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Effect of November 2016 Medicare and Medicaid Programs Policy of Requirements of
Participation (RoP) for Nursing Homes on Quality Measures

BY

Lynn Naves Carpenter

A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

Dedication

To Arthur O'Leary, the best mentor I could have ever hoped for. Your belief in me over the past 19 years inspired me to return to school and achieve my dreams. I would never be where I am today without your never-ending support and encouragement.

EFFECT OF NOVEMBER 2016 MEDICARE POLICY REQUIREMENTS OF PARTICIPATION (RoP) ON NURSING HOMES AND QUALITY MEASURES

BY

Lynn Naves Carpenter

Approved by:

Chair, Project Committee	Jillian Harvey, MPH, PhD	Date
Member, Project Committee	Walter Jones, PhD	Date
Member, Project Committee	Amy Martel, MD	Date

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Abstract of Dissertation Presented to the
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In Partial Fulfillment of the Requirements for the
Degree of Doctor of Health Administration

EFFECT OF NOVEMBER 2016 MEDICARE POLICY REQUIREMENTS OF
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Lynn Naves Carpenter

Chairperson: Jillian Harvey, MPH, PhD
Committee: Walter Jones, PhD
Amy Martel, MD

Policymaking has a long and complex history in long-term care, which is one of the most highly regulated industries in the United States. The Final Rule for Reform of Requirements of Participation (RoP) for Long-Term Care Facilities was published with Phase I of III effective November 26, 2016. A retrospective program evaluation using data from the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare was conducted of 14,210 SNFs/NFs. This study used a quantitative approach to determine the impact of the RoP on four quality measures: percentage of long-stay residents who received an antipsychotic, long-stay residents with moderate to severe pain, long-stay residents who were physically restrained, and short-stay residents with pressure ulcers that are new or worsened. Data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 24. Significant changes were observed in the percentage of each of the four quality measures pre- and post-implementation of the RoP. Logistic models indicate the influence of ownership and location on quality measure percentages RoP. This study adds to existing literature regarding the impact of regulatory stringency on nursing homes and provides important recommendations for policymakers and future research.

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CHAPTER I INTRODUCTION

Policymaking has a long and complex history in long-term care, which is one of the most highly regulated industries in the U.S. (Brady, 2001; Eskildsen & Price, 2009; Kumar et al, 2006). In 2016, the Final Rule for Reform of Requirements of Participation (RoP) for Long-Term Care Facilities was published with Phase I of III effective November 28, 2016 (Medicare & Medicaid Programs, 2016). The Final Rule was the first overhaul of regulations for long-term care facilities since 1991. The cost of implementing the new regulatory requirements, per facility, is estimated at approximately \$62,900 for the first year, and \$55,000 per year thereafter (Medicare & Medicaid Programs, 2016; Unroe, Ouslander & Saliba, 2017).

There is little research available pertaining to the impact of the 2016 RoP for long-term care facilities. There is research, however, demonstrating a lack of evidence to support improvements in the quality of care provided by nursing homes due to regulations; therefore, the addition of more regulations may not be effective in improving quality of care (Brady, 2001). As stated by Brady (2001), “to the extent that there are problems with the quality of care provided by certain nursing homes, those problems do not exist because of a lack of regulation” (p.5).

Though nursing homes are often referred to as long-term care facilities, most offer short-term skilled nursing and rehabilitation services in addition to long-term care services. Skilled Nursing Facilities (SNFs) are certified to receive Medicare funding for services provided to Medicare beneficiaries, often referred to as short-stay patients or residents. Nursing Facilities (NFs) provide long-term care services through Medicaid or personal (private) funds.

The Centers for Medicare and Medicaid Services (CMS) contract with each State to enforce nursing home regulations (Mukamel et al, 2012). State Surveyors, employed by Health and Human Services, are required to conduct certification surveys for Medicare and/ or Medicaid

certified SNFs/ NF every 9 to 15 months. The ‘annual survey’ is an assessment of the facility’s compliance with over 150 standards which must be met to continue to receive funding through Medicare and/ or Medicaid (Castle & Ferguson, 2010). Additionally, surveyors must investigate consumer complaints, sometimes resulting in additional compliance surveys. Deficiencies are cited for areas not meeting standard(s) and require a plan of correction be submitted by the facility within 10 days. Scope and severity are assigned for each deficient area and can result in civil monetary penalties (CMPs), loss of funding, and/ or mandated changes in leadership. According to Winzelberg (2003), the punitive approach to regulation of nursing homes will continue to be ineffective in improving quality of care due to the unique service population and environment in each home. Additionally, though the regulations and process are outlined in a standardized approach, there is discrepancy amongst different surveyors and states regarding how and which homes are cited and at what scope and severity.

Nursing homes continue to experience significant cuts in Medicare and Medicaid reimbursement (Siegel et al, 2014) and a critical staffing shortage (JCAHO, 2014). In the State of New Hampshire alone, the average daily cost to provide care and services per nursing home resident is under-funded by Medicaid by \$46.39 (American Health Care Association, 2017). The lack of evidence demonstrating the beneficial effects of increased regulatory scrutiny and high costs of compliance in achieving improved quality of care is a difficult sell to providers and consumers (Walshe, 2001).

The purpose of this research project is to gain understanding of the impact of the 2016 RoP (Phase I) on resident care. This will enable providers to gain a better understanding of the impact of the RoP, the results of their efforts to comply with the regulations and provide policymakers with data regarding the impact of the RoP.

The demand for nursing home care is expected to increase in the coming decades (Eskildsen & Price, 2009). The 65 and over population is expected to increase from 12% in 2005 to 20% by 2050 (Cohn & Taylor, 2010; Hoffman, 2018). The annual turnover rate for licensed Nursing Home Administrators is estimated at 57% (Siegel, Leo, Young & Castle, 2014), primarily attributed to the challenging regulatory environment and shortage of nursing staff (AHCA, 2014; Angelilli, Gifford, Shah & Mor, 2001; Castle, N., 2006). The negative aspects of these regulations and requirements on resident choice and quality of life, the burnout and turnover of staff, the unsatisfied residents and family members, and the lack of evidence supporting improved quality of care is exasperating. It is important to understand the effects of these regulatory changes on the nursing home environment, including patients, residents, families, staff, and other stakeholders. This research seeks to provide a better understanding of the process and reasoning behind the changes in regulations, and what if any benefits will be experienced by the consumer in respect to improved quality of care.

Background and Need

In the mid- 1900s, poorhouses were established in the United States as a place for the poor and infirm to reside. Poor houses were supported with federal tax dollars, and eventually became the nursing home as we know it today (Winzelberg, 2003). As part of the establishment of the Social Security Act in 1935, management of the funding of benefits for the aged were transitioned to State agencies (ssa.gov, n.d.). During this time, there were several concerns raised by both the public and political sectors regarding the poor conditions and quality of care in nursing homes (IOM, 1986), though the licensing and/ or regulatory process was discouraged due to the increasing need for nursing homes and beds (Winzelberg, 2003). During the 1930s

and 1940s, the sense was that most nursing homes could not meet the basic requirements of the regulatory process and therefore would have been forced to close.

In the 1950s, a study conducted by the Council of State Governments found that nursing homes were not providing quality services (IOM, 1986) and many were considered ‘substandard.’ From this study, the Public Health Service began consideration of licensing programs at the state level (IOM, 1986). Through these processes, many homes continued to be labeled as ‘substandard’, though the continued fear of enforcement shutting down the operations of the homes prohibited pursuance of the issues as it was thought that it would take time for homes to comply with standards (United States Special Committee on Aging, 1975).

By 1961, the United States Senate had created the Special Committee on Aging, chaired by Utah Senator Frank Moss (IOM, 1986). The Committee held several hearings on the issues that had been experienced in nursing homes, and by 1963, the first standards for nursing homes receiving Federal funding were issued (IOM, 1986). Two years later, in 1965, Amendments to the Social Security Act created the Medicare (healthcare coverage for those 65 and over) and Medicaid (healthcare coverage for low income individuals) programs (Eskildsen & Price, 2009). By 1966, the percentage of nursing home residents receiving Medicaid was over 60% (IOM, 1986). The demands made by members of Congress, consumers, and advocacy groups for nursing homes receiving federal funding to meet basic standards and requirements was profound.

In the 1970s, nursing homes garnered the attention of the public and policymakers due to negative outcomes including abuse, bed sores, and poor care (Kapp, 2014). Under the Nixon Administration, oversight of nursing home regulations transitioned from the State to the Federal level (Hovey, 2000). Frank Moss (D-UT), Chair of the Special Committee on Aging went undercover as a Medicaid resident to undergo the experience personally (Etzioni, 1977). From

this experience, the Moss Committee (IOM, 1986) was established and began holding hearings over a 4-year period to establish testimony against federal regulatory efforts. Stories continued to be published regarding the horrors of nursing homes; a fire that killed 32 residents in a nursing home in Ohio, food poisoning that killed 36 residents in a nursing home in Maryland, and a class action lawsuit, *Smith v. O'Halloran*, was filed in Colorado by a group of nursing home residents receiving Medicaid (Horowitz, 2009). The lawsuit claimed that the federal government, and specifically the Secretary of HHS, had not followed through on their responsibilities to ensure quality of care in nursing homes, and they had suffered needlessly because of it.

In 1980, the Health Care Financing Administration (HCFA) proposed changes to nursing home rules to include evaluation of the care provided to residents (IOM, 1986). These proposed changes were not passed into law and remained in a holding pattern through the end of the Carter administration. A new reform effort was initiated by the incoming Reagan Administration, who sought to streamline the regulations for nursing homes (Kapp, 2014) and allow for facilities with good survey and certification records to achieve compliance through accreditation by the Joint Commission on Accreditation of Hospitals (American Association of Homes and Services for the Aging, 2008). These proposed changes produced negative reactions from several stakeholders, including lawmakers, consumers, and providers (IOM, 1986). Most believed that the proposed changes did not address the “fundamental weaknesses in the regulatory system” (AAHSA, 2008, p.17). The reactions resulted in the proposed changes to nursing home regulations being postponed and left the prior rules from 1974 in effect. Additionally, during this time, a federal court ruled that Medicaid Law requires the Secretary of Health and Human Services to prove that providers receiving federal funds are meeting the requirements of participation in the program, including quality of care (Brady, 2001).

In 1983, Congress asked the Institute of Medicine (IOM) to conduct a review of nursing home performance. The 18-month study of nursing home issues by the IOM Committee resulted in numerous regulatory recommendations per members of the committee, few of which were supported by evidenced-based research or outcomes (Kapp, 2014). In addition to the IOM Committee findings and recommendations, the General Accounting Office (GAO) published a report detailing its concerns with the lack of oversight of nursing homes by DHHS (Horowitz, 2009). The “window of opportunity” (Longest, 2016, p.136) was provided for stricter regulatory oversight due to the ongoing, publicized issues with nursing homes, along with the *Smith v. O’Halloran* case “winding its way through courts” (Horowitz, 2009, p. 2). As such, Congress chose to take the recommendations and incorporated them as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987, also known as the Nursing Home Reform Act (Brady, 2001).

Over the next two decades, there was little evidence that the influx of regulatory requirements on the long-term care industry had any effect on improving resident outcomes or quality of care. The Minimum Data Set (MDS) was introduced in 1991, requiring SNFs/ NFs to assess residents health status and capabilities in performing activities of daily living (ADLs) (Castle & Ferguson, 2010). The MDS is comprised of 350 areas of assessment completed for each short-stay and long-term resident in the SNF/ NF (Au et al, 2019; Eskildsen & Price, 2009; Grabowski et al, 2008). The MDS is completed on minimum of a quarterly basis and transmitted to CMS where it is analyzed. The data from MDS is aggregated to provide information at the facility, state, and national level for twenty-eight publicly reported quality measures (QMs) (Centers for Medicare & Medicaid Services, 2019; Mor, 2005). MDS data is also used to

determine reimbursement rates and provide surveyors with focus areas for observation during regulatory compliance visits (Rahman & Applebaum, 2009).

Quality measures (QMs) were developed by the Center for Health Systems Research and Analysis to provide indicators of structural, procedural, and outcome measures (Castle & Ferguson, 2010). QMs were first publicly reported in 2002 as part of Nursing Home Compare. Despite the “overwhelmingly extensive and complex set of formal command-and-control rules we [have] promulgated on the federal and state levels to govern the operation of nursing homes” (Kapp, 2014, p.886-887) the industry continued to experience significant quality of care issues (Kumar, Norton & Ensinosa, 2006) as evidenced by continued citations of actual harm and immediate jeopardy survey results. The idea of “deemed status” (Hovey, 2000, p.52) emerged again in 1998, as it had in the 1980’s, proposing the idea of allowing accreditation through JCAHO (similar to oversight of hospitals) to improve quality and decrease the costs of regulatory oversight. This idea was quickly dismissed due to opposition from the Clinton Administration, interest groups such as AARP, stating JCAHO did not meet the necessary standards of oversight required for nursing homes (Hovey, 2000).

In 2005, CMS began the pilot of a new survey process in five states to achieve a more systematic, objective approach to the survey process and address the ongoing concerns expressed by the GAO and Congress regarding the regulatory oversight of nursing homes. The Quality Indicator Survey (QIS) was developed in response to criticisms of the current process for survey and certification in nursing homes which had been voiced by consumers, providers, Congress, GAO, survey agencies as well as CMS (White et al, 2007). The goals of the QIS survey were to increase the accuracy and efficiency of the survey process in addition to providing increased focus on resident- centered care and quality outcomes (AAHSA, 2008).

A 2007 study completed by ABT found the QIS survey failed to attain any of its primary goals (White et al, 2007). The study assessed quality in the five domains of incontinence, nutrition, pressure ulcers, choice, and activities. There were no differences found in accuracy or relationship between quality and citations received by facilities undergoing the QIS and standard survey (White et al, 2007) and “both failed to detect many residents with poor pressure ulcer and weight loss outcomes” (White et al, 2007, p. v).

On May 15, 2008, Congressman Stupak (D-MI) requested release of the CMS report regarding the evaluation of the QIS pilot at a Meeting of the House Committee on Energy & Commerce Subcommittee on Oversight and Investigations (AAHSA, 2008). He was told that the report was not available by the Acting Administrator of CMS, Kerry Weems, who cited that it was still being finalized and an action plan was being developed prior to making the report available to the Committee (AAHSA, 2008). This report was not made available to the Committee until the following summer, as CMS did not wish the Committee to see the failure of the attempt to improve the survey and certification process through the new QIS process (White et al, 2007).

The micro aspect of the regulatory process is met with disdain by providers due to the punitive and disheartening survey process (Walshe, 2001). Consumers (patients, residents, family members) have mixed feelings about these policies. Some are frustrated with the stringent ‘rules’ that come as part of the regulatory process and inhibit their ability to live in their home; simple pleasures such as a choice of curtains, having a coffee maker, or keeping eye drops at their bedside become non-existent due to the need to achieve regulatory compliance (Kapp, 2000). At the local, state, and national levels, stakeholders deploy a variety of methods to have their voices heard and participate in policymaking.

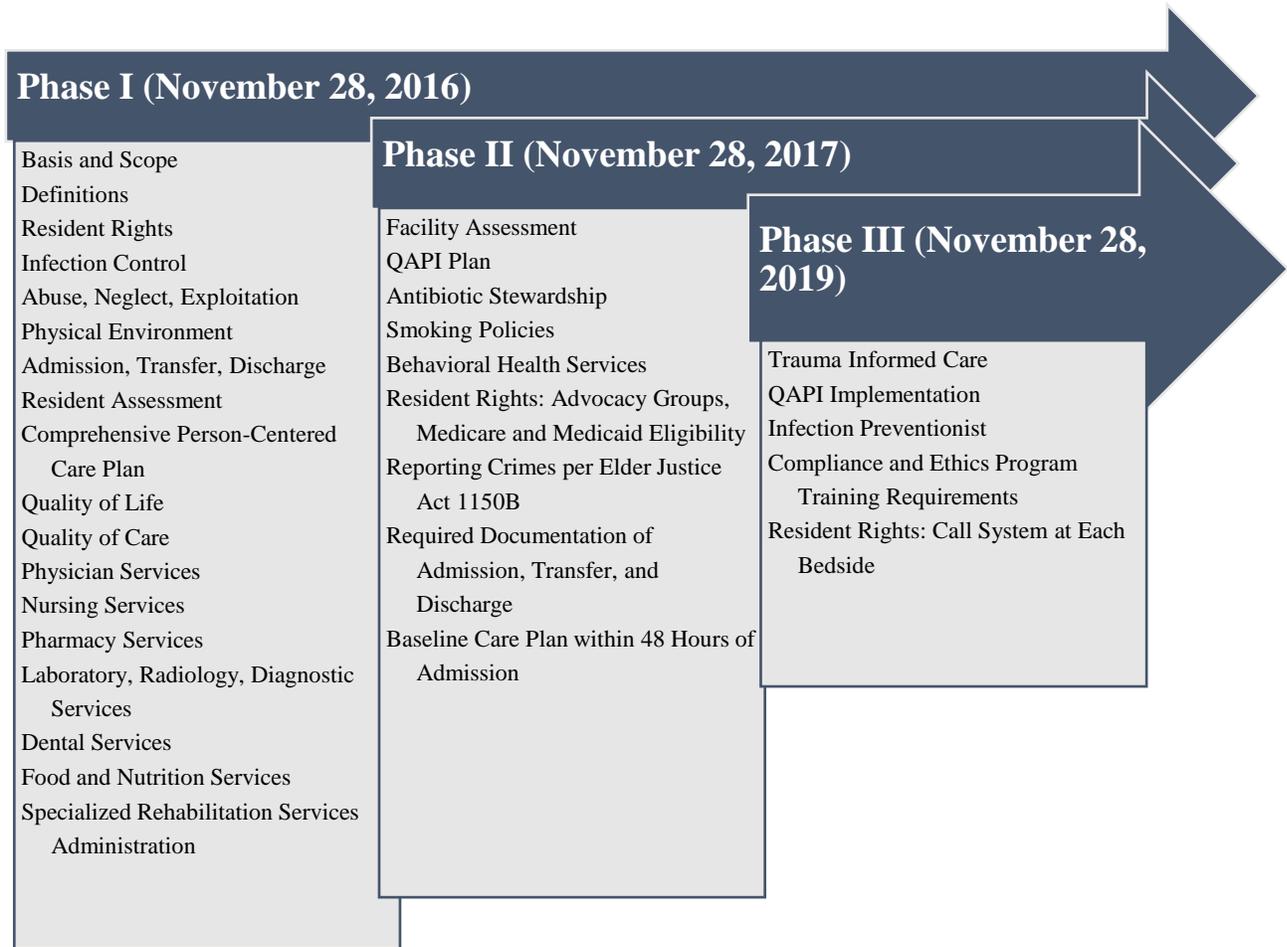
Federalism is well represented when it comes to policymaking and regulatory oversight of long-term care facilities (Longest, 2016; Walshe, 2001). Every level of government is involved in a specific way, with a great deal of overlap. The Requirements of Participation (RoP) are finalized in the Legislative Branch, and implemented by the Executive Branch, Centers for Medicare & Medicaid Services. The RoP, or regulations, are monitored and enforced at both the State and Federal levels. At the local level, many cities, towns, and/or counties have their own requirements and/or regulations pertaining to nursing homes, such as licensure for convalescent care or food licensing. Furthermore, skilled nursing and long-term care facilities are reimbursed for care and services provided to most residents by the Centers for Medicare & Medicaid Services (Medicare beneficiaries) and by State Departments of Health and Human Services (Medicaid beneficiaries), the same agencies responsible for ensuring regulatory compliance.

Historically, policy actors have capitalized on the opportunity to draw attention to adverse stories of nursing homes and “play on the fears of the politically powerful baby boom generation” (Brady, 2001, p.3) to gain votes by advocating for tougher regulatory oversight. Reviewing the history of regulations in long-term care, there are several examples of “legislators as suppliers” (Longest, 2016, p. 69); from the Congressman that shared his own story as an orderly in a nursing home during the Moss hearings (IOM, 1986) to support the need for additional regulations to address the poor care and neglect he witnessed, to the experienced shared by Moss himself as an ‘undercover’ resident of a nursing home (Etzioni, 1977). As stated by Hovey (2000), “every time an expose of poor nursing home care is presented in the media, there is a call among our political leaders to crack down on the nursing home industry” (p.43). These dynamics can result in policy decisions that are made quickly to appease voters and gain

votes, without consideration for the long-term impact of the costs, both to providers (costs to comply) and regulators (cost to enforce) (Longest, 2016). Alternatively, Hoffman (2018) argues that public choice theory deters politicians from focusing on issues pertaining to the aging population due to the high cost of funding programs. Hoffman believes there is a general tendency of political actors and the public to avoid the ‘non-glamorous’ issues of aging and mortality as they are generally viewed as unpleasant and do not assist in gaining votes.

In 2015, CMS published the Proposed Rule outlining substantial changes to the regulations for long-term care, the first of its kind since OBRA in 1987 (Unroe, Ouslander & Saliba, 2017). Thousands of public comments were made, resulting in changes in the effective date(s) of the proposed regulations. The purpose of the final rule is to update regulatory requirements for SNFs/ NFs to meet the needs of both short-stay and long-term care residents, as well as the differences in acuity of the population as compared to twenty-five years prior. The final rule, published in October 2016, is arranged to be implemented in three phases (Figure 1) (Unroe, Ouslander & Saliba, 2017).

Figure 1. Requirements of Participation: Phases I, II, III, and Effective Dates



Source: Unroe, Ouslander, and Saliba (2017)

Problem Statement

Long-term care has a lengthy history of stringent regulations developed in response to highly publicized poor outcomes (Eskildsen & Price, 2009). Phase I of the Medicare and Medicaid Requirements of Participation (RoP) for Long-Term Care Facilities went into effect on November 27, 2016. According to Unroe, Ouslander, and Saliba (2017), the cost of implementing these rules is estimated at approximately \$62,900 for the first year, and \$55,000

per year thereafter. However, it is not known if these costly new rules have any impact on quality of care.

Research Question and Research Hypotheses

How do CMS quality measures (QMs) compare pre- and post-implementation of Phase I of the Medicare and Medicaid Programs Reform of the Requirements for Long-Term Care Facilities?

H1. The percentage of short-stay residents with pressure ulcers that are new or worsened will decline post- implementation of the Phase I Requirements of Participation.

H2. The percentage of long-stay residents who self-report moderate to severe pain will decline post- implementation of the Phase I Requirements of Participation.

H3. The percentage of long-stay residents who were physically restrained will decline post-implementation of the Phase I Requirements of Participation.

H4. The percentage of long-stay residents who received an antipsychotic medication will decline post-implementation of the Phase I Requirements of Participation.

The four quality measures (QMs) included in this study were selected for several reasons. These QMs are evidenced-based measures of quality of care (Ward, 2016) and exist as publicly reported quality measures pre- and post-implementation of the Phase I RoP. Additionally, all have been utilized as indicators of quality of care in SNFs/NFs in prior studies (Castle & Ferguson, 2010; Grabowski et al, 2008; Kapp, 2000; Kumar, Norton & Encinosa, 2006; Wade, 2016) and in quality initiatives such as Advancing Excellence and the National Nursing Home Quality Improvement Campaign (<http://www.nhqualitycampaign.org/>). According to Castle & Ferguson (2010), the QMs selected for this study are “quality indicators used in prominent quality initiatives” (p. 433). The QMs have been gathered and publicly reported by CMS since

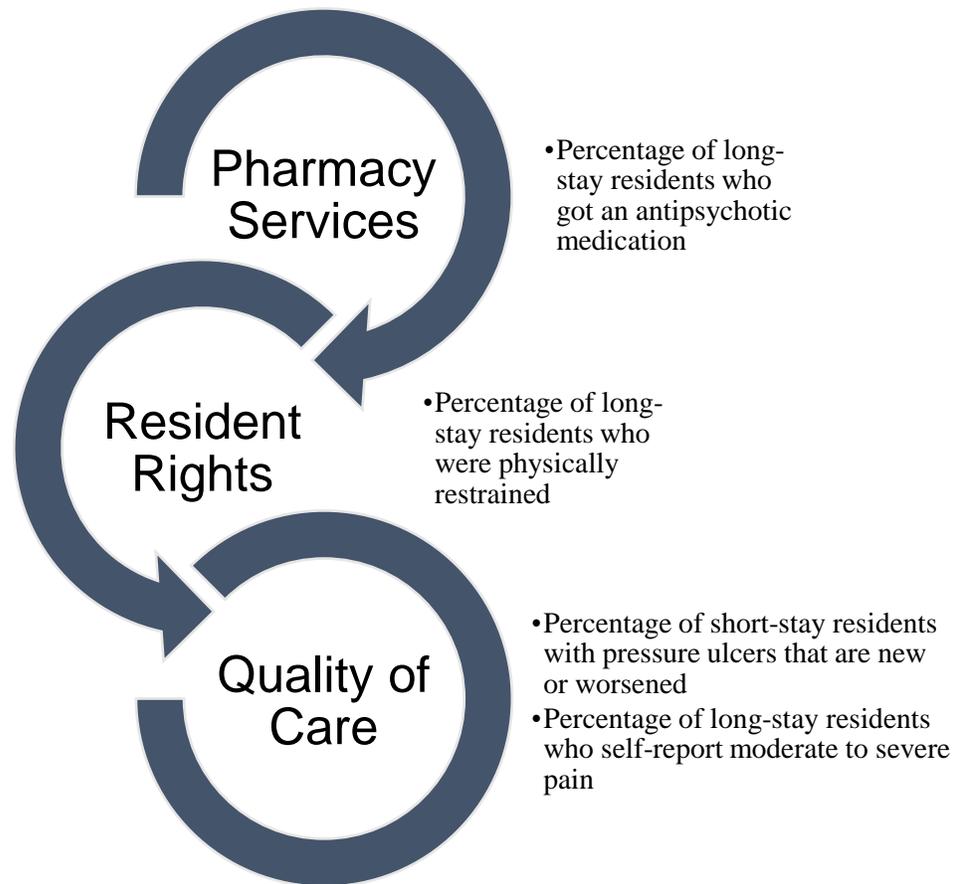
2008; three of the four QMs in this study have been publicly reported since 2010 (see Table 3).

Population

This is a retrospective program evaluation of quality of care using data from Nursing Home Compare. Nursing Home Compare data are collected by the Centers for Medicare & Medicaid (CMS) Nursing Home Compare MDS Quality Measures (QMs). This data is derived from nursing home resident's Minimum Data Set (MDS), transmitted to CMS by Medicare and Medicaid certified facilities. The files are available to the public for all nursing home-based skilled nursing facilities (SNFs) and nursing facilities (NFs), and exclude critical access hospital (CAH) swing beds. QMs are available on a national level and provide information about the quality of care provided in SNFs/ NFs (Castle & Ferguson, 2010). The variables needed for each of the measures are publicly reported by the Centers for Medicare & Medicaid Services Nursing Home Compare online database. Data sets were compared for the year prior to implementation (January to December 2015) and one year after (January to December 2017) the change in the RoP for 14,210 SNFs/ NFs in the United States.

Three of the overarching themes of the Phase I RoP include Pharmacy Services, Resident Rights, and Quality of Care. For purposes of this study, the corresponding quality measure(s) are matched with the Phase I component (Figure 2).

Figure 2. Phase I Requirements of Participation and Corresponding Quality Measures



CHAPTER II LITERATURE REVIEW

As noted in Chapter I, there is limited empirical evidence pertaining to the effects of increased regulations on quality of care in skilled nursing facilities. Reference to regulatory stringency and quality improvement in evidence-based studies conducted apropos nursing home quality measures and improvement initiatives is scant (Kumar et al, 2006). Several sources of literature were reviewed through EMBase, MEDLINE, Scopus, and HEINOnline. Keywords include regulatory requirements, Medicare regulations, skilled nursing facilities, quality of care, and quality measures as well as Boolean operator (AND). Studies, articles, and books pertaining to quality measures and regulatory oversight in skilled nursing facilities over the past twenty-five years were reviewed.

Most of the literature reviewed contemplate the relationships between quality measures and five-star ratings, the scrutiny of the regulatory process, and the flaws in regulatory oversight (Castle & Ferguson, 2010; Levenson, 2010; Walshe, 2001). OBRA regulations were implemented in 1987, however, quality measures were not developed and implemented until 2002 (Grabowski et al, 2008). Therefore, it is possible that prior studies did not have comparison groups or the ability to measure quality of care and the effect of regulatory changes pre- and post-implementation (Walshe, 2001). The RoP of 2016 is the first major overhaul of SNF regulations since 1991; the addition of the quality measures in 2002 allows for measurement of the effectiveness of regulatory stringency on quality of care.

Regulations and Quality of Care

In his article, Winzelberg (2003) argues the regulation of nursing homes over the past 50 years has not ensured or improved quality of care in skilled nursing facilities/ nursing facilities (SNFs/ NFs). Despite the implementation of the OBRA regulations, concerns continue to arise

regarding the quality of care provided in SNFs/NFs. Determining whether the regulations themselves, and/ or the enforcement of such are the issue remains a challenge for researchers (Kapp, 2000; Winzelberg, 2003). Increases in civil monetary penalties for deficiencies and increased transparency via mandatory public reporting have yet to resolve the issue. Despite the lack of evidence proving the effectiveness of increased regulations, policymakers continue to believe this is the best way to ensure quality of care.

Traditionally, SNF/NF deficiencies cited during annual or complaint surveys conducted by state agencies are used to determine the level of quality in nursing homes. There are numerous issues with the process, foremost being the inconsistency amongst surveyors and State survey teams in the number and levels of citations (Castle & Ferguson, 2010; Winzelberg, 2003). The number of differences amongst SNFs presents an additional challenge to defining quality. Approximately 90% of SNFs/NFs receive Medicare and Medicaid funding in the United States (Mukamel et al, 2011). Though all are part of the same comparison group, they vary in the types of care, comorbidities, and population they service. Additionally, States vary in philosophies pertaining to regulation and control of markets, some having a higher level of regulatory stringency compared with others. Comparing survey results as a means of defining levels of quality of care becomes increasingly challenging considering these differences. A change to accreditation to improve quality of care in nursing homes, along with a process to promote innovative practices is suggested (Kapp, 2000; Winzelberg, 2003). Standardization of the survey process and the development of programs to allow surveyors to focus on the homes requiring a higher level of oversight and separating the survey and enforcement agencies to decrease potential conflicts of interest are also suggested.

The consequences for non-compliance with regulatory standards include fines, citations, and mandatory personnel changes (Mukamel et al, 2012). Enforcement agencies and providers incur these costs of compliance. A quantitative study by Mukamel et al. (2012) utilized 2005 and 2006 MDS data for 16,352 Medicare and Medicaid certified nursing homes in the United States to determine the effect of regulations on quality. The objective of the study was to determine if stringent quality regulations are cost-effective and contribute to better quality nursing home care. The study considered structural, process, and outcome measures of quality. The study addressed the endogeneity between regulations and quality by utilizing instrumental variables. The Harrington Regulation Stringency Index (HRSI) was used as a cost measure. Z scores were calculated for average deficiencies (citations) per facility, percent of facilities with any deficiencies, percent of facilities with deficiencies of G level scope and severity or greater, percent of facilities substandard, and civil monetary penalties per facility. Logistic regression allowed for the calculation of risk-adjusted rates by facility, with a score of 1 or greater indicating worse than average, less than one indicating better than average quality. The study controlled for competition, market median income, hospital wage index, 2004 Medicaid rates, facility size, ownership, hospital, multi-facility organization, and staffing standards. Two-stage least-squares models were estimated for each of seven quality measures to analyze the relationship between regulation and quality.

Results of the study found significant discrepancies in HRSI and quality measures amongst States. Four of the seven areas of quality outlined in the study, including CNA and LPN staffing, urinary incontinence, and ADL decline were found to improve with increased regulatory stringency. RN staffing, high-risk pressure ulcers, and hotel expenditures were not found to be statistically significant in relation to regulatory stringency. From a comparative

effectiveness standpoint, the authors pose the question of regulatory stringency versus increasing competition and transparency regarding care outcomes (Castle & Ferguson, 2010; Mukamel et al, 2012). Overall, the study reports competition is more effective than regulatory stringency in ensuring quality of care, however, regulation is more effective in ensuring quality than progress reports.

In the United States, Medicaid is the primary payer for nursing home care, accounting for sixty to seventy percent of nursing home bed days (Grabowski et al, 2008; Hoffman, 2018). In 2015, the average Medicaid shortfall in the US was -11.8% (AHCA, 2016). While Medicare funding can make up for some of the deficit, SNF/NF margins continue to decline, totally 12.5% in 2015. Because Medicare accounts for a much smaller percent of bed days, approximately 14.2% in 2014, total margins were -2.5% in 2015. Private rates can be increased to offset some of the deficit; however, only 10-20% of nursing home bed days are reimbursed with private funds, including long-term care insurance (AHCA, 2016; Hoffman, 2018). The regulatory mandates to increase levels of nursing staff, including Registered Nurses (RNs), Licensed Practical Nurses (LPNs) and Certified Nursing Assistants (CNAs) is expensive, considering there are no increases in reimbursement levels to support doing so. A study by Bowblis (2015) used 1999-2004 Medicare Cost Reports and OSCAR data for 13,318 nursing homes to determine the financial impact on SNFs after implementation of the minimum staffing requirements regulations. Medicare and Medicaid provided seventy-five percent of the funding for the SNFs included in the study. Bowblis' study references the unintended negative consequences of regulators attempting to improve quality of care actually having the opposite effect by causing SNFs to endure a deficit, resulting in a negative impact on resident quality of care. Levenson (2010) stresses the importance of adequate reimbursement and incentives to allow providers to

meet quality standards. Payment policies must consider the acuity, needs, and preferences of the resident as opposed to diagnosis or issue.

Quality Measures and Quality of Care

The Centers for Medicare & Medicaid Services (CMS) utilizes data from the MDS to calculate publicly reported quality measures for nursing homes (Wade, 2016). The QM data was developed to assist consumers in obtaining information about quality of care in nursing homes. Data is updated quarterly and publicly available on the Nursing Home Compare website (medicare.gov/nursinghomecompare). The data represent process and outcome measures; however, they do not capture engagement measures such as satisfaction and relationships with caregivers (Kapp, 2000).

The four quality measures selected for the study, including percentage of short-stay residents with pressure ulcers that are new or worsened, percentage of long-stay residents who self-report moderate to severe pain, percentage of long-stay residents who were physically restrained, and the percentage of long-stay residents who got an antipsychotic medication were chosen for several reasons. These QMs are evidenced-based measures of quality of care (Ward, 2016) and exist as publicly reported quality measures pre- and post-implementation of the Phase I RoP. Prior studies have utilized pressure ulcers, restraints, pain, and antipsychotic use as measurements of quality of care (Miller et al, 2014; Mukamel et al, 2012). Mukamel (2012) included MDS data for decline in ADLs, high-risk pressure ulcers, and urinary incontinence as outcome measures of quality.

Table 1. CMS Quality Measures and Implementation Dates

	Quality Measure	Date Implemented
Short-Stay	Percent of Residents with Pressure Ulcers that are New or Worsened	10/1/2010
Long-Stay	Percent of residents who self-report moderate to severe pain	10/1/2010
	Percent of Residents who were Physically Restrained	10/1/2010
	Percent of Residents who Received an Antipsychotic Medication	4/1/2012

Source: Centers for Medicare and Medicaid Services (2019)

A study by Grabowski et al. (2008) used MDS data for 12 quality indicators to determine the effect of payer source on nursing home quality. The study collected OSCAR data to determine descriptive statistics for the 1.6 million residents included in the study. Payer information for each of the seven States included in the study was obtained from each Medicaid office. Linear regression models tested the relationship between the independent and dependent variables (payer status and quality indicators, respectively). The results indicated consistency in

quality of care amongst payer sources, specifically Medicaid, in comparison with higher paying sources including Medicare and private resources.

A study funded by the Robert Wood Johnson Foundation (Swafford, Miller, Tsai, Herr, and Ersek, 2009) conducted a literature synthesis to find evidenced-based information regarding the effectiveness and improvement activities pertaining to pain management in nursing homes. A total of 472 articles were initially reviewed by the lead author, with 419 excluded for not meeting the specific criteria of the study. The remaining 53 articles were reviewed by two authors, with 10 meeting the final criteria for the study specific to systematic approaches to pain practices in nursing homes. The research found the most successful programs following a quality improvement methodology, with the use of established pain management quality improvement teams, ongoing education, and support from internal and/ or external consultants. A process for ongoing monitoring and revisions of the program, as well as the use of tools and resources for pain assessment and interventions were suggested. Additionally, opportunities to work with other facilities to foster sharing of best practices and support were also determined to have a meaningful effect on the improvement of pain management practices in nursing homes.

The practices in the literature varied from the use of MDS data to verbal pain reporting processes (Swafford et al, 2009). A statistically significant impact on the assessment and management of pain was noted for facilities receiving education, support, and/ or utilizing a quality improvement methodology. The study noted the critical elements of successful pain management programs as those of organizational structure, assessment and management of pain processes, educational opportunities, and measurement of pain.

Pressure ulcers reflect staffing levels and competency of staff, which are meaningful indicators of quality of care (Blankart, Foster & Mor, 2019; Gruneir & Mor, 2008). Pressure

ulcers have a significant impact on quality of life, including risk of infection, decrease in ambulatory status, pain, an increased need for care and services, and risk of mortality. Financial implications for both provider and resident range between \$10,000 and \$86,000 (Clarke et al, 2005) per pressure ulcer. A study by Au et al. (2019) references the beneficial impact of quality improvement methodologies in the management of skin integrity processes (systems) in SNFs. A proactive approach to pressure ulcer prevention, including staffing levels, equipment, reimbursement rates, and training, is a notable measure of quality of care (Gruneir & Mor, 2008). Important components include the ability to assess, document, and track measurements and characteristics for existing wounds.

According to CMS (Reform of Requirements for Long Term Care Facilities, 2016) and several studies, antipsychotic utilization is another important indicator of quality of care (Lau, Kasper, Potter & Lyles, 2004; Lucas et al, 2014). The reform created a new category of regulations under 'Pharmacy Services', moving antipsychotic regulations from the quality of care category. Despite this change, the use of psychotropic drugs is considered an indicator of quality of care, defined by CMS as achieving or maintaining the highest level of well-being according to patient-directed preferences and care needs.

In the United States, over 50% of nursing home residents have a diagnosis of Alzheimer's disease or another dementia (Harris-Kojetin et al., 2016). Most of these patients have lost their ability to communicate verbally and non-verbally due to the progression of the disease. This loss of ability to communicate results in patients demonstrative aggressive, paranoid, sometimes destructive behaviors (Salzman, 2013). Medications such as benzodiazepines and antidepressants have been utilized to treat these behavioral and psychological symptoms of dementia (BPSD) in the past with minimal results (Triforo, Sultana

& Spina, 2014). Due to the lack of effective medications, providers turned to antipsychotic medications to treat these patients (Salzman, 2013). Additionally, the use of physical restraints has been associated with higher rates of injury in SNF/ NF residents (Neufeld et al, 1999).

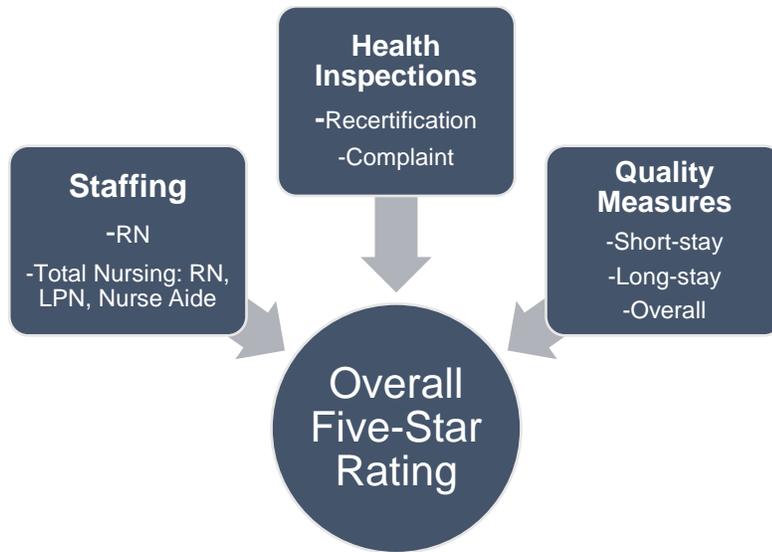
The Agency for Healthcare Research and Quality (AHRQ) conducted a study in 2006 to determine the effects of antipsychotics on the rate of mortality for elderly patients with dementia (Maglione et al, 2011). The study found the mortality rate for those receiving antipsychotics to be 3.5% as compared to 2.3% for those receiving the placebo (Maglione et al, 2011). In 2007, the Office of Inspector General embarked on a study at the request of Senator Charles Grassley regarding the use of antipsychotic medications in nursing home residents (Levinson, 2011). The results of the study were published in 2011, reporting that approximately 14% of nursing home residents with dementia received an antipsychotic medication for a diagnosis unrelated to those approved by the Food and Drug Administration (FDA). The FDA black box warning specifically reads “increased mortality in elderly patients with dementia related psychosis” (Levinson, 2011, p.4). Though the drugs are approved for use in patients diagnosed with Huntington’s disease, Tourette’s disorder and schizophrenia, they are commonly used for nursing home patients with diagnoses of dementia with psychosis or dementia with behavioral disturbances. This information, in addition to the high costs of atypical antipsychotic use- \$13 billion in 2007 alone- caused the OIG to call for major changes in the use of these medications in the elderly with a diagnosis of dementia in nursing homes.

Five-Star Rating

In 2008, the Centers for Medicare & Medicaid Services (CMS) developed and implemented the Five-Star Quality Ratings, publicly available on Nursing Home Compare (www.medicare.gov/nursinghomecompare/). The Five-Star rating system was created to assist

consumers in assessing and selecting nursing homes based on a variety of factors, including inspection results, staffing, and quality indicators (Centers for Medicare & Medicaid Services, 2019).

Figure 3. Conceptual Model, Overall Five-Star Rating Composition



Health Inspections. Results of the last three health inspection surveys are compiled to develop a five-star rating for this component. Each nursing home is given a rating of one to five stars in comparison to other nursing homes in their State. A number of points are assigned to each deficiency received, with a greater number of points assigned to deficiencies of higher scope and severity (Table 5).

Table 2. Scope and Severity, Health Inspection Deficiencies

Severity	Scope		
	Isolated	Pattern	Widespread
Immediate jeopardy to resident health or safety	J 50 points* (75 points)	K 100 points* (125 points)	L 150 points* (175 points)
Actual harm that is not immediate jeopardy	G 20 points	H 35 points (40 points)	I 45 points (50 points)
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D 4 points	E 8 points	F 16 points (20 points)
No actual harm with potential for minimal harm	A 0 point	B 0 points	C 0 points

Source: Centers for Medicare & Medicaid Services, October 2019, p. 3

The nursing homes with the lowest number of points are granted a five-star rating as a top 10% performer within their State. The middle performers (seventy percent of the homes in the State) are assigned two, three, or four stars. The bottom 20%, considered low performers, are given a one-star rating. The relative weight of the prior three recertification and complaint surveys are detailed in Table 6.

Table 3. Five-Star Health Inspection Composition

Recertification	Weight Contribution to Five-Star Health Inspection Rating	Complaint	Weight Contribution to Five-Star Health Inspection Rating
Most Recent	50%	12 months or less	50%
Second Most Recent	33.3%	13-24 months	33.3%
Third Most Recent	16.7%	25-36 months	16.7%

The health inspection component of the overall five-star rating is updated monthly to account for recent recertification, complaint, and follow-up surveys.

Staffing. The staffing component of the five-star rating is based on total nursing, including Registered Nurses (RN), Licensed Practical Nurses (LPNs), and Nurse Aides (NAs)

and RN staffing. Staffing numbers are submitted by providers electronically on a quarterly basis to CMS via the Payroll-Based Journal (PBJ) (CMS, 2019). Hours per resident day are calculated and adjusted for resident acuity based on MDS data. The staffing component of the five-star rating is updated quarterly.

Quality Measures. The quality measure component of the five-star rating is updated quarterly based on fifteen quality measures derived from the MDS or Medicare claims-based data (CMS, 2019). Scores are calculated for long-stay, short-stay, and overall quality measures (Table 4). The overall quality measure score is utilized in the overall five-star facility rating. Nursing homes are given points for each quality measure (Tables 7, 8), with a higher score representing higher quality. Four quarters of data are utilized to develop the quality measure score to reduce variation and bias (CMS, 2019).

Table 4. Five-Star Quality Measures: Type, MDS versus Claims Based, and Points

Quality Measure	Short-Stay or Long-Stay	MDS or Claims Based	Maximum Number of Points
Percent of residents whose need for help with activities of daily living has increased	Long-Stay	MDS	150
Percent of residents whose ability to move independently worsened	Long-Stay	MDS	150
Percent of high-risk residents with pressure ulcers	Long-Stay	MDS	100
Percent of residents who have/had a catheter inserted and left in their bladder	Long-Stay	MDS	100
Percent of long-stay residents who report moderate to severe pain**	Long-Stay	MDS	**
Percent of residents with a urinary tract infection	Long-Stay	MDS	100
Percent of residents experiencing one or more falls with major injury	Long-Stay	MDS	100
Percent of residents who received an antipsychotic medication	Long-Stay	MDS	150
Number of hospitalizations per 1,000 long-stay resident days	Long-Stay	Claims	150
Number of outpatient emergency department (ED) visits per 1,000 long-stay resident days	Long-Stay	Claims	150
Percent of residents who made improvement in function	Short-Stay	MDS	150
Percent of SNF residents with pressure ulcers that are new or worsened	Short-Stay	MDS	100
Percent of residents who newly received an antipsychotic medication	Short-Stay	MDS	100
Percent of short-stay residents who report moderate to severe pain**	Short-Stay	MDS	**
Percent of short-stay residents who were re-hospitalized after a nursing home admission	Short-Stay	Claims	150
Percent of short-stay residents who have had an outpatient emergency department (ED) visit	Short-Stay	Claims	150
Rate of successful return to home and community from a SNF	Short-Stay	Claims	150

**In October 2019, CMS removed the quality measures for percentage of long- and short-stay residents reporting moderate to severe pain. This change was made due to speculation nursing homes with higher rates of pain may seek intervention with opioids (CMS, 2019), a conflict of interest with the current opioid crisis in the United States. These measures have been in place since 2010 and have been a meaningful measure of quality of care in several studies (Castle & Ferguson, 2010; Dulal, 2018; Grabowski et al, 2008; Xu et al, 2016). With data available through 2019, the pain quality measure for long-stay residents will be utilized in this study.

Table 5. Overall Quality Measure Rating Categories

	1-Star	2-Stars	3-Stars	4-Stars	5-Stars
Points Range	299-943	944-1132	1133-1298	1299-1474	1475-2300

Overall Rating. The CMS considers health inspection ratings to be most important in providing an overall five-star rating for each nursing home. Overall rating begins with health inspection star rating, with one star added for staffing rating of four to five or subtracted for staffing rating of one. One star is then added for a quality measure rating of five or subtracted for a rating of one.

CHAPTER III METHODOLOGY

This study is a retrospective program evaluation using data from the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare to compare nursing home quality measures pre- and post-implementation of Phase I of the Medicare and Medicaid Programs Reform of Requirements for Long-Term Care Facilities. Nursing Home Compare data are collected by the Centers for Medicare & Medicaid (CMS) Nursing Home Compare MDS Quality Measures (QMs). This data is derived from nursing home resident's Minimum Data Set (MDS), transmitted to CMS by Medicare and Medicaid certified facilities. The files are available to the public for all nursing home-based skilled nursing facilities and exclude critical access hospital (CAH) swing beds. QMs are available on a national level and provide information about the quality of care provided in SNFs/ NFs (Castle & Ferguson, 2010).

The four quality measures selected for this study include the percentage of short-stay residents with pressure ulcers that are new or worsened, percentage of long-stay residents who self-report moderate to severe pain, percentage of long-stay residents who were physically restrained, and the percentage of long-stay residents who got an antipsychotic medication were selected for several reasons. These QMs are evidenced-based measures of quality of care (Ward, 2016) and exist as publicly reported quality measures pre- and post-implementation of the Phase I RoP. Additionally, all have been utilized as indicators of quality of care in SNFs/NFs in prior studies (Castle & Ferguson, 2010; Grabowski et al, 2008; Kapp, 2000; Kumar, Norton & Encinosa, 2006; Wade, 2016) and in quality initiatives such as Advancing Excellence and the National Nursing Home Quality Improvement Campaign (<http://www.nhqualitycampaign.org/>). According to Castle & Ferguson (2010), the QMs selected for this study are “quality indicators used in prominent quality initiatives” (p. 433). The QMs have been gathered and publicly

reported by CMS since 2008; three of the four QMs in this study have been publicly reported since 2010 (see Table 3).

Quality measures provide information on structural, process, and outcome measures in nursing homes. For the purposes of this study, process and outcome measures are used to determine the effect of the RoP Phase I on quality in nursing homes. The process measures indicate what the SNF/ NF is doing to provide care and services to residents. Outcomes measures indicate the effectiveness of processes and systems.



Research Design

A quantitative approach to test the four study hypotheses was conducted. This approach was used based on the quantitative nature of the data used in the study, and the lack of prior statistical analysis regarding the impact of regulatory stringency on quality measures in SNFs/ NFs. The quality measures included in this study have been used as measures of quality in prior studies, with three of the four- pressure ulcers, restraints, and pain- endorsed by the National Quality Forum (Centers for Medicare & Medicaid Services, 2019).

Sample Selection

The datasets from January to December 2015 and January to December 2017 were downloaded from <https://data.medicare.gov/data/nursing-home-compare>. SNFs/ NFs with missing data were excluded, as well as those who operate as part of a hospital. The dataset was cleaned to eliminate SNFs/ NFs with missing data and to solely include the quality measure variables of interest to the study (Figure 5). The final sample size for the study included 14,210 Medicare and/ or Medicare certified skilled nursing facilities (SNFs)/ nursing facilities (NFs) in the United States. SNFs/ NFs residing in a hospital were excluded due to the distinct differences in comparison with non-hospital-based facilities.

The measure score was filtered by inclusion criteria, comprised of ownership, bed certification, location (state), and zip code. These variables were included due to the evidence-base supporting the influence of ownership, number of beds per facility, and local markets on quality of care in SNFs/ NFs (Kapp, 2000). Data were linked by provider number.

Figure 5. Data Exclusion and Synthesis Process

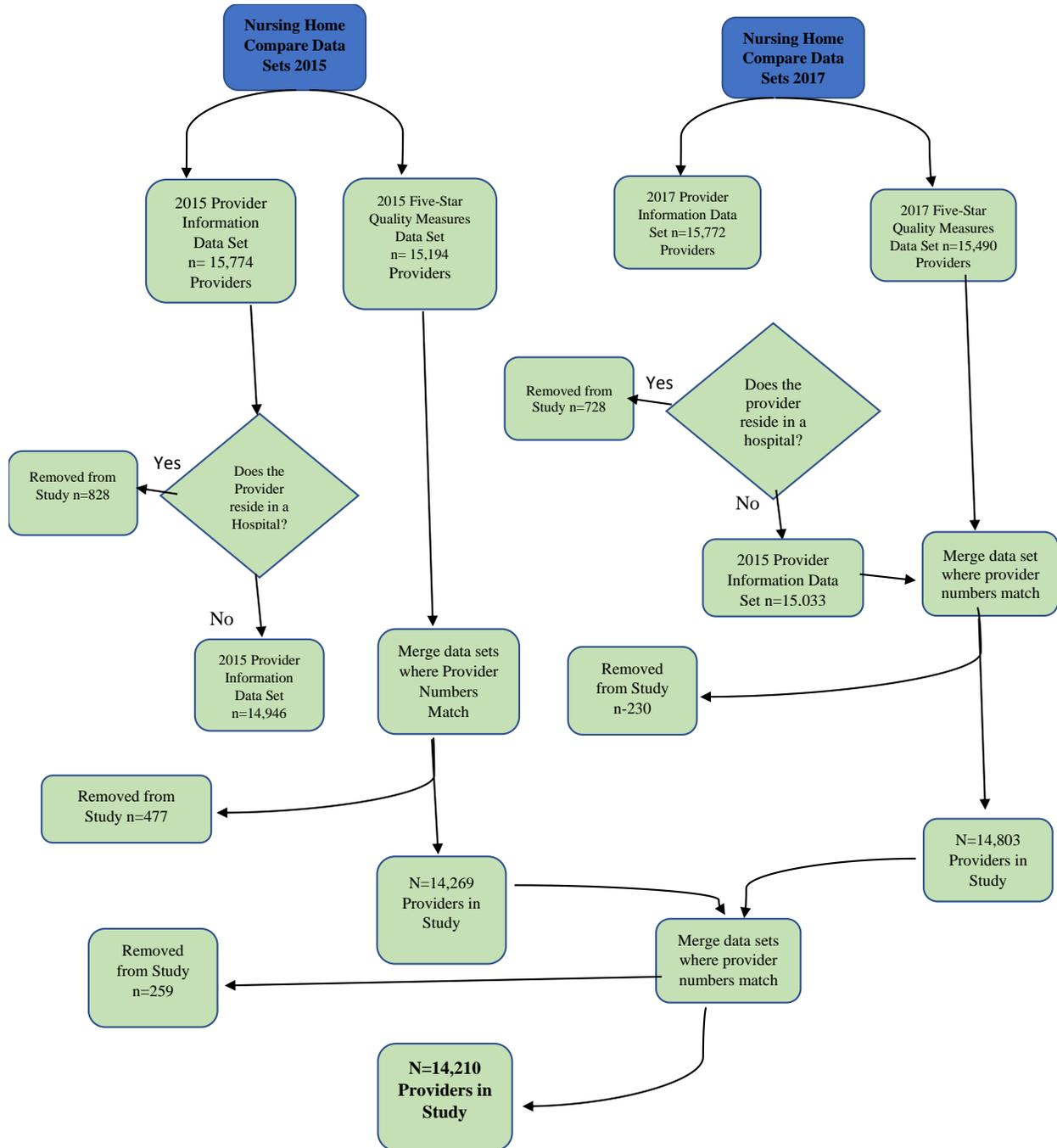


Table 6. Covariates and Definitions

Covariate	Definition	Type
Bed Cert	Number of certified beds	Integer
Ownership	For profit- Corporation For profit- Individual For profit- Limited liability For profit- Partnership Government- City Government- City/ County Government- County Government- Federal Government- Hospital Government- State Non profit- Church related Non profit- Corporate Non profit- Other	Label
State	Provider State	2-character postal abbreviation
Zip	Provider Zip Code	5-digit zip code

Source: Centers for Medicare & Medicaid Services, n.d.

Instrumentation

The Statistical Package for the Social Sciences (SPSS) version 24 was used to analyze and compare data by quarter for January to December 2015 (pre-implementation) and January to December 2017 (post-implementation) of the 2016 Medicare RoP Phase I.

Data Set Description

Publicly available archival data from the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare (<https://data.medicare.gov/data/nursing-home-compare>) for 14, 210 nursing homes in the United States were utilized for this study. The data is derived from the

Minimum Data Set (MDS), completed quarterly for all SNF/ NF residents. The MDS is completed by professional staff in the SNF/ NF and transmitted to CMS, where it is added to a national database (Centers for Medicare & Medicaid Services, 2019).

Table 7. Quality Measures: Definition, Numerator, and Denominator

Quality Measure	Definition	Numerator	Denominator	Exclusions
Percentage of Short-Stay residents with pressure ulcers that are new or worsened	% short-stay residents with new or worsened pressure ulcers stage II-IV	Short-stay residents with new or worsening stage II-IV pressure ulcer(s) in past quarter)	All residents with assessments in past quarter	Data from look-back unavailable
Percentage of Long-Stay residents who report moderate to severe pain	% long-stay residents who report at consistent moderate to severe pain in the past 5 days OR one episode of severe pain	Long-stay residents who report: 1)at least one episode of daily moderate/ severe pain <u>and/ or</u> 2) severe pain of any frequency	All long-stay residents with assessments in past quarter	Residents without numeric pain indicators and/ or those not assessed
Percentage of Long-Stay residents who were physically restrained	% long-stay residents with daily physically restraint	Long-stay residents with daily trunk or limb restraints or prevention of rising from bed or chair	All residents with assessments in past quarter	Areas of MDS Section P that are not assessed (trunk, limb restraints, chair prevents rising)
Percentage of Long-Stay residents who received an antipsychotic medication	% of long-stay residents who received antipsychotic in the quarter (if MDS completed in quarter)	Long-stay residents who received antipsychotic medication during assessment	All residents with assessments in past quarter	Residents with diagnosis of Schizophrenia, Tourette's Syndrome, Huntingtons Disease

Source: Centers for Medicare & Medicaid Services (2019)

Variables

Descriptive statistics were used to examine the changes that occurred to the selected quality measures (Table 8). These include four quality measures: percentage of short-stay residents with pressure ulcers that are new or worsened, percentage of long-stay residents who report moderate to severe pain, percentage of long-stay residents who were physically restrained, and percentage of long-stay residents who received an antipsychotic medication. The quality measures are numerical in nature and are further defined in Table 9. The study also provides

descriptive statistics summarizing the number of certified beds in the nursing home, ownership type, and location.

Table 8. Variables

Variables	Percentage of Short-Stay residents with pressure ulcers that are new or worsened	Percentage of Long-Stay residents who report moderate to severe pain	Percentage of Long-Stay residents who were physically restrained	Percentage of Long-Stay residents who received an antipsychotic medication
Covariates	Number of Certified Beds	Ownership	State	Zip Code

Table 9. Quality Measures: Implementation, Definition, Type

	Quality Measure	Date Implemented	Definition	Type of Data
Short Stay	Percent of Residents with Pressure Ulcers that are New or Worsened	10/1/2010	% short-stay residents with new or worsened pressure ulcers stage II-IV	Numerical
Long Stay	Percent of residents who self-report moderate to severe pain	10/1/2010	% long-stay residents who report at least one episode of moderate to severe pain in the past 5 days	Numerical
	Percent of Residents who were Physically Restrained	10/1/2010	% long-stay residents with daily physically restraint	Numerical
	Percent of Residents who Received an Antipsychotic Medication	4/1/2012	% of long-stay residents who received antipsychotic in the quarter (if MDS completed in quarter)	Numerical

Research Question and Research Hypotheses

How do CMS quality measures (QMs) compare pre- and post-implementation of Phase I

of the Medicare and Medicaid Programs Reform of the Requirements for Long-Term Care Facilities?

H1. The percentage of short-stay residents with pressure ulcers that are new or worsened will decline post- implementation of the Phase I Requirements of Participation.

H2. The percentage of long-stay residents who self-report moderate to severe pain will decline post- implementation of the Phase I Requirements of Participation.

H3. The percentage of long-stay residents who were physically restrained will decline post-implementation of the Phase I Requirements of Participation.

H4. The percentage of long-stay residents who received an antipsychotic medication will decline post-implementation of the Phase I Requirements of Participation.

Data Analysis

Descriptive statistics were used to identify trends pre- and post-implementation of the Requirements of Participation Phase I. Univariate analysis was conducted separately for each of the four quality measures to determine the mean and standard deviation. Normally continuous variables were tested using a t-test. Non-normally distributed continuous data were tested utilizing nonparametric tests (Wilcoxon), and categorical data were compared using a Chi-square test. A bivariate analysis was conducted for each of the 4 quality measures, comparing means by quarter from prior to implementation of RoP (2015) and post implementation of RoP (2017). The mean and standard deviation for each of the quality measures are reported in Table 12.

Logistic models were used to examine effect of contextual geographic measures as needed. Logistic modeling of key measurements was conducted to determine the influence of State (location) and ownership type for each facility. Models were pared down to show variable

factors with significant p values. States with significance were placed in the comparison group, while the remaining states were arranged to create the reference group (Table 10).

Table 10. Reference and Comparison Groups: Logistic Model

States in Reference Group		States in Comparison Group	
AK	ND	CT	NY
AL	NH	DE	OH
AR	NM	FL	OK
AZ	NV	IA	OR
CA	PA	ID	SD
CO	PR	IL	TN
DC	RI	KY	WI
GA	SC	LA	
HI	TX	MA	
IN	UT	ME	
KS	VA	MO	
MD	VT	MS	
MI	WA	NE	
MN	WV	NJ	
MT	WY		
NC			

Limitations

There are limitations to the use of quality measures (QMs) as quality of care metric. QMs are derived from minimum data set (MDS) information. The MDS is completed by facility staff, and despite training, there is room for subjectivity or errors in data entry (Castle & Ferguson, 2010). Interpretation of the questions and approaches to gathering data are potentially variable. To address this issue, CMS implemented MDS focused surveys as means to substantiate the accuracy of MDS coding in SNFs/ NFs.

Protection of Human Subjects

The study did not require IRB approval as there were no human subjects involved and the

data for the study was de-identified and publicly available.

CHAPTER IV RESULTS

Results/Findings

This retrospective study using data from the Centers for Medicare & Medicaid Services (CMS) Nursing Home Compare was conducted to determine the effects of the Medicare and Medicaid Requirements of Participation (RoP) Phase I for Long-Term Care Facilities on four quality measures. The publicly available dataset was revised to exclude critical access hospital (CAH) swing beds and facilities with missing data. Approximately 800 facilities did not report quality measure data in either 2015 or 2017, potentially due to closure, de-certification, or new certification after 2015. The final dataset included 14,210 Medicare and/or Medicaid certified Skilled Nursing Facilities (SNFs)/ Nursing Facilities (NFs) of the 15,600 in the United States, or ninety-one percent of facilities (Harris-Kojetin et al, 2019). The Statistical Package for the Social Sciences (SPSS) version 24 was used to analyze and compare data.

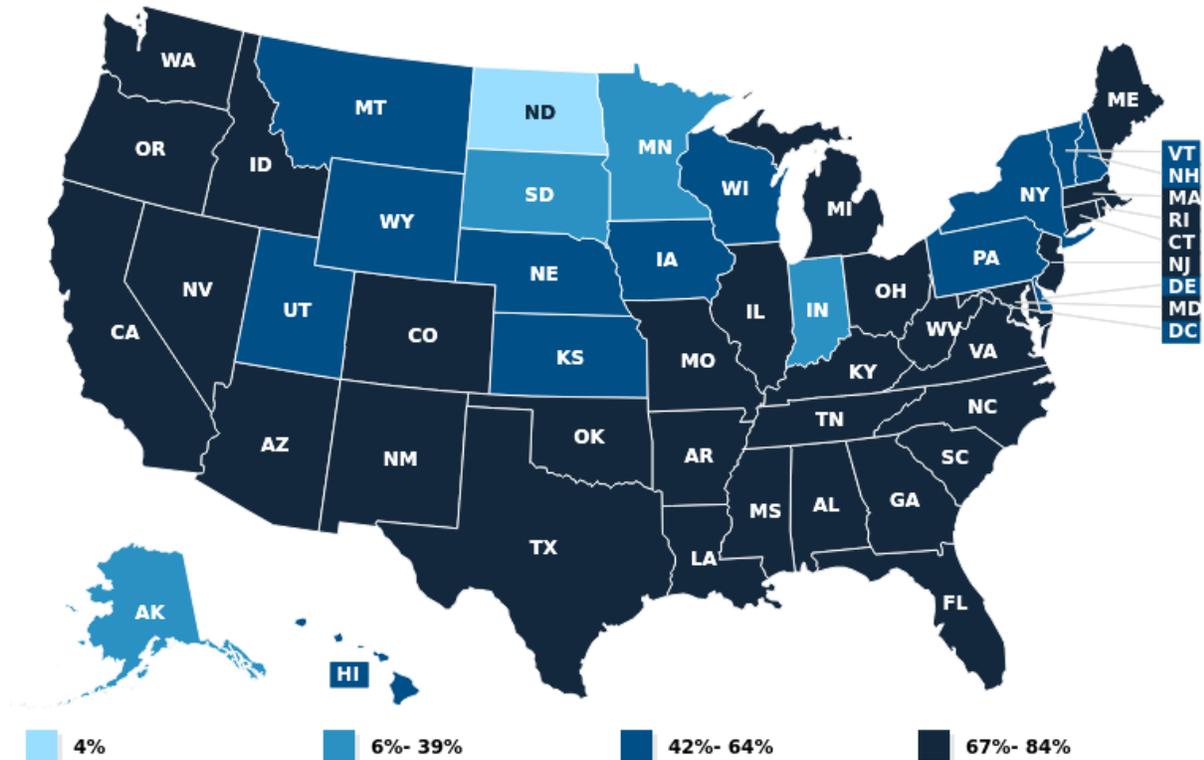
On average, there are 110.2 certified beds (SD 58.7) (Table 10). The mean number of beds was the same (110.2) in both 2015 and 2017, with a .4 decrease in standard deviation from 2015 (58.7) to 2017 (58.3). The majority of SNFs/ NFs were owned by a for-profit corporation (9,235 or 65%), for-profit partnership (753 or 5.3%), or county government (400 or 2.8%). Figure 6 provides information regarding the percentage of for-profit facilities by state (Kaiser Family Foundation, 2017).

Table 11. Descriptive Statistics: Number of Certified Beds and Ownership Type

Organizational Characteristics	2015	2017
Number of Certified Beds -Mean (std)	110.2 (58.7)	110.2 (58.3)
Ownership Type n(%)	14210 (100)	
For profit- Corporation	9235 (65)	
For profit- Individual	486 (3.4)	
For profit- Limited Liability	51 (.4)	
For profit- Partnership	754 (5.3)	
Government- City	57 (.4)	
Government- City/ County	80 (.6)	
Government- County	400 (2.8)	
Government- Federal	12 (.1)	
Government- Hospital	110 (.8)	
Government- State	116 (.8)	
Non profit- Church related	542 (3.8)	
Non profit- Corporation	2204 (15.5)	
Non profit- other	163 (1.1)	

Figure 6.

Distribution of Certified Nursing Facilities by Ownership Type: For Profit, 2017



SOURCE: Kaiser Family Foundation's State Health Facts.

Descriptive statistics were utilized to calculate the number and percentage of SNFs/NFs in each State (Table 11). Of the top five States with the highest number of SNFs/NFs in the U.S., Texas (1140, 8%) and California (1071, 7.5%), comprise almost 16%. Ohio (906, 6.4%), Illinois (688, 4.8%) and Florida (688, 4.7%) round out five States with the highest number of facilities.

Table 12. Number and Percentage of SNFs/ NFs by State

State	Number of Facilities	Percent of Total SNFs/ NFs(U.S)
AK	4.0	0.0
AL	213.0	1.5
AR	217.0	1.5
AZ	138.0	1.0
CA	1071.0	7.5
CO	203.0	1.4
CT	217.0	1.5
DC	13.0	0.1
DE	44.0	0.3
FL	668.0	4.7
GA	308.0	2.2
HI	31.0	0.2
IA	378.0	2.7
ID	63.0	0.4
IL	688.0	4.8
IN	516.0	3.6
KS	268.0	1.9
KY	256.0	1.8
LA	265.0	1.9
MA	387.0	2.7
MD	217.0	1.5
ME	92.0	0.6
MI	402.0	2.8
MN	309.0	2.2
MO	480.0	3.4
MS	179.0	1.3
MT	54.0	0.4
NC	403.0	2.8
ND	62.0	0.4
NE	174.0	1.2
NH	69.0	0.5
NJ	339.0	2.4
NM	66.0	0.5
NV	44.0	0.3
NY	556.0	3.9
OH	906.0	6.4
OK	281.0	2.0
OR	132.0	0.9
PA	660.0	4.6
PR	2.0	0.0
RI	81.0	0.6
SC	173.0	1.2
SD	89.0	0.6
TN	291.0	2.0
TX	1140.0	8.0
UT	91.0	0.6
VA	264.0	1.9
VT	34.0	0.2
WA	203.0	1.4
WI	343.0	2.4
WV	103.0	0.7
WY	23.0	0.2
Total	14210.0	100.0

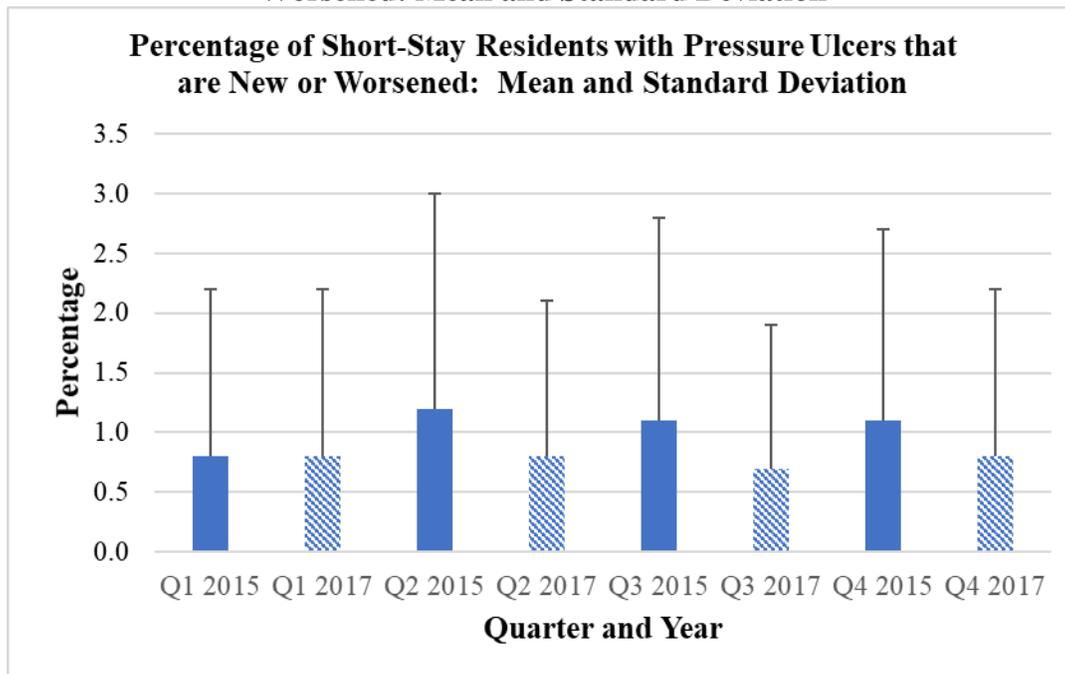
Non-parametric analysis was conducted using Wilcoxon Signed-rank tests to determine if there was a statistically significant difference in quality measures scores pre-implementation (2015) and post-implementation (2017) of the Requirements of Participation (RoP) (Table 12). This approach was used to compare the means for each quality measure by quarter and year.

Table 13. Mean and Standard Deviation by Quarter and Year

Metric	2015-Q1 Mean (SD)	2017-Q1 Mean (SD)	p-value	2015-Q2 Mean (SD)	2017-Q2 Mean (SD)	p-value	2015-Q3 Mean (SD)	2017-Q3 Mean (SD)	p-value	2015-Q4 Mean (SD)	2017-Q4 Mean (SD)	p-value
Percentage of long-stay residents who received an antipsychotic medication	18.4 (10.2)	15.6 (9.9)	<.0001	17.6 (9.9)	15.4 (9.9)	<.0001	17.1 (9.8)	15.3 (9.8)	<.0001	16.8 (9.6)	15 (9.5)	<.0001
Percentage of long-stay residents who self-report moderate to severe pain	6.6 (6.3)	5.4 (5.9)	<.0001	8.4 (7.6)	5.1 (5.7)	<.0001	8.1 (7.4)	5.0 (5.6)	<.0001	7.5 (7.0)	5.7 (6.4)	<.0001
Percentage of long-stay residents who were physically restrained	1.0 (2.7)	0.4 (2.0)	<.0001	0.9 (2.6)	0.4 (2.0)	<.0001	0.8 (2.7)	0.4 (2.0)	<.0001	0.8 (2.5)	0.4 (2.0)	<.0001
Percentage of short-stay residents with pressure ulcers that are new or worsened	0.8 (1.4)	0.8 (1.4)	0.96	1.2 (1.8)	0.8 (1.3)	<.0001	1.1 (1.7)	0.7 (1.2)	<.0001	1.1 (1.6)	0.8 (1.4)	<.0001

H1. The percentage of short-stay residents with pressure ulcers that are new or worsened will decline post-implementation of the Phase I Requirements of Participation.

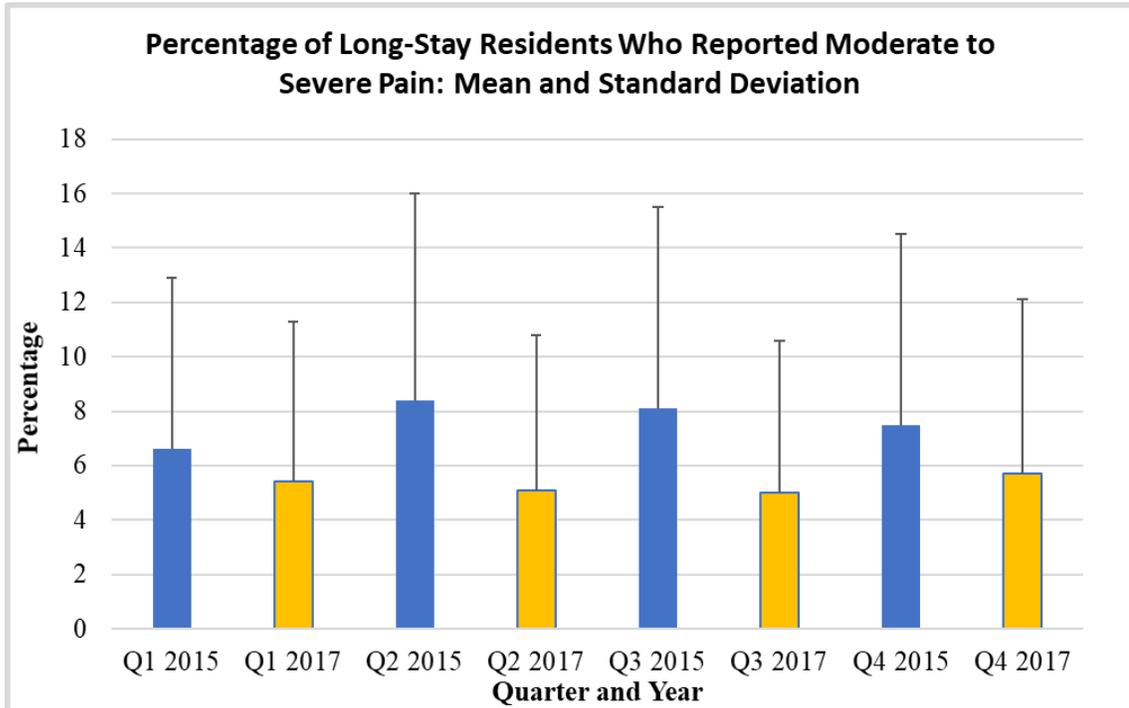
Figure 7. Percentage of Short-Stay Residents with Pressure Ulcers that are New or Worsened: Mean and Standard Deviation



The mean percentage of short-stay residents with pressure ulcers that are new or worsened was unchanged when comparing quarter 1 in 2015 and quarter 1 2017 ($p=0.96$). When comparing means for 2015 (range of 0.8 to 1.2) and 2017 (0.7 to 0.8) for quarters two, three, and four, all showed a statistically significant decline ($p<.0001$). Standard deviations (SD) reflect large variations in means for each quarter and year. In 2015, standard deviation ranged from 1.4 to 1.8. In 2017, the range was 1.2 to 1.4. The comparison of means shows a statistically significant decrease in the percentage of short-stay residents with pressure ulcers that are new or worsened when comparing quarters two, three, and four in 2015 and 2017, thereby accepting the null hypothesis (Figure 7).

H2. The percentage of long-stay residents who self-report moderate to severe pain will decline post-implementation of the Phase I Requirements of Participation.

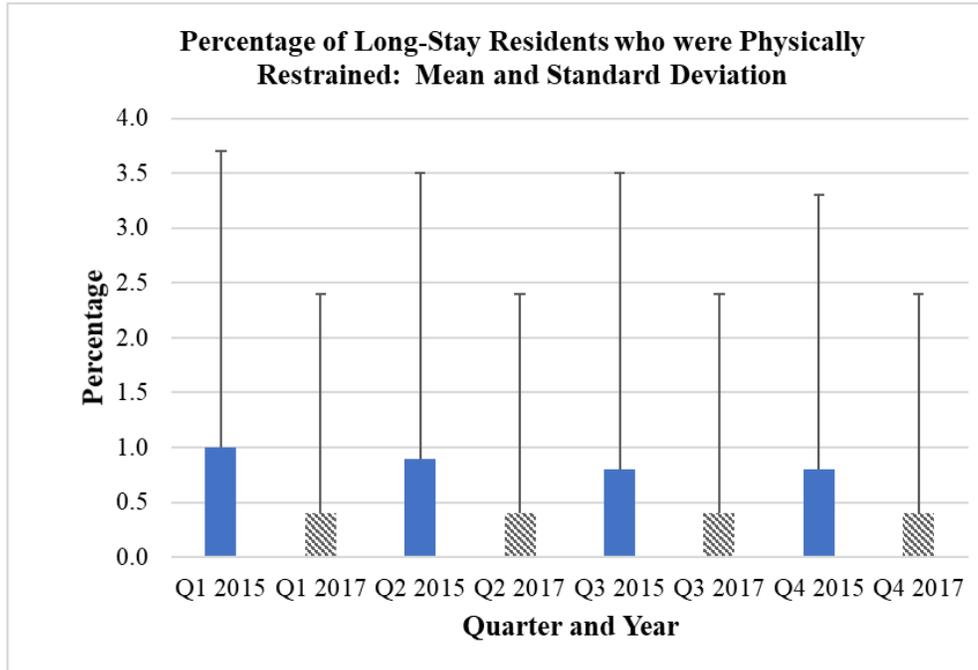
Figure 8. Percentage of Long-Stay Residents who Reported Moderate to Severe Pain: Mean and Standard Deviation



The mean percentage and standard deviation showed a statistically significant decline quarters one through four in 2017 in comparison to 2015 ($p < .0001$). When comparing means for 2015 (range of 6.6 to 8.4) and 2017 (range of 5.0 to 5.7) for quarters two, three, and four, all showed a statistically significant decline ($p < .0001$). Standard deviations (SD) reflect large variations in means for each quarter and year. In 2015, the standard deviation ranged from 6.3 to 7.6. In 2017, the range was 5.6 to 6.4. The comparison of means and standard deviation reflect a statistically significant decline in the percentage of long-stay residents who reported moderate to severe pain when comparing 2015 and 2017, thereby accepting the null hypothesis (Figure 8).

H3. The percentage of long-stay residents who were physically restrained will decline post-implementation of the Phase I Requirements of Participation.

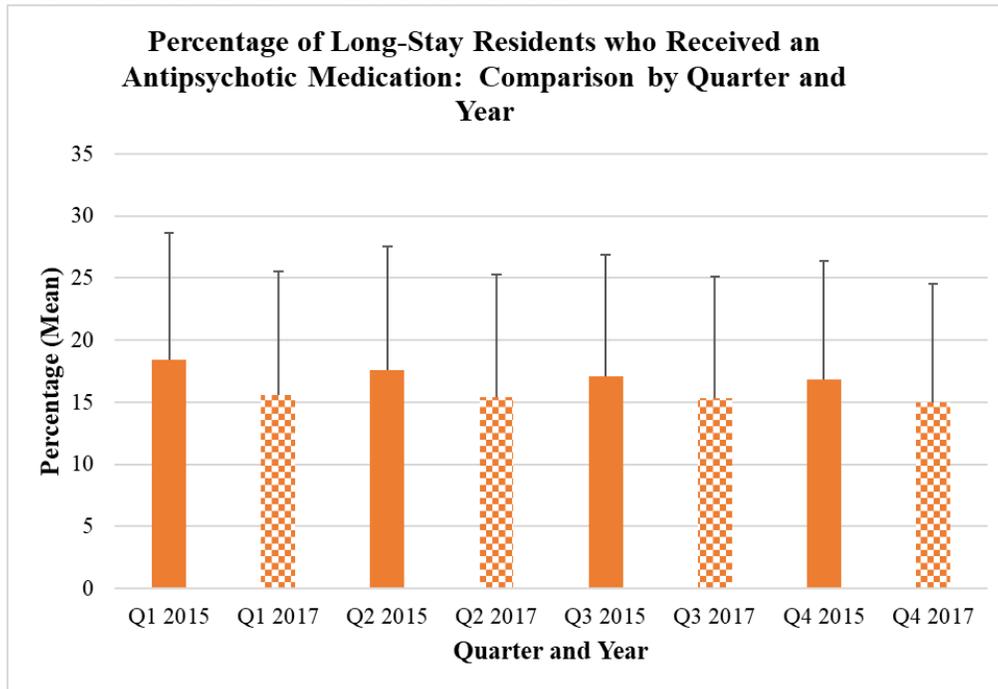
Figure 9. Percentage of Long-Stay Residents who were Physically Restrained: Mean and Standard Deviation



The mean percentage and standard deviation of long-stay residents who were physically restrained showed a statistically significant decline quarters one through four in 2017 in comparison to 2015 ($p < .0001$). When comparing means for 2015 (range of 0.8- 1.0) and 2017 (0.4) for quarters two, three, and four, all showed a statistically significant decline ($p < .0001$). Standard deviations (SD) reflect large variations in each quarter of 2015 with a range of 2.5 to 2.7 in 2015. In 2017, the SD was consistent at 2.0. The comparison of means and standard deviation reflect a statistically significant decline in the percentage of long-stay residents who were physically restrained when comparing 2015 and 2017, thereby accepting the null hypothesis (Figure 9).

H4. The percentage of long-stay residents who received an antipsychotic medication will decline post-implementation of the Phase I Requirements of Participation.

Figure 10. Percentage of Long-Stay Residents who Received an Antipsychotic Medication: Mean and Standard Deviation



The mean percentage and standard deviation of long-stay residents who received an antipsychotic medication showed a statistically significant decline quarters one through four in 2017 in comparison to 2015 ($p < .0001$). The mean percentage and standard deviation showed a statistically significant decline quarters one through four in 2017 in comparison to 2015 ($p < .0001$). When comparing means for 2015 (range of 16.8 to 18.4) and 2017 (range of 15 to 15.6) all quarters showed a statistically significant decline ($p < .0001$). Standard deviations (SD) reflect large variations in means for each quarter and year, with a range of 9.6 to 10.2 in 2015 and a range of 9.5 to 9.9 in 2017. The comparison of means and standard deviation reflect a statistically significant decline in the percentage of long-stay residents who received an antipsychotic medication when comparing 2015 and 2017, thereby accepting the null hypothesis (Figure 10).

Table 14. Odds Ratio results for Comparison Quarter 4 2015-2017***States are compared to reference group (Table 10); Ownership is compared to For-Profit**

Parameter: Odds Ratio (pvalue)	% of long-stay residents who received an antipsychotic medication	% of long-stay residents who self-report moderate to severe pain	% of long-stay residents who were physically restrained	% of short-stay residents with pressure ulcers that are new or worsened
CT	1.034 (0.1797)	1.451 (0.0029)	2.208 (0.0003)	1.299 (0.2891)
DE	0.383 (0.0114)	1.471 (0.1611)	1.205 (0.5845)	1.166 (0.8533)
FL	1.174 (0.0002)	1.298 (0.0003)	2.478 (<.0001)	1.342 (0.0307)
IA	0.815 (0.6106)	0.682 (0.0043)	0.615 (0.1778)	1.011 (0.6598)
ID	0.367 (0.0023)	0.653 (0.205)	0.309 (0.0181)	0.736 (0.3088)
IL	0.782 (0.2467)	1.16 (0.0165)	1.009 (0.1428)	0.998 (0.3884)
KY	1.234 (0.0049)	1.464 (0.0008)	1.829 (<.0001)	1.016 (0.6599)
LA	1.363 (0.0003)	1.891 (<.0001)	2.379 (<.0001)	0.831 (0.0861)
MA	0.887 (0.7735)	1.326 (0.0018)	1.851 (<.0001)	1.325 (0.1101)
ME	0.529 (0.0215)	0.413 (0.0008)	0.099 (0.0004)	1.189 (0.7225)
MO	0.721 (0.0652)	0.715 (0.0061)	0.56 (0.0404)	1.154 (0.6453)
MS	0.967 (0.4337)	1.321 (0.0299)	1.646 (0.003)	0.81 (0.1302)
NE	0.764 (0.4349)	0.444 (<.0001)	0.171 (<.0001)	0.791 (0.1457)
NJ	1.616 (<.0001)	1.315 (0.0068)	1.806 (<.0001)	1.377 (0.0703)
NY	2.073 (<.0001)	1.793 (<.0001)	1.847 (<.0001)	1.366 (0.026)
OH	1.343 (<.0001)	1.145 (0.011)	1.272 (0.0025)	1.255 (0.1224)
OK	0.604 (0.0042)	0.912 (0.804)	0.437 (0.0086)	0.845 (0.0992)
OR	0.618 (0.091)	0.294 (<.0001)	0.046 (<.0001)	1.21 (0.6043)
SD	0.514 (0.0163)	0.666 (0.1067)	1.208 (0.361)	1.41 (0.4751)
TN	1.282 (0.0014)	0.825 (0.317)	1.964 (<.0001)	1.085 (0.9899)
WI	0.727 (0.1316)	0.725 (0.0289)	0.396 (0.0021)	1.154 (0.6728)
Non profit	0.926 (0.4663)	1.022 (0.1261)	0.815 (0.7471)	0.923 (0.7207)
Government	0.766 (<.0001)	0.813 (0.0002)	0.61 (<.0001)	0.916 (0.491)

Logistic modeling of key measurements indicates the influence of State (location) and ownership type for each facility. Models were pared down to show variable factors with significant p values. States with significance were placed in the comparison group, while the remaining states were arranged to create the reference group. In Connecticut, short-stay patients with pressure ulcers observed a 30% increase in reduction of key measurements but the findings were not significant (OR=1.299, p=0.2891) (Table 13). Long-stay physically restrained residents saw a 121% (2.2-fold) increase in reduction of key measurements and the findings were significant (OR=2.208, p=0.0003).

Of the twenty-one states in the comparison group, eleven experienced an increase in the odds of reduction in percentage quality measures included in the study. Five States observed increases in reduction of long-stay antipsychotic use with statistical significance. Florida had a 17% increase in the reduction of long-stay antipsychotics (p=0.0002), Louisiana a 36% increase in reduction (p=0.0003), New Jersey 62% increase in reduction (p=0.0001), New York 107% (2.1 fold) increase in reduction (p=0.0001), and Ohio a 34% increase in reduction (p=0.0001). Other States had an increase in the reduction of antipsychotic use, including Kentucky (23%) and Tennessee (28%), but neither were significant (p=0.0049 and 0.0014 respectively).

Four states observed increases in reduction of long-stay moderate to severe pain with significant findings. Florida had a 30% increase in the reduction of long-stay moderate to severe pain (p=0.0003), Louisiana 89% (p=0.0001), New York 79% (p=0.0001), and Oregon 29% (p=0.0001).

Seven States, in addition to Connecticut, observed increases in the reduction of long-stay physical restraints with significant findings. Florida had a 148% (2.4 fold) increase in the reduction of physical restraints (p=0.0001), Kentucky 83% (p=0.0001), Louisiana 138% (2.4 fold, p=0.0001), Massachusetts 85% (p=0.0001), New Jersey 81% (p=0.0001), New York 85% (p=0.0001), and Tennessee 96% (p=0.0001). None of the States observed an increase in the reduction of new or worsened short-stay pressure ulcers with significance.

Table 15 provides data regarding states in the comparison group and higher/ lower odds ratios post-implementation of the Requirements of Participation for the four quality measures included in the study; percentage of long-stay residents who received an antipsychotic medication, percentage of long-stay residents who self-report moderate to severe pain, long-stay residents who were physically restrained, and short-stay residents with pressure ulcers that are new or worsened.

Table 15. Quality Measure Ratings and Odds Ratios by U.S. Region

	Average Quality Measure Star-Rating and Standard Deviation*	Number of States in Comparison Group	Number of States with higher OR	Number of States with lower OR
West	3.81 (1.31)	1	0	1
Northeast	3.58 (1.33)	5	4	1
Midwest	3.39 (1.38)	8	2	6
South	3.19 (1.39)	7	5	2

*Yuan et al (2018).

Logistic modeling of ownership observed significant findings in comparing for-profit, non profit, and government owned SNFs/ NFs. Using for-profit facilities as the reference group, government owned facilities were 23% less likely than for-profit facilities to observe a decrease in the reduction of long-stay antipsychotic use ($p=0.0001$), 19% less likely to observe a decrease in long-stay moderate to severe pain ($p=0.0002$), and 39% less likely to observe a decrease in percentage of long-stay physical restraints ($p=0.0001$). Government owned facilities were 7% less likely to observe a decrease in the percentage of short-stay pressure ulcers, though this was not statistically significant ($p=0.491$). Non profit facilities were 7% less likely than for-profit facilities to experience a decrease in antipsychotic use, though not statistically significant ($p=0.4663$). Non profit facilities were 18% less likely to experience a reduction in the percentage of physical restraints ($p=0.7471$) and 8% less likely to observe a reduction in short-stay pressure ulcers ($p=0.7207$), though neither were statistically significant. Non profit facilities had a 2% increase in the likelihood of reduction in the percentage of long-stay moderate to severe pain, but the findings were not significant ($p=0.1261$).

CHAPTER V DISCUSSION

Long-term care has a lengthy history of stringent regulations developed in response to highly publicized poor outcomes (Eskildsen & Price, 2009). Phase I of the Medicare and Medicaid Requirements of Participation (RoP) for Long-Term Care Facilities went into effect on November 27, 2016. According to Unroe, Ouslander, and Saliba (2017), the cost of implementing these rules is estimated at approximately \$62,900 for the first year, and \$55,000 per year thereafter. However, it is not known if these costly new rules have any impact on quality measures.

The purpose of this research project was to gain understanding of the impact of the 2016 RoP (Phase I) on quality measures in skilled nursing facilities (SNFs)/ nursing facilities (NFs). Results will enable providers to gain a better understanding of the impact of the RoP on four SNF/NF quality measures and provide policymakers with information regarding the impact of the RoP. This chapter will discuss major findings of the study, relationship to literature, interpretation of results, recommendations for future research, study limitations, and a final summary.

Research Question and Hypotheses

How do CMS quality measures (QMs) compare pre- and post-implementation of Phase I of the Medicare and Medicaid Programs Reform of the Requirements for Long-Term Care Facilities?

H1. The percentage of short-stay residents with pressure ulcers that are new or worsened will decline post- implementation of the Phase I Requirements of Participation.

H2. The percentage of long-stay residents who self-report moderate to severe pain will decline post- implementation of the Phase I Requirements of Participation.

H3. The percentage of long-stay residents who were physically restrained will decline post-implementation of the Phase I Requirements of Participation.

H4. The percentage of long-stay residents who received an antipsychotic medication will decline post-implementation of the Phase I Requirements of Participation.

The results of the study indicate three major findings, including 1) statistically significant reduction post-implementation of the Requirements of Participation (RoP) in the mean percentage of short-stay residents with pressure ulcers that are new or worsened, the percentage of long-stay residents who self-report moderate to severe pain, the percentage of long-stay residents who were physically restrained, and the percentage of long-stay residents who received an antipsychotic medication; 2) the influence of ownership; and 3) the influence of location (State).

Interpretation of the Results

The results of the study indicate statistically significant decreases in the mean percentage of each quality measure for fifteen of the sixteen quarter comparisons, 2015 to 2017. Logistic models indicate the influence of ownership type (for-profit, non profit, and governments) and location (State) in predicting the odds of reduction in each quality measure variable percentage in 2017 from 2015.

Comparison of Means Pre- and Post-implementation of the Requirements of Participation

Reductions in the mean percentage of short-stay residents with pressure ulcers that are new or worsened were observed post-implementation of the RoP ($p=.0001$) for three of the four comparisons. While quarter one did not have a significant change in mean percentage when comparing 2015 and 2017 ($p=0.96$), quarters two through four indicate a significant decline in mean percentages post-implementation of the RoP.

Reductions in the percentage of long-stay residents with antipsychotic use, physical restraints, and moderate to severe pain were observed for all quarters post-implementation of the RoP ($p=.0001$).

There are several factors aside from the implementation of the RoP that may have impacted the improvements in quality measure outcomes when comparing 2015 and 2017. The Hospital Readmissions Reduction Program (HRRP) was introduced by CMS in 2010 to reduce preventable readmissions to the hospital within 30 days of discharge (Zuckerman, Sheingold, Orav, Ruhter & Epstein, 2016). The HRRP is part of the CMS value-based care initiative, which includes financial penalties to hospitals who do not meet the risk-adjusted national averages for readmissions (CMS, n.d.; McIlvennen et al, 2015). The Protecting Medicare Act of 2014 (PAMA) announced penalties to skilled nursing facilities (SNFs) of up to 2% for Medicare Fee-For-Service patients returning to the hospital within 30 days of discharge, effective in 2018 (CMS, n.d.). These programs have provided increased incentives to SNFs to improve quality outcomes. Additionally, the growth of Accountable Care Organizations (ACOs) and their requirements of participation (minimum of 3-star rating, staffing levels, utilization and numbers of physician extenders) have caused SNFs to improve their performance to stay competitive and ensure they are selected as preferred providers (Chang et al, 2019).

Influence of Ownership

The influence of ownership on nursing home quality has been well-studied (Hillmer, Wodchis, Gill, Anderson & Rochon, 2005; Qi, Luke, Crecelius & Maddox, 2019; Yuan, Louis, Cabral, Schneider, Ryan & Kazis, 2018). The outcomes of this study indicate the influence of ownership status on reductions in the percentage of antipsychotic use, physical restraints, moderate to severe pain, and pressure ulcers (quality measures) in nursing homes. Non profit

and government owned facilities had a lower likelihood of reduction in quality measure percentages in comparison to for-profit SNFs/NFs. Prior studies indicate higher quality in non profit versus for-profit facilities (Qi et al, 2019; Yuan et al, 2018). A study by Yuan et al (2018) indicates quality measures star rating of 3.54 (SD 1.33) in non profit facilities, 3.40 (1.38) in for-profit, and 3.15 (1.48) for government owned facilities. Hillmer et al (2005) conducted a systematic review of studies researching the correlation between ownership and quality in nursing facilities. While most of the studies indicated non profit facilities experiencing better quality processes and outcomes, a few reported the opposite or no differences. Additional considerations, such as acuity or case-mix and payer-mix may have an impact when considering ownership and quality measure outcomes.

Influence of State/ Location

Robust literature exists regarding the influence of state (location) on SNF/ NF quality measure outcomes. As mentioned in Chapter II, Mukamel et al (2011) references the variances in quality measures amongst states due to the acuity of nursing home residents and the impact on the measurement of quality and regulatory compliance. Yuan et al (2018) report average quality measure star ratings of 3.58 (SD 1.33) in the Northeast, 3.39 (1.38) in the Midwest, 3.19 (1.39) in the South, and 3.81 (1.31) in the West. Variances amongst states were evident for the four quality measures included in this study, as reported in Table 14.

As described in the literature, there are several factors influencing quality measure outcomes. Studies have found that pressure ulcers reflect staffing levels and competency of staff, both impacted by payer-mix and state Medicaid funding (Blankart, Foster & Mor, 2019; Grabowski et al, 2008; Gruneir & Mor, 2008). Grabowski et al (2008) found a direct relationship between quality of care amongst payer sources, indicated stronger quality indicators for higher payer

sources such as Medicare and private funding, and lower indicators of quality for Medicaid.

Levenson (2010) underscores the importance of considering acuity, needs, and preferences of the resident in setting reimbursement.

Additional factors having an impact on the variances in quality measure outcomes between states include minimum staffing requirements (Bowblis, 2015), regulatory stringency at the state and local levels, and levels of competition and transparency (Castle & Ferguson, 2010; Mukamel et al, 2012). Lastly, demographic factors, such as income and education levels, unemployment rates, and poverty levels have proven to be a factor in quality measure differences amongst states (Yuan et al, 2018).

Study Limitations

While this study adds important and timely information to the existing knowledge base surrounding the effects of regulatory stringency on quality measures in Skilled Nursing Facilities (SNFs)/ Nursing Facilities (NFs), there are several limitations to be considered. Key study limitations include 1) the use of Minimum Data Set (MDS) Data; 2) Patient Characteristics and Demographic Information; 3) External and Internal Factors.

Use of Minimum Data Set (MDS)

Given the limited sources of data pertaining to nursing homes, this study utilized Nursing Home Compare Minimum Data Set (MDS) collected by the Centers for Medicare & Medicaid Services to conduct a retrospective program evaluation. The Minimum Data Set (MDS) was introduced in 1991, requiring skilled nursing facilities (SNFs)/ nursing facilities (NFs) to assess resident's health status and capabilities in performing activities of daily living (ADLs) (Castle & Ferguson, 2010). The MDS information is also used to determine reimbursement, focus of survey inspections, and as a publicly reported measure of quality in nursing homes (Rahman &

Applebaum, 2009). While the reliability and validity of earlier versions of the MDS was disputed, the implementation of MDS 3.0 in October 2010 brought greater validity and inter-rater reliability by standardizing the tool and providing means to engage the resident in the assessment process.

The aspects and consequences of coding the MDS are abundant and can provide motivation to manipulate responses to increase reimbursement, improve survey outcomes, and/or improve public perception of the facilities performance. Reliability and validity depend on several factors, including the experience and training of the licensed nurse(s) completing the MDS, and the engagement of the resident and interdisciplinary team in the process (Saliba & Buchanan, 2012). A report by the Government Accountability Office (2018) indicated inaccuracies in self-reported data, including short-stay pressure ulcers, long-stay antipsychotic use, physical restraints, and moderate to severe pain. While a reduction in each of these measures was observed between 2011 and 2014, the report indicated it could not attribute the improvements to quality versus difficult to determine whether observed trends reflect actual changes in quality, data issues, or both. The report indicates a lack of systematic approach to monitor the accuracy of the data. While data is validated by surveyors during compliance and regulatory visits, there is potential for inaccuracy as only a small selection of reviews are conducted.

Additional limitations to the use of the MDS data included the inability to obtain data by calendar year hence the need to compare quarter to quarter 2015 and 2017 for each of the four quality measures. The datasets were difficult to employ, and data was non-normally distributed with wide variances. Due to these challenges, logistic modeling was confined to one quarter (quarter four) 2015 and 2017.

Patient Characteristics and Demographic Factors

This study did not incorporate several demographics such as age, acuity, and payer mix, all of which have been identified as having an impact on facility quality measures through a variety of evidenced-based studies (Change et al, 2016; Hillmer et al, 2005; Mays et al, 2018). The literature indicates the effects of payer mix on quality improvement and outcomes in SNFs/NFs (Bowblis, 2015; Levenson, 2010). The inability to include patient characteristics and demographic factors may present limitations to the generalizability of the results and may have influenced the results of the study. Controlling for these factors and comparing data at the resident level may reveal varying results regardless of location or ownership type (Levenson, 2010).

External Factors

As mentioned earlier, the Hospital Readmissions Reduction Program (HRRP), the Protecting Medicare Act of 2014 (PAMA), and the growth of Accountable Care Organizations (ACOs) may have impacted the desirable reduction in percentages of short-stay pressure ulcers that are new or worsened, long-stay physical restraints, antipsychotic use, and moderate to severe pain. Financial incentives for improved performance suggest the development of strategies and new approaches to care by SNFs/NFs to meet the criteria and ensure penalties are not appointed. These penalties can have devastating consequences for facilities who are already underfunded by Medicaid (AHCA, 2017; Siegel et al, 2014).

Additional external factors that may influence quality measure outcomes include participation in QIN-QIO initiatives, state or national quality award programs, incentives at the national, state, or local level by payer sources or regulatory agencies, changes in reimbursement levels or policies, or other state or local influences.

Internal Factors

There are several internal factors that may impact the changes in quality measure outcomes providing additional study limitations. This study did not include factors such as changes in leadership of individual SNFs/ NFs between 2015 and 2017, the leadership styles, education and/or experience of facility leaders (including the Administrator and Director of Nursing), or changes in ownership. Performance based compensation or incentives, availability of resources or consultants, staffing levels, experience and qualifications of management and direct care staff, and numbers of ancillary staff members may impact quality measure outcomes.

Policy and Research Implications

This study was the first to consider the impact of Requirements of Participation (RoP) Phase I on four skilled nursing facility (SNF)/(NF) quality measures. The RoP was the first overhaul of nursing home regulations in almost thirty years. Prior regulatory updates were made prior to implementation of the quality measures, providing little opportunity for quantitative measurement of potential impact of the changes on quality in SNFs/NFs. This study has added to existing knowledge by providing quantitative data regarding the impact of regulatory stringency on four SNF/NF quality measures.

Previous literature has provided mixed results regarding the impact of regulatory stringency on quality in nursing homes. While the results of this study indicates a significant and positive change in quality measure outcomes relating to the percentage of antipsychotic use, physical restraints, moderate to severe pain, and pressure ulcers for nursing home residents, it also suggests the influence of ownership and location (state) on the quality measures for Skilled Nursing Facilities/ Nursing Facilities. More research is needed to explore these influences in addition to various patient characteristics and demographic factors (Yuan et al, 2018). A more

robust study inclusive of all quality measures is recommended, using annual data for comparison. Consideration of staffing levels, payer mix, acuity, and retention and turnover of key staff, including facility leadership (Administrator and Director of Nursing) is recommended. Retention, turnover, training, and experience of facility staff completing the MDS should also be considered as a means of comparison.

There are several policy implications for the results of this study. In the past, policy makers have looked to regulatory stringency to ‘fix’ quality problems in SNFs/NFs. Given the costs of compliance for SNFs/NFs, and the resources necessary for oversight of regulatory compliance and enforcement, consideration of quantitative methods to determine effectiveness are paramount. It also provides an opportunity for policy makers to question the variances amongst states and providers; are those responsible for ensuring compliance applying the regulations consistently? Is the level of oversight appropriate? Policy makers should also consider opportunities to improve the reliability and validity of the MDS data used to establish the quality measures. Without accurate data, it is impossible to determine the impact of regulatory stringency on quality outcomes.

Lastly, policy makers should consider therapeutic jurisprudence in lawmaking and oversight of SNFs/NFs (Kapp, 2000). Feedback from stakeholders, including residents, is imperative to quality of life and quality of care for those residing in nursing homes. Factoring resident satisfaction and quality of life when considering the impact of regulatory stringency, as they are the most important declaration of all.

Conclusion

Long-term care is one of the most highly regulated industries in the U.S. On November 28, 2016, Phase I of the Final Rule for Reform of Requirements of Participation (RoP) for long-

term care facilities was implemented by the Center for Medicare & Medicaid Services (CMS). Given the scant research on the effectiveness of regulatory stringency on improving quality in nursing homes, the hefty costs and a lack of potential increases in funding at the state or federal levels, the potential effects of the RoP were questionable.

A review of the literature resulted in few evidence-based studies conducted apropos the implementation nursing home quality measures. The RoP of 2016 was the first major overhaul of SNF/NF regulations since 1991. Quality measures were not implemented until 2002, therefore opportunities to conduct quantitative studies pre- and post-implementation of regulatory requirements have been limited. Studies included in the literature review found inconsistencies in regulatory compliance and enforcement amongst surveyors (Castle & Ferguson, 2010; Winzelberg, 2003), differing philosophies in regulation and control of markets (Mukamel et al, 2011). Reimbursement, patient acuity, payer mix, staffing levels, and competency of staff were identified as additional factors impacting quality measures and regulatory compliance in nursing homes (Blankart, Foster & Mor, 2019; Grabowski et al, 2008, Gruneir & Mor, 2008).

The results of this study indicate a significant decrease in the mean percentage of long-stay residents with antipsychotic use, long-stay physical restraints, and long-stay moderate to severe pain when comparing quarters one through four pre-(2015) and post-implementation (2017) of the RoP. The percentage of short-stay residents with new or worsening pressure ulcers observed a significant decrease in mean for quarters two through four when comparing 2015 and 2017. Logistic models indicate the influence of ownership and location (state) on quality measure odds ratios. That said, there are several additional factors that must be considered to determine the influence that patient, demographic, internal, or external factors may have on the

results. Regardless, the results provide invaluable, preliminary information for policy makers and providers regarding the impact of Phase I of the RoP, as well as important considerations for future research.

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