered at an LTCH were appropriate for the diagnosis;
- whether the services met recognized standards;
- whether the services could be provided at a lower level of care or on an outpatient basis; and
- whether the services provided were high quality and were complete and adequate.

QIOs examined cases for medical necessity of admissions and procedures, for evidence of premature discharge and for interrupted stays (where PAC-referred patients are readmitted to an acute facility for short stays and then returned to the PAC facility). They reviewed diagnosis codes to determine if cases were correctly diagnosed, and whether the hospital had provided adequate information to support the diagnosis, as well as whether the admission and discharge from the LTCH hospital were appropriate. [10] The RTI team worked with CMS' Office of Clinical Standards and Quality to identify QIOs in states with high numbers of LTCHs and developed interview protocols. Interview findings are summarized below.

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[9] The Medicare, Medicaid, and SCHIP Extension Act of 2007 moved the oversight function of LTCH review from CMS-contracted QIOs to Medicare's fiscal intermediaries and Medicare administrative contractors.

[10] LTCHs were reviewed under the same criteria as acute care hospitals.

Level of care criteria. To determine whether admissions, discharge, and continued stay in an LTCH are appropriate, QIOs used a set of screening criteria, typically an assessment tool such as the InterQual™ or the criteria developed by MassPRO.[11] [12] All but one QIO that RTI interviewed used the InterQual™ criteria as guidelines for determining whether an LTCH case is appropriate or should be referred to a physician for further review.

The InterQual™ and MassPRO tools both require that LTCH patients meet similar general criteria, but the InterQual™ tool is much more detailed, requiring more medical information and additional criteria to be met in order for a case to qualify as an appropriate admission to an LTCH. Although there are some differences between the two tools in the criteria for levels of physician oversight and nurse staffing, both require that patients need regular daily intervention or monitoring from health professionals to qualify for LTCH coverage. Specific screening criteria vary depending upon the patient's diagnoses. Both assessment tools aim to have the reviewers determine the necessary level of medical services, and to consider whether the level of services could have been delivered in a less intensive setting such as a SNF or at home with certified home health agency care.

Comparison with patients at other types of facilities. As part of its interviews with QIOs, RTI specifically asked how the QIOs differentiated between cases needing LTCH services and those that would be better served in a short-stay acute hospital, an inpatient rehabilitation facility (IRF), or a skilled nursing facility (SNF). LTCH cases were expected to differ from short-stay acute hospital cases because they required longer stays but less intense care; thus the

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[11] CMS, through the Iowa QIO, has contracted with McKesson Health Solutions to give QIOs access to the InterQual™ level of care assessment tools.

[12] MassPRO, the Massachusetts QIO, developed a set of screening criteria which were approved in 1995 by CMS; this set of criteria is also available to all QIOs who wish to use it to evaluate the appropriateness of admission and level of care in LTCHs.

QIOs in some respects considered LTCHs to be transition facilities between acute hospitals and SNFs. Most QIOs said that cases that were appropriate to go to LTCHs instead of IRFs or SNFs had a number of co-morbidities and needed an intense level of care with frequent physician and nurse visits.

Claims Analysis. Under the CMS contract, RTI also conducted an analysis of MedPAR claims from calendar year 2004 (CY2004) to determine what proportion of LTCH admissions could be considered medically complex based on outlier status as well as diagnosis (*see Appendix A Table A-1).* Overall, 43 percent of LTCH claims in the CY2004 data were classified as short-stay outliers and were therefore paid less than the full LTCH DRG amount. This should not be taken as evidence, however, that a similarly large proportion of cases were less complex or would not have met rigorous LTCH admission criteria. A large proportion of shorter LTCH stays are due to death or acute readmissions, indicating that short-stay outlier status is not a good indicator of lower complexity.

RTI identified that most of the common LTCH DRGs – such as respiratory illnesses requiring ventilator supports, pulmonary edema and respiratory failure, skin ulcers, and skin grafts – are conditions that could be categorized as more complex. However, other LTCH admissions for rehabilitation, degenerative nervous system disorders, psychoses, and post-surgical aftercare, which would not generally be classified as medically complex, were found in LTCHs, and were common in at least a subset of LTCHs. This suggested that LTCH admissions could be a mixture of more and less complicated cases. The claims data for inpatient cases reveal that for these less complex diagnosis groups, the great majority of claims are found in the less expensive inpatient psychiatric facility (IPF), IRF or SNF settings. For example, although DRG 249 (Aftercare, musculoskeletal disorders) accounted for 5 percent of LTCH cases in 2004

and was the second most common LTCH DRG, 80 percent of Medicare cases with a principal diagnosis that would have been grouped to DRG 249 were discharged to SNFs. Also, degenerative nervous system disorders (DRG 12) was the third most common LTCH DRG, but IPFs saw 6.5 times more degenerative nervous system disorder cases than LTCHs, and SNFs saw 17 times more cases than LTCHs.

The diagnoses and procedures included in standard claims databases provide relatively little information to help distinguish levels of acuity or severity. Thus, the patient attributes that motivate a post acute care referral decision to one level of care or another may be largely unobserved in empirical studies based on this type of secondary data. RTI's work underscored the need for additional clinical information to be incorporated into the empirical models, and for refining the techniques used to statistically control for the effects of remaining unmeasured differences in patient severity.

Clinical Indicators. To address the issue of patient-level criteria recommended in the June 2004 MedPAC report, CMS also contracted with RTI to conduct Technical Expert Panels (TEPs) with the goal of identifying a set of clinical indicators that could determine the appropriate care setting for medically complex patients. The first TEP, convened on January 30, 2007, was comprised of physicians, nurses, and hospital administrators representing LTCHs, acute care hospitals, IRFs, and SNFs – the primary inpatient settings for treating these medically complex patients. After discussion, the TEP participants reached a consensus that LTCHs provide a service that is comparable to general acute step-down units and that is not unique to LTCHs.

Though representatives from the LTCHs clearly described the medical complexity and severity of illness of their patient populations, much of the variation in patterns of LTCH use was

thought to be driven by geography and access to LTCH facilities. This opinion is consistent with empirical findings by RTI (Gage et al. 2007) as well as MedPAC (MedPAC 2004). In the many areas of the country without access to LTCH services, acute hospitals treat the medically complex patients for their entire episode of acute care. As a result of the TEP discussion, RTI was not able to confirm assertions from LTCH representatives that medically complex patients treated in LTCHs were significantly different from medically complex patients treated in acute settings. Panel members did agree that more work needed to be done to measure outcomes for medically complex patients treated in each of these settings.

A second TEP was convened on November 6, 2007, focusing on Medicare patients requiring mechanical ventilation or medically complex populations. The panel focused on prolonged mechanical ventilation (PMV) patients to allow for meaningful comparisons across provider types, because these patients are relatively clinically homogenous and their likelihood of using LTCHs is influenced by a few key attributes. Panel members included LTCH physicians and administrators, physicians from both acute hospitals and SNFs in areas without LTCHs, and several IRF physicians, thus representing the multiple settings where PMV patients are treated. The second TEP used a case vignette approach to assess which patients were appropriate for admission to the different facility types. TEP members reported that there were significant differences between the levels of patient morbidity that the acute care hospitals and LTCHs would treat as compared to the levels that SNFs and IRFs would treat, but that LTCH patients and those treated in short-stay acute care hospital step-down units were virtually indistinguishable. There was consensus regarding the medical profile of patients who belonged in either an LTCH or a step-down unit; but as one acute care physician stated, "there is no such thing as an LTCH-only patient." Furthermore, panelists agreed that some but not all of the

medically complex patients currently treated in LTCHs would be classified as "stable critical care" patients. The panelists also discussed realistic definitions of stability for critical care patients in different institutional settings, and the extent to which stability would typically be based on vital signs, dependence on vasopressors (intravenous drugs administered to raise blood pressure), or physician judgment.

Staffing levels were discussed and compared between facility types. Both LTCHs and IPPS step-down units typically have a nurse-to-patient ratio of 1 to 4 or 1 to 5, which distinguishes the more intensive level of care available in these settings from the level of care in SNFs and IRFs. Multidisciplinary teams of providers were the model of care in both LTCHs and step-down units of short-stay acute hospitals. Members of the panel indicated that discharges from acute care hospitals to LTCHs often occur because the LTCH is known to provide specialized treatment for particular types of patients, but also noted that hospital resource constraints often drive patient placement of very sick and expensive patients when there is an LTCH placement option.

II.C.2 Analysis of Outcomes

RTI's claims analyses were also used to revisit the questions of whether specialized LTCH services were actually producing better outcomes for patients. An initial set of analyses used episodes of care constructed from Medicare short-stay acute discharges in 2004 that had an APR-DRG severity score of 2 or higher, from a broad array of DRGs. Multivariate analysis was used to identify factors predicting LTCH post-acute care use, readmission rates, and length of stay in the initial hospitalization. The two most important factors in predicting LTCH admission were severity of illness (APR-DRG score of 3 or 4) and residence in a state with high availability

of LTCHs *(see Appendix A Table A-2)*.[13] Controlling for age, gender, race, severity score, number of co-morbid conditions, and critical care use, the model estimated that (a) location in a state with high availability of LTCHs was associated with a reduction of 1.1 days in acute length of stay and (b) actual LTCH use within the episode was independently associated with another reduction of 1.3 days in acute length of stay (both significant at $p<.001$). A more troubling finding was that use of an LTCH was associated with a 64 percent increase in the probability of acute readmission, where readmission was defined as any subsequent admission to an acute facility within the defined episode. PAC users have higher chances of readmission compared to non-PAC users because the patient that remains in the acute setting *as a substitute for PAC* has less opportunity to be readmitted. Nevertheless, it is also possible that LTCH patients were transferred too soon from acute hospitals.

The RTI contract also included two subsequent claims-based analyses of LTCH outcomes for Medicare episodes that were constructed only from beneficiaries with ventilator-related DRGs during their initial acute care admission. The first analysis was an area-level study, designed to compare average outcomes across patients living in metropolitan areas that had access to LTCH beds to average outcomes for clinically similar patients living in matched metropolitan areas that had no LTCHs. The second analysis was a person-level study that examined outcomes only for beneficiaries in specific states with a history of high LTCH use (Texas, Louisiana and Oklahoma). It compared outcomes for clinically similar cases that were either referred to an LTCH or that remained in the acute care setting. Both analyses used a stratified approach to implement the concept of statistical adjustment to obtain "clinically similar" patients, using predicted LTCH referral probabilities to group patients according to

[13] The sample excluded DRGs for which there is little or no history of LTCH use. The models did not test for individual DRG effects.

clinical and patient demographic characteristics. Outcomes for LTCH users and non-LTCH users can then be compared by group. Both studies examined differences in Medicare payments, length of stay, readmissions and mortality, among other outcomes.

The area-level analysis found no systematic differences in average outcomes between episodes from areas that have LTCHs and those that do not, whether the episode was classified as low, medium or high-likelihood LTCH referral. "High-likelihood" episodes in this model had an average referral probability of 30 percent or higher and tended to be cases with 96 or more hours of ventilator support and/or tracheotomies and/or high ICU use in the acute care setting. The area-level study also found strong evidence that in the high-likelihood episode group, LTCHs substituted primarily for extended stays in acute care facilities, while among the less complex ventilator cases LTCHs substitute for SNF or IRF care.

The second analysis estimated episode-level differences in outcomes rather than average area-level differences. A propensity score approach was used to identify six groups of episodes, within each of which LTCH use effectively simulated random assignment. [14] This analysis found considerable differences in LTCH outcome effects between the least likely and most likely LTCH referral groups:

- Among the two most likely referral groups (almost exclusively acute care hospital long-term ventilator cases with tracheostomies), Medicare payments were the same or lower, mortality was lower, and the chances of being discharged home was higher for

[14] Propensity scores are another modeling option for controlling for selection effects in non-experimental data. The first stage is to estimate the likelihood of the "treatment" variable (in this case, LTCH use) based on patient clinical and demographic factors only, in order to group observations based on treatment likelihood. The groups are formed to simulate random assignment by making sure that, within each individual group, the observed patient attributes of those who receive the treatment (LTCH users) are statistically similar to the attributes of those who do not (non-LTCH users).

those referred to LTCHs (relative to those remaining in acute care settings for the duration of their episode).[15]

- Among the two least likely referral groups (least complex ventilator cases), Medicare payments were much higher, hospital stays were longer, and all other outcome measures were the same of worse for those referred to LTCHs versus those remaining in acute care settings.

Outcomes analyses using propensity scores supported the earlier conclusion from MedPAC that LTCHs may provide beneficial and cost-effective services for a subset of complex patients, but not to all types of cases admitted to this setting. In the three states used for the RTI study, only about 30 percent of the actual PMV admissions to LTCHs were classified into the two groups where the most benefit was observed, while one-fifth were classified in the lowest two groups. However, these states were identified for the study because of their unusually high LTCH bed supply, and their admission patterns should not be considered representative of other parts of the country.

RTI attempted to apply similar modeling to other respiratory or medically complex cases in order to expand the conclusions beyond the PMV population, but found that the prediction models for LTCH use were not as robust. It concluded that additional statistical approaches should be investigated and additional measures obtained to be able to model LTCH treatment effects in other types of cases.

II.C.3 Margins Analysis

In addition to considering the overall LTCH profiles and patient outcomes, the CMS contract included a review of LTCH Medicare payments compared to hospital costs, before and

[15] Readmission rates following a discharge to home were slightly higher for those referred to LTCHs. In order to make a fair comparison across PAC and non-PAC users, the definition of a readmission for this study effectively excluded hospital-to-hospital transfers and focused on success or failure in the final case disposition.

after implementation of LTCH PPS. RTI found that LTCH Medicare margins immediately following PPS (FY 2003 and 2004) were very high, in total and as compared to general acute hospital margins for similar cases *(see Appendix A Tables A-3 and A-4).* For example, for mechanical ventilator patients grouped to DRG 475, the median LTCH-PPS margin was 23.1 percent. In IPPS settings it was only 13.1 percent overall; median margins were quite high for cases staying 10 days or less (42.6 percent), but severely negative for those staying longer (-27.1 percent).

II.C.4 Summary

As part of two studies of the LTCH industry completed for CMS, RTI International has interviewed Quality Improvement Organizations responsible for determining the appropriateness of LTCH care, analyzed claims data to describe patients receiving care in LTCHs, and organized two Technical Expert Panels of providers and administrators from multiple inpatient care settings (Gage et al. 2005 and Gage et al. 2007). The consensus from all of these efforts is that LTCH patients are medically complex and require intensive amounts of medical services, but that the level of care provided in LTCHs is also available in other settings, primarily step-down units of short-stay acute hospitals. Further research is required to compare clinical outcomes and Medicare payments for similar patients across these two settings. Medicare payments are of particular interest, because under the current payment system, a complex patient in an acute hospital who moves into the step-down unit generates one prospective payment, while a complex patient transferred from an acute hospital to an LTCH generates two separate payments. When comparing LTCH patients to those in step-down units, it will continue to be important to adequately control for selection issues. TEP participants indicated that acute-step down units may serve to relieve ICU over-crowding and so have patients who would not be stable enough

for transfer to LTCHs. Claims analysis of LTCHs pointed to a mixture of more and less complex diagnoses in their case mix.

II.D. RECENT LTCH LEGISLATIVE/REGULATORY CHANGES AND CURRENT STATUS

Regulatory and legislative changes have affected the LTCH industry in the last few years. The two principal changes include CMS' "25 Percent Rule" and the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007, with additional minor changes in the American Recovery and Reinvestment Act (ARRA) of 2009.

II.D.1 The 25 Percent Rule

The "25 percent rule" refers to a payment limitation on co-located LTCHs that reduces LTCH PPS payments if more than 25 percent of admissions to an HwH or satellite LTCH are transfers from the co-located (or "host") ACH. CMS established the 25 percent rule to discourage patient shifting due to discharge patterns from a host hospital to its co-located LTCH, recognizing that the host hospital can have a strong financial incentive to discharge its complex, high-cost patients into the co-located LTCH in order to minimize losses under the DRG payment method.

For discharges occurring on or after October 1, 2004, CMS reduces payments for LTCH discharges transferred from the host hospital if the admission occurs after a specific effective threshold percent has been met. Initial regulations allowed for the threshold percent to be phased in over four years, reaching 25 percent by FY 2007 (69 FR 48916).[16] LTCH admissions that

[16] The phase-in established a baseline percent for each co-located facility in FY 2004, but applied no payment adjustment in that year. Thresholds were set at the lesser of the baseline or 75 percent in FY 2005; baseline or 50 percent in FY 2006; and baseline or 25 percent in FY 2007.

qualify as high-cost outliers at the host hospital are not counted toward the 25 percent threshold, and they are excluded from the payment reduction once the threshold is met. In rural areas or in urban areas with a single or dominant acute hospital, the threshold is 50 percent. For LTCH claims that are subject to the reduction, payments are adjusted to equal the lesser of the LTCH PPS amount or the amount that would have been payable if the LTCH had been an IPPS facility.

The 25 percent rule was to be expanded to apply to all LTCHs whether co-located or not, with a new phase-in period starting July 2007 (72FR 26870). The Medicare, Medicaid and SCHIP Extension Act of 2007 (MSEA, PL 110-173) prevented this, however, and also extended some of the phase-in for the co-located providers and raised the thresholds for LTCHs in rural and dominant-hospital areas to 75 percent (73 FR 26788).

II.D.2 Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007

The Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007 featured several legislative provisions related to LTCHs, including changes to the 25 percent threshold rule, the application of facility criteria for LTCH admissions, and a moratorium on new LTCH facilities and new beds in existing facilities, with certain limited exceptions.

Limits on the 25 Percent Rule Implementation. In three ways, the MMSEA significantly weakened the 25 percent rule. First, for a three-year period, it limited the phased-in implementation of the 25 percent rule for certain HwHs and satellites, by allowing up to 50 percent of an LTCH's Medicare patients to be admitted from the LTCH's host hospital (instead of 25 percent starting in FY 2008) without incurring a payment adjustment. Second, for a three-year period, MMSEA allowed 75 percent (instead of 50 percent) of admissions to HwHs and satellites in rural areas or in urban areas with a single or dominant acute hospital. Third, for three

years the Act also blocked CMS from applying the 25 percent rule to freestanding LTCHs and co-located LTCHs ("grandfathered") operating prior to September 30, 1995.

New LTCH Criteria. As of January 1, 2008, MMSEA added three additional requirements to be a Medicare-certified LTCH. Prior to MMSEA, the only conditions for an LTCH-PPS Medicare payment were that a facility must 1) have a provider agreement to participate as a hospital and 2) have an average length of stay of 25 days or more for its Medicare patients. MMSEA requires that LTCHs must have

- **A patient review process** that 1) is documented in medical record, 2) screens patients prior to admission for LTCH appropriateness, 3) validates within 48 hours that patients meet LTCH admission criteria, 4) regularly evaluates patients throughout their stay for continuation of LTCH care, and 5) assesses available discharge options when patients no longer meet continued stay criteria;
- **Active physician involvement** with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time; and
- **Interdisciplinary treatment teams** for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

LTCH Expansion Moratorium. Effective December 29, 2007, MMSEA also imposed a three-year moratorium on the construction of *new* LTCHs and LTCH satellites, unless one of the following conditions was met by a LTCH as of the date of the enactment of this Act (December 29, 2007):

- The LTCH began its qualifying period for payment as a long-term care hospital under section 412.23(e) of title 2, Code of Federal Regulations, on or before the date of the enactment of the Act;
- The LTCH has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for a long-term care hospital, and has expended, before the date of the enactment of the Act, at least 10 percent of the estimated cost of the project (or, if less, $2,500,000); or

- The LTCH has obtained an approved certificate of need in a State where one is required on or before the date of the enactment of the Act.

The legislation also established a three-year moratorium on the increase of LTCH beds in *existing* LTCH facilities unless both of the following conditions are met:

- The LTCH is located in a state where there is only one other LTCH; and

- The LTCH requests an increase in bed size following the closure or decrease in beds of another LTCH in the state. [17]

Medical Necessity Review Responsibility. MMSEA required the Secretary—under contracts with fiscal intermediaries (FIs) or Medicare Administrative Contractors (MACs)—to conduct reviews of the medical necessity of LTCH admissions and continued stays. These reviews are to be conducted for discharges occurring between October 1 2007 and October 1, 2010.

II.D.3 American Recovery and Reinvestment Act (ARRA) of 2009

The enactment of the American Recovery and Reinvestment Act (ARRA) of 2009 on February 17, 2009, provided an additional exception to the 2007 moratorium from the MMSEA on the increase in beds in existing LTCHs and LTCH satellites. For an existing LTCH or facility that obtained a certificate of need (CON) for an increase in LTCH beds (in a state where a CON is required), the LTCH was permitted by ARRA to increase its number of beds to the number specified on the CON, as long as the CON was issued on or after April 1, 2005, and before

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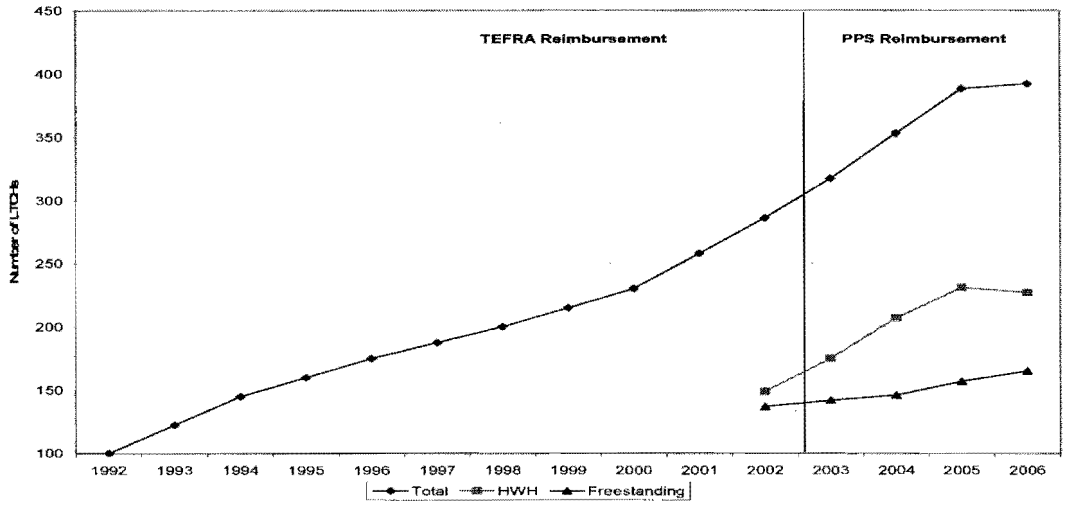
[17] As of April 1, 2009, CMS reports that nearly 50 new LTCHs have been formed since the moratorium in the MMSEA, primarily due to exceptions provided in the law. This is evidence that the first three exceptions have been granted frequently, but because they are based on qualifying prior commitments, fewer new LTCHs should be expected through the end of 2010.

December 29, 2007. ARRA also expanded the categories of LTCHs that would be subject to the delay in the implementation of the 25 percent threshold rule.

II.D.4 Current Status and Issues Raised in the March 2008/2009 MedPAC Reports

The March 2008 and March 2009 MedPAC Reports to Congress presented updates on the status of the LTCH payments and services. One of the more significant findings in the MedPAC report was that growth in the number of LTCHs had slowed in 2006 and 2007. Between 1992 and 2005, MedPAC found that the total number of LTCHs increased by 300 percent from 97 to 388, and more than one third of which were added between 2002 and 2005, after the implementation of LTCH PPS (see Figure II.D.1). There was a net increase of four Medicare-participating LTCHs from 2005 to 2006, and another four between 2006 and 2007 (MedPAC 2009). They concluded that the supply of LTCH providers would remain stable through 2011, as it would be influenced during that time by the terms of the MMSEA moratorium rather than by Medicare payments. As discussed above, however, significant exceptions to the moratorium were included in the legislation, resulting in a large increase in the number of LTCHs in 2008. Exceptions are based on prior facility commitments (undertaken before the moratorium was enacted in December of 2007); consequently, fewer exceptions will likely be granted in subsequent years.

Figure II.D.1
Growth in the Number of LTCHs, 1992 – 2006



Source: MedPAC, Report to Congress, Medicare Payment Policy: Section 6: Long-term Care Hospital Services, March 2008, p. 226.

Between 2002 and 2005, MedPAC also found that HWHs were growing at a much faster rate than freestanding LTCHs—15.7 percent per year versus 4.6 percent (see Figure II.D.1). However, between 2005 and 2006, there was actually a decline in the number of HWHs from 231 to 227 (a 1.7 percent reduction). MedPAC believes that this is probably due to the implementation of the 25 percent rule, which policymakers expected would slow down entry of HWHs into the Medicare program (MedPAC, 2008). At the same time, the number of freestanding LTCH facilities continued to grow, at a slightly higher rate (5.1 percent annually versus their previous growth of 4.6 percent). According to MedPAC, new LTCHs entering the market tend to locate in market areas where LTCHs already exist, raising questions about whether there are sufficient numbers of chronically critically ill patients to support the number of LTCHs in a given community. MedPAC concludes that "Seen in this light, recent slowing in

growth of facilities, cases, and Medicare spending may indicate that the industry is approaching equilibrium after a period of explosive growth spurred by overpayment and inappropriate admissions."

Medicare spending on LTCHs increased rapidly after the LTCH-PPS was implemented in FY 2003, but has leveled since 2005 (MedPAC 2008). Spending increased by 37 percent between 2003 and 2004 and by 22 percent between 2004 and 2005, but was flat between 2005 and 2006.

II.D.5 MedPAC's March 2008 Letter to CMS

On March 24, 2008, MedPAC sent a letter to CMS regarding its previous request for the development of facility and patient criteria (Hackbarth 2008). After finding that only among patients with the greatest severity were Medicare payments per episode similar for LTCH users and others, MedPAC (2004) had previously recommended that LTCHs be defined using facility and patient criteria in order to make sure that admitted patients are medically complex. In a comment on the RY 2009 LTCH PPS proposed rule, MedPAC stated the following:

> "In MedPAC's June 2004 Report to the Congress, we recommended that the Congress and the Secretary define LTCHs using facility and patient criteria, to ensure that the patients admitted to these facilities are medically complex. We specified that facility-level criteria should characterize the level of LTCH care by features such as staffing, patient evaluation, review processes, and mix of patients; while patient-level criteria should identify specific clinical characteristics and treatment modalities. We made this recommendation because our qualitative and quantitative research found that beneficiaries treated in LTCHs cost Medicare more than those treated in alternative settings; however, the cost differences narrowed considerably if LTCH care was targeted to patients who appeared most suitable for this level of care. That led us to conclude that Medicare should ensure that LTCHs treat only appropriate patients. The types of cases treated by LTCHs can be (and are) treated in other settings, particularly in step-down units of many acute-care hospitals. *Therefore, it is not possible (nor desirable) to develop criteria defining patients who can be cared for exclusively in LTCHs. Rather, CMS should seek to define the* ***level of care*** *typically furnished in LTCHs, step-down units of many acute-care hospitals, and some specialized skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs)." (MedPAC 2008)* (Emphasis added)"

II.D.6 Summary

Several new LTCH legislative provisions were enacted with MMSEA of 2007 including a weakening of the 25 Percent Rule, patient review processes, active physician involvement, interdisciplinary treatment teams, and a three-year moratorium on increasing LTCH beds in existing facilities and construction of new facilities. From 2005 to 2006 there was a net increase of just four LTCHs and preliminary data for 2007 suggest that there have been no further increases.

In its 2004 Report to Congress, MedPAC indicated that LTCHs should be defined using facility and patient criteria in order to make sure that admitted patients are medically complex. In 2007, RTI held a technical expert panel (TEP) which found that patients treated in LTCHs are generally comparable to patients treated in acute hospitals step-down units and are not unique to LTCHs. The TEP also recommended developing Centers of Excellence for treating these medically complex cases and setting equitable payment rates across hospitals. In March of 2008, MedPAC refined its earlier (2004) opinion regarding the definition of LTCHs in terms of facility and patient criteria and stated that it was not possible to develop criteria defining patients who can be cared for exclusively in LTCHs and that instead, CMS should seek to define the level of care typically furnished in LTCHs, step-down units and some specialized SNFs and IRFs.

Section IIIa which follows provides an examination of the clinical characteristics of the LTCH population focusing on defining medical complexity, identifying critically complex patients, predicting outcomes for these patients using severity scoring systems, and evaluating quality of care for these patients. This section reviews research that attempts to define patients who are critically ill with complex conditions. Section IIIb describes research CMS is

sponsoring over the next 18 months that is intended to update and refine our understanding of Medicare LTCH patients and payments to answer some of the unresolved questions presented in this section.

III. IDENTIFYING CRITICALLY COMPLEX PATIENTS AND RECOMMENDATIONS FOR ADDITIONAL RESEARCH

III.A. IDENTIFYING CRITICALLY COMPLEX PATIENTS AND THEIR OUTCOMES

III.A.1 Identifying Critically Ill Patients

As the March 24, 2008 letter from MedPAC to CMS indicated, CMS should attempt to define the level of care typically furnished for patients in LTCHs, acute care step-down units specialized SNFs, and IRFs. Many of the patients in each of these types of facilities are critically ill. This section addresses the issue of defining medically complex and chronically critically ill patients and the care they require.

III.A.1.1 Defining the Medically Complex and Chronically Critically Ill (CCI)

Chronically, critically ill populations are diverse and there is no single accepted definition of a medically complex patient or one who is chronically critically ill. We reviewed the existing published literature on the characteristics of medically complex and chronically critically ill patients and the range of definitions used by researchers. Because LTCHs by definition focus on patients with longer term needs, we focused on the *chronically* critically ill (CCI) patient. In addition, when examining these patients, we focused on patients in need of long-term hospital-level care, rather than patients who need long-term assistance with activities of daily living or other lower-intensity services.

The literature search used a two-step approach to identify definitions of CCI patients. First, we used MedLine and PubMed searches of academic journals using logical combinations of the following key words and their derivatives: "chronically critically ill," "critically ill," "critically complex cases," "definitions," and "LTCH." Second, we carefully reviewed the

archives of three journals that are particularly relevant to CCI patients that potentially use LTCHs. These journals include: *Critical Care Medicine, Critical Care Clinics, Chest,* and *Clinics in Chest Medicine.* [18] Overall, more that 200 academic journal articles were examined for this review.

In general, we found two alternative types of definitions of the CCI population: 1) ones that define the CCI population in general terms and 2) specific operational definitions that are used to define the population in order to undertake analytical studies of the CCI population.

CCI Definitions. We found 14 different studies with general definitions of the CCI dating from 1985. The CCI definition found to be cited the most in subsequent literature was that offered by Nierman in the 2002 *Critical Care Clinics* publication dedicated to CCI patients:

> A growing population of patients survives acute critical illness only to become chronically critically ill, with profound debilitation and ongoing respiratory failure. Although prolonged dependence on mechanical ventilation is a defining characteristic, chronic critical illness (CCI) may be more appropriately viewed as a syndrome encompassing multiple characteristics including metabolic, endocrine, physiologic, and immunologic abnormalities. These derangements, initiated by an episode of sepsis, accompanied by dysfunction of various organ systems, and perpetuated by acquired morbidities, serve to slow or preclude recovery from a wide range of acute forms of medical, surgical, and neurologic critical illness. Care of the chronically critically ill is extremely challenging, protracted, and resource-intensive, requiring multidisciplinary expertise, substantial commitment on the part of caregivers, and weeks to months of hospitalization. Unfortunately, even with excellent care in specialized units in acute care hospitals, long-term acute care facilities or skilled nursing facilities, many of these patients continue to require mechanical ventilation and/or other forms of intensive support, with high rates of early mortality and extreme functional dependence.

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[18] Entire issues of *Critical Care Clinics* published in 2002 (Volume 18) and *Clinics in Chest Medicine* published in 2001 (Volume 22, Number 1, March 2001) were devoted to chronic critical illness.

In reviewing definitions of the chronic critically ill (CCI) in the literature, we found six factors or attributes of CCI that were commonly used in the 14 studies identified. These factors are (and are presented in declining order of number of studies mentioning each factor):

- Prolonged mechanical ventilation (PMV) for several weeks or months.
- The patient recovers from the acute illness phase, is medically stabilized and discharged from the ICU, but because of complications remains functionally dependent upon continued hospital-level care.
- The patient has multiple organ system failure or dysfunction.
- The patient has multiple or chronic co-morbidities (e.g. coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), diabetes).
- The patient has acute care hospital-acquired morbidities such as sepsis and/or pressure ulcers as a result of his or her prolonged hospital stay.
- The patient has had a tracheostomy performed for long-term mechanical ventilation.

The majority of studies included all of these factors in their definition of CCI except for having a tracheostomy (see Table 111-1). The most common factor in the 14 studies was the inclusion of PMV for several weeks or months: 13 of the 14 studies include PMV in their definition of CCI. This is not surprising because PMV is the most easily identified group of LTCH patients—as high as 25 percent of the discharges identified in one study (Eskildsen 2007). Nationally, they account for the largest group (about 10 percent) of Medicare LTCH admissions (Gage, 2007).

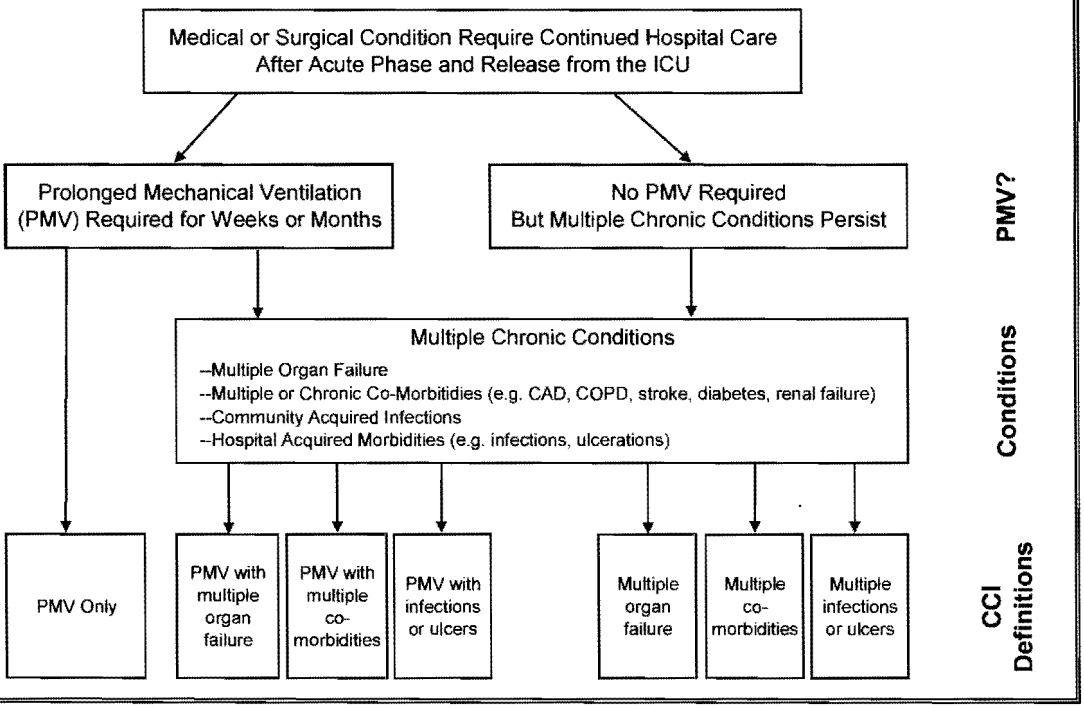
Table III-1

Six Factors Included In Alternative General Definitions of the Chronically Critically Ill (CCI)

Study	PMV Required for Weeks or Months	Stabilized from Acute Phase & Released from ICU, But Functionally Dependent Requiring Continued Care	Multiple Organ System Failure or Dysfunction	Multiple or Chronic Co-Morbidities	Acquired Morbidities Such As Recurrent Infections (e.g. sepsis) and/or Ulcers	Trach Performed	Description and Other
Girard (1985)	x	x		x			Many patients are successfully treated and discharged from the ICU, but a large % of critically ill do not improve and become CCI
Papa-Kanaan (2001)		x					This population has lower serum albumin levels, wider A-a gradients, and increased prevalence of ulcers.
Brem (2002)	x	x	x	x	x		CCI patients are almost universally at high risk for developing pressure ulcers. They typically have multiple comorbid illnesses (e.g. malnutrition, diabetes, renal failure, sepsis), and are ventilator-dependent and immobile for an extended period of time.
Nierman (2002 a)	x	x	x	x	x		Besides PMV, CCI may be more appropriately viewed as a syndrome of multiple characteristics including metabolic, endocrine, physiologic, and immunologic abnormalities which serve to slow or preclude recovery from a wide range of acute critical illnesses.
Nierman (2002 b)	x	x	x	x	x		CCI issues include wearing and chronic comorbidities such as congestive heart failure, renal failure or COPD, nutrition/metabolic support, psychiatric issues, rehab, ulcers, infections, and family issues.
Carson (2002)	x	x					Investigators have chosen different defintions based upon clinical interventions, administrative coding practices, resource utilization, hospital type, or their own sense of when a patient has been in the ICU too long.
Carson (2006)	x	x	x		x		CCI patients are characterized by PMV, muscle atrophy and neuromuscular weakness, recurrent infections with multi-drug-resistant organisms, delirium, and discomfort.
Thomas (2002)	x	x	x	x			Patients with CCI may be in need of renal dialysis, cardiac pacing, nutrition, gastric intubation, and monitoring in addition to PMV. Most patients have indwelling bladder or intravenous catheters and a variety of monitoring devices.
Danis (2004)	x					x	Although researchers do not use a uniform defintion, some investigators have used the performance of tracheostomy for continued MV as an indicator of CCI.
Nelson (2004)	x	x	x		x		PMV is a hallmark of CCI, but derangements of multiple organ systems are also characteristic of CCI, as are general debilitation and the recurrence of nosocomial infections and other major comlications.
Nelson (2005)	x	x	x		x	x	CCI is not simply prolonged acute critical illness or respiratory failure but a syndrome of significant, characteristic derangements of metabolism and of neuroendocrine, neuropsychiatric, and immunologic function.
Daly (2005)	x	x	x	x			CCI patients have experienced a critical illness and recoverd from the acute phase but remain dependent on intensive medical/nursing because of complications such as respiratory failure, stroke, or renal failure.
Mechanick (2005)	x	x		x	x	x	Though there is no consensus for the defenition of what constitutes CCI, the important features are: prolonged intensive care with mechanical ventilation, tracheostomy, distinctive neuroendocrine physiology and profound debilitation.
Douglas (2007)	x			x			CCI patients are those who require PMV, expensive stays in ICUs and are generally older than 60; they have more than a single comorbid condition (e.g. coronary artery disease, COPD) and high mortality rates.

Based upon our review of the studies, seven working definitions of the chronically critically ill appear to emerge 1) PMV only, 2) PMV with multiple organ failure, 3) PMV with multiple co-morbidities, 4) PMV with infections or ulcers, 5) multiple organ failure, 6) multiple co-morbidities and 7) multiple infections or ulcers. A logic diagram for these definitions is presented in Figure III-1.

Figure III-1
Logic Diagram for Defining the Chronically Critically Ill



Operational Definitions of PMV. As discussed above, the most commonly-used factor related to CCI patients is prolonged mechanical ventilation (PMV). Researchers use a variety of operational definitions of PMV, including greater than 24 hours, or more than 2, 4, 14, 21 or 29 days. The most widely used definitions of PMV use DRG groups 475, 483, 541, and 542

(MacIntyre, 2005).[19] MacIntyre (2005) indicates that these DRG definitions generally apply to patients who have required at least 6 hours of daily mechanical ventilation for more than 21 days which is consistent with the observation that the majority of patients who are transferred to an LTCH have received ventilation for at least 21 days. In May 2004, the National Association for Medical Direction of Respiratory Care (NAMDRC) sponsored a 2-day conference to, among other things; establish a recommendation for an operational definition of PMV. Their primary recommendation was:

> *Prolonged Mechanical Ventilation should be defined as the need for 21 or more consecutive days of mechanical ventilation for 6 or more hours per day. Research is needed to better understand which definitions of PMV are most commonly used, how they are currently being employed, and how they impact costs, outcomes, and reimbursement in the United States.*[20]

Non-PMV cases. There is less literature regarding definitions of CCI for non-mechanical ventilation cases. Because LTCHs provide services to other types of complex non-ventilation patients including those requiring cancer treatment and pain management, this is an important topic. Interviews with LTCHs (MedPAC, 2004; RTI, 2007) also indicate that in addition to PMV, medically complex cases treated at LTCHs may include multisystem organ failure, contagious infections, and complex wounds needing extended care (See Figure III-1). One study of survival after prolonged critical illness at four LTCHs (Dematte-D'Amico 2003)

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19 DRG 475 represented respiratory system diagnosis with ventilator support, DRG 483 represented tracheostomy with mechanical ventilation for 96 hours or more with principal diagnosis except for face, head, and neck, DRG 541 represented tracheostomy with mechanical ventilation for 96 hours or more with principal diagnosis except face, mouth, and neck diagnosis with major operating room procedure, and DRG 542 represented tracheostomy with mechanical ventilation for 96 hours or more with principal diagnosis except face, mouth, and neck diagnosis without major operating room procedure. As of October 2004, CMS replaced DRG 483 with DRGs 541 and 542. These DRGs which fell under the LTCH PPS system were all replaced in FY 2008 with the MS (Medicare Severity)-LTCH-DRG system that includes DRGs 3, 4, 207, and 208 for PMV cases.

20 Cox (2007) used the NAMDRC-recommended operational definition of PMV (21 consecutive days of mechanical ventilation for 6 or more hours per day) to study ICU patient outcomes but also compared this to an alternative definition of 96 hours or more of mechanical ventilation plus a tracheostomy. Carson (2008) also used the NAMDRC-recommended definition to study ICU patient outcomes.

determined that 46 percent of the patients were non-ventilator dependent, 83 percent had organ system failure and 60 percent had multiple organ system failure.

We found only a limited number of non-PMV CCI definitions in reviewing the literature. Most are limited to cases of multisystem organ failure. (PMV patients can also have multisystem organ failure). Multiple studies discuss non-PMV ***multisystem organ failure***.[21] Van den Berghe (2002) indicates:

> *By definition, critical illness is any condition requiring support of failing vital organ systems without which death would ensue...If onset of recovery does not follow within a few days of intensive care, critical illness often becomes prolonged, and organ system support is frequently needed for several weeks.*

Thomas (2002) indicates:

> *Critical illness (CI) or injury has been defined as a medical condition that impairs one or more vital organ system, jeopardizing the patient's survival...Patients with CI are usually managed in the Intensive Care Unit (ICU). Many reasons, primarily financial constraints and demand for ICU beds, often make it necessary to discharge seriously ill patients from the ICU with multiple unresolved medical problems and in need of continuing complex medical care including mechanical ventilation. These are patients with chronic CI (CCI).*

The literature also addresses patients with multiple organ system failure as it relates to shorter-term acute critical illness rather than longer-term chronic critical illness (CCI). This type of short-term acute critical illness is often referred to as multiple organ dysfunction syndrome/failure (MODS) and is defined as altered organ function during sepsis, septic shock, or systemic inflammatory response syndrome. The systems generally affected include: respiratory, cardiovascular, renal, hepatic, gastrointestinal, hematological, endocrine, and the central nervous

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[21] Mechanick (2002) also states that, "*The metabolic syndrome of chronic critical illness consists of: 1) multisystem organ dysfunction resulting from the initial acute injury and chronic INA (immune-neuroendocrine axis) activation.....*"

system (see Wickel 1997, Fry 2000, Johnson 2001, and Vincent 2007). These specific types of organ failures are consistent with the findings of Dematte-D'Amico et al.'s (2003) study of prolonged critical illness patients (PMV and non-PMV cases combined) at four LTCHs which found that 54 percent of patients had respiratory failure, 18 percent had cardiovascular failure, 15 percent had renal failure, and 42 percent had gastrointestinal or hepatic failure.

Many definitions of CCI include reference to multiple comorbidities. The CCI have many complex, ongoing and overlapping issues requiring attention to chronic comorbidities such as congestive heart failure, COPD, renal disease, diabetes, or obesity. Carson (2005) notes that in developing risk factors for the CCI, "critically ill patients admitted to the ICU with significant comorbidities are at higher risk, especially those with underlying heart disease, chronic obstructive pulmonary disease, and kidney disease. For surgical patients, preoperative instability, COPD, prolonged operation, and in the case of cardiac surgery patients, increased by-pass time are important risk factors for PMV." The Barlow study (Scheinhorn 2007) indicates that for the patients admitted to 23 LTCHs for PMV weaning, patients had an average of 2.6 premorbid diagnoses per patient. More than 42 percent of these patients had COPD, 26 percent had coronary artery disease, 21 percent had congestive heart failure, 23 percent had diabetes mellitus, and 7 percent had renal insufficiency.

Due to ***multiple comorbid conditions*** such as diabetes, renal failure, sepsis and malnutrition, chronically critically ill patients are at high risk for developing pressure ulcers and other types of wounds. Brem (2002) indicates that pressure ulcers are related to a number of negative outcomes including increased morbidity (including pain and discomfort), increased mortality, poor utilization of healthcare, and large financial expenditures. Patients with chronically critically ill conditions may recover from their acute stages of illness but still require

intensive nursing care for treatment of wound healing. Some patients may develop wounds and ulcers during the acute phase of their illness in the ICU that carry over to the chronic illness phase; others may develop ulcers during the chronic phase of illness after ICU discharge. Even with careful treatment, wounds can occur in the CCI population. (Brem 2002). Skin conditions are among the top 5 reasons for LTCH admissions in the Medicare program, accounting for a substantial portion of cases as either a primary or secondary complication (Gage, 2007).

A large share of the CCI population develops complex wounds. Robnett (1986) found that 41 percent of patients in surgical ICUs had pressure ulcers and the Barlow study (Scheinhorn 2007) found that 42 percent of patients admitted to LTCHs had pressure ulcers at the Stage II level or above.[22] The literature has also consistently found that patients with pressure ulcers are at very high risk for mortality. Studies by Allman (1986), Thomas (1996), and Brown (2003) indicate one-year mortality rates of between 60 and 78 percent and two year mortality rates as high as 84 percent among those that develop pressure ulcers while in hospitals.

Some studies have sought to determine the underlying risk factors associated with the development of ulcers in the CCI population. Eachempati (2001) found that emergency room admissions, age, days in bed, and days without nutrition were independent predictors of decubitus ulcers. In a study of critically ill patients admitted to ICUs, multivariate analysis indicated that there were five factors that were independently significant indicators of pressure ulcer development including: norepinephrine infusion, APACHE II score, fecal incontinence, anemia, and length of stay (Theaker 2000).

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[22] See the National Pressure Ulcer Advisory Panel (NPUAP) website at www.npuap.org for definitions.

Neuromuscular dysfunction (NMD) has been increasingly recognized as an important risk factor for CCI patients resulting in significant morbidity and mortality (Khan 2008). NMD includes both critical illness myopathy (CIM) and critical illness polyneuropathy (CIP). CIM is an acute myopathy causing prolonged muscle weakness and paralysis while CIP is an acute axonal neuropathy mainly affecting the lower limb nerves. NMD is not often documented in the literature because it is difficult to measure clinically due to the unavailability of electrophysiological examination and histologic samples in many ICUs (De Johghe 2002). However, when NMD is measured, it is a very common condition either leading to or associated with CCI. Studies of CCI patients in ICU settings using electrophysiological and histologic techniques have indicated NMD abnormalities ranged from 47 percent to 90 percent and 71 percent to 96 percent respectively (De Johghe 2002). The consequences of NMD in the CCI population can be profound and long lasting: evidence of chronic partial denervation of the muscle has been found in greater than 90 percent of long-stay CIP patients up to five years after ICU discharge (Fletcher 2003).

Summary of Definition of Medically Complex and CCI Patients

There is no single accepted definition of a medically complex patient or one who is chronically critically ill (CCI). In general, the CCI patient is one who partially recovers from the acute phase of illness but remains dependent upon continued hospital-level care outside of the ICU during the chronic phase. Based upon our review of the literature, there are a number of patient-related factors that are commonly associated with alternative definitions of the CCI including: 1) tracheostomy performed and/or prolonged mechanical ventilation (PMV) for several weeks or months, 2) multiple organ system failure, 3) multiple or chronic co-morbidities (e.g., CAD, COPD, diabetes), and hospital-acquired morbidities such as sepsis and/or pressure ulcers.

PMV is the most common factor cited among reviewed CCI definitions more than likely because as this condition represents the largest group of Medicare LTCH admissions. As discussed earlier, both MedPAC and RTI found that LTCHs achieved better outcomes at lower Medicare costs for PMV weaning patients. Thus, it appears as though PMV weaning is one category of medically complex CCI patients that may define a class of LTCH-appropriate patients. However, the vast majority of CCI patients do not require PMV. Such patients have varying combinations and levels of organ failure, co-morbidities, infections, pressure ulcers, and or other chronic condition complexities. Unfortunately, the literature as it currently exists sheds little light on which of these conditions and combinations are sufficiently medically complex as to define LTCH-appropriate patients.

Technical Expert Panel (TEP) Discussions. As discussed in Chapter II.C.2 above, CMS contracted with RTI in 2004 to develop criteria for LTCH patients and facilities. As part of this effort, RTI conducted two Technical Expert Panels (TEPs) with the aim of identifying clinical indicators that distinguish the medically complex populations that LTCHs appropriately treat and that differentiate levels of need, including ICU, step-down, and general acute care. In summary, the TEPs concluded that PMV patients were relatively homogenous in their likelihood of using LTCHs, however, this population comprised only about 15 percent of all LTCH cases. The other 85 percent of the LTCH patients were much more diverse in their chances of using LTCHs (other than by virtue of proximity) and thus it is difficult to predict who among this group will use an LTCH and identify the characteristics of those who will achieve better outcomes using an LTCH.

III.A.1.2 Predicting Outcomes Using Severity Scoring Systems

One of MedPAC's conclusions was that patient criteria should be developed with the intent to ensure that patients admitted to LTCHs have a good chance of improvement (MedPAC 2004). The challenge for care providers is to determine in advance those patients that have a good chance of surviving and improving. This type of information would assist patients and families in understanding expected outcomes, allow for a more efficient allocation of resources, and assist in the evaluation of new therapies and interventions (Carson 2002). Analysts have already developed fairly accurate prognostic models for patients admitted to the acute care hospitals' ICU units. However, a great deal remains to be done in developing these models for CCI patients admitted to LTCHs.

Predicting ICU Outcomes. To measure the potential for alternative patient outcomes, acute care hospitals collect data to make determinations as to the severity of illness of patients admitted to ICUs. This severity of illness information is then used to predict the risk of death and other outcomes in the hospital on the basis of various prognostic modeling systems. Such prognostic systems have been (and continue to be) validated (and improved) based upon actual and predicted in-hospital mortality rates. Early identification of high risk patients provides information to care givers and relatives who can then make the best choices about future courses of treatment.

The first model of disease severity was the Therapeutic Intervention Scoring System (TISS) that was developed in 1974 (Afessa, et al. 2007). Since then, numerous physiologic-oriented prognostic models have been developed predicting ICU outcomes (primarily mortality). The primary ICU-based severity-of-illness models for adults are 1) Acute Physiology and Chronic Health Evaluation (APACHE), 2) Simplified Acute Physiology Score (SAPS), and 3)

Mortality Probability Model (MPM).[23] These models are developed based upon data collected by hospital staff within the first 24 hours of a hospital stay. Input variables for the models generally include age, chronic and acute conditions, admission circumstances and various physiologic measures.

According to the literature, the APACHE system appears to be most widely used to predict ICU outcomes (Strand and Flatten, 2008). The APACHE II system has been validated extensively and even though it is the oldest system in use, it continues to perform relatively well in many validation analyses (Harrison, et al. 2006). Several generations of these models have also been developed and tested for predictability of ICU hospital mortality (see Table III-2).[24]

Table III-2: Key Information Regarding Alternative Severity of Illness Models

Model	Year Published	Collection of Data	aROC[1/] (ICU mortality prediction performance)	External Validation?
APACHE II	1985	First 24 hr. in ICU	0.86 (very good)	Yes
APACHE III	1993	First 24 hr. in ICU	0.90 (excellent)	Yes
APACHE IV	2006	First 24 hr. in ICU	0.88 (very good)	No
SAPS II	1993	First 24 hr. in ICU	0.86 (very good)	Yes
SAPS III	2005	ICU within 1 hr.	0.85 (very good)	No
MPM II 0	1993	ICU admission	0.82 (very good)	Yes
MPM II 24	1993	At 24 hr. in ICU	0.84 (very good)	Yes

Source: Strand K and Flatten H, "Severity Scoring in the ICU: A Review," *Acta Anaesthesiol Scand,* 2008; 52: 467-78.

1/ aROC refers to the area under the receiver operating characteristic. The test will have an aROC of 1.0 if it is a perfect predictor of hospital mortality and would have a value of 0.5 if it was no better than chance alone. According to Afessa (2007), 1.00 is perfect, 0.90-0.99 excellent, 0.80-0.89 very good, 0.70-0.79 good, 0.60-0.69 moderate and <0.60 poor.

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23 These ICU-based severity-of-illness modes are in turn used as independent variables in prognostic models which predict ICU outcomes.

24 Currently there is a trend toward using the APACHE III system as it performs better regarding discrimination and it has also been extensively validated (Harrison, et al. 2006, Markgraf, et al. 2000). On the other hand, the APACHE IV system was only recently introduced and has yet to be externally validated. One often-cited validation study of APACHE III was performed by Siro, et al. (1999) where the authors examined the predictive validity of the model in a large community-based cohort of patients over a four year period. The authors concluded that the APACHE III ICU risk stratification tool explains a substantial amount of the variation in observed mortality rates and that it can be successfully implement in a spectrum of hospitals.

Various other severity scoring systems have also been developed including multiple organ system failure models and the Thomson Medstat Episode Group (MEG) model.

- Three **Multiple Organ System Failure** (MOSF) models were developed in the mid-1990s including: Multiple Organ Dysfunction Score (MODS), Sequential Organ Failure Assessment (SOFA), and the Logistic Organ Dysfunction System (LODS). Each of these organ failure assessment models assign values to six organ systems including: 1) respiratory, 2) hematology, 3) liver, 4) cardiovascular, 5) central nervous system, and 6) renal function. While each of the models has been validated to a limited extent outside of their original populations, there is a lack of evidence that these models can perform in a common patient population (Afessa, et al. 2007). Additionally, future organ failure models could include gastrointestinal and endocrine organ dysfunction components because they are important for the critically ill.
- The Thomson **Medstat Episode Group** (MEG) model is a disease staging tool used for evaluating medical complexity. This model is an episode-of-care-based tool dependent upon clinical definitions of the severity of illness. Individual disease stages are not based upon treatment but on natural disease progression. MEG uses complex logic to develop clinically relevant, severity-rated, and disease-specific groupings of inpatient, outpatient, and prescription drug claims into hundreds of clinically similar disease categories based upon the disease staging patient classification system. Each episode of care can be categorized into a stage of illness which relates that episode to the severity of the illness.

Predicting LTCH Outcomes for the CCI. The severity of illness scoring systems mentioned above were developed in the acute ICU population. These systems were not developed or validated using populations of CCI patients and as a result caution should be used interpreting such data (Carson 2002). Few studies have been completed which predict outcomes for the CCI in general and for LTCHs in particular.

Carson (1999) analyzed the performance of APACHE II in predicting the outcomes of 133 mechanically ventilated patients who were consecutively admitted to a large urban LTCH from ICUs at acute care hospitals. While age, reported performance prior to acute-care

hospitalization, diabetes, and renal failure were found to be statistically related to one year post-admission mortality, APACHE II scores were found to be unrelated to this outcome.[25]

Carson and Bach (2001) examined the performance of four severity of illness scoring systems (APACHE II, MPM II, SAPS II, and LODS).[26] The study examined 182 patients transferred from 37 acute care hospital ICUs to a single urban LTCH in Chicago over a one-year period. The authors found that none of these indexes distinguished well between the patients who lived and the patients who died. They also found that none of the indexes assigned correct probabilities of death to individual patients. The authors concluded that:

> *Investigators and clinicians should use caution in using severity-of-illness measures developed for acutely ill patients to describe critically ill patients admitted to long-term care units. As clinical practice and research focus more on these latter patients, development of adequately performing severity-of-illness measures appropriate to this patient population will be needed.*

In a study that was not limited to mechanical ventilation patients, Dematte-D'Amico (2003) examined 300 admissions to four LTCHs over the period January through June 1999. The study modeled LTCH discharge survival as a function of age, APACHE III score calculated within 72 hours prior to LTCH admission, and residual organ system failures (OSF). Using logistic regression analysis, the authors concluded that only age and OSF were predictive of LTCH survival.

Carson et al. (2008) developed a prognostic model for predicting one-year mortality in 300 patients requiring mechanical ventilation for at least 21 days. The model did not include any

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[25] Information regarding performance prior to acute care hospitalization was obtained through surveys of patients or families by case managers at time of LTCH admission. Questions assessed the patient's previous mental status, physical capabilities, ability to manage activities of daily living, previous living arrangements, and a general statement of the patient's functional dependence or independence.

[26] LODS is the Logistic Organ Dysfunction System.

of the severity of illness scoring systems such as APACHE. Instead, the model included simple clinical variables such as 1) requirements for vasopressors (agents that produce vasoconstriction and a rise in blood pressure), 2) requirements for hemodialysis, 3) low platelet counts and 4) age 50 and older. The authors concluded that these four predictive variables, when measured on day 21 of mechanical ventilation, can be used to identify patients at highest and lowest risk of death from PMV. The authors indicate that the first three variables reflect ongoing systemic inflammation and multi-organ failure and age likely reflects lower physiological reserve independent of acute organ failure and specific co-morbidities. The authors did not mention conclusions about the model's performance for those at moderate risk of death from PMV. They also cautioned that external validation using multiple tertiary care centers in diverse regions is warranted before clinical or research application of this model can be considered.

Based upon a review of the literature, extensive primary and validation work remains to be completed if we are to have predictive models capable of accurately determining which patients admitted to LTCHs have a good chance of improvement and survival. The dearth of evidence in this area makes it more difficult to address MedPAC's directive concern with identifying patients expected to improve. Additionally, while there are few predictive models for LTCH vital outcomes (e.g. improvement and survival), we could find no academic studies in the literature which are predictive of LTCH resource utilization.

III.A.1.3 Clinical Profiles of LTCH Admissions

Do patients admitted to LTCHs meet the definitions of chronically critically ill (CCI) patients? How do the patients at all LTCHs match up with these definitions of the CCI? RTI's Phase II report (Gage 2007) examined the distribution of DRGs across LTCHs in 2003. The single most common DRG was for ventilator support (DRG 475), at 12.3 percent of Medicare

admissions. Some LTCHs specialize in providing ventilator services. In fact, at least one LTCH only had ventilator admissions in 2003. Four other respiratory-related DRGs (79, 87, 88, and 89) accounted for almost 16 percent of all LTCH Medicare admissions. Wound-related care. accounted for 10 percent of all LTCH Medicare patients, although at some hospitals it was more than 40 percent. Rehabilitation (DRG 462) accounted for 8.3 percent of all Medicare LTCH admissions, but these also tended to be concentrated in certain facilities. Although psychiatric conditions (DRGs 426, 427, 428, 429, and 430 combined) represented 8.7 percent of all percent of Medicare LTCH admissions, the median across all LTCHs in the 2003 sample was less than 0.4 percent, because while a small number of LTCHs appeared to specialize in these types of cases, use of LTCHs for psychiatric care was relatively uncommon.

MedPAC's 2008 report presented an updated analysis of the characteristics of LTCH patients. It focused on the 15 LTCH-DRGs that accounted for 60 percent of LTCH cases in 2006 (see Table III-3 below). The MedPAC findings from 2006 are generally consistent with RTI's 2003 analyses. For example, the 2006 data indicate that DRG 475, which accounted for 12.3 percent of LTCH DRGs in 2003 accounted for 12.1 percent in 2006. Skin ulcers (DRG 271) and septicemia (DRG 410) were the second and third most common LTCH-DRGs in 2006, followed by DRG 87 (pulmonary edema and respiratory failure) and DRG 79 (respiratory infections).

Table III-3: The Top 15 LTCH-DRGs in 2006[27]

LTCH-DRG	Description	Percentage
475	Respiratory system diagnosis with ventilator support	12.1%
87	Pulmonary edema and respiratory failure	5.0
79	Respiratory infections and inflammation age >17 with CC	4.7
89	Simple pneumonia and pleurisy age >17 with CC	3.6
88	Chronic obstructive pulmonary disease	3.5

[27] For directly comparable DRGs between the RTI and MedPAC studies, the following comparisons apply: DRG 475 (vent): RTI 12.3 percent/MedPAC 12.1 percent; DRGs 426, 427, 428, and 429 (respiratory): RTI 15.9 percent/MedPAC 16.8 percent; DRG 416 (septicemia age>17): RTI 3.5 percent/MedPAC 5.1 percent; DRG 249 (aftercare): RTI 4.6 percent/MedPAC 3.5 percent; and DRG 462 (rehabilitation): RTI 8.3 percent/MedPAC 2.3 percent.

LTCH-DRG	Description	Percentage
271	Skin ulcers	5.4
263	Skin graft and/or debridement for skin ulcer with CC	3.0
416	Septicemia age >17	5.1
418	Postoperative and post-traumatic infections	2.0
466	Aftercare, without history of malignancy	3.7
249	Aftercare, musculoskeletal system and connective tissue	3.5
12	Degenerative nervous system disorders	3.2
127	Heart failure and shock	2.7
316	Renal failure	1.9
462	Rehabilitation	2.3
	Top 15 LTCH-DRGs	61.9
	Total	100.0

SOURCE: MedPAC analyses of MedPAR data from CMS. (MedPAC 2008)

III.A.1.4 Alternative Vital Discharge and Quality of Life Outcomes for CCI Patients

In general, LTCHs are the most costly post-acute care setting for Medicare patients (MedPAC 2004). One of the recommendations adopted by MedPAC in 2004 was to develop patient criteria to ensure that LTCH patients had a good chance of improvement. What do we know about the outcomes of critically ill patients? How are these outcomes measured?

We examined outcome measures for CCI patients treated in alternative settings. We found two types of outcome measures that were most frequently cited in the literature: namely vital discharge outcomes (survival, weaning, and disposition) and health care quality of life (HCQOL) outcome measures.

Vital discharge outcomes. Nearly all of the literature we found relates to outcomes for PMV patients. We found studies for three different sites of service: ICUs, Noninvasive Respiratory Care Units (NRCUs—which are primarily step-down units within acute care

hospitals) and LTCHs. We found that the four most-often cited vital discharge outcomes are the percentage of:

- PMV admissions surviving at discharge;
- PMV admissions weaned from PMV at discharge;
- PMV admissions surviving at 12 months after discharge; and
- PMV survivors discharged that are going home.

Table III-4 and Figures III-2 through III-5 present the findings from a review of the vital discharge outcomes in the literature. We examined 31 studies of vital discharge outcomes, including 8 studies for ICUs, 12 for NRCUs, and 11 for LTCHs which were completed over the time periods 1987 through 2008.

We found that outcome measures tended to vary the most in the NRCU setting and least in the LTCH setting. Within the NRCU setting alone, the percentage of admissions surviving at discharge ranged from as low as 33 percent to as high as 96 percent. Importantly, these studies do not control for differences in patient acuity or facility differences (admissions criteria, staffing levels or treatment approaches).

Many of the high survival rates noted in the NRCU setting (upwards of 90 percent) are related to observations made in studies by Gracey (1992, 1995, 1997, and 2000). These studies relate to admissions to a ventilator-dependent step-down unit (VDU) at St. Mary's Hospital in Rochester, Minnesota. St. Mary's admissions require that the patient is either capable of being liberated from the ventilator or likely to return to the community. Additionally, patients with multiple organ failure are not admitted to the VDU. Thus, very strict admission criteria at St. Mary's are the likely cause of the unusually high rate of positive outcomes. Few LTCHs have

such strict admissions criteria as St. Mary's and as a result, LTCH discharge survival rates tend generally to be not as high.

Table III-4

Survival, Weaning, and Disposition Outcome Studies for Prolonged Mechanical Ventilation Patients

Study	Study Pop. Size	Mean Age	Percent Female	Relative Share of Conditions Leading to PMV [1/]	Mean ICU Vent Days Prior to Transfer	Mean Post-ICU Vent Days	Study Outcomes: Percent of Admissions Surviving at Discharge	Percent of Admissions Weaned at Discharge	Percent of Admissions Surviving at 12 Months	Percent of Discharged Survivors Going Home
Intensive Care Unit (ICU) Studies										
Spicher (1987)	245	60	-	Med>Surg	31	-	39%	-	29%	60%
Gracey (1992)	104	66	41%	Surg>Med	60	-	58%	49%	39%	75%
Douglas (2002)	392	66	41%	Med>Surg	16	-	51%	30%	34%	27%
Combes (2003)	347	65	36%	Surg>Med	37	-	57%	-	29%	-
Engoren (2004)	429	66	43%	Med>Surg	24	-	78%	44%	42%	-
Cox (2007)*	267	66	41%	Med>Surg	16	-	80%	-	52%	9%
Cox (2007)*	114	66	39%	Med>Surg	27	-	69%	-	42%	6%
Carson (2008)	300	56	44%	Surg>Med	35	-	56%	50%	38%	16%
Noninvasive Respiratory Care Unit (NRCU) Studies [2/]										
Elpern (1989)	95	71	-	Med>Surg	13	-	33%	32%	16%	-
Indihar (1991)	171	-	54%	COPD	55	39	60%	34%	-	-
Cordasco (1991)	99	-	-	Med=Surg	-	-	75%	25%	-	-
Gracey (1992)[3/]	61	-	-	COPD	34	16	95%	87%	-	60%
Nava (1994)	42	-	-	COPD	-	-	71%	36%	-	-
Gracey (1995)[3/]	132	67	52%	Surg>Med	42	46	90%	80%	73%	57%
Latriano (1996)	224	67	47%	Med>Surg	23	43	50%	47%	-	39%
Gracey (1997)[3/]	206	-	-	Surg>Med	-	-	92%	74%	-	77%
Dasgupta (1999)	212	68	55%	Med=Surg	25	13	82%	60%	-	28%
Gracey (2000)[3/]	420	67	52%	Surg>Med	37	10	94%	60%	53%[4/]	-
Stoller (2003)	162	65	59%	Med>Surg	-	-	83%	-	43%	28%
Quinnell (2006)[5/]	67	66	-	COPD	-	-	96%	96%	68%	81%
Long Term Care Hospital (LTCH) Studies										
Scheinhorn (1994)	421	70	59%	Med>Surg	49	39	71%	53%	20%	45%
Petrak (1996)	388	72	53%	Med>Surg	42	-	66%	51%	-	-
Gluck (1996)	72	-	-	Med>Surg	-	-	63%	19%	-	-
Clark (1997)	113	65	56%	Med=Surg	-	-	61%	47%	-	-
Bagley (1997)	278	67	53%	Med>Surg	-	43	53%	38%	-	41%
Scheinhorn (1997)	1,123	69	57%	Med>Surg	44	39	71%	56%	24%	43%
Scalise (1997)	47	-	-	-	-	-	77%	62%	-	-
Bach (1998)	86	-	-	-	-	-	48%	34%	-	-
Carson (1999)	133	71	52%	Med>Surg	25	-	50%	38%	23%	18%
Seneff (2000)	1,702	71	53%	-	21	-	49%		33%[6/]	26%
Scheinhorn (2007)[7/]	1,419	72	50%	Med>Surg	34	15	75%	54%	48%	29%

1/ Indicates whether a greater share of patients in the study received PMV care as a result of a medical or a surgical condition.
2/ NRCUs are generall a step-down unit from an acute care hospital ICU.
3/ All admissions are to a ventilator-dependent unit (VDU) at Saint Marys Hospital in Rochester, Minnesota. The admitting physician has to attest in writing that the patient is either capable of being liberated from the ventilator or likely to return to the community. Patients with multiple organ failure are not admitted to the VDU.
4/ Values cited are for four years after discharge.
5/ The Respiratory Support & Sleep Centre (Papworth Hospital) accepts patients recovered from acute illnesses that caused PMV.
6/ Value at 6 months.
7/ This is the Barlow Study and it presents median values.
* The first Cox entry defines PMV as 96+ hours of mechanical ventilation with trach, the second 21+ days of mechanical ventilation.

Figure III-2
Percent of Prolonged Mechanical Ventilation Patient Admissions Surviving at Discharge for 31 Alternative Studies Presenting These Results

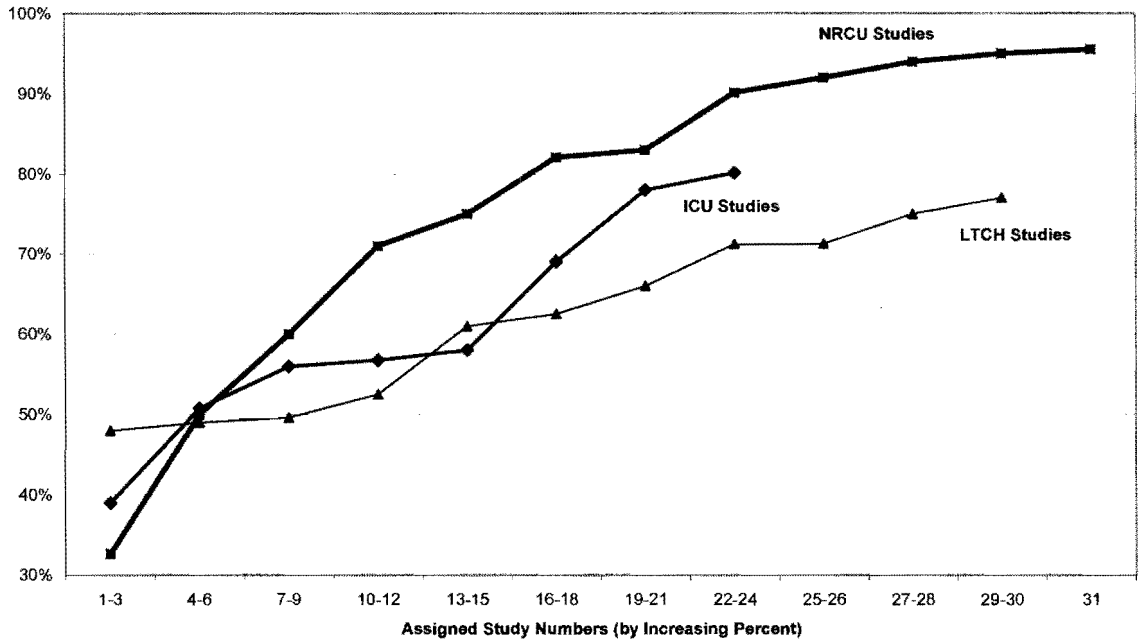


Figure III-3
Percent of Prolonged Mechanical Ventilation Patient Admissions Weaned at Discharge for 25 Alternative Studies Presenting These Results

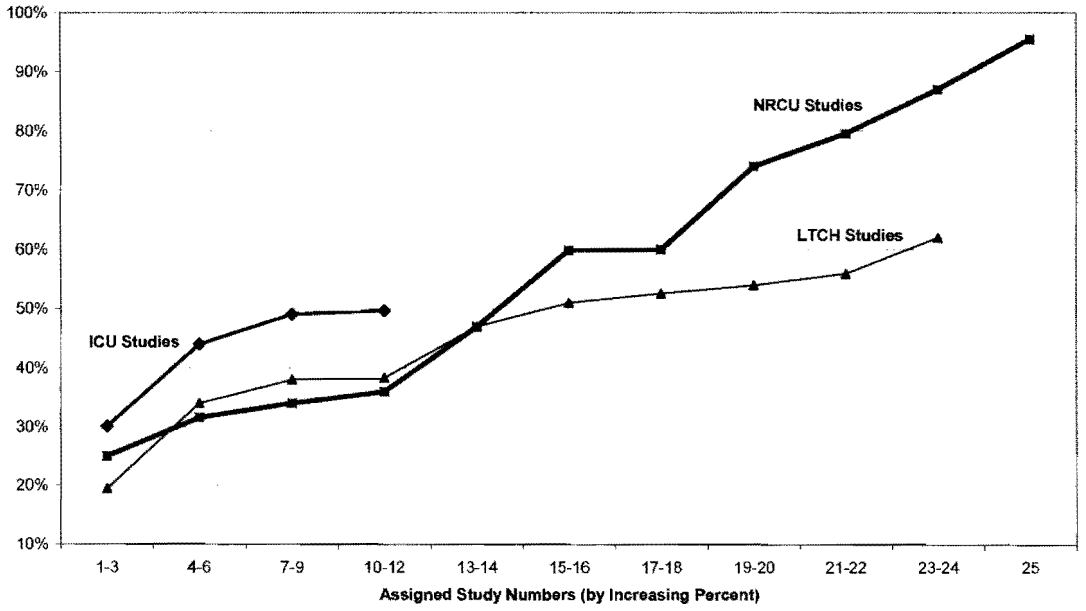


Figure III-4
Percent of Prolonged Mechanical Ventilation Patient Admissions Surviving At One Year After Discharge for 18 Alternative Studies Presenting These Results

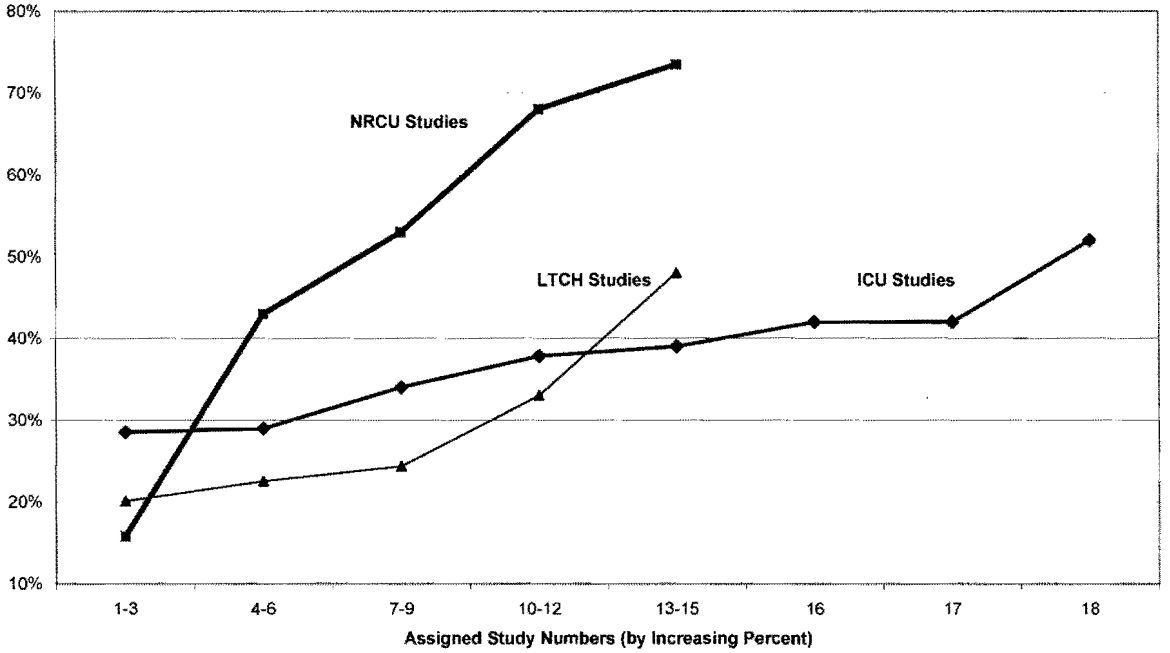
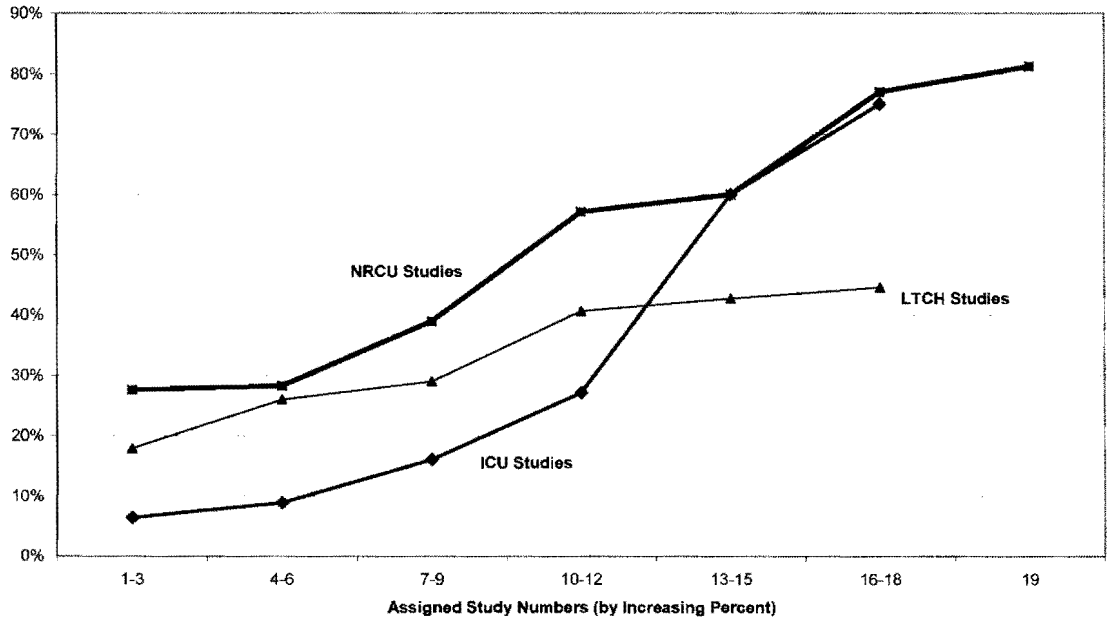


Figure III-5
Percent of Prolonged Mechanical Ventilation Survivors Going Home After Discharge for 19 Studies Reporting These Results



While lower than in NRCUs, discharge survival rates also exhibit a large degree of variation in LTCHs. Similar to NRCUs, whose outcomes vary considerably based upon admission criteria (selective or nonselective), LTCHs have variable admission criteria and staffing patterns, and hence, variable discharge outcomes. We observe that the discharge survival rates for LTCHs vary between 48 percent and 77 percent depending upon the 11 studies reviewed. Of particular note is the Barlow study (Scheinhorn, et al. 2007b) which found a relatively high discharge survival rate of 75 percent. However, this overall multi-center result was for the combination of 23 individual LTCH facilities which had discharge survival rates that varied between 53 and 100 percent.

One conclusion of the 2005 NAMDRC PMV Consensus Conference (MacIntyre, et al. 2005) was that the wide variation in patient populations, facility resources, and admission/discharge practices limit the significance of hospital survival as an outcome measure across alternative care settings and as a result, one year survival may be more clinically meaningful. Despite the very wide range of discharge survivability noted in the studies above for PMV patients in various setting, variability in survival at one year post-discharge is more modest, with the exception of three very selective NRCUs (Gracey, et al. 1995, Gracey, et al. 2000, and Quinnell, et al. 2006). In all of the 16 studies in the literature reviewed here (excluding the three selective NRCUs), generally less than half of patients admitted were still living one year after discharge. In many studies, less than one third of patients were surviving one year after admission. These results paint a bleak picture for the long term outcome of the CCI patient. We also found that less than 50 percent of LTCH patients (low of 18 percent for Carson 1999 and high of 45 percent for Scheinhorn (1994)) discharged alive were able to go home; the remainder are admitted to nursing homes, rehabilitation centers, or back to acute care hospitals.

We found one study on vital care discharge outcomes that was not limited to ventilator-dependent patients.[28] This study (Dematte-D'Amico 2003) examined 300 LTCH admissions to four LTCHs between January and June 1999 and found that post-discharge survival and dispositions to home are highly dependent upon the number of organ system failures the patient has when they were admitted to the LTCH (see Table III-5 below). For example, for patients with no organ system failures, 75 percent survived at time of discharge and 44 percent went home. On the other hand, if the patient had 4 or more organ system failures, only 31 percent survived and none went home. For the entire population overall, 31 percent survived and 14 percent went home. These overall outcomes, which include non-PMV patients, are considerably worse in comparison to PMV-only patients that were discharged from LTCHs (reviewed above).[29]

Table III-5: Survival and Disposition Outcomes for PMV and non-PMV Patients at 4 LTCHs

Number of Organ System Failures at Admission	Percent of LTCH Admissions Surviving At Time of Discharge	Percent of LTCH Admissions Going Home After Discharge
0	75%	44%
1	48%	25%
2	20%	5%
3	9%	0%
4 or more	5%	0%
Total	31%	14%

Quality of Life. We also examined health care quality of life (QOL) measures for PMV and CCI patients. There are four QOL measures examining physical dysfunction commonly found in the literature:

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28 54 percent of patients had respiratory failure, 42 percent had GI/hepatic failure, 24 percent had central nervous system failure, 18 percent had cardiovascular failure, 15 percent had renal failure, and 41 percent had active infections.

29 No information was available regarding differences in outcomes between PMV and non-PMV patients.

- **The Sickness Impact Profile (SIP):** SIP uses 136 questions to evaluate 12 QOL domains: work, recreation, emotional behavior, alertness, home management, sleep, body care, eating, ambulation, mobility, communication, and social interaction. Greater values of SIP have worse QOL. The normal population has a SIP of about 5; patients with ALS and chronic pain have global SIP scores of about 35 and 30 respectively.

- **Nottingham Health Profile (HHP):** NHP measures subjective functional status with 38 yes/no statements in six domains: physical mobility, pain, sleep, energy, emotional reactions, and social isolation. The range of possible scores is 0 to 100 in each dimension. The higher the score, the greater the limitations in activity or the more distressing the social or emotional reactions. Scores for the general population range from 7 for mobility to 14 for energy.

- **Standard Form 36 (SF-36).** The SF-36 uses 36 items to measure eight QOL domains: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. Scores are 0-100 and higher scores indicate better functioning.

- **Zubrod:** The Zubrod score runs from 0 to 5, with 0 denoting perfect health and 5 death: 0 – Asymptomatic; 1 - Symptomatic but completely ambulatory; 2 - Symptomatic, <50 percent in bed during the day; 3 - Symptomatic, >50 percent in bed, but not bedbound; 4 – Bedbound; and 5—Death. While some may argue that the Zubrod scale is a functional status score rather than a QOL score, we believe that it can be classified as a QOL score because the other three scores include functional status as a QOL measure.

The vast majority of the literature regarding physical dysfunction QOL outcome measures has been undertaken for ICU patients. We could only find one study that examined NRCUs and only one that examined LTCHs; in total we found eight studies that examined QOL. All studies examined PMV patient outcomes between 6 months and 3 years after hospital discharge (see Table III-6). It should be kept in mind that there is self-selection relating to these outcome measures—only those that are still alive and at least minimally lucid at follow-up can provide QOL scores.

The overall findings for PMV patients using the NHP and SF-36 measures taken from five different studies suggest there is significant deterioration in QOL scores, particularly functional status scores. The Zubrod and SIP measures at first glance appear to paint a

somewhat different picture. The Zubrod functional status scores for the Barlow population (Scheinhorn, et al. 2007a,b) indicate that 79 percent were "good or better" prior to hospitalization, 31 percent were "good or better" at discharge and 60 percent were "good or better" at one year follow up. For the Chatila (2001) study using the SIP measure, there appeared to be minimal impairment in the QOL at long-term follow-up (2 years). However, it appears that these optimistic results are likely affected by selection bias. The Chatila study was conducted in an NRCU that only accepted patients who were stable and without renal failure, and who were expected to have good rehabilitation potential and a high expectation for returning home. In contrast, the Douglas (2002) study followed consecutive or unselected patients. The SIP scores were much worse for the Douglas patients and at a level that indicated a need for substantial daily care. The Scheinhorn (2007a,b) population using the Zubod score included a lot of selective LTCHs and 30 percent of patients were lost to follow-up, most likely the ones still at SNFs.

In addition to physical dysfunction QOL measures, many would argue that cognitive dysfunction QOL measures are more important than physical dysfunction in terms of patient values or utilities. Nelson, et al. (2006) found that 68 percent of NRCU PMV survivors were too profoundly impaired to respond to telephone cognitive assessments and 62 percent were dependent in all activities of daily living some six months after discharge.

The literature, by far, suggests that most long-term survivors of CCI are burdened with a high degree of physical and cognitive limitations and very low quality of life outcomes. Only the minority of CCI patients who survive long-term with intact cognition have generally good emotional function.

A higher presence of palliative care medicine is beginning to gain traction in the CCI literature. In a study of NRCU PMV patients, Nelson, et al. (2004) measured self-reported symptom burden for these CCI patients at 3 to 6 months post discharge. Approximately 90 percent were symptomatic, 44 percent reported pain at the highest levels, more than 60 percent reported psychological symptoms at the highest levels, and 90 percent reported severe distress due to communication difficulties. Nelson, et al. (2004) concluded that given the high levels of distress noted in their study, care providers should give greater attention to relief of pain and other distressing symptoms.

The results of this literature review highlight the problems inherent in identifying the specific patient-level factors for LTCH level admissions. The literature on the CCI populations is useful for specifying complicating factors that taken in combination with other complications, identify a chronically, critically ill patient. Many of these measures have been included in the Continuity Assessment Record and Evaluation (CARE) tool, because they are not currently collected by Medicare. Better measures are needed to identify the need for more intensive services within these broader populations.

Table III-6
Physical Dysfunction Quality of Life Studies for Survivors of Prolonged Mechanical Ventilation (PMV)

Study	Study Pop. Size	Site	Participation Criteria	Mean Ventilation Days	Follow-up Time	Mean Age	Percent Female	HRQOL Outcomes
Chatila (2001)	25	NRCU	consecutive admissions to NRCU over 4 years	45 days	2 years	59	52%	Measure: Sickness Impact Profile (SIP).[1/] The mean Global and Physical SIP scores for NRCU population were both 12 in comparison to a generaly healthy population score of 5, ALS score of 35, and chronic pain score of 30. Authors conclude there is minimal inpairment in the QOL at long-term follow-up.
Douglas (2002)	392	ICU	Short Term Group: 24 to 96 hours MV compared to Long Term Group: more than 96 hours MV	Short Term: 2 days, Long Term: 16 days	1 year	66 for both Groups	41% for both groups	Measure: Sickness Impact Profile (SIP).[1/] Authors assesed whether there was a difference between the two groups on overall SIP scores at 12 months. Although the Short Term Group had consistently better SIP scores, the differences in QOL between the two groups were not statistically significant. Global SIP was between 17 and 20 and Physical SIP was between 15 and 21. These SIP scores are much worse than Chatila indicating need for substantial daily care.
Niskanen (1999)	718	ICU	>96 hours stay in the ICU	14 days	6 months	56	34%	Measure: Nottingham Health Profile (NHP)[2/] Range of possible scores is 0-100 with higher scores indicating greater limitations in activity. Study found NHP physical mobility/energy scores of 35/38 for respiratory failure patients and 30/35 for all patients aged 65-74 yrs which are statistically different in comparison to the general population scores of 5/13 and 15/18 respectively. Respiratory failure had worse QOL scores versus the general population with deterioration in all dimensions measured.
Combes (2003)	347	ICU	>14 days of mechanical ventilation	36 days	3 years	63	34%	Measure: Nottingham Health Profile (NHP)[2/] Study found NHP physical mobility/energy scores of 25/46 for PMV patients which are statistically different in comparison to general population scores of 5/18. Compared with those of a general population, the PMV scores were significantly worse for each of the NHP domains, except social isolation.
Engoren (2004)	429	ICU	patients with tracheostomy for PMV as a result of respiratory failure	24 days	1 year	66	43%	Measure: SF-36[3] (Short Form-36) uses 36 items to measure 8 QOL domains; scores are 0-100 and higher scores indicate better functioning. Functional status scores are poor at one year for patients that are ventilator dependent (mean of 22) or with trachestomy (mean of 25), but are better for those that are liberated from mechanical ventilation (mean 50). Most respondents had good emotional health (mean 83 to 100), but remained with major physical limitations.
Chelluri (2002)	817	ICU	48 hours or more of mechancial ventilation	NA	1 year	65	46%	Measure: SF-36 (Short Form-36). Compared with random samples of the US population, participants had worse scores at 1 year on the SF-36 physical and social function domains but comparable scores on the mental health and emotional domains. The majority of survivors described their health as good or better and would opt for mechanical ventilatory support again if they had to relive the experience.
Cox (2007)	791	ICU	Short Term Group (STG): less than 48 hours MV compared to Long Term Group (LTG): more than 48 hours MV	16	1 year	66	41%	Measure: SF-36 (Short Form-36). Despite having better pre-admission function status scores than patients ventilated for less than 48 hours (56 for STG vs 61 for LTG), those ventilated for 48 hours or more have statistically lower functional capabilities after one year (46 for STG vs 31 for LTG).
Scheinhorn (2007)	1419	LTCH	1,419 consecutive admissions to 23 LTCHs in the US	15	1 year	72	50%	Measure: Zubrod Functional Status Scores. Scores indicate that 1) patients were largely independent before their illness and PMV (79% good or bettter), 2 functional status falls to expected lows in an elderly population with PMV following a catastrophic illness (1% good or better), 3) functional status at discharge in the surviving patients was less than premorbid but improved from that at transfer to the LTCH (31% good or better), and 4) continued gains were evident at 12 months after hospital admission but below premorbid levels (60% good or better).

1/ SIP has 136 questions for 12 QOL domains; greater values have worse QOL. The general population has a SIP of about 5. Patients with ALS and chronic pain have global SIP scores of about 35 and 30 respectively.
2/ The NHP is composed of six dimensions (physical mobility, energy, pain, sleep, social isolation , and emotional reactions). The range of possible scores is 0 to 100 in each dimension. The higher the score, the greater the limitations in activity or the more distressing the social or emotional reactions. Scores of the general population range from 7 for mobility to 14 for energy.
3/ The SF-36 uses 36 items to measure 8 QOL domains: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, enery/vitality, social functioning, role limitations due to emotional problems, and mental health. Scores are 0-100 and higher scores indicate better functioning.

NRCU is a noninvasive respiratory care unit which are generally a step-down unit from an acute care hospital ICU.
MV indicates mechanical ventilation.

One of the most difficult issues to address is the identification of patients with an expected prognosis for improvement. As Carson and others showed, it is difficult to predict which cases are likely to improve, especially among the CCI populations. The Medicare program is responsible for ensuring that beneficiaries receive the most appropriate care in the most cost-effective setting. Any revised policies regarding LTCH will need to consider whether patients should be transferred from the acute hospital to an LTCH despite the low likelihood of improvement or if a different care configuration would be more appropriate. As discussed in the next part of this section, these are some of the issues that will be examined over the coming years.

III.B. ONGOING RESEARCH

The preceding sections of this report summarized the research that has been done to date to address issues and questions relevant to LTCHs. The preponderance of evidence from both quantitative and qualitative data analyses seems to confirm that there is a subset of long-staying medically complex patients, including but not limited to those on ventilators, for whom the level of care offered by LTCHs is clinically appropriate. For this group, LTCH care may also be cost-effective to the Medicare program, since better outcomes are observed with similar or even lower Medicare payments per episode of care. However, for other long-staying LTCH patients, there is little evidence of improved outcomes and considerable evidence of greater cost to Medicare. Distinguishing between these two groups is not straightforward with available data. For this reason, current research projects contracted by CMS involve primary data collection to better distinguish patients who are appropriate for LTCH care.

Additional work sponsored by CMS is currently underway to identify appropriate LTCH patients that can be used to guide admissions criteria, Medicare facility certification, Medicare

payment, and other Medicare regulatory interventions. Because LTCHs often receive very sick patients as transfers from acute hospitals, the chief research challenge for secondary data analyses has been to find appropriate methods to control for selection bias when comparing costs and clinical outcomes across post-acute care settings. Most claims-based analyses provide important background information, but with the exception of tracheotomy and long-term ventilator support patients, they have had difficulty identifying strong predictors of LTCH transfer. Original data collection on medically complex patients in a variety of acute and post-acute care settings is needed to better define LTCH- appropriate patients and to document their cost and resource use patterns.

CMS is sponsoring studies to meet these research needs through a contract with Kennell and Associates and RTI International ("Determining Medical Necessity and Appropriateness of Care in Medicare Long-Term Care Hospitals"). Studies undertaken under this contract address four key questions:

- What factors empirically define the types of chronic, complex medical conditions described in Section IIIA that currently receive treatment in both general acute care hospitals and LTCHs?
- What facility level factors are associated with appropriate provision of care in LTCHs?
- What factors indicate appropriateness of admissions, discharges, and treatment modalities, medical complexity, quality of care and improvement potential for patients commonly treated in LTCHs?
- What reforms are needed to ensure parity in Medicare payments, access to care and quality of care between patients treated in LTCHs and patients with similar conditions treated in other settings?

Further secondary data analysis and analysis of new primary data will be able to provide recommendations for LTCH patient and facility standards and Medicare payment reform. These

studies build on the past research to improve definitions of the LTCH-appropriate population and facility characteristics. The expected completion date for this work is June 2011.

New Primary Data Collection and Analysis

The Medical Necessity and Appropriateness of Care contract will collect standardized data on patient case-mix, outcomes, and resources used across different sites of care. The facilities sampled will be representative of key study populations taken from geographic areas with appropriate PAC providers, and the patient sample size will be large enough to provide sufficient evidence for questions of interest regarding these most medically complex patients.

The primary data collections will provide more refined measurements of patient complexity and severity than have been available in the past using DRGs or other classification methods. The data will be collected using the Continuity Assessment Record and Evaluation (CARE) tool, which was developed in 2007 under CMS contract to RTI in order to standardize case-mix measurement across acute hospitals and post-acute settings (including long term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities and home health agencies). The CARE tool is comprised of four types of standardized measures: medical severity, functional impairment severity, cognitive impairment severity, and factors associated with discharge destination decisions. Having standardized items is critical to allowing comparisons of populations using alternative treatment settings, including intermediate care units in acute hospitals and the different types of post acute care providers, and to measuring severity, clinical improvements, and other outcomes associated with their Medicare-covered treatments.

This project will use the CARE tool to collect data from acute care hospitals, LTCHs, and IRFs. Data collected data from these facilities will be supplemented by CARE tool data that is

being collected as part of RTI's work for CMS in the Post Acute Care Payment Reform Demonstration (PAC-PRD). The CARE tool is designed to measure patient severity of illness across all inpatient settings. In addition to the clinical information, cost and resource utilization data will be collected in intermediate care units of acute hospitals and in LTCHs, SNFs and IRFs, to compare the staffing assignments and treatment times provided to the different types of patients in each of the three settings.

The Medical Necessity and Appropriateness of Care study will also obtain qualitative information about the management of critically ill patients who require prolonged acute care from site visits to be conducted at 30 hospitals or sub-acute skilled nursing facilities. Discussions with key staff at these 30 institutions will help in understanding the clinical practices and the organization and management of acute and post-acute care for critically ill patients, to identify their patterns of care, and to gain insight into why these patterns of care are used.

The Medical Necessity and Appropriateness of Care study differs from activity under the initial PAC-PRD data collection contract by focusing on specific populations typically treated in LTCHs. It will collect both admission and discharge information on select cases in acute hospitals, since past work has shown that longer stays in the short-term acute hospital substitute for LTCH care for the more complex patients, particularly in geographic areas that have no LTCHs. It will also collect information on cost and resource use in the acute hospitals, which was not included as part of the PAC-PRD study. Cost and resource use data will identify the types of professionals involved in individual patient care and help address questions about the facility criteria (such as staffing resources) needed for appropriate care of these types of patients. Integrated clinical and resource use data collected from each setting will be useful to support

CMS recommendations regarding resource needs for appropriate care and potential outcome measures for specific populations.

Data collection in the acute hospital is expected to be limited to the step-down units since these units provide services most comparable to those in LTCHs. Some step-down units specialize in ventilator weaning while others specialize in relatively "longer term" treatment of medically complex cases (average length stay of at least 25 days). These hospital units can be found throughout the country. In areas that lack LTCHs, they are assumed to be providing the main substitute setting for LTCH-appropriate services. Hospital-level summaries of average use of ICU and step-down days for DRGs commonly referred to LTCHs will be calculated from Medicare claims data and used to guide the sample selection for recruiting acute care hospitals.

The new primary data collected will also be used to help refine case-mix measures and develop improved payment models that take advantage of the CARE tool's more detailed measures of medical severity and patient function. The case-mix models will be similar to those developed in the PAC-PRD study. The larger sample size of "LTCH-like" cases in the Medical Necessity and Appropriateness of Care project will allow greater specificity for some of these cases that may be rarer events in the PAC-PRD dataset (particularly those treated in the acute hospital step-down units). In a modification to the PAC-PRD study, RTI is collecting additional CARE data for patients who may be appropriate for treatment in LTCHs. Larger sample sizes will assure statistical power to detect differences in resource use and outcomes across patient types and settings. The PAC-PRD supplemental data collection will occur between September 2009 and September 2010.

Additional data collection under the Medical Necessity and Appropriateness of Care study will allow a larger sample of critically ill patients. It will also allow examination of potential care substitution between LTCHs and acute care hospitals. CARE data collected through this project will be supplemented by LTCH data collected from the PAC-PRD project to allow better data on severity, outcomes, and resource use for critically ill patients. Refined case-mix measures based on CARE tool items will provide important information for considering potential reforms in the payment models.

Medicare claims studies

The Medical Necessity and Appropriateness of Care contract will support additional claims-based comparison studies of hospital costs, Medicare payments and margins, and clinical outcomes across PAC settings. These analyses will compare Medicare payments and costs between patients treated in LTCHs and patients with similar conditions treated in other settings. Payment parity is important not only because of equity issues across different providers, but also because differences in reimbursement opportunities create incentives that can influence providers' decisions on admission, discharges and transfers. An understanding of financial incentives is critical to understanding the role of LTCHs in the continuum of acute and post-acute care.

The claims studies under the Medical Necessity and Appropriateness of Care contract will examine Medicare margins (defined as payments less costs, expressed as a percent of payments) for a wide range of conditions treated both in the LTCH and for patients with extended acute care hospital stays. Claims data will be used to construct beneficiary episodes of care for the most common conditions that result in LTCH use, and stays within each episode will

be converted to costs using detailed data from the Medicare cost reports. A propensity model approach similar to that done earlier by RTI for CMS will be used to identify the complex admissions to acute care hospitals that also have the highest likelihood of subsequent LTCH use. In the high-likelihood group of acute care hospital discharges, IPPS margins will be computed for those that remained in IPPS settings for the entire stay, and compared to the IPPS and LTCH PPS margins for those that used both settings. The study will construct beneficiary episodes of care using the 100 percent Medicare claims files from a year's worth of episodes spanning care in 2007 and 2008.[30] The margins study will also look at 1) IPPS tracheotomy and ventilator support cases, 2) other respiratory cases typically referred to LTCHs, and 3) other LTCH patient types referred for wound care, complex rehabilitation or septicemia. To improve the referral probability modeling, explanatory variables will be expanded to include detail on days in step-down versus critical care units, charges for specific services such as dialysis or specialized wound therapies, and will explore combinations of co-morbid conditions that may improve predictive power for LTCH use.

Informing LTCH policy

Findings from the analyses conducted through the PAC-PRD and the Medical Necessity and Appropriateness of Care contract will provide important information to CMS and the Congress that will guide refinement of laws and regulations governing LTCH care. LTCHs are an important part of the Medicare service delivery system, providing adequate level care to severely ill patients. The underlying objective of the Medical Necessity and Appropriateness of

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30 As part of the identification of episodes, the study will also provide updated descriptive information on the types of populations currently using LTCHs based on 100 percent of LTCH admissions in the study period.

Care study has been to determine the most appropriate payment methodology for patients requiring LTCH level care and appropriate methods for addressing cross-site payment inequities.

CMS is also conducting a study of the chronically critically ill (CCI) population and payment recommendations for this population. This study is being conducted by Kennell and Associates and RTI (known as the Chronically Critically Ill Population Payment Recommendations (or CIPP-PR) study) and will build on the work done in the PAC-PRD and the Medical Necessity and Appropriateness of Care studies to define the CCI population using CARE data collected in these studies as well as claims data. The study will use claims data supplemented by CARE and CRU data to develop site-neutral payments for the CCI population. This project is scheduled to be completed in September 2012.

CMS is responsible for monitoring the quality of care provided. Results based on CARE tool data may also prompt regulatory changes that ensure LTCHs and other facilities treating very complex cases have appropriate resources in place and satisfactory care outcomes. The products of research based on CARE tool data described here will lead to information that can be used to make recommendations to deal with the policy issues regarding LTCHs.

APPENDIX A

Supporting Data

Table A-1
Distribution of LTCH admissions by type of payment adjustment, 2004

DRG		Number of LTCH admissions	Prior hospitalization (Percent)	Prior acute outlier (Percent)	LTCH short stay outlier (Percent)
475	Respiratory System Diagnosis With Ventilator Support	12,078	84.8	16.9	40.3
249	Aftercare, Musculoskeletal System & Connective Tissue	5,637	83.1	2.8	37.6
12	Degenerative Nervous System Disorders	5,286	74.4	3.4	30.3
271	Skin Ulcers	4,808	69.3	5.2	41.4
462	Rehabilitation	4,641	77.7	6.7	35.8
87	Pulmonary Edema & Respiratory Failure	4,598	86.8	16.5	53.5
88	Chronic Obstructive Pulmonary Disease	4,341	81.8	3.5	44.0
89	Simple Pneumonia & Pleurisy Age >17 w CC	4,335	86.2	4.7	44.6
466	Aftercare w/o History of Malignancy As Secondary Diagnosis	4,124	90.5	16.2	37.1
79	Respiratory Infections & Inflammations Age >17 w CC	3,984	87.0	9.4	35.8
416	Septicemia Age >17	3,688	87.3	11.7	41.0
263	Skin Graft &/or Debrid for Skin Ulcer or Cellulitis w CC	3,338	58.4	4.1	34.7
127	Heart Failure & Shock	3,327	86.5	7.0	40.4
316	Renal Failure	2,174	87.7	19.3	81.0
430	Psychoses	1,850	13.6	0.1	89.8
418	Postoperative & Post-Traumatic Infections	1,801	85.5	15.1	40.3
277	Cellulitis Age >17 w CC	1,721	82.2	2.3	44.7
238	Osteomyelitis	1,606	83.6	5.0	30.8
76	Other Resp System O.R. Procedures w CC	1,587	78.0	19.2	35.2
144	Other Circulatory System Diagnoses w CC	1,417	90.7	12.2	39.1
452	Complications of Treatment w CC	1,406	83.5	21.3	33.2
130	Peripheral Vascular Disorders w CC	1,261	69.0	4.9	38.6
188	Other Digestive System Diagnoses Age >17 w CC	1,166	86.3	19.5	43.3
320	Kidney & Urinary Tract Infections Age >17 w CC	1,150	80.6	2.4	36.4
296	Nutritional & Misc Metabolic Disorders Age >17 w CC	1,102	77.2	7.9	41.2

(continued)

Table A-1 (continued)
Distribution of LTCH admissions by type of payment adjustment, 2004

DRG		Number of LTCH admissions	Prior hospitalization (Percent)	Prior acute outlier (Percent)	LTCH short stay outlier (Percent)
415	O. R. Procedure for Infectious & Parasitic Diseases	927	80.7	14.4	41.3
468	Extensive O.R. Procedure Unrelated To Principal Diagnosis	927	78.9	14.8	37.9
217	Wnd Debrid & Skn Grft except Hand, for Muscskelet & Conn Tiss Dis	857	75.2	5.5	30.6
182	Esophagitis, Gastroent & Misc Digest Disorders Age >17 w CC	847	85.7	9.3	37.0
465	Aftercare w History of Malignancy As Secondary Diagnosis	817	92.8	16.4	42.0
294	Diabetes Age >35	782	79.0	2.9	35.9
483	Tracheostomy except for Face, Mouth & Neck Diagnoses	667	68.4	17.8	34.9
463	Signs & Symptoms w CC	651	63.1	4.8	38.9
461	O.R. Proc w Diagnoses of Other Contact w Health Services	640	80.9	17.8	38.3
82	Respiratory Neoplasms	610	76.6	4.6	50.5
126	Acute & Subacute Endocarditis	574	91.5	11.9	35.2
243	Medical Back Problems	555	56.1	1.4	31.4
34	Other Disorders of Nervous System w CC	544	74.5	13.4	48.7
120	Other Circulatory System O.R. Procedures	522	73.0	8.1	37.4
172	Digestive Malignancy w CC	439	78.6	6.4	53.5
269	Other Skin, Subcut Tiss & Breast Proc w CC	427	60.7	2.8	42.6
256	Other Musculoskeletal System & Connective Tissue Diagnoses	417	80.8	7.2	36.0
287	Skin Grafts & Wound Debrid for Endoc, Nutrit & Metab Disorders	369	70.7	3.0	45.3
14	Specific Cerebrovascular Disorders except TIA	366	82.8	6.6	35.3
101	Other Respiratory System Diagnoses w CC	363	90.1	10.7	37.2
331	Other Kidney & Urinary Tract Diagnoses Age >17 w CC	362	85.4	17.1	40.6
440	Wound Debridements for Injuries	350	71.7	19.4	41.4
204	Disorders of Pancreas except Malignancy	347	90.8	26.2	43.8
429	Organic Disturbances & Mental Retardation	347	32.0	1.7	90.5
20	Nervous System Infection except Viral Meningitis	44	88.8	11.2	33.6

Table A-2
Factors predicting acute discharge outcomes, 2004

	1 LTCH Admission Odds Ratio	2 Acute Readmission Odds Ratio	3 Acute LOS Coefficient (SE)
Intercept			6.44***
Age	1.00***	0.99***	-0.03***
Female	0.996	0.96***	0.25***
White	0.63***	0.85***	-0.94***
APR DRG 3	1.72***	1.03***	2.16***
APR DRG 4	2.19***	0.64***	4.85***
No. of comorbids	1.04***	1.04***	0.27***
Severe days	1.03***	0.99***	0.97***
Acute LOS	0.982***	0.99***	
High LTCH state	2.75***	0.95**	-1.12***
Any LTCH use		1.64***	-1.29***
No. Observations	288,569	288,569	288,568

NOTES: *** indicates $p < 0.0001$, ** $p < 0.001$.

Table A-3
LTCH PPS margins by DRG

Diagnosis Group	Percent of cases	Aggregate average margin	Aggregate total income or (-)loss	
			$ millions	% total income
475: Respiratory Dx w/Ventilator support	10%	21.3%	$172.3	34%
249: Aftercare, musculoskeletal disorders	5%	7.2%	$11.1	2%
271: Skin ulcers	5%	4.5%	$7.7	2%
12: Degenerative nervous system disorders	5%	4.0%	$5.6	1%
88: COPD	4%	13.7%	$16.3	3%
466:Aftercare, no history malignancy	4%	7.0%	$8.4	2%
89: Pneumonia & Pleurisy w/ CC	4%	13.8%	$17.1	3%
87: Pulmonary edema & respiratory failure	4%	27.7%	$52.5	10%
462: Rehabilitation	4%	-0.1%	-$0.1	0%
416 Septicemia	3%	10.4%	$12.1	2%
All other DRGs	52%	9.9%	$203.9	40%
Total	100%	12.4%	$506.7	100%

SOURCES: RTI analysis of CMS HCRIS and MedPAR claims files, federal years 2003 and 2004. Restricted to claims from facilities electing payment under 100 percent federal rates.

Table A-4
Median margins by setting and discharge disposition, for two key LTCH DRGs

	Number of cases	Median margin percent			
			By discharge disposition		
		All	Died	Home	Transfers
DRG 475-Respiratory Diagnoses w/ Ventilator Support:					
IPPS stays <= 10 days	48,065	42.6	44.1	45.8	36.3
IPPS stays >10 days	49,285	-27.1	-38.8	-15.0	-27.2
All IPPS stays	97,350	13.1	12.4	25.1	2.2
All LTCH stays	10,210	23.1	20.9	26.3	24.1
DRG 012-Degenerative Nervous System Disorders:					
IPPS stays <= 10 days	41,961	16.0	0.7	19.1	14.3
IPPS stays >10 days	5,237	-107.5	-151.6	-104.0	-106.6
All IPPS stays	47,198	14.5	-16.6	20.5	10.5
All LTCH stays	9,487	7.5	1.1	10.4	7.5

SOURCES: RTI analysis of CMS HCRIS and MedPAR claims files for fiscal year 2004. LTCH claims restricted to those from facilities paid using 100 percent federal rates. The margin percent is defined as the payment minus the cost, divided by the pay. This quantity is multiplied by 100 percent to equal the margin percent.

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LIST OF ACRONYMS

Acronym	Description
ACH	Acute Care Hospital
APACHE	Acute Physiology and Chronic Health Evaluation
APR-DRG	All Patient Refined-DRG
CAD	Coronary Artery Disease
CARE tool	Continuity Assessment Record and Evaluation tool
CCI	Chronically Critically Ill
CI	Critically Ill
CIM	Critical Illness Myopathy
CIP	Critical Illness Polyneuropathy
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic Obstructive Pulmonary Disease
ED	Emergency Department
DRG	Diagnosis Related Group
HCQOL	Health Care Quality of Life
HWH	Hospital-Within-Hospital
ICU	Intensive Care Unit
IPF	Inpatient Psychiatric Facility
IPPS	Inpatient Prospective Payment System
IRF	Inpatient Rehabilitation Facilities
LODS	Logistic Organ Dysfunction System
LTCH	Long Term Care Hospital
LTCH-DRG	Long Term Care Hospital DRG
LTCH-PPS	Long Term Care Hospital Prospective Payment System
MedPAC	Medicare Payment Advisory Commission
MEG	Medstat Episode Group
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007
MODS	Multiple Organ Dysfunction Score
MOSF	Multiple Organ System Failure
MPM	Mortality probability Model
NALTH	National Association of Long Term Hospitals
NAMDRC	National Association for Medical Direction of Respiratory Care
NPUAP	National Pressure Ulcer Advisory Panel
NHP	Nottingham Health Profile
NMD	Neuromuscular Dysfunction
NRCU	Noninvasive Respiratory Care Unit
OLS	Ordinary Least Squares
OSF	Organ System Failure
PAC	Post Acute Care
PAC-PRD	Post Acute Care Payment Reform Demonstration
PMV	Prolonged Mechanical Ventilation
PPS	Prospective Payment System
QIO	Quality Improvement Organization

LIST OF ACRONYMS

(Continued)

Acronym	Description

QOL	Quality of Life
SAPS	Simplified Acute Physiology Score
SF-36	Standard Form 36
SCHIP	State Children's Health Insurance Program
SIP	Sickness Impact Profile
SNF	Skilled Nursing Facilities
SOFA	Sequential Organ Failure Assessment
TEFRA	Tax Equity and Fiscal Reform Act of 1982
TEP	Technical Expert Panel
TISS	Therapeutic Intervention Scoring System
VDU	Ventilator-Dependent Step-Down Unit