U.S. Department of Health and Human Services

Office of Inspector General

Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries

OEI-06-14-00530
November 2018

oig.hhs.gov

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Report in Brief
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Long-term-care hospitals (LTCHs) are inpatient hospitals that treat patients who are very ill—often with several acute and/or chronic conditions—and require care for an extended period. LTCHs provide continued, acute-level care for patients following their stays in traditional acute-care hospitals.

Key Takeaway
Almost half (46 percent) of Medicare patients in long-term-care hospitals experienced adverse events (21 percent) or temporary harm events (25 percent) during their stays. In many cases, physician reviewers determined that the harm could have been prevented if the hospitals had provided better care; in other cases, patients' health conditions made them susceptible and the harm was not preventable.

What OIG Found

The Office of Inspector General (OIG) found that 21 percent of Medicare patients in LTCHs experienced adverse events, which are particularly serious instances of patient harm resulting from medical care. The four categories of adverse events include outcomes such as prolonging a patient's LTCH stay or necessitating transfer to another facility; requiring life-saving intervention; resulting in permanent harm; and contributing to death. (Five percent of Medicare patients in LTCHs experienced adverse events that contributed to or resulted in their deaths.) An additional 25 percent of patients experienced temporary harm events, which are patient harm that required medical intervention but did not cause lasting harm.

The overall percentage of patients in LTCHs who experienced either type of harm (adverse events or temporary harm events) is 46 percent, higher than OIG found in hospitals (27 percent), skilled nursing facilities (33 percent), and rehabilitation hospitals (29 percent). Patient stays in LTCHs present more opportunities for harm events because the stays are longer, but the number of harm events per patient day was similar between LTCHs and other post-acute-care settings and lower than in non-LTCH acute-care hospitals.

Over half of these adverse events and temporary harm events (54 percent of harm events) were clearly or likely preventable. Preventable harm events were often related to substandard care (58 percent) and medical errors (34 percent). Forty-five percent of harm events were found to be clearly or likely not preventable, often because the patients were highly susceptible to harm due to other health conditions or poor overall health.

What OIG Recommends

In response to prior OIG work, the Centers for Medicare & Medicaid Services (CMS) and Agency for Healthcare Research and Quality (AHRQ) took important steps to raise awareness of adverse events and temporary harm events and to reduce harm in several inpatient settings. AHRQ and CMS should tailor their ongoing efforts to improve patient safety to address the specific needs of LTCHs. We recommend that AHRQ and CMS collaborate to create and disseminate a list of potential harm events in LTCHs and that CMS include information about patient harm in its outreach to LTCHs. CMS and AHRQ concurred with our recommendations.

Full report can be found at oig.hhs.gov/oei/reports/oei-06-14-00530.asp

Why OIG Did This Review

In a series of reports from 2008 to 2016, OIG found that adverse events and temporary harm events are common, endanger patient health, and are costly to the Medicare program. In a 2010 study, OIG found that 27 percent of hospitalized Medicare beneficiaries experienced such events, costing Medicare approximately $4.4 billion a year. OIG then expanded on this work by examining post-acute-care settings, finding that 33 percent of Medicare beneficiaries in skilled nursing facilities and 29 percent of Medicare beneficiaries in rehabilitation hospitals experienced harm. This report builds upon this prior work, focusing on Medicare stays in LTCHs.

How OIG Did This Review

OIG reviewed medical records for 587 Medicare beneficiaries admitted to LTCHs in March 2014 to establish a national incidence rate of adverse events and temporary harm events. The review was conducted in two stages. In the first stage, nurses screened records for possible harm events. In the second stage, physicians conducted a comprehensive review of the records flagged as containing possible harm events. Physicians identified the harm events, determined the level of harm, whether the events were preventable, and the factors that contributed to the events.

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BACKGROUND

Objectives

1. To estimate the incidence of adverse events and temporary harm events for Medicare patients admitted to long-term-care hospitals (LTCHs),
2. To assess the extent to which adverse events and temporary harm events were preventable and to identify factors contributing to these events.

Adverse Events and Temporary Harm Events in Health Care

The term "adverse event" describes harm to a patient as a result of medical care or in a healthcare setting, including the failure to provide needed care. An adverse event indicates that the care resulted in an undesirable clinical outcome not caused by underlying disease. We separately identify temporary harm events, which are events that harmed patients and required medical intervention but did not cause lasting harm.

Adverse events and temporary harm events include medical errors and general substandard care that result in patient harm, such as infection caused by the use of contaminated equipment. However, adverse events and temporary harm events do not always involve errors, negligence, or poor quality of care and are not always preventable, such as an unexpected allergic reaction.[1] The Institute for Healthcare Improvement (IHI), a nonprofit advisory group to hospitals and other healthcare systems, further explains that "unpreventable events are only an innovation away from being preventable" and that including all causes of harm in research allows for better comparisons over time.[2] In addition, CMS's Partnership for Patients initiative, which focuses on making care safer by reducing 11 core types of harm, describes a long-term goal of reducing "all-cause harm" for Medicare beneficiaries.[3] All-cause harm includes "any event during the care process that results in harm to a patient, regardless of the cause."[4]

[1] R.M. Wachter, *Understanding Patient Safety*, 2nd edition, McGraw-Hill, 2012, p.15.
[2] F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series 2009, p. 5.
[3] CMS, *About the Partnership*. Accessed at https://partnershipforpatients.cms.gov/about-the-partnership/what-is-the-partnership-about/lpwhat-the-partnership-is-about.html on May 29, 2018.
[4] CMS, Survey and Certification, S&C: 13-19-Hospitals, March 15, 2013 Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf on June 5, 2018.

Office of Inspector General Reports on Adverse Events

In a series of reports from 2008–2016, the Office of Inspector General (OIG) found that adverse events and temporary harm events are common and costly to the Medicare program.[5] The OIG reports include incidence rates for all causes of harm, and also provide an assessment by physician reviewers of which events were considered preventable. In a 2010 study, OIG found that 27 percent of hospitalized Medicare beneficiaries experienced adverse or temporary harm events.[6] Nearly half of the events were preventable, and hospital care associated with events cost Medicare approximately $4.4 billion a year. OIG also found that hospital staff did not recognize or did not report 86 percent of adverse events and temporary harm events when they occurred.[7]

Following the 2010 study, OIG expanded its work on adverse events by examining post-acute-care settings. In 2014, OIG found that 33 percent of Medicare residents in post-acute skilled nursing facility (SNF) stays experienced adverse events and temporary harm events.[8] Over half (59 percent) of these events were preventable, and care associated with these events cost Medicare approximately $2.8 billion in a single year. In 2016, OIG looked at another post-acute-care setting, rehabilitation (rehab) hospitals, and found that 29 percent of Medicare patients experienced adverse events during their stay with an estimated cost to Medicare of at least $92 million a year.[9] This report builds upon previous OIG work in post-acute-care settings, focusing on LTCHs.

Post-Acute Care in LTCHs

LTCHs are inpatient hospitals that specialize in treating long-term and clinically complex patients, often with several acute and/or chronic conditions. The patients are often very ill and require inpatient care for an extended time. Compared with all Medicare patients, those admitted to LTCHs are disproportionately disabled (under age 65), over age 85, or diagnosed with end-stage renal disease. These patients may require acute-level services for extended periods of time and many are near the end of life. In 2015, 25 percent of LTCH patients died either in an LTCH or within 30 days of discharge.[10]

[5] OIG released 12 reports on adverse events in hospitals from 2008–2016, including reports about the incidence of adverse events, methods for identifying adverse events, State reporting systems, and public disclosure of event information. All reports are available at https://oig.hhs.gov/newsroom/spotlight/2012/adverse.asp.

[6] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[7] OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, OEI-06-09-00091, January 2012.

[8] OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-11-00270, February 2014.

[9] OIG, *Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00110, July 2016.

[10] Medicare Payment Advisory Commission (MedPAC), *Report to Congress: Medicare Payment Policy*, March 2017, p. 300.

Over one-third of patients in LTCHs have respiratory conditions, with *pulmonary edema and respiratory failure* (often symptoms of congestive heart failure) as the most frequently reported diagnosis. The second most frequently reported diagnosis is *respiratory system diagnosis with ventilator support for 96 or more hours*. Other common reasons for treatment in LTCHs include septicemia or severe sepsis, and complex wound infections.[11]

With approximately 400 LTCH providers in the Medicare Program, LTCHs are less common than other types of post-acute-care providers and account for approximately six percent of Medicare expenditures for post-acute care.[12, 13] To receive Medicare designation as an LTCH, hospitals must meet all the requirements for short-term acute-care hospitals and have an average length of stay greater than 25 days.[14] In fiscal year 2015, Medicare spent $5.3 billion on LTCH care, with an average stay costing Medicare over $40,000.[15]

Federal Efforts to Improve Quality and Safety in LTCHs

Accreditation Organization and State Agency Surveys

As it does for all Medicare- and Medicaid-certified hospitals, the Centers for Medicare & Medicaid Services (CMS) oversees LTCH compliance with a set of minimum quality and safety standards known as the hospital Conditions of Participation (CoPs).[16] LTCHs demonstrate compliance with the hospital CoPs through on-site surveys conducted by Medicare-approved accreditation organizations or State survey agencies. CMS provides interpretive guidance and survey procedures regarding the hospital COPs in its *State Operations Manual*.[17]

Quality Assessment and Performance Improvement (QAPI)

In accordance with the CoPs, LTCHs are required to develop and maintain a Quality Assessment and Performance Improvement (QAPI) program.[18] To satisfy QAPI requirements, LTCHs must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital."[19] To accomplish this, LTCHs must "measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations."[20]

[11] Ibid.
[12] Ibid.
[13] MedPAC, *A Data Book: Health Care Spending and the Medicare Program*, Chart 8-2, June 2015, p. 114.
[14] Social Security Act § 1861(ccc) and 42 CFR § 412.23(e).
[15] MedPAC (2017), Op. cit., pp. 289, 300.
[16] The Secretary's authority to establish the CoPs is at Social Security Act § 1861(e)(9). The current CoPs are found at 42 CFR part 482.
[17] CMS, *State Operations Manual*
[18] 42 CFR § 482.21.
[19] 42 CFR § 482.21(c)(2).
[20] 42 CFR § 482.21(a)(2).

To facilitate comparison and benchmarking of adverse events, the Agency for Healthcare Research and Quality (AHRQ), the lead Federal agency charged with improving healthcare safety and quality, developed a set of definitions and reporting formats for patient safety events, known as the Common Formats. AHRQ encourages the use of the Common Formats by hospitals in their internal event reporting systems.[21]

LTCH Reporting of Quality Data

In accordance with the Affordable Care Act, CMS established the LTCH Quality Reporting Program and the LTCH Compare website.[22, 23, 24] The LTCH Compare website is available to the public and currently includes eight measures, five of which relate to adverse events, such as the percent of patients with pressure ulcers that are new or worsening and rates of health-care-associated infections. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) further requires hospitals to submit standardized quality measures that allow for comparison among post-acute-care providers.[25] LTCHs that fail to submit the required data are penalized two percentage points in their annual payment update.

Methodology

This report estimates the national incidence of adverse events and temporary harm events that occurred in LTCHs using a representative sample of Medicare beneficiaries in LTCHs. Our study population included all Medicare LTCH beneficiaries (patients) admitted to LTCHs in March 2014. The estimated national incidence rates are limited to events that occurred in the first 25 days of the LTCH stay. The rates are composed of all patient harm events regardless of whether they were preventable. We do not provide a cost estimate for these events because we determined that the cost methodology used in prior studies would not yield useful results. LTCHs provide acute-level services so transfers to other acute-care facilities are typically unnecessary and patients are often admitted with complex diagnoses and comorbidities, such that the Medicare payment classification is unlikely to be changed as the result of a patient harm event. Other cost methodologies would require the collection of additional information from providers or beneficiaries.

[21] AHQR, PSNET *Patient Safety Primer: Reporting Patient Safety Events*. Updated June 2017. Accessed at https://psnet.ahrq.gov/primers/primer/13/reporting-patient-safety-events on April 16, 2018.
[22] CMS, *LTCH Quality Public Reporting*. Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Public-Reporting.htm I on February 20, 2018.
[23] P.L. 111-148 § 3004(a). Social Security Act, § 1886(m)(5).
[24] Fed. Reg. 51475, 51743-51756, 51839-51840 (August 18, 2011).
[25] IMPACT Act of 2014, P.L. 113-185 §§ 2(a) and 2(3)(c), Social Security Act, §§ 1899B and 1886(m)(5).

Sample Selection and Profile

Using Medicare claims data from the National Claims History file, we selected a simple random sample of 600 Medicare beneficiaries out of the 11,460 beneficiaries who began LTCH stays in March 2014. We excluded 13 beneficiaries from the selected sample (7 beneficiaries with no Medicare payment, 5 beneficiaries from hospitals that were currently under OIG investigation, and 1 beneficiary with insufficient documentation). As a result, the reviewed sample consisted of 587 beneficiaries who had a total of 588 LTCH stays. The average length of stay was 26.3 days.

Data Collection

We requested complete medical records for the sampled beneficiaries' LTCH stays. As part of this request, we asked administrators to provide key documents, including pre-admission screening documentation and post-admission physician evaluation. Because the longest LTCH stays can last years, we limited our review and only counted events that occurred during the first 25 days of the stay, which is the minimum average length of stay required for facilities to be classified as LTCHs. We applied the 25-day limit during the clinicians' reviews and it was not a factor in the sample selection.

Identification of Adverse Events and Temporary Harm Events. We conducted a two-stage medical record review to identify adverse events and temporary harm events in the sampled records. (See Appendix A for a detailed description of the medical record reviews and Appendix B for a glossary of selected clinical terms used to describe events.)

The first stage was a screening process using a modified version of the Global Trigger Tool (GTT) methodology designed by IHI to identify Medicare LTCH patients who may have experienced events.[26] Two registered nurses used a trigger tool to review the medical records (see Appendix C for a list of the triggers used to identify events). The screeners identified the records of 326 beneficiaries who were likely to have experienced events.

In the second stage, physicians reviewed the medical records of the 326 beneficiaries identified by nurses as likely to have experienced adverse or temporary harm events. Physicians examined the records to identify events and described them using a structured data collection instrument. Physicians used a guidance document to improve consistency.

The physician panel included seven physicians who participated in our prior studies of acute-care hospitals, SNFs, and rehab hospital events (specialists in cardiology, infectious disease, internal medicine, orthopedics, surgery, geriatrics, neurology, and physiatry) and an LTCH physician who was also a Certified Medical Director accredited by the Society for Post-Acute and Long-Term Care Medicine. The physician reviewers also consulted with a

[26] F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series 2009.

geriatric psychiatrist and a pulmonologist/intensivist in particularly difficult cases.

Assessment of severity. The physician reviewers assigned each event to one of five harm levels using a modified version of the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Medication Errors (NCC MERP Index). We distinguish between "adverse events" (levels F-I on the index) and "temporary harm events" (level E on the index) to separately identify events that were more likely to affect cost and length of stay. Both types of events represent harm to patients resulting from medical care. (See Exhibit 1.)

Exhibit 1: Modified Version of the NCC MERP Index for Categorizing Errors Used in the OIG Study of Adverse Events in LTCHs

Event Type	Level	Description
Adverse Event	I	Harm occurred that may have contributed to or resulted in the patient's death.
	H	Harm occurred that required intervention to sustain the patient's life.
	G	Harm occurred that contributed to or resulted in permanent patient harm.
	F	Harm occurred that prolonged the LTCH stay, became primary reason for treatment, or resulted in transfer to another hospital for observation, emergency treatment, or inpatient care.
Temporary Harm	E	Harm occurred that caused temporary harm that required intervention.

Source: Adapted from the © NCC MERP Index for Categorizing Errors. Revised February 20, 2001.

Assessment of preventability. The physician reviewers assigned each event to one of five preventability determinations—clearly preventable, likely preventable, likely not preventable, clearly not preventable, or unable to determine. They selected a rationale for each preventability determination from a list of 16 options, which, among other options, included *the provision of appropriate treatment or preventive care in a substandard way* (preventable) and *patient experienced the event despite efforts by staff to avoid harm* (not preventable). An OIG-developed algorithm was also available to guide physicians on difficult preventability decisions.

Data Analysis

We analyzed the medical review results and generated estimates of event incidence and preventability. We projected the findings to the population of an estimated 11,212 Medicare beneficiaries admitted to LTCHs during

March 2014.[27] We calculated the incidence rates as the percentage of beneficiaries in the sample who experienced at least one harm event. For estimates and corresponding 95-percent confidence intervals, see Appendix D.

As an additional measure, we calculated two ratios of incidence density: events per 1,000 patient days and events per 100 hospital admissions.[28] These measures are commonly used by hospitals and medical researchers.[29] See Appendix E for further explanation of the calculation method.

Limitations

These results, as with all medical record reviews, are subject to physician interpretation and clinical judgment. Additionally, it is unlikely that the reviewers identified all adverse events and temporary harm events within our sample of Medicare beneficiaries in LTCHs. First, the scope of the medical record review included only the first 25 days of LTCH stays. Any harm that occurred after the 25th day was not included in the results. Second, all medical record reviews are dependent on available documentation. Omitted information could lead reviewers to miss some events or assess the preventability differently.

Finally, the GTT screening methodology used in the first stage of the review is not a comprehensive medical review. Some events may be missed because the screeners are focused on a particular set of triggers. Analysis in a prior OIG study found that compared to a comprehensive medical review by physicians, the GTT screening methodology identified 93 percent of the patients with events.[30]

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

[27] The sample was selected from a population of 11,460 Medicare beneficiaries admitted to LTCHs during March 2014. The projected population of 11,212 beneficiaries accounts for beneficiaries in our sample that were excluded from the review. The 95-percent confidence interval for this estimated population is (11,081–11,342).

[28] To be consistent with the overall incidence of event, we limited the length of stay to 25 days in the incidence density calculation.

[29] K.M. Arias, *Outbreak Investigation, Prevention, and Control in Health Care Settings: Critical Issues in Patient Safety*, Second Edition, Jones and Bartlett Publishers, 2009, pp. 330-331.

[30] OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-11-00270, February 2014.

FINDINGS

Twenty-one percent of Medicare patients had adverse events during their LTCH stays

One in five Medicare patients (21 percent) experienced adverse events during their stays in LTCHs. These events resulted in harm within the four most serious categories (F-I) on our modified NCC MERP Index and represent both preventable and not preventable events. The majority (53 percent) of adverse events experienced by patients caused F level harm (meaning it prolonged the LTCH stay, became the primary reason for treatment, or required transfer to another facility.) Over 40 percent resulted in the need for life-saving intervention (21 percent) or contributed to death (20 percent), and the final 6 percent of events contributed to permanent harm. See Exhibit 2. We estimate that a total of 2,388 Medicare patients experienced at least one adverse event during the study period. Seventeen percent of these patients experienced more than one adverse event. See Appendix F for a list of the 456 events in our sample with detailed descriptions and levels of harm.

Exhibit 2: Adverse Events by Level of Harm (n=150)

Level of Harm	Percentage of Adverse Events
F level: Prolonged the LTCH stay, became primary reason for treatment, or required transfer to another facility	53%
G level: Contributed to or resulted in permanent patient harm	6%
H level: Required intervention to sustain the patient's life	21%
I level: Contributed to or resulted in patient death	20%

Source: OIG analysis of LTCH stays for 587 Medicare patients entering an LTCH in March 2014.

Adverse events most often related to healthcare-acquired infections (45 percent) with 31 percent related to the use of medication, and the remaining 23 percent related to general patient care.[31] See Exhibit 3 for the types of adverse events within each category.

Respiratory infections were the most common type of adverse event.[32] One event involved a patient admitted to the LTCH with respiratory failure. The patient was on a ventilator and had a surgically-created opening in the throat to allow the passage of air. Well after admission, the patient began showing signs of a lower respiratory tract infection (tracheobronchitis), with

[31] The percent of healthcare-acquired infection adverse events was significantly higher than that of medication-related adverse events ($p<0.05$) and patient care related adverse events ($p<0.001$).

[32] The percent of patients with respiratory infections is significantly higher than the second most common type of event in the sample, bleeding associated with anticoagulants ($p<0.001$).

a respiratory culture and chest x-ray confirming the diagnosis. Providers waited over a week to begin appropriate treatment with antibiotics, and it took several additional days to get the infection under control. The long-standing infection ultimately damaged the patient's kidneys and contributed to a dangerously high potassium level.

Another adverse event also involved a delay in care as the staff failed to identify signs of sepsis. The patient, who entered the LTCH with chronic congestive heart failure and renal syndrome, complained in the morning of abdominal distention and nausea, and had an abnormally low oxygen reading. The patient did not receive treatment and developed signs of severe sepsis that evening, including an acute change in mental status. The patient died of sepsis several hours later.

Exhibit 3: Adverse Events Were Most Often Related to Healthcare-Acquired Infections (n=150)

Types of Adverse Events	Percentage of Events*
Adverse Events Related to Infections	45%
•LTCH-acquired respiratory infections	23%
•Sepsis not associated with another event	7%
•Vascular-catheter associated infections	5%
•*Clostridium difficile* infections	3%
•Surgical site infections	3%
•Urinary tract infections associated with urinary catheters	2%
•Other infection-related adverse events	3%
Adverse Events Related to Medication	31%
•Bleeding associated with anticoagulants	9%
•Hypoglycemic events	9%
•Delirium and other changes in mental status	6%
•Fluid, electrolyte, and metabolic disorders	3%
•Acute kidney injury or insufficiency	2%
•Other medication-related adverse events	3%
Adverse Events Related to Patient Care	23%
•Respiratory issues other than infections, such as aspiration	5%
•Venous thromboembolisms, deep vein thrombosis, or pulmonary embolisms	5%
•Bleeding not associated with anticoagulants	3%
•Pressure ulcers	3%
•Fluid, electrolyte, and metabolic disorders (not medication related)	2%
•Other patient care events	6%
Total	100%

Source: OIG analysis of LTCH stays for 587 Medicare patients who entered an LTCH in March 2014.
*The total does not equal 100 percent due to rounding.

Five percent of Medicare LTCH patients experienced adverse events that contributed to or resulted in their deaths

These I-level events project to an estimated 573 deaths during the study period. The patients who experienced events that contributed to deaths suffered from serious and unresolved medical conditions, including cancer, morbid obesity, dementia, renal failure, and diabetes. Physician reviewers reported that many entered the LTCH with a poor prognosis.

In many cases, the patients had serious conditions that, while not directly related to the event, caused their health to be more fragile. One 65-year-old patient had several serious health problems, including a tracheostomy (surgically-created opening in the throat to allow the passage of air) placed following surgery for esophageal cancer, and developed fatal septic shock as a result of an infected Stage 4 pressure ulcer. Another patient with a recent relapse of leukemia died from a bacterial infection (meningoencephalitis) that resulted in fluid in the brain after staff were slow to recognize the infection despite the patient exhibiting confusion and fevers, and with laboratory results showing evidence of infection.

Five percent of Medicare LTCH patients experienced adverse events that resulted in transfer to an acute-care hospital, emergency department, or another specialty care provider

An estimated 554 LTCH patients were transferred to other facilities as the result of an event during our study period. For each event that resulted in a transfer, physicians assigned a severity rating of F-level harm or higher. One of the transferred patients in our sample was a 69-year-old man whose urethra was injured while staff changed his urinary catheter. The injury led to urinary retention and significant blood loss. Due to the degree of harm and complexity of the needed treatment, the patient was transferred to an acute-care hospital for a blood transfusion and further management. In another case, a patient with multiple chronic conditions and on blood thinning medication developed bleeding around the brain (subdural hematoma) over a 24-hour period. The patient was transferred to an acute-care hospital for surgery to relieve pressure on the brain, a procedure that the LTCH was not equipped to perform.

An additional 25 percent of Medicare patients had temporary harm events during their LTCH stays

In addition to the 21 percent of patients who experienced adverse events, 25 percent of Medicare patients in LTCHs experienced temporary harm events. These events were classified as E-level harm on the NCC MERP Index, which is defined as harm events that required intervention but did not prolong the LTCH stay, necessitate higher levels of care, require life-sustaining intervention, or result in lasting harm. We estimate that 2,770 LTCH patients experienced at least 1 temporary harm event during the study month. Of these patients, 1,108 had more than 1 unrelated event. Additionally, 39 percent of patients who experienced an adverse event also

had temporary harm events during their stays. As with adverse events, temporary harm events represented a wide array of conditions from the three clinical categories (see Exhibit 4 for the types of temporary harm events within each category).

Exhibit 4: Temporary Harm Events Were Most Often Related to Medication (n=306)

Types of Temporary Harm Events	Percentage of Events
Temporary Harm Events Related to Medication	49%
•Hypoglycemic events	17%
•Delirium and other changes in mental status	10%
•Bleeding associated with anticoagulants	5%
•Constipation, obstipation, or ileus	5%
•Acute kidney injury or insufficiency	3%
•Allergic reactions	3%
•Other medication-related temporary harm events	5%
Temporary Harm Events Related to Infection	26%
•Soft tissue or other nonsurgical infections	9%
•Thrush (fungal infection of the mouth or throat)	4%
•Urinary tract infections associated with urinary catheters	4%
•*Clostridium difficile* infection	3%
•LTCH-acquired respiratory infections	3%
•Other infection-related temporary harm events	4%
Temporary Harm Events Related to Patient Care	25%
•Pressure ulcers	7%
•Bleeding not associated with anticoagulant	3%
•Venous thromboembolisms, deep vein thrombosis, or pulmonary embolisms	3%
•Skin tears, abrasions, or breakdowns	3%
•Falls with injury	2%
•Other patient-care-related temporary harm events	6%
Total	100%

Source: OIG analysis of LTCH stays for 587 Medicare patients entering an LTCH in March 2014.

Half of the temporary harm events (49 percent) related to the use of medication. These harm events included delirium, excessive bleeding due to anticoagulants, and allergic reactions. Episodes of hypoglycemia (abnormally low blood sugar) are categorized as medication events because maintaining appropriate blood sugar levels in diabetics relies on insulin and oral anti-diabetic medication management. These episodes were the most frequently occurring temporary harm events and accounted for 17 percent of temporary harm events overall.[33] The remaining temporary harm events related to infections (26 percent), such as soft tissue infections and

[33] The percent of hypoglycemia temporary harm events was significantly higher than the second most common type of temporary harm event, delirium and other changes in mental status ($p<0.05$).

catheter-associated urinary tract infections, and patient care events (25 percent), such as pressure ulcers and falls resulting in injury.

Although many cases of temporary harm within the sample represented instances of fairly minor harm to the residents, other temporary harm events caused harm that was significant for the residents. We did not classify these events as adverse events because they did not prolong the LTCH stays, necessitate higher levels of care, require life-sustaining intervention, or result in lasting harm. Physician reviewers indicated that many temporary harm events could have developed into more serious events if LTCH staff had not provided a timely intervention. For example, 40 percent of the hypoglycemic temporary harm events had documentation of blood glucose levels lower than 40 milligrams. Blood glucose levels under 70 are considered low and often require an adjustment to insulin or diabetic medication. If left untreated, severe hypoglycemia can lead to seizures, coma, and even death.[34]

In one event in our sample categorized as a patient care-related temporary harm, an LTCH patient experienced an overload of intravenous fluid, which resulted in difficulty breathing and triggered an episode of congestive heart failure. Another patient was treated for a blood clot (deep venous thrombosis) after placement of a central line catheter (catheter used for long-term administration of medication) resulted in arm swelling. In each of these cases, LTCH clinical staff acted to ameliorate the harm before it could result in more serious injury.

Longer stays in LTCHs present more opportunities for adverse events and temporary harm events

With 46 percent of Medicare patients experiencing either adverse or temporary harm events, the incidence of harm in LTCHs is higher than the OIG identified in other healthcare settings, including acute-care hospitals (27 percent), SNFs (33 percent), and rehab hospitals (29 percent).[35] However, in comparing harm rates across settings, it is important to note that patients in LTCHs have longer lengths of stay on average than patients in acute-care hospitals, SNFs, or rehab hospitals. These longer lengths of stay result in more medical interventions over time and, therefore, more opportunities for harm to occur. The average length of stay for the LTCH patients in our sample was 26.3 days. In comparison, average lengths of stay for samples in similar OIG studies were 5.2 days in acute care hospitals, 15.5 days in SNFs, and 12.7 days in rehab hospitals.[36]

[34] American Diabetes Association, *Hypoglycemia (Low Blood Glucose)*. Accessed at http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html on March 30, 2018.

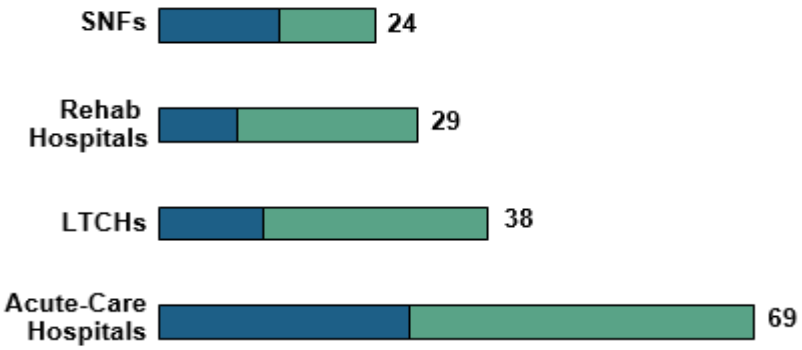
[35] The incidence rate in LTCHs was statistically different from each of the other settings reviewed (i.e., acute-care hospitals, SNFs, and rehab hospitals, $p<0.0001$).

[36] The samples were taken from different months and years. The sample for acute-care hospitals was drawn from October 2008; the sample for SNFs was drawn from August 2011; and the sample for rehab hospitals was drawn from March 2012.

Using a different metric to measure the frequency of events, the rate of events in LTCHs looks more comparable to other post-acute settings (SNFs and rehab hospitals) and lower than acute-care hospitals. Incidence density is a metric often used by healthcare facilities to track performance, and is defined as the number of events per 1,000 patient days. We found that the incidence density in LTCHs was 38 adverse events and temporary harm events per 1,000 patient days. Prior OIG reports found that patients admitted to acute-care hospitals experienced a significantly higher number of events per day, with 69 events per 1,000 patient days and that Medicare patients in rehab hospitals and SNFs experienced fewer events per 1,000 patient days (29 events in rehab hospitals and 24 events in SNFs) than LTCHs (38 events).[37, 38] See Exhibit 5.

Exhibit 5: Medicare LTCH patients experience more events per patient day than patients in other post-acute care settings, but less than acute-care hospitals.

LTCH Medicare patients experienced about 38 adverse events and temporary harm events per 1,000 patient days.



Sources: OIG analysis of LTCH stays for 587 Medicare patients entering an LTCH in March 2014; and reported statistics from OIG reports OEI-06-09-00091, OEI-06-11-00270, and OEI-06-14-00110.

Compared with acute-care hospitals, the lower number of events per day in LTCHs may be attributable to differences in the patient populations and the care provided. Acute-care hospitals treat sudden and often urgent illnesses and injuries and, therefore, are more likely to perform surgical and other procedures that can put patients at risk. Although LTCHs treat medically complex and high acuity patients, clinicians and staff may have more opportunity to become familiar with their patients' conditions, owing to their longer stays, which may result in care that is better-suited to the patients and less likely to result in harm events. For more information about incidence density in LTCHs, see Appendix E.

[37] The incidence density in LTCHs was statistically different from rehab hospitals ($p<0.01$) and SNFs ($p<0.0001$).

[38] The incidence density in LTCHs was statistically different from acute-care hospitals, $p<0.0001$).

Almost one-quarter (22 percent) of Medicare LTCH patients experienced more than one unrelated event

Physicians determined that these harm events were not cascade events wherein one event led to another, but were separate events unrelated to other harm experienced by the patient. In some cases, the patients experienced the same type of event on more than one occasion, and in other cases the events were completely dissimilar and involved different conditions, factors, and harm levels.

In one case, a patient experienced five events during a single LTCH stay, with the fifth event ultimately leading to the patient's death. The 76-year-old patient was admitted to the LTCH for antibiotic therapy and physical therapy following an ankle fracture. First, the patient became ill upon starting medication to treat an exacerbation of chronic obstructive pulmonary disease (COPD). Second, the patient developed oral thrush (fungal infection of the mouth) as a result of antibiotics. Third, the patient became lethargic as a result of a hypoglycemic event with a blood glucose of 38. Fourth, days after the prior events, the patient aspirated during a feeding and developed pneumonia associated with the aspiration. Fifth, the patient contracted a blood stream infection from a central line catheter used for long-term administration of the patient's antibiotics.

As the patient's medical condition declined, he was transferred to an intensive care unit within the LTCH, but began having difficulty breathing and became difficult to arouse. The LTCH pulmonologist recommended intubation, but after several failed attempts, the patient was transferred to an acute-care hospital and later died.

Over half of adverse events and temporary harm events were preventable

The incidence rates for adverse events and temporary harm events include both preventable and not preventable events, but physician reviewers also assessed each event to determine whether it could have been prevented. Using the documentation in the medical records, they determined that over half of adverse events and temporary harm events (54 percent) were clearly or likely preventable and that most of the remaining events (45 percent) were clearly or likely *not* preventable. Physicians were unable to make a determination for the remaining one percent of events because of incomplete documentation or complexities in the patients' conditions. If we were to include only preventable events in the incidence rates, the percent of Medicare patient in LTCHs that experienced preventable adverse events would be 14 percent (rather than 21 percent) and the percent of patients that experienced preventable temporary harm events would also be 14 percent (rather than 25 percent). Event-specific preventability assessments are included in Appendix F.

Adverse events were more likely to be preventable than temporary harm events (62 percent of adverse events were preventable versus 50 percent of temporary harm events).[39] Exhibit 6 presents the percentage of events within each category of preventability.

Exhibit 6: Adverse Events and Temporary Harm Events by Preventability Determination (n=456)

Preventability Assessment	Percentage of All Events
Preventable—Harm could have been avoided through improved assessment or alternative actions	54%
Clearly preventable	7%
Likely preventable	47%
Not Preventable—Harm could not have been avoided given the complexity of the patient's condition or care required	45%
Likely not preventable	42%
Clearly not preventable	3%
Unable to Determine Preventability	1%

Source: OIG analysis of LTCH stays for 587 Medicare patients admitted in March 2014.

Preventable events were often related to substandard care and medical errors

Physician reviewers determined that over half (58 percent) of preventable events affecting Medicare patients in LTCHs involved clinicians' providing appropriate treatment or preventive care, but in a substandard way, and one-third (34 percent) related to errors in medical judgment, skill, and management. One medical error involved a patient that developed blood clots (bilateral deep venous thrombosis) after the physician failed to sign a standard authorization for prophylactic blood thinning medication and it was never provided.

Another medical error occurred as LTCH clinicians over-medicated a patient who was suffering from volume overload (a condition in which there is too much fluid in the body). A nephrologist on site recorded that the patient received too much diuretic medication, used to rid the body of excess fluid, which resulted in dehydration and acute kidney injury. See Exhibit 7 for a full list of the preventability rationales cited by physician reviewers for preventable events.

[39] The difference between adverse events and temporary harm events for preventability was statistically significant at the 95-percent confidence interval ($p<0.05$).

Exhibit 7: Rationales for Events Determined Preventable (n=245)

Rationales for Preventable Events	Percentage of Preventable Events*
Substandard treatment / preventive care	58%
Error was related to medical judgment, skill, management	34%
The patient's progress was not adequately monitored	25%
Patient care plan was inadequate	23%
Clinicians did not provide necessary treatment	18%
Equipment failure or other breakdown	3%
Poor communication among caregivers	2%
Lack of access to a physician or specialist	2%
Admission assessment was inadequate for the patient	2%
Other	12%

Source: OIG analysis of LTCH stays for 587 Medicare patients who entered an LTCH in March 2014.
*Reviewers often selected more than one rationale per event.

Hypoglycemic events were the most frequently occurring type of preventable event[40], with physician reviewers classifying 71 percent of all hypoglycemic events as preventable. Medicare patients in LTCHs exhibited a high incidence of diabetes, requiring providers to actively manage their blood glucose levels. Among patients who were diabetic (42 percent), 18 percent experienced a hypoglycemic event.

Physician reviewers noted that in several cases, hypoglycemic events related to the providers' reliance on sliding-scale insulin therapy. Sliding-scale insulin therapy is a medication regimen that adjusts the dose of insulin ordered based on the measured blood glucose level. It attempts to correct abnormal blood glucose levels after they occur, rather than preventing the abnormal levels before they occur. Although it is still common practice, its exclusive use is discouraged by current clinical practice guidelines because it is associated with unsafe fluctuations in blood glucose levels.[41]

As previously stated, most of the patient deaths in our sample involved patients with multiple serious health conditions, making the care very complex. In a few cases, though, events were clearly preventable. One event involved a 91-year-old patient with end-stage renal disease and a recent hospital admission for sepsis, who entered an LTCH for ongoing care that included intravenous antibiotics. The patient had severe and

[40] The percent of preventable hypoglycemic episodes was significantly higher than the second most common type of preventable event, delirium and other changes in mental status ($p<0.05$).
[41] The American Medical Directors Association, the American Association of Clinical Endocrinologists and the American College of Endocrinology recommend the use of multi-modal (basal, prandial, and correctional) insulin instead of sliding-scale insulin in noncritically ill adult patients.

unrecognized hypothyroidism, suffering from a low body temperature, low blood pressure, and decreased mental status, along with a significantly abnormal thyroid test. Yet the patient's thyroid replacement medication was dosed too low and not increased until 4 days before the patient's death. Physician reviewers determined that the diagnostic and therapeutic interventions were insufficient in identifying and addressing this patient's condition.

Patient susceptibility or poor health status was a factor in most (81 percent) of the events that were not preventable

Eighty-one percent of the events physician reviewers identified as not preventable were associated with patients who were highly susceptible to the events or in particularly poor health. Patients in LTCHs are often extremely debilitated and require high levels of care from a range of specialists, increasing their exposure to medical interventions. Many had a poor prognosis and required acute level patient care for an extended time.

In one event assessed as not preventable, the patient experienced a wound infection at the site of a prior post-operative drain site on the abdomen. During the preceding acute-care hospitalization, the patient underwent a colectomy (removal of part of the colon) for diverticulosis (pouches in the wall of the colon), followed by a complicated course with multiple extensive surgeries on the colon that resulted in sepsis from an anastomotic leak (breakdown of a surgical connection) with widespread contamination. The physician reviewer considered this patient to be highly susceptible to the infection during the subsequent LTCH stay because of the anastomotic leak during the prior hospitalization that had resulted in contaminated feculent fluid in the area. Exhibit 8 provides the most common preventability rationales cited by the reviewers for all events determined not preventable.

Exhibit 8: Rationales for Events Determined Not Preventable (n=206)

Rationales for Not Preventable Events	Percentage of Not Preventable Events*
Patient was highly susceptible to event because of health status	81%
Patient's diagnosis was unusual or complex, making care difficult	36%
Event occurred despite proper assessment and procedures followed	24%
Care provider could not have anticipated event with information available at the time	12%
Harm was anticipated but was considered acceptable given alternatives	12%
Other	4%

Source: OIG analysis of LTCH stays for 587 Medicare patients who entered an LTCH in March 2014.
*Reviewers were allowed to select more than one rationale per event.

For other events determined not preventable, the patient's diagnosis or treatment was unusual or complex, making care difficult (36 percent of not preventable events). One such event involved a young patient who was paraplegic with multiple wounds, a bone infection, a blood clot (deep venous thrombosis), and a urinary tract infection. The patient was receiving antibiotics through a central line catheter designed for long-term use: a peripherally inserted central catheter (PICC) line. LTCH staff discovered the patient contaminating his own line (using a syringe to inject crushed up pain medication into the PICC line). The patient later developed a fungal infection of the bloodstream.

In other cases, the potential for harm was known, but the harm was considered acceptable given the alternative of not providing care (12 percent of not preventable events). One event that was not preventable involved a patient on blood thinning medication who experienced recurrent urinary retention. The retention necessitated placement of a urinary catheter, which led to the patient hemorrhaging and requiring a blood transfusion. Reviewers determined the event was likely not preventable because, if left untreated, the urinary retention could have led to sepsis or kidney injury.

CONCLUSION AND RECOMMENDATIONS

Prior OIG reports demonstrated that adverse events and temporary harm events are common in many healthcare settings, endanger patient health, and result in a significant financial cost to Medicare. Almost half of Medicare patients in LTCHs experienced harm, more than OIG measured in acute-care hospitals, SNFs, and inpatient rehab hospitals. This higher rate of patient harm may be due, in part, to longer stays and high patient acuity. However, reviewers also found that over half of the harm was preventable and many events were the result of medical error. Providers and overseers should follow evidence-based practices and use systems-based approaches to prevent patient harm and ensure that LTCH patients receive an appropriate standard of care. Researchers also should continue to identify and promote safe practices in the LTCH setting.

In our prior reports about adverse events, we made a series of recommendations to AHRQ, the coordinating body for healthcare quality improvement, and to CMS, the largest healthcare payer and Federal overseer of patient safety and CoP compliance in LTCHs. In response, AHRQ and CMS took important steps to raise awareness of adverse events and to reduce harm to patients. In 2011, CMS introduced its Partnership for Patients initiative, a public and private collaboration to improve healthcare quality and safety, including during transitions from acute to post-acute care. CMS also finalized a tool for hospital surveyors to assess QAPI programs in 2014, and compiled resources and information about adverse events and temporary harm events at a website specific to SNF resident safety.

AHRQ and CMS should tailor their ongoing efforts to improve patient safety to address the specific needs of LTCHs. Although LTCHs provide acute-level services and are required to meet the same Federal requirements as acute-care hospitals, they serve a population that typically requires high-acuity care for longer periods of time. These patients have an increased exposure to medical interventions and, therefore, an increased risk of harm. AHRQ and CMS should attend to the unique needs and vulnerabilities associated with this setting.

We recommend:

AHRQ and CMS should collaborate to create and disseminate a list of potential adverse events in LTCHs

Identification of patient harm is critical to the success of patient safety efforts, providing facility staff the information to correct problems and reduce harm. Our physician review of medical records found that many events were the result of substandard care or medical errors. They also found that Medicare patients in LTCHs were particularly susceptible to some

types of harm. AHRQ and CMS should seek appropriate opportunities within their existing programs to raise awareness of the types of harm events that occur in LTCHs.

In response to OIG recommendations in earlier reports about adverse events in acute-care hospitals, SNFs, and rehab hospitals, AHRQ and CMS collaborated to create lists of potentially reportable adverse events. The lists are in various stages of review and use, but have been used by the agencies and facilities to inform providers, measure performance, and/or to promote safety. Such a list could also be used as a resource for educating LTCH staff about patient safety and developing ways to measure facility performance. AHRQ and CMS should expand these efforts to provide information about adverse events and temporary harm events in LTCHs. This list could be an addendum to the list of acute-care hospital events or a stand-alone document specific to LTCHs.

This study identified a high rate of harm, illustrating not only common events but representing a broad range of potential harm that occurred in this complex patient population. AHRQ and CMS should use this list to highlight the most common types of harm in LTCHs, as well as the broader range of events identified in all settings and that providers may not routinely consider in safety practices. Appendix F of this report provides descriptions of the events found in our sample, which could serve as a starting point for AHRQ and CMS efforts.

CMS should include information about potential events and patient harm in its quality outreach to LTCHs

CMS efforts to improve safety practices in acute-care hospitals apply to LTCHs, but additional education tailored to LTCHs would further promote safe care practices and bring attention to the special needs of LTCH patients. The educational correspondence or materials should include a definition of "adverse events;" a list of potential adverse events for staff education on the range of harm that patients can experience; evidence-based best practices for reducing harm in the LTCH setting; and best practices for improving staff identification and reporting of adverse events. Sharing patient safety education tailored to LTCHs will complement the efforts underway for acute-care hospitals, SNFs, and rehab hospitals.

AGENCY COMMENTS AND OIG RESPONSE

CMS and AHRQ concurred with our recommendations. Both agencies responded that they will work collaboratively to create and disseminate a list of potential adverse events in LTCHs. CMS responded that it will include information about potential events in its outreach to LTCHs, including newsletters, webpages, and technical assistance. Additionally, CMS described its ongoing efforts to improve the quality of care and reduce adverse events in LTCHs, including its oversight of LTCH QAPI programs and administration of the LTCH quality reporting program.

OIG appreciates the agencies' concurrence and continued commitment to improving patient safety. Adverse events and temporary harm events are common in LTCHs and are often preventable. It is important that AHRQ and CMS take action to include LTCHs in patient safety efforts. A better understanding of the potential for and types of patient harm in LTCHs will assist providers and overseers in identifying and reducing patient harm.

For the full text of the comments, please see Appendix G.

APPENDIX A: Methodology for Identifying Events and Determining Preventability

We conducted a two-stage medical record review to identify adverse events and temporary harm events that affected the sampled beneficiaries. In the first stage, two registered nurses (referred to as "screeners") identified possible patient harm events using a trigger tool methodology and "flagged" the medical records of those patients. Records flagged by nurses were reviewed in the second stage of the medical record review. The second stage included comprehensive medical record reviews conducted by one of seven contracted physicians. Every record was reviewed by a screener and, if flagged, reviewed by a physician.

Stage One: Nurse Review. To identify beneficiaries who were likely to have experienced events during their stays, screeners reviewed medical records for the LTCH stays using a trigger tool. The trigger tool was based on the IHI GTT instrument that we modified for the LTCH environment.[42] (See Appendix C.) The protocol requires screeners to look for "triggers" that indicate possible patient harm.

A trigger is a clue that may be the result of an event. It could inherently be the harm, such as a pressure ulcer, or a reference that indicates possible harm, such as transfer to a higher level of care. The triggers served as alerts, prompting the screeners to explore the records further. The trigger tool also included options to select "other" if harm was found but was not related to a listed trigger. The screeners used the triggers to find possible events, but only flagged the records for which they determined that adverse or temporary harm events likely occurred.

For each possible event, the screeners recorded a description of the event and the level of harm. Of the 587 beneficiaries in the sample, screeners flagged 326 beneficiaries' records (56 percent) for the second stage of review. The flagged records could include more than one possible event.

The screening process enabled us to reduce the number of cases requiring a comprehensive medical record review by a physician. As in the other OIG studies of adverse event incidence, physician reviewers indicated that the results of the stage one screening helped them to readily identify potential events for consideration.

Stage Two: Physician Review. One of seven physicians reviewed the medical records for each of the 326 beneficiaries flagged in the initial screening. The physician reviewers represented a variety of specializations and experience, including cardiology, infectious disease, internal medicine,

[42] Griffin, Loc. cit.

orthopedic surgery, geriatrics, neurology, and physiatry. One of the physicians was an LTCH physician and a Certified Medical Director accredited by the Society for Post-Acute and Long-Term Care Medicine. Six of the seven served as physician reviewers in prior OIG studies of adverse events. The physician reviewers also consulted with a geriatric psychiatrist and a pulmonologist/intensivist in a few particularly complex cases.

The physician reviewers conducted thorough reviews of the complete medical records and also read other information made available to them (e.g., administrative data, hospital discharge summaries from prior hospitalizations, and select readmission records). Physicians independently identified adverse events and temporary harm events and also confirmed or dismissed the potential events identified by the screeners in the first stage of review. For each event identified, the physician reviewers followed a structured protocol that required them to describe the event, the relevant evidence and its location in the medical record, the level of harm experienced by the patient, and whether the event was preventable.

Physician Guidance Document. Physicians used a guidance document to assess cases. The guide provides definitions and considerations for specific types of events and includes a list of frequently asked questions. The guide was built using clinical research literature, professional and Government guidelines, decisions made in prior OIG studies, and consultations with subject-matter experts.

The guidance also provides instructions that are applicable to a wide range of cases, including how to assess event timing, underlying disease, related events, and recurring events:

- Present on admission—We excluded events that occurred before the patient entered the LTCH or were attributable to care provided prior to admission.
- Underlying disease—We excluded events that were part of the underlying disease.
- Related events—When an initial event caused a series of related and dependent events, we combined the events into a "cascade" event and counted it as a single event.
- Recurring events—When an event recurred during an LTCH stay (e.g., two episodes of hypoglycemia), we considered the timeframe and the circumstances of the event. We counted recurring events as a single event if they happened under similar circumstances or were less than 7 days apart. We counted them as separate events if the circumstances that led to the events were different or the events were more than 7 days apart.

Assessment of Severity. As in prior OIG studies, physician reviewers assigned each event to one of five levels of harm using a modified version of the NCC MERP Index. The levels ranged between E (temporary harm) and I (contributing to death). (See Exhibit 1 on page 6.) However, a new issue emerged in the LTCH environment—the distinction between E-level temporary harm and F-level adverse events was less clear. Patients enter LTCHs with complex medical issues for an extended time, making it difficult to determine whether an event prolonged the length of the stay, and because LTCHs provide the same services as acute-care hospitals, serious events may not require transfers to other facilities.

As a result, we revised the definition associated with the F-level of harm. In prior OIG studies, the F-level of harm included events that prolonged the stay or required transfer to another facility for observation, emergency treatment, or inpatient care. In this study, we also included events that became the primary reason for the patient's care as F-level.

Assessment of Preventability. The physician reviewers assigned each event to one of five preventability determinations and identified factors that contributed to the events. (See the five-point scale in Exhibit A-1.) Physicians also selected a rationale for each determination based on a list of 16 contributing factors gleaned from prior research and experience in OIG studies of adverse events.

Preventability determinations are necessarily subjective and required the physicians to use clinical experience and judgment. Physicians based decisions on the circumstances of the specific case and also considered accepted standards of care, the expected frequency of certain events, guidance developed during the review process, and group discussion of the patients and cases.

Exhibit A-1: Preventability Determinations

Preventability Determination	Description
Clearly Preventable	Patient harm could definitely have been avoided through improved assessment or alternative actions.
Likely Preventable	Patient harm could likely have been avoided through improved assessment or alternative actions.
Likely Not Preventable	Patient harm could likely not have been avoided given the complexity of the patient's condition or the care required.
Clearly Not Preventable	Patient harm could definitely not have been avoided given the complexity of the patient's condition or the care required.
Unable to Determine	Physicians were unable to determine preventability because of incomplete documentation or case complexity.

Source: *Adverse Events in Long Term Care Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-14-00530).

Assessing an event as *clearly* preventable or *clearly not* preventable required a greater degree of certainty on the part of the reviewer. The expanded scale enabled physicians to make more precise determinations, while our primary statistics collapse *clearly* and *likely* into the larger categories of *preventable* or *not preventable*.

Physician reviewers had access to an OIG-developed algorithm to assist with difficult preventability decisions. The algorithm consisted of a series of questions that led the reviewers to a suggested response. Questions addressed issues such as whether there was a medical error, whether the event could have been anticipated, and how frequently the event occurred given proper care. Physicians could use the algorithm to inform their decision, but also used their clinical judgment to determine whether the suggested response was appropriate in the particular case.

Consistency Discussions and Quality Assurance Reviews. To promote consistency across physician reviewers, we facilitated 19 conference calls during which physician reviewers discussed cases that were complex, difficult to assess, involved issues outside their area of expertise, or had possible implications for other cases. The goal of these calls was to reach consensus and to establish consistency among the reviewers. During the weekly conference calls, we required physicians to discuss all *clearly preventable* and *clearly not preventable* determinations and events that may have contributed to a patient's death. We also encouraged them to bring other cases for discussion at their discretion. We documented the discussions and used the resulting decisions to continually revise our written physician guidance document to further promote consistency.

We also conducted separate quality assurance reviews and discussed any inconsistencies with the reviewers. We compared the identified events, harm-level determinations, and preventability determinations across groups and looked for deviations from our physician guidance document. We then shared the results with physicians and in some cases, changed determinations as a result of the new information and analysis.

Data Analysis

We analyzed the results of the review and generated national estimates of incidence as well as preventability rates. For estimates and corresponding 95-percent confidence intervals, see Appendix D.

Incidence Analysis. We estimated the incidence rates as the percentage of beneficiaries in LTCHs who experienced at least one harm event within the population from which we selected the sample, Medicare beneficiaries admitted to LTCHs during March 2014.

As an additional measure, we calculated two ratios of incidence density: events per 1,000 patient days and events per 100 hospital admissions.[43] These measures are commonly used by hospitals and medical researchers.[44] See Appendix E for further explanation of the calculation method.

Preventability Analysis. We estimated percentages for each preventability classification and for different types of events. We also conducted statistical tests to identify significant differences in preventability rates between adverse events and temporary harm events and across various categories of adverse events, such as medication-related and infection-related events at the 95-percent confidence level.

[43] To be consistent with the overall incidence of harm events, we limited the length of stay to 25 days in the incidence density calculation.

[44] K.M. Arias, *Outbreak Investigation, Prevention, and Control in Health Care Settings: Critical Issues in Patient Safety*, Second Edition, Jones and Bartlett Publishers, 2009, pp. 330-331.

APPENDIX B: Glossary of Selected Terms

Acute kidney injury—Sudden loss of the kidneys' ability to remove waste, also referred to as acute renal insufficiency.

Adverse event—Harm to a patient as a result of medical care or in a healthcare setting, including the failure to provide needed care.

Anticoagulant—Medication that hinders blood coagulation, typically used to avoid blood clots and referred to as blood-thinning medication.

Arrhythmia—Condition of abnormal cardiac (heart) rhythm.

Aspiration—Accidental inhalation of foreign material into the lungs.

Congestive heart failure—Condition in which the heart is unable to maintain adequate circulation of blood in the tissues of the body.

Conjunctivitis—Infection or inflammation of the mucous membrane of the eye or eyelid.

Deep vein thrombosis (DVT)—A condition marked by the formation of a thrombus (blood clot) within a deep vein (as of the leg or pelvis) that is potentially life threatening if dislodgment of the thrombus results in pulmonary embolism blocking the pulmonary (lung) artery.

Delirium—Mental disturbance characterized by acute confusion, disordered speech, and hallucinations.

Dialysis—Medical procedure to remove wastes and toxins from the blood, and to adjust fluid and electrolyte imbalances.

Hypoglycemia—Condition of abnormally low blood sugar (glucose) level.

Hypotension—Condition of abnormally low blood pressure.

Ileus—Partial or complete obstruction of the bowel, marked by a painful distended abdomen, vomiting, toxemia, and dehydration.

Methicillin-resistant *Staphylococcus aureus* (MRSA)—Bacteria that are resistant to many antibiotics. MRSA can cause a variety of problems including skin infections, sepsis, pneumonia, and bloodstream infections.

Obstipation—Condition of severe constipation (abnormally delayed passage of dry, hardened feces) that can result in bowel obstruction.

Percutaneous Endoscopic Gastrostomy (PEG)—A procedure in which a flexible feeding tube is placed through the abdominal wall and into the stomach. This allows nutrition, fluids, and/or medications to be put directly into the stomach, bypassing the mouth and esophagus.

Peripherally inserted central catheter (PICC)—A device used to draw blood and give treatments, including intravenous fluids, drugs, or blood

transfusions. A thin, flexible tube is inserted into a vein in the upper arm and guided (threaded) into a large vein above the right side of the heart called the superior vena cava. A needle is inserted into a port outside the body to draw blood or give fluids. A PICC may stay in place for weeks or months and helps avoid the need for repeated needle sticks.

Pressure ulcer/injury—Ulceration of tissue deprived of adequate blood supply by prolonged pressure, also called decubitus ulcer and bedsore. Pressure ulcers/injuries are classified into four stages: Stage 1 is intact skin with nonblanchable redness; Stage 2 is a shallow ulcer or blister indicating damage to the epidermis; Stage 3 is damage extending through all layers of the skin; and Stage 4 is damage through all the layers of the skin and underlying muscle, tendons, or bone.[45]

Pulmonary embolism—Obstruction of the pulmonary (lung) artery, often marked by shortness of breath; chest pain with inhalation; and, in severe cases, low blood pressure and death.

Sepsis—Systemic response to a serious, usually localized infection of bacterial origin, such as inflammatory response syndrome.

Tachycardia—Condition of rapid heart rate.

Temporary harm event—Harm to patient that required intervention but did not cause lasting harm, classified as E level on patient harm index.

Thrush—Inflammation of the mouth and throat, caused by fungus.

Urinary tract infection (UTI)—Infection of the tract through which urine passes and can include the kidney, ureters, bladder, and/or urethra.

Volume overload—Condition in which there is too much fluid in the body, such as fluid given intravenously (by vein) at a higher rate or larger volume than can be absorbed or excreted.

[45] Press release: "National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury." Accessed at http://www.npuap.org/ on March 8, 2018.

APPENDIX C: LTCH Trigger Tool Worksheet

The IHI GTT uses "triggers" to signal possible adverse events and temporary harm events. For this study, OIG and its contracted clinical consultants built a "trigger tool" specific to LTCH stays based on the IHI GTT. To develop this trigger tool, we reviewed and selected triggers from the IHI GTT and from among the triggers that were included in prior OIG studies. We chose triggers that the clinicians determined to be most applicable to LTCH stays. See exhibit C-1 for the list of triggers used for this study.

Exhibit C-1: Triggers Listed on the Trigger Tool Worksheet

Care Module Triggers		Care Module Triggers (continued)	
C1	Acute mental status change	C22	Urinary retention
C2	Aspiration	C23	New onset diarrhea
C3	Call to physician or family members	C24	Prolonged constipation or obstipation
C4	Code, Rapid Response Team, or Emergency Medical Services	C25	Diagnostic radiology or imaging studies
C5	Death	C26	New or worsening contracture
C6	Drop in hemoglobin or hematocrit, or unplanned transfusion	C27	Transfer to higher level of care within facility
C7	Studies for emboli, pulmonary embolism, or deep venous thrombosis	C28	Care—Other
C8	Fall	Medication Module Triggers	
C9	Family complaint	M1	Abnormal electrolytes
C10	Any infection	M2	Abrupt medication stop
C11	New or increased diuretics	M3	Anti-emetic use
C12	High or low body temperature	M4	Diphenhydramine (Benadryl) use
C13	In LTCH stroke or transient ischemic attack	M5	Elevated international normalized ratio (INR) or partial thromboplastin time greater than 100 seconds
C14	New or worsening onset of incontinence	M6	Glucose less than 50, Glucagon or Dextrose supplement given
C15	Insertion or use of urinary catheter	M7	Abrupt onset hypotension
C16	Patient incident or accident	M8	Naloxone (Narcan) use
C17	Pressure ulcer	M9	Flumazenil (Romazicon) use
C18	Emergency department visit	M10	Epinephrine or Norepinephrine use
C19	Unplanned transfer to acute-care hospital (including admission thru emergency department or to an observation unit)	M11	Sodium Polystyrene (Kayexalate administration)
C20	Restraint use	M12	Abnormal drug levels
C21	Rising serum creatinine or acute dialysis	M13	Thrombocytopenia

Medication Module Triggers (continued)		Medication Module Triggers (continued)	
M14	Total white blood count less than 3000 or greater than 12,000	M20	Medication—Other
M15	Vitamin K administration (AquaMephyton)	Procedure Module Triggers	
M16	Antibiotics started in LTCH	P1	Postoperative or postprocedure complication
M17	Beginning or increasing pain medication	P2	Procedure intubation, reintubation, recanulation, new Bilevel Positive Airway Pressure (BiPAP), or new Continuous Positive Airway Pressure (CPAP)
M18	New administration of parenteral fluid	P3	Postoperative or postprocedure troponin level of greater than 1.5 ng/ml
M19	Rising alanine aminotransferase (ALT) / aspartate aminotransferase (AST)—Liver Function Test	P4	Procedure—Other

Source: *Adverse Events in Long Term Care Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-14-00530).

Appendix D: Estimates, Confidence Intervals, and Key Statistics

The estimates included in this report are based on a sample of 587 Medicare patients admitted to LTCHs during March 2014. The resulting incidence rates were projected to the population of 11,212. Below, we present the corresponding 95-percent confidence intervals. See exhibit D-1 for beneficiary level statistics and exhibit D-2 for event level statistics.

Exhibit D-1: Beneficiary Level Estimates, Confidence Intervals, and Key Statistics

Estimate Description	Sample Size (n)	Percentage of Beneficiaries	95-Percent Confidence		Number of Beneficiaries	95-Percent Confidence	
			Lower Bound	Upper Bound		Lower Bound	Upper Bound
Event Experiences for All Beneficiaries							
Experienced at least one adverse or temporary harm event	587	46.0%	42.1%	49.9%	5,157	4,712	5,602
Experienced at least one preventable adverse or temporary harm event	587	30.0%	26.5%	33.7%	3,362	2,954	3,769
Experienced at least one adverse event	587	21.3%	18.2%	24.7%	2,388	2,024	2,751
Experienced at least one preventable adverse event	587	13.8%	11.3%	16.8%	1,547	1,241	1,853
Experienced at least one temporary harm event and no adverse event	587	24.7%	21.5%	28.3%	2,770	2,386	3,153
Experienced at least one preventable temporary harm event and no adverse event	587	14.1%	11.6%	17.1%	1,585	1,276	1,894
Experienced multiple events	587	21.8%	18.7%	25.2%	2,445	2,078	2,812
I-level harm—Experienced adverse event that contributed to death	587	5.1%	3.6%	7.2%	573	378	768
H-level harm—Experienced adverse event that required intervention to sustain the patient's life	587	5.1%	3.6%	7.2%	573	378	768

G-level harm—Experienced adverse event that contributed to or resulted in permanent patient harm	587	1.5%	0.8%	2.9%	172	63	281
F-level harm—Experienced adverse event that resulted in prolonged LTCH stay or became primary reason for treatment	587	11.9%	9.6%	14.7%	1,337	1,050	1,624
Transferred to an acute-care hospital because of an adverse or temporary harm event	587	4.9%	3.5%	7.0%	554	362	746
Experienced a cascade event	587	7.3%	5.5%	9.7%	821	590	1,052
Diagnosed with diabetes	587	42.1%	38.2%	46.0%	4,718	4,277	5,158
Experienced hypoglycemic episode	587	9.7%	7.6%	12.3%	1,089	826	1,351
Beneficiaries Who Experienced at Least One Adverse Event or One Temporary Harm Event							
Transferred to an acute-care hospital as the result of an adverse or temporary harm event	270	10.7%	7.6%	14.9%	554	362	746
Experienced a cascade event	270	15.9%	12.1%	20.7%	821	591	1,052
Beneficiaries Who Experienced at Least One Adverse Event							
Experienced adverse event that contributed to death (I-level harm)	125	24.0%	17.5%	32.0%	573	378	768
Experienced multiple adverse or temporary harm events	125	56.0%	47.4%	64.2%	1,337	1,050	1,624
Experienced multiple adverse events	125	16.8%	11.3%	24.2%	401	237	566
Experienced additional temporary harm event	125	39.2%	31.2%	47.8%	936	691	1,181
Beneficiaries Who Experienced at Least One Temporary Harm Event and No Adverse Events							
Experienced multiple temporary harm events	145	40.0%	32.5%	48.0%	1,108	844	1,372
Beneficiaries with Diabetes							
Experienced at least one adverse event or temporary harm event	247	50.2%	44.1%	56.3%	2,368	2,006	2,731
Experienced at least one hypoglycemic event	247	18.2%	14.0%	23.4%	860	624	1,095

Source: Office of Inspector General analysis of LTCH stays for 587 Medicare beneficiaries in March 2014.

Exhibit D-2: Event Level Estimates, Confidence Intervals, and Key Statistics

Estimate Description	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
All Adverse Events and Temporary Harm Events				
Temporary harm event (E-level harm)	456	67.1%	62.6%	71.3%
Adverse harm event	456	32.9%	28.7%	37.4%
F-level harm—Prolonged LTCH stay or hospital admission	456	17.3%	14.1%	21.1%
G-level harm—Permanent patient harm	456	2.0%	1.1%	3.6%
H-level harm—Life-sustaining intervention required	456	7.0%	5.0%	9.8%
I-level harm—Contributing to or resulting in death	456	6.6%	4.7%	9.2%
Cascade event	456	9.6%	7.3%	12.6%
Resulted in transfer to an acute-care hospital	456	7.0%	5.0%	9.9%
Clinical Category for All Adverse Events and Temporary Harm Events				
Medication adverse and temporary harm event	456	43.2%	38.9%	47.6%
Medication-related adverse event	197	10.1%	7.6%	13.2%
Medication-related temporary harm event	197	32.9%	28.9%	37.1%
Infection adverse and temporary harm event	456	32.7%	28.8%	36.8%
Infection-related adverse event	149	14.9%	12.0%	18.3%
Infection-related temporary harm event	149	17.8%	14.5%	21.6%
Patient care adverse and temporary harm event	456	24.1%	20.6%	28.0%
Patient-care related adverse event	110	7.7%	5.6%	10.4%
Patient-care related temporary harm event	110	16.4%	13.4%	20.1%
Level of Harm and Preventability for Adverse Events				
F-level harm—Prolonged LTCH stay or hospital admission	150	52.7%	44.7%	60.5%
G-level harm—Permanent patient harm	150	6.0%	3.2%	10.8%
H-level harm—Life-sustaining intervention required	150	21.3%	15.5%	28.6%
I-level harm—Contributing to or resulting in death	150	20.0%	14.5%	26.9%
Preventable events	150	62.0%	54.0%	69.4%
Clinical Category and Event Types for Adverse Events				
Adverse event related to infections	150	45.3%	37.8%	53.1%
LTCH-acquired respiratory infection	150	23.3%	17.6%	30.2%
Sepsis not associated with another event	150	6.7%	3.6%	11.9%

Vascular-catheter associated infection	150	4.7%	2.3%	9.2%
Clostridium difficile infection	150	2.7%	1.0%	6.6%
Surgical site infection	150	2.7%	1.0%	6.6%
Urinary tract infection associated with urinary catheter	150	2.0%	0.7%	5.8%
Other infection-related event	150	3.3%	1.4%	7.6%
Adverse events related to medication	150	31.3%	24.5%	39.1%
Bleeding associated with anticoagulant	150	8.7%	5.3%	13.9%
Hypoglycemic event	150	8.7%	5.2%	14.2%
Delirium and other changes in mental status	150	6.0%	3.0%	11.6%
Fluid, electrolyte, and metabolic disorders	150	2.7%	1.0%	6.7%
Acute kidney injury or insufficiency	150	2.0%	0.7%	5.9%
Other medication-related adverse event	150	3.3%	1.4%	7.6%
Adverse events related to patient care	150	23.3%	17.5%	30.4%
Respiratory issues other than infections	150	4.7%	2.3%	9.3%
Venous thromboembolism, deep vein thrombosis, or pulmonary embolism	150	4.7%	2.3%	9.3%
Pressure ulcer	150	3.3%	1.4%	7.6%
Bleeding not associated with anticoagulant	150	2.7%	1.0%	6.6%
Fluid, electrolyte, and metabolic disorder	150	2.0%	0.7%	5.8%
Other patient care-related adverse event	150	6.0%	3.2%	10.8%
Preventability for Temporary Harm Events				
Preventable event	306	49.7%	44.0%	55.4%
Clinical Category and Event Types for Temporary Harm Events				
Temporary harm events related to medication	306	49.0%	43.6%	54.5%
Hypoglycemic event	306	17.3%	13.4%	22.1%
Delirium and other changes in mental status	306	10.1%	7.4%	13.8%
Bleeding associated with anticoagulants	306	5.2%	3.2%	8.5%
Constipation, obstipation, or ileus	306	5.2%	3.3%	8.3%
Acute kidney injury or insufficiency	306	2.9%	1.6%	5.5%
Allergic reaction	306	2.9%	1.6%	5.4%
Other medication-related temporary harm event	306	5.2%	3.3%	8.2%
Temporary harm events related to infection	306	26.4%	21.9%	31.6%
Soft tissue or other nonsurgical infection	306	9.2%	6.5%	12.7%
Thrush	306	4.2%	2.5%	7.0%

Urinary tract infection associated with urinary catheter	306	3.6%	2.0%	6.3%
Clostridium difficile infection	306	2.9%	1.6%	5.4%
LTCH-acquired respiratory infection	306	2.9%	1.6%	5.4%
Other infection-related temporary harm event	306	3.6%	2.1%	6.2%
Temporary harm event related to patient care	306	24.5%	20.1%	29.5%
Pressure ulcer	306	6.5%	4.2%	10.1%
Bleeding not associated with anticoagulant	306	3.3%	1.8%	5.9%
Venous thromboembolism, deep vein thrombosis, or pulmonary embolism	306	3.3%	1.8%	5.9%
Skin tear, abrasion, or breakdown	306	2.9%	1.6%	5.4%
Fall with injury	306	2.3%	1.1%	4.6%
Other patient-care-related temporary harm event	306	6.2%	4.0%	9.5%
Preventability Classification for All Adverse Events and Temporary Harm Events				
Preventable adverse and temporary harm event	456	53.7%	49.0%	58.3%
Clearly preventable	456	7.2%	5.2%	10.0%
Likely preventable	456	46.5%	42.0%	51.1%
Not preventable adverse and temporary harm event	456	45.2%	40.6%	49.8%
Likely not preventable	456	42.1%	37.6%	46.7%
Clearly not preventable	456	3.1%	1.8%	5.2%
Unable to determine preventability of adverse and temporary harm event	456	1.1%	0.5%	2.6%
Preventable adverse event	456	20.4%	16.9%	24.4%
Clearly preventable adverse event	456	3.3%	2.0%	5.5%
Likely preventable adverse event	456	17.1%	13.8%	21.0%
Not preventable adverse event	456	11.8%	9.2%	15.2%
Likely not preventable adverse event	456	11.6%	9.0%	14.9%
Clearly not preventable adverse event	456	0.2%	0.0%	1.5%
Unable to determine preventability of adverse event	456	0.7%	0.2%	2.0%
Preventable temporary harm event	456	33.3%	28.9%	38.1%
Clearly preventable temporary harm event	456	3.9%	2.5%	6.2%
Likely preventable temporary harm event	456	29.4%	25.3%	33.8%
Not preventable temporary harm event	456	33.3%	29.2%	37.7%
Likely not preventable temporary harm event	456	30.5%	26.4%	34.9%
Clearly not preventable temporary harm event	456	2.9%	1.6%	4.9%

Unable to determine preventability of temporary harm event	456	0.4%	0.1%	1.7%
Rationales for All Events Determined To Be Preventable				
Substandard treatment or preventive care	245	57.6%	51.3%	63.6%
Error related to medical judgment, skill, or management	245	33.9%	27.9%	40.4%
Patient progress not adequately monitored	245	25.3%	20.1%	31.4%
Patient care plan was inadequate	245	23.3%	18.3%	29.1%
Necessary treatment was not provided	245	18.4%	14.1%	23.5%
Equipment failure or other breakdown	245	2.9%	1.3%	6.3%
Poor communication among caregivers	245	2.4%	1.1%	5.2%
Lack of access to physician or specialist	245	2.0%	0.9%	4.7%
Admission assessment was inadequate for patient	245	1.6%	0.6%	4.2%
Other	245	11.8%	8.4%	16.5%
Rationales for All Events Determined To Be Not Preventable				
Patient was highly susceptible to event because of health status	206	80.6%	75.0%	85.2%
Patient's diagnosis was unusual or complex, making care difficult	206	35.9%	29.1%	43.3%
Event occurred despite proper assessment and procedures	206	23.8%	18.0%	30.7%
Care provider could not have anticipated the event with information available at the time	206	12.1%	8.4%	17.2%
Harm was anticipated but was considered acceptable given alternatives	206	12.1%	8.1%	17.7%
Other	206	4.4%	2.2%	8.5%

Source: Office of Inspector General analysis of LTCH stays for 587 Medicare beneficiaries in March 2014.

APPENDIX E: Rates of Adverse Events and Temporary Harm Events by Patient Days and LTCH Admissions

Healthcare facilities commonly measure adverse events by incidence density, which takes into account the period during which patients are observed. For example, incidence density is often used in measuring healthcare-acquired infections because risk can increase with the length of exposure to the health care environment.[46] IHI cites advantages to using incidence density metrics over standard incidence rates that measure the number of events per patient.[47] IHI reports that measuring total events by patient days or hospital admissions enables hospitals to count multiple events experienced by the same patient.

The sample of 587 Medicare beneficiaries that entered an LTCH in March 2014 included 588 total hospital stays (admissions) and a total of 12,000 days in the hospital (patient days). We calculated patient days by subtracting the admission date for each LTCH stay from its discharge date. To be consistent with the overall incidence of harm events, we limited the length of stay in this metric to a maximum of 25 days. Exhibit E-1 provides ratios for adverse events and temporary harm events in the sample per 1,000 patient days and per 100 admissions. Exhibit E-2 provides the rates of harm events per 1,000 patient days for SNFs, rehab hospitals, and acute-care hospitals, in addition to LTCHs.

Exhibit E-1: Rates of Adverse Events and Temporary Harm Events in the Sample by Patient Days and Hospital Admissions

Category	Per 1,000 Patient Days*	Per 100 Admissions
Adverse Events	13	26
Temporary harm events	26	52
Adverse events and temporary harm events combined	38	78

Source: Office of Inspector General analysis of LTCH stays for 587 Medicare beneficiaries in March 2014.
*The length of LTCH stay used in the incidence density analysis is capped at 25 days because the physician reviews were limited to the first 25 days of each stay.

[46] K.M. Arias, *Outbreak Investigation, Prevention, and Control in Health Care Settings: Critical Issues in Patient Safety* (Second Edition), Jones and Bartlett Publishers, 2009, pp. 330-331.
[47] Griffin, Op. cit., p. 13.

Exhibit E-2: Rates of Adverse Events and Temporary Harm Events per 1,000 Patient Days across Settings

Estimate Description	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Rate of harm event per 1,000 patient days in SNFs	653	24.3%	20.4%	28.1%
Rate of harm event per 1,000 patient days in rehab hospitals	417	29.3%	24.3%	34.3%
Rate of harm event per 1,000 patient days in LTCHs	587	38.0%	33.9%	42.1%
Rate of harm event per 1,000 patient days in acute-care hospitals	780	69.4%	61.2%	77.5%

Source: Office of Inspector General analysis of LTCH stays for 587 Medicare beneficiaries in March 2014, rehab hospital stays for 417 Medicare beneficiaries in March 2012, SNF stays for 653 Medicare beneficiaries in August 2011, and hospital stays for 780 Medicare beneficiaries in October 2008.

APPENDIX F: Adverse Events and Temporary Harm Events Identified in the Sample

Exhibits F-1 and F-2 contain information about adverse events and temporary harm events identified in the sample, including the description, harm level, and preventability. Exhibit F-1 contains information about adverse events (150 adverse events). Exhibit F-2 contains information about temporary harm events (306 events). Harm levels are labeled as F through I, in accordance with the NCC MERP Index. Preventability determinations are labeled as CP (clearly preventable), LP (likely preventable), LNP (likely not preventable), CNP (clearly not preventable), and UTD (unable to determine.)

Exhibit F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=150)

Adverse Event	Harm Level	Preventability
Adverse Events Related to Infections (68)		
LTCH-acquired respiratory infections (35)		
1. Pneumonia contributing to patient death	I	LP
2. Pneumonia contributing to patient death	I	LP
3. Respiratory syncytial virus (RSV) pneumonia associated with aspiration resulting in transfer to an acute-care hospital and contributing to death	I	LP
4. Pneumonia contributing to patient death	I	LNP
5. Cascade with pneumonia leading to hypotension and hypoxia and ultimately death	I	UTD
6. Pneumonia with septic shock (*Klebsiella pneumoniae*) resulting in an acute-care hospital admission and contributing to death	I	UTD
7. Pneumonia and respiratory failure with delayed recognition and treatment resulting in transfer to an acute-care hospital	H	LP
8. Pneumonia	H	LNP
9. Aspiration and respiratory failure	H	LNP
10. Pneumonia with respiratory failure requiring intubation and sending to an acute-care hospital	H	LNP
11. Cascade with aspiration pneumonia leading to sepsis leading to acute kidney injury	G	LNP
12. Cascade in which tracheal laceration led to decreasing oxygen saturation resulting in sending to an acute-care hospital for treatment	F	CP
13. Aspiration pneumonitis/pneumonia with inadequate preventive care	F	LP

14. Cascade with opioids (respiratory depressant) complicated by morbid obesity and sleep apnea leading to aspiration pneumonia	F	LP
15. Cascade with respiratory infection while on ventilator leading to acute kidney injury and hyperkalemia (K+ 6.2)	F	LP
16. Pneumonia while on ventilator	F	LP
17. Pneumonia with delayed recognition and treatment	F	LP
18. Aspiration pneumonia	F	LNP
19. Aspiration pneumonia	F	LNP
20. Cascade with pneumonia leading to septic shock	F	LNP
21. Cascade with pneumonia leading to septic shock while on a ventilator	F	LNP
22. Pneumonia	F	LNP
23. Pneumonia	F	LNP
24. Pneumonia	F	LNP
25. Pneumonia while on a ventilator	F	LNP
26. Pneumonia resulting in an acute-care hospital admission	F	LNP
27. Pneumonia while on a ventilator	F	LNP
28. Pneumonia while on ventilator	F	LNP
29. Pneumonia while on ventilator	F	LNP
30. Pneumonia while on ventilator	F	LNP
31. Pneumonia while on ventilator	F	LNP
32. Pneumonia with dyspnea treated with BiPAP	F	LNP
33. Pneumonia/respiratory failure, suspected aspiration	F	LNP
34. Recurrent pneumonia	F	LNP
35. Tracheobronchitis while on ventilator	F	LNP
Sepsis not associated with other event types (10)		
1. Cascade with candidemia with widespread infection treated with ineffective medication for several days, leading to increased bruising, respiratory failure, and contributing to death	I	LP
2. Cascade with peritonitis in the wake of PEG placement followed by sepsis, hypotension, acute kidney injury, "shock liver," requiring treatment at an acute-care hospital and contributing to death	I	LP
3. Cascade with stage 4 infected pressure ulcer leading to septic shock and contributing to patient death	I	LP
4. Sepsis due to intra-abdominal sepsis associated with aspiration	I	LP
5. Sepsis with delayed recognition contributing to patient death	I	LP
6. Septic shock with worsening pulmonary status resulting in patient death	I	UTD

7. Cascade with septic shock related to urinary catheter with delayed recognition leading to respiratory failure and profound electrolyte imbalance resulting in an acute-care hospital admission	H	LP
8. Cascade with non-antiseptic debridement of sacral decubitus leading to sacral infection followed by blood stream infection requiring treatment at an acute-care hospital	F	LP
9. Sepsis with inadequate monitoring and delayed recognition	F	LP
10. Septicemia (MRSA and Klebsiella) with delayed recognition	F	LP
Vascular-catheter associated infections (7)		
1. Central line related sepsis/fungemia contributing to death	I	LP
2. Fungal central line-associated bloodstream infection leading to acute renal failure and contributing to death	I	LP
3. Probable PICC line infection (persistent Stenotrophomonas bacteremia) leading to septic shock and death with concurrent urinary tract infection (Acinetobacter multi-drug resistance [MDR]) associated with a urinary catheter	I	LP
4. PICC line associated with *Escherichia coli* sepsis contributing to patient death	I	LNP
5. PICC line associated with Enterococcus and transfer to an acute-care hospital	F	LP
6. Prolonged PICC line placement associated with sepsis	F	LP
7. Presumed dialysis catheter source of sepsis	F	LNP
Clostridium difficile infections (4)		
1. Cascade with severe *Clostridium difficile* infection with delayed diagnosis leading to sepsis resulting in toxic metabolic encephalopathy, treatment at an acute-care hospital	F	CP
2. *Clostridium difficile* infection	F	LP
3. *Clostridium difficile* infection	F	LP
4. *Clostridium difficile* infection following antibiotics	F	LP
Surgical site infections (4)		
1. Abdominal wall abscess associated with dislodged feeding tube which required sending to an acute-care hospital for treatment	F	LP
2. PEG site infection resulting in PEG change in an acute-care hospital	F	LP
3. Soft tissue infection at PICC entrance site extending into axilla	F	LP
4. Abscess at tracheostomy site	F	LNP
Urinary tract infections associated with urinary catheters (3)		
1. Cascade initiated by clinical urinary tract infection associated with urinary catheter leading to sepsis resulting in hypotension and admission to an acute-care hospital	F	LP

2. Cascade with clinical urinary tract infection associated with urinary catheter leading to septic shock	F	LP
3. CDC-defined catheter-associated urinary tract infection (CAUTI)	F	LP
Soft tissue or other nonsurgical infections (2)		
1. Infected, necrotic chest wall wound	F	LP
2. Ischial osteomyelitis	F	LNP
Ventilator-associated events (2)		
1. CDC-defined infection-related ventilator-associated complication	F	LNP
2. CDC-defined infection-related ventilator-associated complication	F	LNP
Other infection-related adverse events (1)		
1. Meningoencephalitis with delayed recognition contributing to patient death	I	LP
Adverse Events Related to Medication (47)		
Bleeding associated with anticoagulants (13)		
1. Gastrointestinal bleeding while on anticoagulant (intravenous heparin) contributing to death	I	CP
2. Epistaxis (significant bleeding from the nose) while on anticoagulants (heparin and aspirin) contributing to patient death	I	LNP
3. Cascade with gluteal hematoma while on anticoagulant (warfarin) leading to anemia and acute kidney injury and sent to an acute-care hospital for treatment	H	LP
4. Cascade with hematuria (excessive bleeding) while on anticoagulant (warfarin) following self-removed urinary catheter injury leading to hypotension and eventually requiring an acute-care hospital admission	H	LP
5. Cascade in which retroperitoneal bleeding due to anticoagulants (warfarin and enoxaparin) led to hypotension and blood loss anemia requiring transfusions	H	LNP
6. Cascade with significant epistaxis due to anticoagulation (warfarin) and tube feedings leading to aspiration pneumonia and transfer to an acute-care hospital	H	LNP
7. Large subdural hematoma while on heparin resulting in an acute-care hospital admission and surgical treatment	G	LNP
8. Iatrogenic traumatic oropharyngeal bleeding related to suctioning in patient with tracheostomy	F	LP
9. Penile bleeding while over-anti-coagulated (INR 4.5) leading to catheter change	F	LP
10. Hematuria (blood in urine) following urinary catheterization while on anticoagulation with warfarin	F	LNP
11. Lower gastrointestinal bleeding while on warfarin	F	LNP
12. Traumatic urinary catheter insertion in patient on an anticoagulant medication (enoxaparin) led to hemorrhage requiring transfusion	F	LNP

13. Heparin induced thrombocytopenia complicated by abdominal wall hematoma	F	CNP
Hypoglycemic events (13)		
1. Hypoglycemia with lethargy (blood glucose of 29, 46)	H	CP
2. Cascade with hypoglycemia with unresponsiveness and triggering a seizure (blood glucose of 22, 23, 25)	H	LP
3. Hypoglycemia requiring substantial administration of glucose (D50 x 2) followed by D10 infusion (blood glucose of 36, <20)	H	LP
4. Hypoglycemia with cool and clammy skin (blood glucose of 30, 33)	H	LP
5. Hypoglycemia with decreased responsiveness (blood glucose of 47, 37)	H	LP
6. Hypoglycemia with lethargy (blood glucose of 30)	H	LP
7. Hypoglycemia with lethargy on two separate occasions (blood glucose of 36, 22)	H	LP
8. Hypoglycemia with lethargy, clammy, and cool to the touch (blood glucose of 22, 38, 29)	H	LP
9. Hypoglycemia with somnolence (blood glucose of 27, 37)	H	LP
10. Hypoglycemia with unresponsiveness (blood glucose of 32)	H	LP
11. Severe hypoglycemia with hypothermia and confusion (blood glucose of 39)	H	LP
12. Hypoglycemia episodes over several days (blood glucose of 25, 40)	F	LNP
13. Hypoglycemia in a brittle diabetic (blood glucose ranging from 22 - 45)	F	LNP
Delirium and other changes in mental status (9)		
1. Cascade with oversedation while on multiple opioid medications leading to a fall resulting in a subdural hematoma, requiring acute-care hospital care, and ultimately death	I	CP
2. Altered mental status and respiratory failure secondary to opioids (hydromorphone and fentanyl)	H	CP
3. Lethargy with hypotension while on opioid pain medication (morphine immediate release)	H	CP
4. Respiratory depression while on opioid medication in morbidly obese patient	H	LNP
5. Cascade with confusion while on multiple psychotropic medications leading to fall with injury to shoulder	F	LP
6. Delirium while on antipsychotic medication (risperidone) and opioid (oxycodone)	F	LP
7. Failure to identify and treat delirium due to multiple medication (antihistamine [diphenhydramine] and anti-anxiety [benzodiazepine-alprazolam]) over several days	F	LP

8. Oversedation with hypotension due to multiple anti-anxiety and opioid medications	F	LP
9. Toxic metabolic encephalopathy due to opioid pain medication (oxycodone) with underlying renal and liver failure resulting in transfer to an acute-care hospital	F	LP
Fluid, electrolyte, and metabolic disorders related to medication (4)		
1. Severe hypothyroidism with inadequate treatment and contributing to death	I	CP
2. Volume overload with subsequent pulmonary edema in a patient unable to tolerate volume due to myxedema contributing to patient death	I	CP
3. Cascade with unrecognized and untreated hypothyroidism despite admission with thyroid-stimulating hormone of 28.2 (normal is 0.4-4) leading to myxedema resulting in cardiac arrest-pulseless ventricular tachycardia	H	CP
4. Hyponatremia secondary to medication (spironolactone); transferred to an acute-care hospital	F	LP
Acute kidney injury or insufficiency (3)		
1. Acute kidney injury due to vancomycin	G	LP
2. Acute kidney injury while on a diuretic (furosemide)	G	LNP
3. Acute kidney injury while on colistin resulting in altered mental status and requiring temporary dialysis	F	LNP
Other medication-related adverse events (5)		
1. Intracranial hemorrhage on anticoagulant medication (aspirin, clopidogrel, warfarin, and heparin) contributing to death	I	LNP
2. Omission of appropriate care for life-threatening digoxin level	H	CP
3. Hypotension with bradycardia and unresponsiveness due to antihypertensive medication (lisinopril and clonidine)	H	LP
4. Nausea and vomiting while on immunosuppressant (mycophenolate mofetil) to prevent transplant rejection	F	LNP
5. Unrecognized Stevens-Johnson Syndrome secondary to allopurinol	F	CP
Adverse Events Related to Patient Care (35)		
Respiratory issues (other than infections) (7)		
1. Cascade with aspiration with large amount of gastric contents in tracheal tube followed by cardiac arrest and failed resuscitation attempt contributing to death	I	LP
2. Respiratory distress associated with inadequate monitoring leading to intubation and death	I	LP
3. Aspiration with rhonchi, tachypnea and tachycardia leading to patient death in comfort care patient	I	LNP

4. Aspiration leading to transient hypoxemia with reduced gas exchange and preexisting malignant pleural effusions requiring treatment at an acute-care hospital	H	LP
5. Cascade with significant pleural effusion with failure to recognize and treat leading to respiratory acidosis and cardiac arrest during hemodialysis	H	LP
6. Respiratory failure with delayed response resulting in an acute-care hospital admission	H	LP
7. Mucus plug	F	LNP
Venous thromboembolisms, deep vein thrombosis, or pulmonary embolisms (7)		
1. Acute pulmonary embolus with inadequate prevention contributing to death	I	CP
2. Deep vein thrombosis of bilateral lower extremities with inadequate preventive care	F	LP
3. Pulmonary embolism resulting in transfer to intensive care unit associated with subtherapeutic INR after premature stopping of heparin	F	LP
4. Right upper lobe pulmonary embolus	F	LP
5. Deep vein thrombosis—occluded popliteal and superficial femoral veins	F	LNP
6. Deep vein thrombosis of bilateral lower extremities	F	LNP
7. Deep vein thrombosis upper extremity associated with PICC line	F	LNP
Fluid, electrolyte, and metabolic disorders (not medication related) (3)		
1. Hyperkalemia of 6.7 resulting in asystole/death	I	CP
2. Cascade with hyperkalemia (potassium of 6.2) leading to dysrhythmia due to failure hemodialysis and eventually resulting in related acute-care hospital admission	F	CP
3. Hyperkalemia ultimately treated successfully with fludrocortisone after delayed recognition	F	LP
Pressure ulcers (5)		
1. New sacrococcygeal pressure ulcer that progressed to stage 4 during LTCH stay	G	LP
2. Pressure ulcer of heel that progressed from stage 2 to unstageable during the LTCH stay	G	LP
3. Progression from stage 2 to stage 4 sacral pressure ulcer	G	LP
4. Heel pressure ulcer	F	LP
5. Stage 2 pressure ulcer of heel worsened during stay	F	LNP
Bleeding not associated with anticoagulants (4)		
1. Cascade with gastrointestinal bleeding leading to hypotension, transfusion, and norepinephrine infusion with delay in sending to an acute care hospital	H	LP

2. Acute gastrointestinal bleeding with delayed transfer to an acute-care hospital for treatment	F	LP
3. Bleeding at PEG insertion site	F	LNP
4. Cascade with Foley catheter obstruction leading to urethral dissection and bleeding resulting in blood loss anemia requiring transfusion	F	LNP
Acute kidney injury or insufficiency (2)		
1. Cascade initiated by failed catheter replacement resulting in urethral obstruction leading to renal failure and ultimately death (patient family refused dialysis)	G	LP
2. Acute kidney injury superimposed on chronic renal insufficiency (family refused dialysis)	G	LNP
Delirium and other mental status changes not associated with medication (2)		
1. Inadequately treated and monitored patient with oliguric renal failure who self-removed four hemodialysis catheters leading to death	I	LP
2. Cascade beginning with delirium leading to the dislodgement of the tracheal tube by the patient resulting in desaturation, hypoxemia, replacement of the tube, and aspiration pneumonia	H	LP
Fall with injury (2)		
1. Fall with recurrent right hip fracture associated with inadequate monitoring	F	LP
2. Fall with hip pain	F	LNP
Volume overload (2)		
1. Acute respiratory failure due to congestive heart failure exacerbated by intravenous fluids (fluid overload) contributing to death	I	LNP
2. Acute pulmonary edema due to volume overload from blood transfusion	H	LP
Urinary retention (1)		
1. Cascade with delayed diagnosis of urinary retention leading to nausea/vomiting and aspiration pneumonia	F	LP

Source: OIG analysis of LTCH stays for 587 Medicare beneficiaries entering an LTCH in March 2014.

Exhibit F-2: Temporary Harm Events by Clinical Category and Preventability (n=306)

Temporary Harm Event	Preventability
Temporary Harm Events Related to Medication (150)	
Hypoglycemic events (53)	
1. Hypoglycemia (blood glucose of 38)	CP
2. Hypoglycemia (blood glucose of 40, 46, 47)	CP
3. Hypoglycemia (blood glucose of 44, 29)	CP
4. Hypoglycemia (blood glucose of 44, 45)	CP
5. Hypoglycemia (blood glucose of 45)	CP
6. Hypoglycemia (blood glucose of 45, 49)	CP
7. Hypoglycemia (blood glucose of 46)	CP
8. Hypoglycemia (blood glucose of 48, 40)	CP
9. Hypoglycemia (blood glucose 41, 40, documented as <40, 40, 46, 41, 30, 39)	LP
10. Hypoglycemia (blood glucose documented as <49)	LP
11. Hypoglycemia (blood glucose of 21, 45, 44, 45)	LP
12. Hypoglycemia (blood glucose of 32)	LP
13. Hypoglycemia (blood glucose of 33, repeat 38)	LP
14. Hypoglycemia (blood glucose of 34, 38, 41)	LP
15. Hypoglycemia (blood glucose of 36)	LP
16. Hypoglycemia (blood glucose of 39)	LP
17. Hypoglycemia (blood glucose of 40)	LP
18. Hypoglycemia (blood glucose of 41)	LP
19. Hypoglycemia (blood glucose of 41)	LP
20. Hypoglycemia (blood glucose of 42)	LP
21. Hypoglycemia (blood glucose of 42)	LP
22. Hypoglycemia (blood glucose of 44)	LP
23. Hypoglycemia (blood glucose of 44)	LP
24. Hypoglycemia (blood glucose of 44)	LP
25. Hypoglycemia (blood glucose of 44)	LP
26. Hypoglycemia (blood glucose of 46)	LP
27. Hypoglycemia (blood glucose of 47, 48)	LP
28. Hypoglycemia (blood glucose of 49)	LP
29. Hypoglycemia (blood glucose of 49, 37)	LP
30. Hypoglycemia with lethargy (blood glucose of 38)	LP
31. Hypoglycemia with lethargy (blood glucose of 39)	LP
32. Hypoglycemia with lethargy (blood glucose of 48)	LP

33. Hypoglycemia with near syncope (blood glucose of 51)	LP
34. Hypoglycemia with symptoms (blood glucose of 30)	LP
35. Hypoglycemia with weakness (blood glucose of 30)	LP
36. Hypoglycemic episode (blood glucose of 46)	LP
37. Hypoglycemia (blood glucose <30)	LNP
38. Hypoglycemia (blood glucose of 31)	LNP
39. Hypoglycemia (blood glucose of 33)	LNP
40. Hypoglycemia (blood glucose of 36, 33)	LNP
41. Hypoglycemia (blood glucose of 39)	LNP
42. Hypoglycemia (blood glucose of 39, 49)	LNP
43. Hypoglycemia (blood glucose of 40)	LNP
44. Hypoglycemia (blood glucose of 42)	LNP
45. Hypoglycemia (blood glucose of 45)	LNP
46. Hypoglycemia (blood glucose of 46)	LNP
47. Hypoglycemia (blood glucose of 46)	LNP
48. Hypoglycemia (blood glucose of 46, 47)	LNP
49. Hypoglycemia (blood glucose of 47)	LNP
50. Hypoglycemia (blood glucose of 48)	LNP
51. Hypoglycemia (blood glucose of 48, 39)	LNP
52. Hypoglycemia (blood glucose of 48; repeat 45)	LNP
53. Hypoglycemia with symptoms (shakiness, blood glucose of 60)	LNP
Delirium and other changes in mental status (31)	
1. Delirium while on multiple sedating medications (antipsychotic [ziprasidone] and anti-anxiety [lorazepam])	CP
2. Delirium while on pain and anti-anxiety medication (opioid and benzodiazepine [diazepam])	CP
3. Mental status changes due to opioid analgesics (intravenous hydromorphone)	CP
3. Somnolence due to anti-anxiety medications (lorazepam and clonazepam), nonstandard prescription of benzodiazepines	CP
5. Altered mental status while on anti-anxiety benzodiazepine (clonazepam) medication	LP
6. Cascade in which somnolence in a patient with history of respiratory failure and multiple sedating (psychotropic and pain) medications with frequent falls resulting in back pain	LP
7. Cascade with oversedation and hypotension while on multiple opioids (oxycodone/acetaminophen and fentanyl patch) resulting in multiple falls with pain	LP
8. Confusion while on antiemetic (treatment of vomiting) medication (scopolamine patch)	LP

9. Delirium due to multiple medications (opioids and antidepressants)	LP
10. Delirium due to multiple sedating medications including opioid pain medication (intravenous hydromorphone), multiple psychotropic medications and gabapentin	LP
11. Delirium while on opioid medication (fentanyl)	LP
12. Hallucinations and agitation while on opioid analgesic medication (fentanyl and meperidine)	LP
13. Insomnia and anxiety related to polypharmacy	LP
14. Lethargy due to anti-anxiety medication (chlordiazepoxide)	LP
15. Lethargy while on antipsychotic (haloperidol) medication	LP
16. Lethargy while on multiple psychotropic medications (quetiapine, lorazepam, alprazolam) and opioid (fentanyl)	LP
17. Lethargy while on opioid given for pain (fentanyl)	LP
18. Oversedation due to opioid analgesic (hydrocodone)	LP
19. Oversedation while on anti-anxiety benzodiazepine (alprazolam) medication	LP
20. Somnolence while on anti-anxiety medication (alprazolam)	LP
21. Somnolence while on opioids (intravenous meperidine, hydrocodone, codeine) and antihistamine (diphenhydramine) medication	LP
22. Agitation and oversedation while on antipsychotic (quetiapine) with preexisting Alzheimer's disease	LNP
23. Altered mental status while on anti-anxiety benzodiazepine medication (lorazepam)	LNP
24. Cascade with schizoaffective disorder treated with quetiapine leading to delirium leading to a fall with contusion to head	LNP
25. Confusion and agitation while on anti-anxiety benzodiazepine (lorazepam) medication	LNP
26. Delirium while on antidepressants (mirtazapine and sertraline)	LNP
27. Delirium while on opioid (morphine) and muscle relaxant (cyclobenzaprine)	LNP
28. Delirium while on opioid medication and gabapentin superimposed on pre-existing metabolic encephalopathy	LNP
29. Lethargy while on an antidepressant medication (mirtazapine)	LNP
30. Oversedation while on opioid (hydrocodone)	LNP
31. Somnolence and sedation while on opioid (hydromorphone)	LNP
Constipation, obstipation, or ileus (16)	
1. Constipation with abdominal pain due to opioid pain medication	CP
2. Constipation with abdominal pain due to opioids and immobility	CP
3. Abdominal distension and discomfort while taking opioid analgesic (methadone)	LP
4. Constipation with abdominal distension while on opioid medication (morphine and hydrocodone)	LP

5. Constipation with abdominal distension and pain following opioid medication (hydrocodone and intravenous morphine)	LP
6. Constipation with abdominal distension while on opioid pain medication (hydrocodone)	LP
7. Constipation with abdominal pain while on iron sucrose	LP
8. Constipation with bloating and x-ray revealing abundant rectal stool while on opioid pain medication (oxycodone) and iron (ferrous sulfate)	LP
9. Constipation with distended abdomen while on prn (as needed) hydromorphone associated with inadequate care plan	LP
10. Constipation with fecal impaction and delayed diagnosis while on opioid pain medication (tramadol)	LP
11. Constipation/ileus with nausea while on opioids	LP
12. Fecal impaction with abdominal pain while on iron (ferrous sulfate)	LP
13. Constipation substantiated by x-ray with abdominal pain while on opioid medication (hydrocodone)	LP
14. Abdominal distension with kidneys, ureter, and bladder consistent with ileus while on opioid pain medication (morphine)	LNP
15. Constipation with abdominal discomfort after recently receiving opioid (hydrocodone)	LNP
16. Constipation with abdominal distension while on opioid pain medication (tramadol)	LNP
Bleeding associated with anticoagulants (16)	
1. Bleeding from penis with catheter change due to anticoagulants (enoxaparin and warfarin)	LP
2. Gastrointestinal bleeding while on anticoagulant (heparin)	LP
3. Gastrointestinal bleeding while on anticoagulant (warfarin) with prolonged INR (excessive anticoagulation)	LP
4. Bleeding from tracheostomy site while on an anticoagulation medication (heparin)	LNP
5. Epistaxis (nasal bleeding) associated with anticoagulation (warfarin) and trauma from catheter use	LNP
6. Epistaxis while on enoxaparin with blood loss anemia requiring transfusions	LNP
7. Epistaxis while on heparin	LNP
8. Frank blood from the penile meatus in patient with Foley catheter while on rivaroxaban	LNP
9. Gastrointestinal bleeding (coffee-ground emesis) while anticoagulated	LNP
10. Gastrointestinal bleeding while on anticoagulant (enoxaparin)	LNP
11. Gastrointestinal bleeding while on anticoagulation (heparin and aspirin) requiring transfusion	LNP
12. Hemoptysis (cough with associated bleeding) while on anticoagulants (clopidogrel and fondaparinux)	LNP
13. Lower gastrointestinal bleeding while on anticoagulation medications (enoxaparin and warfarin)	LNP

14. Rectal bleeding due to anticoagulants (enoxaparin and warfarin)	LNP
15. Rectus sheath hematoma while on anticoagulant (warfarin)	LNP
16. Right nares epistaxis while on warfarin	LNP
Acute kidney injury or insufficiency (9)	
1. Acute kidney injury while on antibiotic (vancomycin) and angiotensin-convertor enzyme (ACE) inhibitor (lisinopril)	LP
2. Acute kidney injury while on diuretics (spironolactone and furosemide)	LP
3. Acute kidney injury due to vancomycin	LNP
4. Acute kidney injury while on an antibiotic (vancomycin)	LNP
5. Acute kidney injury while on antibiotic (vancomycin)	LNP
6. Acute kidney injury while on vancomycin	LNP
7. Acute kidney injury while taking multiple medications likely to cause it (ACE inhibitor and diuretics)	LNP
8. Acute kidney injury with hypotension while on ACE inhibitor (lisinopril)	LNP
9. Cascade with acute kidney injury resulting in hyperkalemia while on ACE inhibitor (lisinopril) and diuretic (furosemide)	LNP
Allergic reactions (9)	
1. Diffuse pruritus while on colistin	CNP
2. Drug fever while on antibiotic (piperacillin/tazobactam)	CNP
3. Pruritic back rash treated with an antihistamine (diphenhydramine)	CNP
4. Pruritus due to opioids	CNP
5. Rash developed while on an antibiotic (piperacillin-tazobactam)	CNP
6. Rash while on antibiotics (levofloxacin and vancomycin)	CNP
7. Rash while on antibiotics (piperacillin, tazobactam, and clindamycin)	CNP
8. Skin rash due to antibiotic meropenem	CNP
9. Skin rash on antibiotic ciprofloxacin	CNP
Diarrhea (5)	
1. Diarrhea while on laxatives	LP
2. Diarrhea while on antibiotic	LNP
3. Diarrhea while on antibiotic (clindamycin) and stool softener (docusate)	LNP
4. Diarrhea while on laxative	LNP
5. Diarrhea with nausea while on linezolid	LNP
Other medication-related temporary harm events (11)	
1. Dizziness while on opioid (hydromorphone) medication	LP
2. Seizure related to withdrawal of anticonvulsant medication (levetiracetam)	LP
3. Idioventricular arrhythmia while on cardizem	LNP
4. Metabolic alkalosis due to diuretics (bumetanide)	LNP

5. Profound malaise after initiation of bronchodilator (theophylline)	LNP
6. Nausea and vomiting after starting opioid medication (tramadol)	LNP
7. Skin lesions with slough consistent with Stevens-Johnson syndrome while on the antibiotic meropenem	LNP
8. Trembling with increasing doses of pregabalin	LNP
9. Chorea while on anticonvulsant (levetiracetam)	CNP
10. Worsening tinnitus while on aspirin (acetylsalicylic acid)	CNP
11. Significant elevation of liver function tests	UTD
Temporary Harm Events Related to Infections (81)	
Soft tissue or other nonsurgical infections (28)	
1. Bacterial conjunctivitis	LP
2. Conjunctivitis	LP
3. Conjunctivitis	LP
4. Conjunctivitis, likely viral	LP
5. Fungal infection (axilla)	LP
6. Fungal infection/rash (scrotum and penis)	LP
7. Impetigo due to staphylococcus	LP
8. Local infection at site of PICC insertion	LP
9. Skin infection - *Sarcoptes scabiei* var. *hominis* (Scabies mites)	LP
10. Conjunctivitis	LNP
11. Conjunctivitis	LNP
12. Fungal dermatitis (buttocks) while on steroids and antibiotics	LNP
13. Fungal dermatitis (groin)	LNP
14. Fungal dermatitis associated with diarrhea while on antibiotics	LNP
15. Fungal infection (external genitalia and adjoining perineal skin)	LNP
16. Fungal infection (foot)	LNP
17. Fungal infection (gluteus)	LNP
18. Fungal infection (groin)	LNP
19. Fungal infection (perineal area)	LNP
20. Fungal infection (upper extremity)	LNP
21. Sacral candidiasis in part due to antibiotics and immobility	LNP
22. Skin abscess back shoulder area	LNP
23. Tinea cruris (fungal infection of groin area)	LNP
24. Tinea cruris (perineal)	LNP
25. Tinea cruris with excoriations (groin, perineal)	LNP
26. Vaginal candidiasis	LNP

27. Vaginal candidiasis while on antibiotics	LNP
28. Vaginal candidiasis while on antibiotics	LNP
Thrush (13)	
1. Oral thrush after antibiotics	LNP
2. Oral thrush due to antibiotics	LNP
3. Oral thrush due to antibiotics	LNP
4. Oral thrush due to steroid inhaler	LNP
5. Oral thrush following multiple antibiotics	LNP
6. Oral thrush related to chemotherapy and radiation therapy	LNP
7. Oral thrush while on antibiotics	LNP
8. Oral thrush while on antibiotics	LNP
9. Oral thrush while on antibiotics	LNP
10. Oral thrush while on antibiotics	LNP
11. Oral thrush while on antibiotics	LNP
12. Oral thrush while on antibiotics	LNP
13. Oral thrush while on antibiotics	LNP
Urinary tract infections associated with urinary catheters (11)	
1. CDC-defined catheter-associated urinary tract infection (CAUTI)	LP
2. CDC-defined CAUTI	LP
3. CDC-defined CAUTI	LP
4. CDC-defined CAUTI	LP
5. CDC-defined CAUTI	LP
6. CDC-defined CAUTI	LP
7. CDC-defined CAUTI	LP
8. CDC-defined CAUTI	LP
9. CDC-defined CAUTI	LP
10. Clinical urinary tract infection associated with urinary catheter	LP
11. Urinary tract infection associated with catheter	LP
Clostridium difficile infection (9)	
1. *Clostridium difficile* infection	LP
2. *Clostridium difficile* infection	LP
3. *Clostridium difficile* infection	LP
4. *Clostridium difficile* infection	LP
5. *Clostridium difficile* infection	LP
6. *Clostridium difficile* infection	LP
7. *Clostridium difficile* infection	LP

8. *Clostridium difficile* infection	LP
9. *Clostridium difficile* infection	LP
LTCH-acquired respiratory infections (9)	
1. Aspiration pneumonia	LNP
2. Aspiration pneumonia (MRSA)	LNP
3. Bronchitis	LNP
4. Pneumonia	LNP
5. Pneumonia (suspected aspiration)	LNP
6. Pneumonia (suspected aspiration)	LNP
7. Pneumonia while on ventilator	LNP
8. Pneumonia while on ventilator	LNP
9. Pneumonia/bronchitis	LNP
Surgical site infections (5)	
1. Cellulitis at PEG site	LP
2. Infection at site of ankle surgery	LP
3. Late wound infection and subsequent partial dehiscence due to inadequate wound care	LP
4. Wound infection of below knee amputation suture line with small dehiscence (rupture)	LP
5. Superficial abdominal infection at prior Jackson-Pratt drain site	LNP
Vascular-catheter associated infections (4)	
1. Cellulitis/abscess at PICC site	LP
2. Central line infection followed by sepsis	LP
3. PICC line associated with septicemia (Klebsiella)	LP
4. PICC line associated with fungemia	LNP
Other infection-related temporary harm events (2)	
1. Cascade with sepsis leading to acute kidney injury leading to mental status changes	LP
2. Parotitis due to dehydration	LNP
Temporary Harm Events Related to Patient Care (75)	
Pressure ulcers (20)	
1. Stage 2 nasal pressure ulcer associated with face mask	CP
2. Deep tissue injuries related to ace wraps	LP
3. New stage 2 sacral pressure ulcer	LP
4. Progression of stage 2 to stage 3 sacral pressure ulcer	LP
5. Sacral pressure ulcer	LP
6. Stage 1 coccygeal pressure ulcer	LP

7. Stage 1 facial pressure ulcer associated with BiPAP mask	LP
8. Stage 1 pressure ulcer heel	LP
9. Stage 1 pressure ulcer on sacrum	LP
10. Stage 1 sacral pressure ulcer	LP
11. Stage 2 pressure ulcer of sacrum	LP
12. Stage 2 pressure ulcer of sacrum	LP
13. Suspected deep tissue injury of sacral area	LP
14. Suspected deep tissue injury of the sacrum	LP
15. Worsening pressure ulcer of sacrum	LP
16. New unstageable pressure ulcer (left ischium)	LNP
17. New unstageable pressure ulcer (right ischium)	LNP
18. Progression of stage 2 pressure ulcer to unstageable	LNP
19. Temporal (side of head) pressure ulcer	LNP
20. Unclassified sacral ulcer	LNP
Bleeding not directly associated with anticoagulants (10)	
1. Gross hematuria due to trauma from urinary catheter placement	CP
2. Bleeding at insertion site of venous catheter due to cap falling off PICC line while on anticoagulant medication (warfarin) and antibiotic (linezolid)	LP
3. Bleeding from tracheostomy with hardware-induced soft tissue injury	LP
4. Hematuria (blood in urine) associated with traumatic urinary catheterization	LP
5. Hematuria, likely mechanical from the Foley catheter while on anticoagulants (enoxaparin, clopidogrel, and aspirin)	LP
6. Inadequate monitoring of gastrointestinal bleeding with blood loss anemia (developing over 8 days) requiring transfusions	LP
7. Traumatic catheterization with bleeding following non-function of urinary catheter	LP
8. Epistaxis (nasal bleeding) related to nasal cannula while on aspirin	LNP
9. Epistaxis (significant nosebleed) with nasal cannula irritation	LNP
10. Hematoma of groin associated with hemodialysis catheter	LNP
Venous thromboembolism, deep vein thrombosis, or pulmonary embolism (10)	
1. Deep vein thrombosis of the lower extremity with inadequate preventive care	LP
2. Deep vein thrombosis of upper extremity with suspected infection at intravenous site	LP
3. Deep vein thrombosis of lower extremity	LNP
4. Deep vein thrombosis of upper extremity associated with PICC line	LNP
5. Deep vein thrombosis of upper extremity associated with PICC line	LNP
6. Deep vein thrombosis of upper extremity associated with PICC line	LNP
7. Deep venous thrombosis of upper extremity associated with PICC line	LNP

8. Non-occlusive deep vein thrombosis of lower extremity	LNP
9. Non-occlusive deep venous thrombosis of upper extremity associated with PICC line	LNP
10. PICC line thrombosis of right upper extremity	LNP
Skin tear, abrasion, or breakdown (9)	
1. Urethral erosion with bloody drainage with catheter in place	CP
2. Skin maceration from gastric secretions due to PEG leak	LP
3. Skin tear and abrasion on sacral area	LP
4. Skin tear forearm	LP
5. Abdominal wound opened during bathing	LNP
6. Multiple skin wounds	LNP
7. Skin erosions of lower abdomen and bilateral groin areas	LNP
8. Ulcerated lesion of penile meatus with chronic Foley catheterization	LNP
9. Skin tear of wrist resulting from tape removal	CNP
Fall with injury (7)	
1. Fall with laceration forehead	CP
2. Fall with soft tissue hematoma over left maxillary sinus	LP
3. Fall resulting in skin tear left wrist and contusion on head	LNP
4. Fall with bruising of right eyebrow and right side of face	LNP
5. Fall with contusion forehead	LNP
6. Fall with forearm abrasion	LNP
7. Fall with head contusion	LNP
Acute kidney injury or insufficiency (3)	
1. Hyperkalemia secondary to acute kidney injury	LP
2. Acute kidney injury	LNP
3. Acute kidney injury associated with volume depletion	LNP
Respiratory issues (other than infections) (3)	
1. Aspiration of tube feeding	LP
2. Aspiration of tube feeding with dyspnea (difficulty breathing)	LNP
3. Unstable placement of tracheostomy tube resulting in reliance on BiPAP	LNP
Volume overload (3)	
1. Episode of congestive heart failure from fluid overload	LP
2. Lower extremity edema due to fluid overload in patient with latent congestive heart failure	LP
3. Fluid overload (pulmonary edema) following vigorous intravenous fluids, and red blood cell administration	LNP

Constipation, obstipation, or ileus (2)	
1. Ileus on abdominal x-ray with abdominal pain and inadequate monitoring	LP
2. Constipation with nausea	LNP
Fluid, electrolyte, and metabolic disorders (not medication related) (2)	
1. Cascade with diarrhea leading to electrolyte imbalance leading to ventricular tachycardia	LP
2. Hyperkalemia (potassium of 6.2)	LP
Other patient-care-related temporary harm events (6)	
1. Contact dermatitis of lower extremity (tape)	LNP
2. Left arteriovenous fistula skin ulcer associated with clotted hemodialysis catheter	LNP
3. Pruritus at multiple sites suspected due to contact with adhesion	LNP
4. Transfusion reaction	LNP
5. Ear pain with drainage post hyperbaric treatment	CNP
6. Rash on upper extremities	UTD

Source: OIG analysis of LTCH stays for 587 Medicare beneficiaries entering an LTCH in March 2014.

APPENDIX G: Agency Comments

CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

Date: OCT 10 2018

To: Daniel R. Levinson
Inspector General
Office of Inspector General

From: Seema Verma SV
Administrator
Centers for Medicare & Medicaid Services

Subject: Office of Inspector Draft Report: "Adverse Events in Long Term Care Hospitals: National Incidence Among Medicare Beneficiaries" (OEI-06-14-00530)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report on both preventable and not preventable adverse events in long-term care hospitals. CMS is committed to identifying adverse events in long-term care hospitals and other healthcare settings and improving the quality of care for patients.

As the report notes, CMS oversees long-term care hospitals' compliance with a set of minimum quality and safety standards known as the Conditions of Participation (CoPs). To verify compliance with CoPs, on-site surveys are conducted by Medicare-approved accreditation organizations or State survey agencies. CMS provides interpretive guidance, including guidance for long-term care settings, to assist in the survey process. While many of the CoPs have an impact on quality, the Quality Assessment and Performance Improvement (QAPI) CoP focuses specifically on standards for hospitals to improve quality and safety. As part of the QAPI CoP, long-term care hospitals must identify and reduce medical errors and track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning through the hospital.

In addition, as part of efforts to improve the quality of care in long-term care facilities, the Affordable Care Act established the quality reporting program for inpatient long-term care hospitals, which requires those providers to submit data on selected quality measures. Some of these selected measures address avoidable adverse events, including the Catheter-Associated Urinary Tract Infection Outcome measure. The Improving Medicare Post-Acute Care Transformation Act of 2014 also creates new quality reporting requirements for some post-acute care providers, including long-term care hospitals. Long-term care hospitals are required to report certain data on incidents of major falls, skin integrity, and other quality issues.

CMS appreciates the OIG's work in this area and past work on adverse events in other settings.

OIG Recommendation
AHRQ and CMS should collaborate to create and disseminate a list of potential adverse events in LTCHs.

CMS Response
CMS concurs with this recommendation. CMS will work with AHRQ to create and disseminate a list of potential adverse events in long term care hospitals, similar to its efforts for other patient settings.

OIG Recommendation
CMS should include information about potential events and patient harm in its quality outreach to LTCHs.

CMS Response
CMS concurs with this recommendation. CMS will educate providers about potential events and patient harm through various channels including, for example, the Medicare Learning Network electronic newsletters, quarterly compliance newsletters and webpages, Medicare Administrative Contractor webpages, and quality improvement technical assistance by the Hospital Improvement Innovation Networks.

AHRQ Comments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

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To: Daniel R. Levinson
Inspector General,
Department of Health and Human Services

From: Gopal Khanna
Director
Agency for Healthcare Research and Quality

Subject: OIG Draft Report - Adverse Events in Long-Term Care Hospitals: National Incidence among Medicare Beneficiaries (OEI-06-14-00530)

Thank you for the opportunity to review the draft report entitled, Adverse Events in Long-Term Care Hospitals: National Incidence Among Medicare Beneficiaries (OEI-06-14-00530)

We have specific responses to the recommendation.

1. Recommendation: **AHRQ and CMS should collaborate to create and disseminate a list of potential adverse events in LTCHs**.

AHRQ concurs with this recommendation and will work with CMS to create and disseminate a list of potential adverse events in Long-Term Care Hospitals.

We look forward to following up with you regarding our activities related to the above recommendation, as well as to collaborating as appropriate with our colleagues at CMS. We believe that your previous reports on adverse events in hospitalized Medicare patients have provided valuable information to the public and to Federal and private-sector healthcare leaders. This report promises to do the same by addressing a new and especially vulnerable patient population.

If you or your staff has any questions, please feel free to contact Dr. Jeff Brady, Director, Center for Quality Improvement and Patient Safety at Jeff.Brady@ahrq.hhs.gov or 301-427-1322.

Gopal Khanna

ACKNOWLEDGMENTS

Amy Ashcraft served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Nathan Dong, Jennifer Hagen, Jeremy Moore, and Jesse Valente. Office of Evaluation and Inspections staff who provided support include Joe Chiarenzelli, Evan Godfrey, Althea Hosein, Christine Moritz, Michael Novello, and Melicia Seay.

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