Summer 2021

Leveraging Federal Policies to Prevent and Respond to Communicable Disease Outbreaks

Samuel Clasp, DrPH, JM, MPH, CPE

Leveraging Federal Policies to Prevent and Respond to Communicable Disease Outbreaks in Skilled Nursing Facilities.

by:

Samuel John Peter Clasp, JM, MPH, CPE

(he/him)

A dissertation submitted in partial fulfillment

of the requirements for the degree of:

DOCTOR OF PUBLIC HEALTH

SCHOOL OF PUBLIC HEALTH

GEORGIA STATE UNIVERISTY

2021

Dissertation Committee:

Harry J. Heiman, MD, MPH (Chair)

Tara Ramanathan-Holiday, JD, MPH

David L. Ashley, PhD

Authors Statement

In presenting this dissertation as a partial fulfillment of the requirements for an advanced degree from Georgia State University, I agree that the Library of the University shall make it available for inspection and circulation in accordance with its regulations governing materials of this type. I agree that permission to quote from, to copy from, or to publish this dissertation may be granted by the author or, in his/her absence, by the professor under whose direction it was written, or in his/her absence, by the Associate Dean, School of Public Health. Such quoting, copying, or publishing must be solely for scholarly purposes and will not involve potential financial gain. It is understood that any copying from or publication of this dissertation which involves potential financial gain will not be allowed without written permission of the author.

_____

Signature of author, Samuel Clasp

Approval Page

Leveraging Federal Policies to Prevent and Respond to Communicable Disease Outbreaks in Skilled Nursing Facilities.

By:

Samuel Clasp, JM, MPH, CPE

Approved By:

_____

Harry J. Heiman, MD, MPH (Chair)

_____

Tara Ramnathan-Holiday, JD, MPH (Committee Member)

_____

David L. Ashley, PhD (Committee Member)

Date:

Dedication

This dissertation is dedicated first and foremost to my mother Shirley M. Clasp, for without her none of my accomplishments including this momentous feat would be possible. Thank you for instilling in me the value of education, for being my number one supporter, and for always believing in my ability to accomplish whatever I set my mind to.

This dissertation is also dedicated to my father Lilbert Ephraim, a consummate educator who has always supported me, and has pushed me to be the man I am today. Thank you for always being there, and for encouraging me to tackle life head on, even when I am apprehensive. To my parents, I say thank you for all that you have done to get me to this point. I love you both.

This dissertation is also dedicated to my friends. While most of them thought I was insane for embarking on yet another academic journey, they have supported and championed me along the way. For all the times I have had to vent about school and its many stressors, thank you all for always being a listening ear. Thank you for all the encouragement, and for being some of the greatest friends a person could ask for. I love you all.

Last, but certainly not least. This dissertation is dedicated to my husband Wayne E. Flagg. Thank you for your unconditional support and love throughout this entire academic process, as well as all the others before it. Thank you for always being there and encouraging me to the very end. Words can't fully express how grateful I am to have you in my life. Thank you for everything. I love you.

Acknowledgements

I would like to take this time and opportunity to recognize and thank all the members of my dissertation committee for your guidance, wisdom, patience, and utmost professionalism throughout this dissertation process. I thank you all for your willingness to serve on my dissertation committee, acknowledging the significant time commitment it would take from other pressing matters I'm sure you all are dealing with, as public health professionals right now.

A special thank you to Dr. Harry J. Heiman my dissertation chair. Thank you for accepting the lead role in this process, and for helping me through the DrPH program at Georgia State University, as our program director.

Finally, I would like to acknowledge my cohort mates and other School of Public Health colleagues that I have come to know during my matriculation in the DrPH program. I appreciate all the support and encouragement that you have provided throughout the years, and the vast amounts of knowledge that you have contributed to our program and to the public health profession.

Abstract

Leveraging Federal Policies to Prevent and Respond to Communicable Disease Outbreaks in Skilled Nursing Facilities

Objective: The coronavirus (COVID-19) pandemic significantly impacted the health, safety and well-being of patients and healthcare workers in skilled nursing facilities (SNFs) across the United States (US), resulting in approximately 1.2 million confirmed cases, and 134,000 deaths as of May 30, 2021. The purpose of this study was to apply principles of legal research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps.

Methods: An environmental scan of the Library of Congress, Google Scholar, the Federal Register, Centers for Medicare and Medicaid Services (CMS), and Westlaw Edge databases was conducted to identify federal policies relevant to the prevention and response to communicable disease outbreaks in SNFs. Results were reviewed against study inclusion and exclusion criteria to identify policies to be included in the final analysis. The CDC's Policy Analysis Framework was then used to assess current policies relative to current evidence as well as their overall public health impact, feasibility of implementation, and the economic impact. Gaps in existing policies were identified and policy proposals were made based on the analysis.

Results: The environmental scan identified 571 policies across the five databases. Application of inclusion and exclusion criteria resulted in the elimination of 563, leaving a total of eight policies for review and analysis. Policies were categorized as preventative, responsive, or both. Nursing services (preventative) and Infection Prevention and Control/Training Requirements (responsive and preventative) were identified as policies needing modification to better improve patient care and safety.

Conclusion: While there are many federal policies to prevent and respond to communicable disease outbreaks in SNFs, some of those policies do not reflect the best available scientific evidence. To improve the quality of care and safety for patients in these facilities, changes are needed to existing policies to ensure the appropriate prevention and response to communicable disease outbreaks such as COVID-19, among this vulnerable population.

Table of Contents

List of Tables

List of Abbreviations

ADL – Activities of daily living

ANA – American Nursing Association

CDC - Centers for Disease Control and Prevention

C.F.R. – Code of Federal Regulations

CGNO – The Coalition of Geriatric Nursing Organizations

CMS – Centers for Medicare and Medicaid Services

CNA – Certified Nursing Aide/Assistant

COVID-19 – SARS-CoV-2 or Coronavirus disease 2019

E.O. – Executive Order

FEMA – Federal Emergency Management Agency

HHS – Department of Health and Human Services

IP – Infection Preventionist

IPC – Infection Prevention and Control

LPN – Licensed Practical Nurse

LTCF – Long Term Care Facility

MDRO – Multi-drug Resistant Organisms

MDS – Minimum Data Set

PHE – Public Health Emergency

QAPI – Quality Assurance and Process Improvement

RN – Registered Nurse

RUG – Resource Utilization Group

SNF – Skilled Nursing Facility

WHO – World Health Organization

List of Symbols

§ - Section

Chapter 1: Introduction and Statement of Purpose

This dissertation will examine federal policies aimed at preventing and responding to communicable disease outbreaks in skilled nursing facilities (SNFs) using the Centers for Disease Control and Prevention's (CDC) Policy Analysis Framework. The purpose of this study is to apply principles of legal and policy research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps.

This analysis will highlight the assessment of the federal policies in comparison to expert recommendations and the applicability of this policy analysis framework to public health emergencies. The information ascertained from this dissertation will be useful to aid policy makers, public health practitioners, and healthcare administrators of SNFs in preventing and responding to future communicable disease outbreaks.

This study will proceed by first assessing the role of SNFs in the US healthcare delivery system, key service population demographics, and historic challenges that have affected this healthcare facility type. Second, this study will outline the challenges SNFs have faced during the novel coronavirus 2019 (COVID-19) pandemic (the impetus for this dissertation), the factors that contributed to those problems, and the role that federal and state governments played in either addressing or exacerbating the situation. Third, this study will identify relevant federal communicable disease policies that govern SNFs and any potential gaps in policies, based on a scientific review of the literature and recommended industry standards. Finally, this study will conclude with an assessment of current evidence and expert scientific recommendations utilizing the CDC Policy Analysis Framework and propose actions to help address identified gaps.

Background of the Problem

COVID-19 in Skilled Nursing Facilities

As the United States' population ages and the number of older people with multiple chronic diseases increases, SNFs are becoming an increasingly important part of the healthcare delivery system (Borrayo, 2002). SNFs provide a wide range of health and personal care services to residents who don't require the level of acute care provided in a hospital but require more care than can be provided in a traditional home setting. SNFs, a subset of Long-Term Care Facilities (LTCFs), offer a range of rehabilitation services (physical, speech, and/or occupational therapy), nutritional services, 24-hour supervision, and assistance with activities of daily living) (National Institute of Health , 2017).

This increasing dependence on SNFs has highlighted not only their importance, but the many challenges facing these institutions, such as funding shortages, a lack of adequately trained staff, and the very high potential for the spread of communicable diseases among patients and staff (Borrayo, 2002). Despite their growth and importance, SNFs are especially susceptible to the spread of communicable diseases due to their communal nature, and the specific populations that receive care there, primarily elderly patients, those who are chronically ill, and patients with disabilities (Centers for Disease Control and Prevention, 2020). These challenges directly impacted COVID outbreaks in SNFs across the US in terms of severity and the ability to respond rapidly and adequately.

The first case of COVID-19 in the US was confirmed by the CDC on January 20, 2020 in a patient who presented to an urgent care facility in Washington state after recent travel to Wuhan China. COVID-19 would rapidly become a serious threat to the health and safety of the US population, including patients and staff of SNFs (Holshue, 2020). One month after the first

US case, the first confirmed outbreak in a SNF was identified in King County, Washington, which ultimately led to over 125 cases (patients, staff, and visitors) and 23 deaths (Morbidity and Mortality Weekly Report, 2020). Outbreaks of this nature would continue to spread across US SNFs placing the lives of patients and healthcare workers at risk, leading to 655,110 confirmed cases and 132,608 deaths in patients and 583,756 confirmed cases and 1,931 deaths in healthcare workers as of May 30, 2021 (Centers for Medicare and Medicaid Services, 2021).

As the spread of COVID-19 has affected a staggering number of people throughout SNFs in the US, pervasive racial and socioeconomic disparities have also been seen in the rates of infection and death among low-income individuals and persons of color who are patients in these facilities. Historically, in SNFs across the nation, racial and socioeconomic disparities affect the quality of life and care patients receive. Research indicates that SNFs that mainly house Medicaid (low-income) residents have fewer nurses, lower occupancy rates, more health and quality-related deficiencies, are more likely to be terminated from Medicaid/Medicare programs, are located in the poorest counties, and predominantly serve minority populations (Black and Hispanic) compared with other facilities (Mor & Zinn, 2004). These disparities are reflected in the level of care and outcomes experienced by Black and Hispanic populations and are also reflected in their disproportionate risk of contracting COVID-19 in these facilities (Chidambaram, Neuman, & Garfield, 2020).

Research conducted during the pandemic shows that nationally deaths due to COVID-19 were more common among nursing homes with relatively high proportions of Black and Hispanic residents (Chidambaram, Neuman, & Garfield, 2020). Additionally, SNFs where Black and Hispanic patients make up a significant portion of the patients were twice as likely to have patients diagnosed and/or die from COVID-19 (Gebelopff, 2020). Further, SNFs with at least

25% Black or Hispanic residents reported at least one COVID-19 case, which is double the rate for SNFs where Black and Hispanic people make up less than 5% of the population. These statistics raise significant concerns, as a single case often leads to more cases, which can then become a full outbreak (Gebelopff, 2020).

Mobilizing the response to COVID-19 in SNFs has also been extremely costly. Preliminary studies conducted by the American Health Care Association (AHCA) indicated that it would cost approximately $672 million to test every patient and staff member in licensed SNFs around the nation just once (American Health Care Association, 2020). Per CDC guidance, viral testing of SNF patients is an important addition to other Infection Prevention and Control (IPC) recommendations aimed at preventing COVID-19 from entering facilities, detecting cases quickly and stopping transmission (Centers for Disease Control and Prevention, 2020).

The CDC further recommends that SNFs have a plan for testing patients with a rapid turnaround time to facilitate effective interventions to prevent additional transmission (Centers for Disease Control and Prevention, 2020). Aside from testing, the cost of treatment for patients and staff in SNFs that contract COVID is exorbitant, prompting the U. S. Department of Health and Human Services (HHS) to distribute $7.9 billion to SNFs that were impacted by COVID (U.S. Department of Health and Human Services, 2020).

While the immediate impacts of COVID-19 (acute illness and/or death) in SNFs have been extremely challenging to prevent and respond to, another complication of COVID-19 that requires a significant amount of research and resource allocation is the sequelae of COVID. Sequelae include all of the residual effects (conditions produced) after the acute phase of an illness or injury has terminated (California Health Information Association, 2013). The CDC and other healthcare and public health organizations around the world are working to study the late

sequelae of COVID-19. Many patients who have survived an acute COVID-19 infection have reported persistent symptoms that are of great concern to healthcare providers (Centers for Disease Control and Prevention, 2020). These persistent symptoms have been reported in both older patients (those who may have been at greater risk for severe disease) as well as in physically-fit young survivors of COVID-19. Symptoms range from mild (fatigue, cough, and dyspnea) to severe/life threatening (pulmonary function abnormalities, kidney injuries, cardiovascular damage, and neurological impairments) (Centers for Disease Control and Prevention, 2020).

Federal & State Roles related to SNFs & Healthcare Compliance

The Centers for Medicare and Medicaid Services (CMS), an agency under HHS, plays a key role in the overall direction of the US healthcare system with over 130 million beneficiaries through Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace (Centers for Medicare and Medicaid Services , 2021). In addition to the millions of beneficiaries that receive access to healthcare services administered by CMS, the agency also spends billions of dollars annually to support their other programs (Centers for Medicare & Medicaid Services, 2020).

CMS's significant role in the US healthcare access and delivery systems is derived from authority granted by HHS, which leverages federal funding to incentivize compliance with published rules and regulations. This authority grants them the ability to create policy changes that healthcare providers, private insurances companies providing Medicaid and Medicare plans, and healthcare facilities must follow to participate in the public insurance programs. This significant influence helps to shape the healthcare delivery system in the United States, with

major insurers, healthcare facilities, and healthcare providers usually following the strong signals sent by the rules and regulations published by CMS (DeWalt, Oberlander, & Carey, 2005).

As the importance of SNFs in healthcare delivery continues to increase, challenges facing these facilities have been cast into the spotlight once again. Issues such as quality of care and adequate staffing are once again the focus of discussion for policymakers and public health practitioners alike. (Walshe, 2001). Taking a historical view, as far back as the 1930's, researchers identified issues related to quality of care, abuse, neglect, and mistreatment in many SNFs across the nation. Federal policies around the 1980's, including the Nursing Home Reform Act, worked to improve the conditions of SNFs, and implemented the Health Care Financing Administration's (HCFA--the previous name of the Centers for Medicare and Medicaid Services (CMS)), role in their oversight (Walshe, 2001).

As a part of CMS' involvement in SNFs, federal nursing home regulations with enforcement were approved through several Acts by Congress and created the system that exists today. CMS creates and updates federal regulations to which SNFs participating in the Medicare and Medicaid programs must conform (Walshe, 2001). An example of these regulations is the Conditions of Participation (CoPs) for LTCFs. The CoPs provide all LTCFs (of which SNFs are a sub-category) with the requirements they must meet in order to participate in the Medicare and Medicaid programs (CMS, 2020). CoPs include health and safety standards that are the foundation for improving quality and protecting the health and safety of beneficiaries (CMS, 2020).

CMS works in collaboration with state licensing and certification agencies to ensure that facilities are inspected to check for compliance with federal regulations. If deficiencies are found within SNFs, the state and regional CMS offices work together to enforce the penalties as

described in compliance regulations (Walshe, 2001). In this process, CMS funds most of the Medicare and Medicaid certification costs and oversees state survey agencies that ensure regulations are being correctly implemented and enforced. States also have individual licensing requirements that all SNFs must adhere to, regardless of their participation in Medicare or Medicaid programs (Walshe, 2001). States are also allowed to create licensing requirements that match or exceed federal requirements for the regulation of SNFs within their own jurisdictions (Walshe, 2001).

Purpose and Significance of Study

The purpose of this study is to apply principles of legal and policy research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps. This study is significant to the field of public health because it will be the first time that CDC's Policy Analysis Framework has been utilized specifically to analyze policies regarding the prevention and response to communicable disease outbreaks in the context of SNFs.

The lessons learned from using this approach to prevent and respond to communicable disease outbreaks will provide useful insights into the application of CDC's Policy Analysis Framework to public health decision making for emergency responses. The information gathered will be a valuable resource for public health professionals who work with SNFs to prevent harm and loss of life in the event of future widespread outbreaks. This research will aid policymakers, public health practitioners, and healthcare administrators in making evidence-based decisions that can bolster the prevention and response phases of communicable disease mitigation.

Research Questions

There are a number of federal policies and regulations aimed at preventing and responding to communicable disease outbreaks such as COVID-19 in SNFs. The purpose of this study is to apply principles of legal and policy research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps. These objectives will be accomplished by answering the following research questions:

- What are the federal policies aimed at preventing communicable disease outbreaks in SNFs?
- What are the federal policies aimed at responding to communicable disease outbreaks in SNFs?
- What gaps exist between recommended scientific standards and current federal prevention and response policies for communicable diseases in SNFs?

Answering these questions will contribute to the evidence base as well as provide guidance to policymakers, public health practitioners, and SNF directors on the implementation of policies that will protect the health and safety of patients and healthcare workers.

Methods Overview

This research study will combine two primary methodologies: legal and policy research and the application of CDC's Policy Analysis Framework. Legal and policy research is the process used to identify laws, including statutes, regulations, and court opinions, that apply to the question of interest (Thomson Reuters Legal, 2020). When applied to public health questions, legal and policy research is used to conduct research on the impact laws have on public health (Temple University Center for Public Health Law Research, 2017). The policy analysis

framework will be used to analyze the merits and limitations of these policies, identifying core elements that are effective as well as current gaps.

The methods chosen for this research are evidence-based methodologies that are well respected by experts in the fields of public health, policy research, and policy analysis. The use of these methods will help to ensure the identification of federal policies that fit the scope of the research questions. Additional information regarding the specific methodological steps used in this research can be found in Chapter 3: "Methods."

Key Terms & Definitions

This section provides relevant information related to some key terms and concepts discussed in this research, that will provide additional clarity and understanding.

The CDC is the nation's federal public health and health protection agency, which works to save lives and protect people from health threats, by producing scientific research and guidance from subject matter experts across many fields (Centers for Disease Prevention and Control, 2020). The CDC will be a major reference point throughout this research as they are the premiere public health authority in the US and provide public health policy guidance to LTCFs, including SNFs.

Policy, as defined by the CDC, is a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments or other institutions and is frequently tied to resource allocation (Office of the Associate Director for Policy and Strategy, 2015). Policy, within the context of public health, relates to the development or implementation of public health laws, regulations or voluntary practices that influence systems, organizational change, and individual behavior to support improvements in health (Office of the Associate Director for Policy and Strategy, 2015).

On a global level, the World Health Organization (WHO) defines *health policy* as decisions, plans, and actions that are undertaken to achieve specific health care goals within a society (World Health Organization, 2020). Health policies also help to define health goals, establish targets, outline priorities, define expectations and provide information (World Health Organization, 2020). In this research the health policies will focus on communicable outbreaks in SNFs. Despite these nuances, 'policy' is a catchall term that could include laws, regulations, and rules intended to accomplish specific goals (Public Health Law Center, 2015).

While policies can encompass a wide range of meanings depending on the context, for the purpose of this dissertation, it is important to understand the distinction between laws and regulations at the federal level. Federal laws are bills that have passed both houses of Congress and have been signed by the President or allowed to become law through other non-signatory measures (United States Senate , 2020). Laws can also be created at the state level by passage through the state legislature concluding with signature from the governor, or similar non-signatory processes (United States Senate , 2020).

Federal regulations, however, are rules that are made by executive agencies and codified in the Code of Federal Regulations (United States Senate , 2020). Federal regulations are first proposed by a federal agency, the public is then granted a period in which they may provide public comment in support of or opposing the proposed regulation, the agency then considers public comments and issues the final regulation which may include revisions based on comments received (Board of Governors of the Federal Reserve System, 2018).

Another concept for this research is Infection Prevention and Control (IPC). IPC refers to evidence-based practices and procedures that when consistently applied in healthcare settings, can prevent, or reduce the risk of transmission of infection to health care providers,

patients/residents or visitors (Public Health Ontario, 2020). IPC as a subject matter is grounded in epidemiology of infectious disease, social sciences, and health policy. IPC is unique in the field of patient safety and quality control as it is relevant to healthcare workers and patients at every single health-care encounter (World Health Organization, 2020).

IPC work can be done by healthcare workers or public health practitioners who are specifically trained in this area of expertise, referred to as Infection Preventionists (IPs). IPs include nurses, doctors, epidemiologists, or other health professionals who work to prevent the spread of infection within a healthcare facility (Association for Professionals in Infection Control and Epidemiology, 2020). IPs look for patterns of infection within facilities, observe practices, educate healthcare teams, advise hospital administration, compile relevant data, develop policies and procedures, and coordinate with local and national public health agencies (Association for Professionals in Infection Control and Epidemiology, 2020). Both IPC and IPs are critical in the context of preventing and responding to communicable disease outbreaks in the context of SNFs.

Limitations

One key limitation of this research is the omission of state communicable disease policies for SNFs. Given the significant state to state variation in policies, to properly research, scope, and analyze every relevant policy would require outsourcing help and a time commitment far outside the scope of this research. While these policies may be omitted from this study, the information from this additional layer of analysis could be very impactful for local and state public health practitioners and should be considered as an extension of this initial research.

Another key limitation is the focus solely on federal policies aimed at preventing or responding to communicable disease outbreaks in SNFs and the omission of recovery policies. Due to the limited data and information available related to recovery, speaking to the efficacy or

impact of these policies would be premature. The COVID-19 pandemic is currently ongoing in the US with many places seeing continual fluctuations in the number of new cases and deaths. SNF patients and healthcare workers are still vulnerable during this time. The lack of evidence to fully support recovery policies' effectiveness positions this research study for a second phase that could explore in detail the evidence related to recovery policies and communicable disease outbreaks in SNFs. Additional information regarding the limitations of this study can be found in Chapter 5: 'Discussion, Conclusions, and Recommendations.

Summary

As SNFs comprise a major portion of long-term care delivery across the US, it is more important than ever to ensure that the policies meant to support and protect patients and healthcare workers are both effective and efficient. The COVID-19 pandemic has unfortunately taken a significant toll on the US healthcare system, the economy, and has disrupted many facets of 'normal' life.

Most affected by this pandemic are the elderly and those who have faced longstanding racial and socioeconomic disparities in the US That intersection of individuals most strongly correlates with SNFs, where outbreaks across the nation resulted in approximately 1.2 million confirmed cases, and 134,000 deaths among patients and healthcare workers by the end of May 2021.

These alarming statistics gave rise to this dissertation which sets out to identify the federal policies aimed at preventing and responding to these outbreaks in SNFs by using the methodologies of legal and policy research. In addition to identifying relevant policies, this research will utilize CDC's Policy Analysis Framework to analyze and assess these policies

based on existing evidence and policy recommendations by experts in the field. This research will also address gaps in federal policies and propose policy changes to address those gaps.

While the primary focus of this research is federal SNF communicable disease policies, this dissertation will set the foundation for other research that could be done related to state communicable disease policies in SNFs. Whether the follow up to this analysis at the state-level or the inclusion of recovery policies when reliable data is available, this research will provide much needed information to policymakers, public health practitioners, and other relevant parties to leverage public health policies to prevent and respond to communicable disease outbreaks in the future.

Chapter 2

Literature Review

Chapter 2 presents a review of the literature starting with a historical review of SNFs, followed by a contemporary analysis of SNFs and the challenges they face as a segment of the healthcare delivery system. This review includes literature related to the growth in utilization of SNFs as a healthcare delivery method in the US, IPC in SNFs, historic challenges facing SNFs, and the federal policy guidance for SNFs. Recent literature related to the impact of IPC changes in SNFs and their potential impact on communicable disease transmission in SNFs are also discussed.

Title Searches and Documentation

The literature searches for peer-reviewed articles relevant to the topics outlined above used PubMed, EBSCOhost, Sage Journals, and Google Scholar. CDC and CMS websites were also referenced for background and information on rules governing SNF policies, practices, and guidance for healthcare delivery in these facility types.

Historical Perspective

The federal government formally engaged in the regulation of nursing homes when the Social Security Act (SSA) of 1935 was passed (U.S. Senate Special Committee on Aging, 1974). The SSA established federal-state public assistance programs for the elderly called Old Age Assistance (OAA). The original drafters of the SSA opposed the use of public poorhouses to care for poor elderly persons and thus prohibited the use of OAA funds for residents of public institutions, which led to the creation of voluntary and proprietary nursing homes (Mendelson, 1974).

By 1954, when the first national survey of nursing homes was conducted, there were 9,000 homes classified as SNFs or personal care homes (U.S. Senate Special Committee on Aging, 1974). Prior to the national survey of nursing homes in 1950, amendments to the SSA authorized payments to beneficiaries in public nursing homes and required that states establish programs for licensing SNFs, but did not specify the minimum standards or what enforcement mechanisms should be used (U.S. Senate Special Committee on Aging, 1974).

States began licensing a small number of nursing homes after the 1950's but few of these nursing homes offered skilled nursing services. As a result, the federal government increased their involvement in nursing homes to promote their development (Solon, D, D.E., & Baney, 1957). By 1954, amendments to the Hill-Burton Act were passed to provide federal funds to nonprofit organizations to build SNFs that met federal definitions and held standards comparable with those of hospitals at the time (Solon, D, D.E., & Baney, 1957). In addition to the funds provided by the Hill-Burton Act, the SSA increased federal funding in the OAA and created a separate program which provided funds for medical care of public assistance beneficiaries which also included payments for SNFs (Commission on California State Government Organization and Economy, 1983).

Significant increases in federal funding to SNFs over the years led to federal attention shifting from promoting these facility types, to focusing on issues related to the quality of care being provided. In 1956, the Commission on Chronic Illness called for federal attention to problems with the quality of care in nursing homes (U.S. Senate, 1957). Concerns about the quality of care in SNFs primarily focused on the inadequacy of state licensing standards and the wide variety of state enforcement actions in the time leading up to the passage of the Medicare and Medicaid Acts of 1965.

In 1958 the Public Health Service reported that few states had adequate numbers of staff, the qualifications of the staff varied tremendously, and over half of SNF beds (approximately 308,000) did not comply with the fire and health standards of the Hill-Burton Act (U.S. Department of Health, Education, and Welfare , 1958). In addition to the Public Health Service reports, the 1959 Senate Subcommittee on Problems of the Aged and Aging also reported that only a few SNFs were considered of high quality and most facilities were substandard and had poorly trained staff (U.S. Senate Subcommittee on Problems of the Aged and Aging, 1960). These findings would lead to other important studies regarding SNFs, the quality of care being rendered, and the role of the federal government in ensuring that states held identical licensing standards.

The next substantial report that clearly portrayed the problems with SNFs in the US came from the Senate Special Committee on Aging, which was formed in 1961. The Moss Committee, named for the chairman, Senator Frank Moss, documented variations in state nursing home standards and enforcement efforts. The reasons for the variations, as laid out in the report, included (i) Enforcement meant the closure of facilities, already in short supply, with no place to put the displaced patients, (ii) States had few tools other than the threat of license revocation to bring a home into compliance, (iii) The license revocation itself was of very little use because of protracted administrative or legal procedures required, (iv) Even if the revocation procedure was implemented, judges were reluctant to close a facility when the operator claimed that the deficiencies were being corrected, and (v) Nursing home inspections were geared to surveying the physical plant rather than assessing the quality of care (U.S. Senate Subcommittee on Long-Term Care, Special Committee on Aging, 1970).

Impacts of the introduction of Medicare and Medicaid on SNFs

The creation of Medicare and Medicare in 1965 was a substantial factor in the advancement of nursing homes in the US The formulation of these programs expanded federal funding for nursing home services and was responsible for giving the federal government the authority to set standards for nursing homes wanting to participate and receive federal funds (U.S. Department of Health, Education, and Welfare, 1971).

The establishment of Medicare and Medicaid provided funds for beneficiaries who required additional care post-hospitalization in what were termed extended-care facilities, of which Medicaid paid for the skilled nursing services. Immediately, this program faced significant problems because very few SNFs met the health and safety standards required by the Department of Health, Education and Welfare (U.S. Senate (91st Congress), 1970). Reports from initial applications revealed that over 6,000 facilities applied, but only 740 were fully certified in the first year. Those SNFs that could not otherwise comply with the minimum standards were certified as being in "substantial compliance" (U.S. Senate (91st Congress), 1970).

From the inception of the Medicare and Medicaid programs in 1965 until now, provisions, regulations, and standards have constantly evolved to address concerns related to the quality of care being rendered in these facilities and the levels of reimbursement appropriate for the care of patients. One of the most substantial changes made to address the poor quality of care in SNFs was the passage of the Nursing Home Reform Act in 1987. This Act, for which HCFA, CMS's predecessor, was the primary authority, created stronger requirements and oversight of nursing homes in the US (Harrington, Schnelle, & Margaret, 2016).

The Nursing Home Reform Act worked to implement several initiatives to improve the quality of care in nursing homes. Through further expansion and reauthorization under The

Patient Protection and Affordable Care Act, The Nursing Home Reform Act in 2010 continues to improve policies and procedures and publicly report SNF quality (Harrington, Schnelle, & Margaret, 2016). These policy updates are a clear example of the federal government's attempt to address longstanding problems within SNFs, to improve the quality and standard of care patients receive.

Current Perspectives

As the need to care for an aging population with multiple chronic conditions increases, so does the need for post-acute care (PAC) and long-term care. Data from a 2016 U.S. Census Report on aging entitled *The Population 65 Years and Older in the United States: 2016,* indicates that older Americans (aged 65+) are the fastest growing age group in the country (U.S. Department of Commerce, Economics, and Statistics Administration, 2016). From the beginning of the 20th century (1900) to the beginning of the 21st century (2000), the number of Americans aged 65+ rose 1100% from 3.1 million people to 35 million people (U.S. Department of Commerce, Economics, and Statistics Administration, 2016). As of 2016, there were over 49.2 million people aged 65+, and those numbers are on target to rapidly increase, with scientists predicting that in less than two decades the number of older adults will outnumber kids for the first time in U.S. history (United States Census Burearu , 2018).

One of the most important segments of the LTCF delivery model are SNFs. Over the past two decades, PAC has accounted for the fastest growing segment of Medicare expenditures (Alfarah & Walker, 2019). In fact, expenses in SNFs rose by over $17 billion between 2001 and 2015, with an average of 7.6% annual growth (Alfarah & Walker, 2019). Additionally, during the same time (2001-2015), there was a 26.3% increase in discharges from in-patient acute

hospital settings to PAC facilities, of which SNFs accounted for 85% of the PAC facility types (Werener & Konetzka, 2018),

Data from CMS's SNF Provider Utilization and Payment Data indicates that between 2013 and 2017 the number of distinct patients (one patient admit per calendar year) admitted to SNFs rose 11% to just over 1.9 million patients, and Medicare expenditures for SNF care increased 13.7% to over $31 billion during the same time (Centers for Medicare and Medicaid Services , 2020). Despite those increases in utilization and expenditures, patient demographics remained similar with 39% of patients being male and 61% being female in 2013, and 40% being male and 60% being female in 2017. The only demographic change during this time period is the decrease in average age of patients from 79 years in 2013 to 71 years in 2017 (Centers for Medicare and Medicaid Services , 2020).

These trends highlight the increasing demand for and utilization of SNFs among individuals needing a level of care and disease management above what can be provided in a residential setting, but below the requirements for inpatient hospitalization. These trends in SNF utilization are continuing to rise, as evidenced by a 50% increase in the number of patients discharged from PACs (an increase of 1.2 million discharges) over the past 15 years, of which SNFs were the primary discharging facility (Burke & Juarez-Colunga, 2015). The continual growth and utilization of these facility types is important especially as it pertains to the IPC needs of the facility to protect patients and staff.

As the global pandemic of COVID-19 has demonstrated, SNFs are especially high-risk settings for the transmission of diseases given the congregate nature of these facilities, which places patients, healthcare workers, their families, and other members of the community at risk (Arons, Hatfield, & Reddy, 2020).

Infection Prevention and Control

Infection prevention and control have been longstanding issues facing SNFs. In 2000, thirty-five years after the creation of Medicare and Medicaid and the minimum standards for SNFs, it was estimated that between 1.6 and 3.8 million infections occurred annually in SNFs (Stausbaugh & Joseph, 2000). More recent research indicates that an average of 2 million infections occur in SNF settings annually in the U.S., and these infections are becoming more difficult and expensive to treat (Montoya & Mody, 2012). Researchers believe that this number is severely underestimated and actual numbers are closer to 4-5 million infections per year (Montoya & Mody, 2012).

Contributing to the expense and difficulty of treating infections in SNFs is the nature of the infections that SNF patients are contracting, many of which are from antibiotic-resistant (AR) organisms (organisms that are not readily susceptible to traditional antibiotic regiments) and the misuse of antimicrobials that further exacerbate the issue of AR (Montoya & Mody, 2012). These numbers and increasing difficulty of treatment indicate a significant need for proper IPC in these facility types, to prevent infections and reduce the burdens faced by patients.

Infections in SNFs are not only common, but also more difficult to treat because most are caused by multi-drug resistant organisms (MDROs) due to the high rates of transfer of patients between acute hospital settings and LTCFs such as SNFs (Dumyati, Stone, & Nace, 2017). CDC defines MDROs as microorganism(s), predominantly bacteria, that are resistant to one or more classes of antimicrobial agents (Centers for Disease Control and Prevention, 2015). Preventing infections is an important factor in reducing the burden of MDROs in healthcare settings, and the prevention of antimicrobial resistance through appropriate clinical practices during routine patient care is just as important (Centers for Disease Control and Prevention, 2015).

Infections are a leading cause of morbidity, hospital admission, and mortality among SNF residents which makes the need for IPC management critically important (Montoya & Mody, 2012) . Approximately 20% of SNFs across the U.S. receive a deficiency citation for failure to meet proper infection control standards annually, indicating the need for continued improvement (Stone & Herzig, 2015). These factors led HHS in 2013 to declare IPC in SNFs as one of its priority areas (U.S. Department of Health and Human Services, 2013). This declaration by HHS created working groups of federal agencies tasked with addressing infection control in SNFs, as well as the creation of metrics used to track overall progress of the reduction goal (U.S. Department of Health and Human Services, 2013).

Like MDROs, communicable diseases also have a significant impact on the health of patients and healthcare workers in SNFs. Communicable diseases are illnesses caused by viruses or bacteria that people spread to one another through contact with contaminated surfaces, bodily fluids, blood products, insect bites, or through the air (World Health Organization, 2018). Communicable diseases place patients and staff of SNFs at significant risk for illness and/or death, and place communities in which they reside at great risk for community spread.

SNFs are especially susceptible to the spread of communicable diseases due to their communal nature and the specific populations that receive care there, primarily elderly patients, those who are chronically ill, and patients with disabilities (Centers for Disease Control and Prevention, 2020). Furthermore, communicable diseases also place staff at risk for acquiring those infections. To protect the patients, staff, and communities in which SNFs are located from communicable diseases, it is important to understand the complexities of these facility types and the options available to prevent or mitigate sickness and death.

Adding to the complexity of dealing with communicable disease mitigation in SNFs was the 2019 CMS rule update which amended the requirement for an IP to work in LTCFs from at least part-time, to "sufficient time" at the facility to meet the objectives of the role (Centers for Medicare and Medicaid Services, 2019). This rule change was finalized in 2019 and will go into effect in fiscal year (FY) 2022 (Oct 1, 2021). This change essentially allows for states to dictate how much time is spent by an IP on IPC activities, without setting a minimum federal standard.

This change to policy was made to reduce the burden on facilities and provide additional time for staff to provide care to patients, though this policy change seems to undermine its quality care aim. These changes to IPC policy and an overall lack of substantial IPC policies for SNFs leave these facilities susceptible to communicable disease outbreaks such as COVID-19. Experts agree that IPC programs are a very important part of communicable disease mitigation strategies for hospitals and LTCFs (Lee, Lee, Lee, & Park, 2019).

Skilled Nursing Facility Staffing

The evolution of SNFs as a component of the healthcare delivery system created the ongoing need for skilled professionals able to provide quality care to patients in these settings. As indicated by early reports on SNFs, many facilities provided substandard levels of care, and the training level of staff varied significantly. As improvements were made to professional training and minimum staffing requirements developed, the lack of adequate staffing in SNFs was highlighted.

As the largest clinical provider group, nurses are vital to the success of healthcare facilities (Yanchus, Ohler, & Crowe, 2017). Despite their importance to the healthcare delivery system, nursing shortages are common throughout the healthcare system, and especially in SNFs, which has led to problems with quality (Harrington, Schnelle, & Margaret, 2016).

While SNFs employ various categories of staff that aide in the overall operation of the facility, the primary caregivers are nurses and nursing assistants. These include registered nurses (RNs) who have graduated from a state-approved school of nursing and passed the RN examination and licensed practical nurses (LPNs), who have completed a state-approved practical nursing program and passed the practical nursing examination (National Council of State Boards of Nursing, 2020). RNs and LPNs are both licensed by the state board of nursing. The most common nursing employees in SNFs are certified nursing aides/assistants (CNAs), who are certified to assist with the delivery of direct nursing care to patients under the supervision of a RN (National Council of State Boards of Nursing, 2020).

Nursing staff composition is critical to the continued operation of SNFs across the nation as multiple research studies have shown a positive relationship between nursing home quality and appropriate levels of staffing (Harrington, Schnelle, & Margaret, 2016). Researchers indicate that sufficient nursing staff with the appropriate competencies are required in SNFs for resident safety and to attain or maintain the highest practicable level of physical, mental, and psychosocial well-being of each resident (Harrington, Dellefield, E, & al., 2020). Additionally, reports indicate that there is a strong positive relationship between the number of SNF staff who provide direct care to residents daily and the quality of care and quality of life residents. (Harrington, Dellefield, E, & al., 2020).

Chapter 3: Methods

The purpose of this study is to apply principles of legal and policy research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps. This dissertation aims to answer the following research questions as they relate to federal SNF communicable disease policies:

- What are the federal policies aimed at preventing communicable disease outbreaks in SNFs?
- What are the federal policies aimed at responding to communicable disease outbreaks in SNFs?
- What gaps exist between recommended scientific standards and current federal prevention and response policies for communicable diseases in SNFs?

Answering these questions will contribute to the evidence-base for policies that prevent and control communicable disease outbreaks in SNFs, as well as provide guidance to policymakers, public health practitioners, and healthcare administrators on the implementation of policies to protect the health and safety of patients and healthcare workers.

These questions are focused on addressing the two major elements of communicable disease mitigation which are prevention (what can or should be done to prevent an outbreak from occurring in a SNF) and response (what policies should be utilized to limit the spread of disease and mitigate the impacts of illness and/or death). It also focuses on identifying gaps when comparing current federal policies to existing evidence and recommended best practices by scientific experts in the field.

Methodological Perspective

The methodology utilized for this study is a combination of legal and policy research and the application of CDC's Policy Analysis Framework. The application of legal and policy research is the process used to identify laws, including statutes and regulations, and court opinions, that apply to the question of interest (Thomson Reuters Legal, 2020). The process of legal and policy research begins with asking a question to determine what the legal issue is at hand, then finding the primary sources of law, and finally ensuring that the law being used is good law (still current and valid) (Thomson Reuters Legal, 2020). Given that the nature of this study is to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, the application of legal and policy research is important for identifying policies relevant to the prevention and response of communicable diseases in SNFs.

Legal and policy research has already been utilized as an effective tool in several applications including in several reports related to hospital-acquired infections (HAIs). One such report is the *'Outpatient Settings Policy Options for Improving Infection Prevention'* published by the CDC's National Center for Emerging and Zoonotic Infectious Diseases from the Division of Healthcare Quality Promotion. This report utilized both legal and policy research and principles of legal epidemiology to map out the variability of state, local, territorial, and federal laws related to HAIs, the gaps in those laws, and how those gaps are leaving patients in outpatient settings vulnerable (Division of Healthcare Quality Promotion , 2015).

This study also leveraged information gathered to provide states, locales, territories, and interested federal entities with several policy options to address HAIs within their domains which include addressing facility licensing/accreditation requirements, healthcare provider level training, licensing and certification, HAI reporting requirements and establishment of

investigative authorities into facility outbreaks (Division of Healthcare Quality Promotion , 2015). This report and others like it display the usefulness of applying legal and policy research to ongoing and emerging public health problems, including those related to infectious diseases.

In addition to legal and policy research, the application of CDC's Policy Analysis Framework is another major component of this study. The CDC's Policy Analytic Framework is a guide created for identifying, analyzing, and prioritizing policies that can improve health (Centers for Disease Control and Prevention, 2019). The framework works to improve the analytical basis for identifying and prioritizing policies and improve the strategic approach to identifying and informing the adoption of policy solutions (Centers for Disease Control and Prevention, 2019).

To identify federal policies targeted towards the prevention and response to communicable disease outbreaks in SNFs, the policy analysis framework is a validated tool to identify the elements that should be prioritized for effective and efficient policies. The policy framework and process provide a systematic process to assessing policies based on their health impact, cost of implementation, and feasibility (Centers for Disease Control and Prevention, 2019). The policy analysis framework is designed for use by subject matter expects, community partners, and public officials and administrators throughout the decision-making process (Centers for Disease Control and Prevention, 2019).

The combination of these evidence-based methodologies is useful for achieving the purpose of this study, which is to apply principles of legal and policy research to identify federal policies aimed at preventing and responding to communicable disease outbreaks in SNFs, to assess these policies based on current evidence and expert opinions, and to provide policy proposals to address identified gaps.

Description of Methods

Policies will be analyzed based on key components of the CDC's Policy Analysis Framework which include ***inputs*** (resources required to implement the policy), ***activities*** (actions that comprise the work of the policy effort), ***outputs*** (direct results from activities), and ***impact*** (changes in health outcomes that result from the activities of the policy process) (Centers for Disease Control and Prevention, 2014).

Within this dissertation, several methods will be used to accurately research, identify, analyze, and scope policy options at the federal level. This methodology is focused on clearly identifying policies that provide explicit protections to patients and healthcare workers in SNF settings. This combination of methodologies reflects current practices for public health policy research.

Environmental Scan

- An environmental scan is a proactive, systematic collection of information about events, trends, and expectations of what you might encounter during the policy process (Centers for Disease Control and Prevention, 2019). The environmental scanning process enables the researcher to identify federal policy options for prevention and response.
- Environmental scanning on the federal level will include:
    - Searching the Library of Congress Database and Google Scholar for specific keywords:
        - "skilled nursing facility," "nursing home," "long-term care facility," "coronavirus," "COVID-19," "communicable disease," "infection preventionist" "infection prevention and control"

- These search terms were chosen to accurately find policies specific to SNFs, that fall into the categories of either prevention and/or response.
- Scope: Search results that fit into policies and regulations at the federal level, specific to SNF and/or including SNF will be reviewed and assessed on their merit for meeting inclusion criteria.

- Searching the CMS database for specific keywords:
  - "skilled nursing facility," "nursing home," "long-term care facility," "coronavirus," "COVID-19," "communicable disease," "infection preventionist" "infection prevention and control"
    - These search terms were chosen to accurately find policies specific to SNFs, that fall into the categories of either prevention and/or response.
- Searching the Federal Register for executive orders including specific keywords:
  - "skilled nursing facility," "nursing home," "long-term care facility," "coronavirus," "COVID-19," "communicable disease," "infection preventionist" "infection prevention and control"
    - These search terms were chosen to accurately find policies specific to SNFs, that fall into the categories of either prevention or response.

Legal and policy research

- The Westlaw Edge online legal and policy research service will be utilized to find any federal laws and/or regulations applicable to SNFs and COVID-19.
    - Boolean search string: “skilled nursing facility,” “nursing home,” “long-term care facility,” “coronavirus,” “COVID-19,” “communicable disease,” “infection preventionist” “infection prevention and control”
        - These search terms were chosen to accurately find policies specific to SNFs, that fall into the categories of either prevention or response.

Centers for Disease Control and Prevention’s Policy Analytical Framework

- The CDC’s Policy Analytic Framework is a guide created for identifying, analyzing, and prioritizing policies that can improve health (Centers for Disease Control and Prevention, 2019). The framework works to improve the analytical basis for identifying and prioritizing polices and improve the strategic approach to identifying and informing the adoption of policy solutions (Centers for Disease Control and Prevention, 2019).
    - Policies that meet the inclusion and exclusion criteria will be assessed utilizing this framework to determine their overall merits and deficiencies for prevention and response.
        - This framework and its analysis table (see table 1) will be key for evaluating whether a policy is a best approach for SNFs.

Inclusion & Exclusion Criteria

Based on the outlined methodology, the policies included for additional analysis will be deemed relevant to finding answers to the posed research questions. These federal policies specifically address SNFs by name or LTCFs, of which SNFs are a subgroup, and were federal policies that addressed key elements of communicable disease prevention and response in SNFs through the end of May 2021. Elements of communicable disease prevention and response include adequate staffing, staff training requirements, environmental safety requirements, IPC programs, disease reporting, and other conditions of participation as outlined by CMS. Other policies that were included specifically addressed COVID-19 in SNFs or LTCFs in general, and specifically addressed requirements to prevent the spread of the disease and/or actions facilities must take to appropriately respond to disease outbreaks in SNFs.

Federal policies that were not included for additional analysis included all results that were provided for each search string, but were not relevant to SNFs or LTCF, communicable disease prevention or response, and/or the elements of communicable disease prevention. Some federal policies that were excluded contained communicable disease regulations for acute care hospitals (outside of the intended facility scope), others were relevant to SNFs or LTCFs but were about billing and payment requirements (outside of the relevant topic area for this study).

Analysis

The analysis in this study will utilize CDC's Policy Analysis Framework to determine whether there are gaps in current federal policies and, if so, how the policies can be strengthened, and gap(s) addressed. The analysis tool is important for decision making because it helps to analyze policy options based on public health impact, feasibility, and economic or budgetary

impact. The data utilized to determine the impact of these policies will be gathered through various sources.

To determine public health impact and overall feasibility, information will be gathered from the policies themselves that outline the criteria for implementation, the purpose of the policy, the intended audience, and resources required to implement and enforce the policies. Policy recommendations by experts or organizations in the field of communicable disease prevention and response in SNFs, will be assessed together with evidence from peer-reviewed literature, federal agency reports from agencies such as CMS and CDC, and other relevant sources.

Many of the federal policies developed at the agency level, by executive action, or by congressional action are accompanied by detailed documentation outlining the cost, potential impact, intended audience, purpose, and timeframe of impact. The Office of Management and Budget (OMB) is another valuable sources of economic and budgetary data. OMB's mission is to aid the President and administration in overseeing and preparing the federal budget. OMB also reviews the efficacy of agency policies and procedures, assessing competing funding demands among agencies, and the setting of funding priorities (Office of Management and Budget, 2020) Information regarding impacts and budgetary requirements will also be collected from official agency records and other pertinent federal sources.

Rationale

Legal and policy research and CDC's Policy Analysis Framework were chosen as the methodologies for this policy analysis and dissertation because of their relevance to the research questions at hand, their basis in systematic policy research with concrete steps to inform each step of the process, and because these methods evaluate policy options based on their health

impacts, budgetary impacts, and feasibility (Centers for Disease Control and Prevention, 2019). The combination of these methodologies will help to ensure that the most relevant policies are chosen for further analysis at the federal level. Additionally, the search parameters in conjunction with these methodologies will identify policies that existed prior to the pandemic as well as policies that have been implemented or proposed in direct response to COVID-19.

Limitations

One important limitation to note is the lack of data related to the actual impact of federal policies that have been implemented in response to the COVID-19 pandemic. The ongoing pandemic is constantly in flux with different regions experiencing a range of effects. As a result, the impact of both existing and newly developed policies may not be readily available, so proposed/intended impact will be used as a measure of analysis where necessary.

Table 1: CDC's Policy Analytical Framework Policy Analysis Table

Table 2. Policy Analysis Table

Criteria	Public Health Impact	Feasibility	Economic and Budgetary Impact	
Scoring Definitions	***Low:*** *small reach, effect size, and impact on disparate populations* ***Medium:*** *small reach with large effect size or large reach with small effect size* ***High:*** *large reach, effect size, and impact on disparate populations*	***Low:*** *No/small likelihood of being enacted* ***Medium:*** *Moderate likelihood of being enacted* ***High****: High likelihood of being enacted*	**Less favorable:** *High costs to implement* **Favorable:** *Moderate costs to implement* **More favorable:** *Low costs to implement*	**Less favorable:** *costs are high relative to benefits* **Favorable:** *costs are moderate relative to benefits (benefits justify costs)* **More favorable:** *costs are low relative to benefits*
Policy 1 _____	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	**Budget** ☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)	**Economic** ☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)
Policy 2 _____	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)	☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)
Policy 3 _____	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	☐ Low ☐ Medium ☐ High Concerns about the amount or quality of data? (Yes / No)	☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)	☐ Less favorable ☐ Favorable ☐ More favorable Concerns about the amount or quality of data? (Yes / No)

NOTE: Scoring is subjective and this table is intended to be used as an organizational guide.

Chapter 4: Data & Findings

Purpose

Chapter 4 presents the data and findings from the application of the legal and policy research methodology outlined in this dissertation for federal policies that were in place through May 31, 2021. The data and findings will be categorized into two primary components: prevention and response. These categories align with the research questions posed by this dissertation: what are the federal policies aimed at preventing communicable disease outbreaks in SNFs and what are the federal policies aimed at responding to communicable disease outbreaks in SNFs? These findings, and their assessment in regard to communicable disease prevention and response in SNFs, will inform understanding about the status of federal policy standards as well as illuminate the gaps in current federal policies and the recommended scientific standards. Identified gaps and policy proposals to address those gaps will be discussed in detail in Chapter 5.

The prevention section of chapter 4 will highlight federal policies that primarily deal with the prevention of communicable diseases in SNFs. While some policies are expressly about communicable disease prevention from an epidemiological standpoint (i.e., infection prevention programs), other policies speak to the standards to which SNFs must adhere that mitigate the likelihood of communicable disease outbreaks (i.e., appropriate staffing levels and environmental cleaning).

The response section will highlight federal policies to which SNFs must adhere in the event of a communicable disease outbreak. Given the ongoing COVID-19 pandemic and many policies that were created in response, these will be highlighted for their general response protocols and disease-specific (COVID-19) applications in SNFs.

Finally, the data and findings in this section will be analyzed using the CDC's Policy Analysis Framework to systematically assess the federal policies based on their key components. Details from this analysis will be discussed in Chapter 5.

Results Overview

The Westlaw legal research database was utilized to research federal policies relevant to answering the research questions posed by this dissertation. Based on the search string protocol discussed above, Westlaw identified 2,151 federal regulations. Given the initial search string utilized, the results included all federal regulations with one or more of the search terms within their text. This included many regulations that were irrelevant to the scope of the research questions posed by this dissertation. A search within the initial results was then conducted using the following search string: **"skilled nursing facility" "long term care facilit!" "LTCF" "SNF"** to ensure that only results relevant to SNFs or LTCFs were included. This additional search was able to eliminate 1,676 irrelevant regulations, resulting in 475 regulations for additional review. These 475 results were then scoped utilizing the inclusion criteria to find regulations relevant to the specific research questions. This scoping process resulted in six relevant regulations that met both inclusion and exclusion criteria. The six relevant regulations included for final analysis and review cover a wide range of topics related to SNFs including staffing, infection control, and training requirements.

The Federal Register database was also utilized to research federal policies relevant to the research questions. Utilizing the primary search string, the database identified 29 results. After applying the inclusion and exclusion criteria, eight of the results were scoped as relevant to the research questions.

The Library of Congress database was also utilized to research relevant federal policies. Utilizing the primary search string, the database returned two results, both of which were included as relevant to the answering the research questions.

Google Scholar was used to research the federal policies relevant to the research questions. Utilizing the primary search string, the database identified 54 results. After applying the inclusion and exclusion criteria, none of the results were scoped as relevant to the research questions. The CMS database was also utilized to research federal policies relevant to the research questions. The database identified 11 results of which three were scoped as relevant to the research questions.

After review and analysis of the 17 results scoped as relevant to the research questions from the databases searched, nine of the policies identified were removed from the final count due to duplication. This left a total of eight federal policies for further review that were included in this section.

Nursing Services

The Code of Federal Regulations, Title 42. Public Health, Section 35 (42 C.F.R. § 483.35) provides the current federal regulatory requirements for nursing services in SNFs and LTCFs, including staff requirements. 42 C.F.R. § 483.35 states that "the facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident" (Code of Federal Regulations, 2016).

Per 42 C.F.R. § 483.35, "the facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all patients." Required personnel include licensed nurses (LN) and other nursing personnel (including but not

limited to nurse aides), that the facility must ensure have the specific competencies and skill sets necessary to care for patients' needs as described in the plan of care (Code of Federal Regulations, 2016). SNFs must also use the services of a registered nurse (RN) for at least 8 consecutive hours a day, 7 days a week.

LN personnel can be waived as requirements for SNFs if they meet any number of the waiver conditions as listed in 42 C.F.R. § 483.35. CMS grants states the authority to waive requirements on LNs on a 24-hour basis if the facility can demonstrate that they have been unable to recruit appropriate personnel; if granting such a waiver would not endanger the health or safety of patients, that a RN or physician is designated to immediately respond in the event of an emergency, and whether the facility is in good standing with the state licensing agency (Code of Federal Regulations, 2016). RN services can also be waived for facilities located in rural areas where the supply of SNF services in the area are not sufficient to meet the needs of the individuals residing in the area, the facility only has patients whose physicians have indicated that they do not require the services of a RN or physician for a 48-hour period, or the facility has made arrangements for a RN or a physician to spend time at the facility as determined necessary (Code of Federal Regulations, 2016).

Training Requirements

The Code of Federal Regulations, Title 42. Public Health, Section 483.95 (42 C.F.R. § 483.95) provides the current federal regulatory requirements for training that SNFs must maintain for their personnel (Code of Federal Regulations, 2016). 42 C.F.R. § 483.95 states that "a facility must develop, implement and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles" (Code of Federal Regulations, 2016). Training topics must

include, but are not limited to communication, resident's rights and facility responsibilities, abuse, neglect, and exploitation, quality assurance and performance improvement, infection control, compliance and ethics, required in-service training for nurse aides, required training of feeding assistants, and behavioral health (Code of Federal Regulations, 2016).

Trainings on infection prevention and control programs at the facility are mandatory, and should include the written standards, policies, and procedures for the program as detailed in 42 C.F.R. § 483.80(a)(2) (Code of Federal Regulations, 2016).

Infection Prevention & Control

The Code of Federal Regulations, Title 42. Public Health, Section 483.80 (42 C.F.R. § 483.80) provides the current federal regulatory requirements on infection prevention and control (IPC) in LTCFs, including SNFs. 42 C.F.R. § 483.80 states that "the facility must establish and maintain an IPC program designed to provide a safe, sanitary, and comfortable environment to help prevent the development and transmission of communicable disease and infections" (Code of Federal Regulations, 2020). The IPC program must include, at a minimum, the following elements: (1) a system for preventing, identifying, reporting, and controlling infections and communicable diseases for all patients, staff, volunteers, visitors, and other individuals providing services to the facility and (2) written standards, policies, and procedures for the facility to follow (Code of Federal Regulations, 2020).

Written standards and policies should include surveillance systems that are designed to identify communicable diseases or infections before they can spread to other persons in the facility, policies should also include the reporting structure for communicable diseases, and the standard transmissions-based precautions to be followed to prevent the spread of infections.

Standards should also include resident isolation protocol including the type and duration of isolation (Code of Federal Regulations, 2020).

Facility standards and policies should also detail the situations in which employees with communicable diseases should be barred from direct contact with patients, hand hygiene requirements, antibiotic stewardship programs that include antibiotic use protocols and a use monitoring system, and a system for tracking incidents identified by the SNF and the corrective actions taken by the facility (Code of Federal Regulations, 2020).

In addition to the written standards, policies, and procedures for the facilities, 42 C.F.R. § 483.80 requires SNFs to designate one or more individual(s) as the Infection Preventionist (IP) who is responsible for the facility's infection prevention and control program (Code of Federal Regulations, 2020). The IP must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field, must be qualified by education, training, experience, or certification, must work at least part-time at the facility, and have completed specialized training in IPC. The IP(s) in SNFs must be a part of the quality assessment and assurance committee and report on the IPC activities on a regular basis.

As a result of changes in regulations due to COVID-19, SNFs must electronically report information on standardized forms about suspected and confirmed COVID infections among patients and staff, total number of deaths related to COVID-19 among patients and staff, personal protective equipment (PPE) and hand hygiene supplies in the facility, ventilator capacity and supplies in the facility, access to COVID-19 testing, and staffing shortages (Code of Federal Regulations, 2020). SNFs must also inform patients, their representatives, and families of those residing in facilities by 5pm of the calendar day following the occurrence of either a single

confirmed infection or three or more patients or staff with new-onset of respiratory symptoms within 72 hours of each other (Code of Federal Regulations, 2020).

SNFs must also test patients and facility staff, including individuals providing services under contracts and volunteers, for COVID-19. Testing must be based on the parameters set by the Secretary of HHS, which includes testing frequency, testing parameters for confirmed and suspected cases, testing criteria for asymptomatic individuals, response time for test results, testing standards and protocols, and documentation of testing (offers and results) (Code of Federal Regulations, 2020).

Upon identification of an individual(s) with symptoms consistent with COVID-19 or who test positive for COVID-19, the facility must take actions in conjunction with their IPs to prevent the transmission of COVID-19 (Code of Federal Regulations, 2020). SNFs must also have procedures for addressing patients, staff, and service providers who refuse testing or are unable to be tested and a process for addressing emergency testing supply shortages that includes contacts at the state and local health departments to assist in testing efforts or processing test results (Code of Federal Regulations, 2020).

Quality Assurance and Performance Improvement

The Code of Federal Regulations, Title 42. Public Health, Section 483.75 (42 C.F.R. § 483.75) provides the current federal regulatory requirements for quality assurance and performance improvement (QAPI) programs that LTCFs must maintain to qualify for Medicare and Medicaid reimbursement (Code of Federal Regulations, 2017). Per federal regulations, each LTCF is required to develop, implement, and maintain an effective comprehensive data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life (Code of Federal Regulations, 2017). SNF QAPI programs must maintain documentation and demonstrate

evidence of an ongoing QAPI program that meets the outlined requirements. Requirements include systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities (Code of Federal Regulations, 2017).

SNFs must also maintain a quality assessment and assurance committee consisting of, at minimum, a director of nursing services, the medical director or their designee, at least three other members of staff (one of whom must be in a leadership role), and an IP (Code of Federal Regulations, 2017). These regulations highlight the importance that the federal government places on the quality of care that patients receive while staying at these facility types. The inclusion of an IP in this core team also highlights the role that IPC must play to ensure the safety of patients and healthcare workers in these facilities.

Healthcare Worker Programs

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act); Public Law 116-136 is a $2.2 trillion economic stimulus bill passed in March of 2020, to provide emergency assistance and health care response for individuals, families and businesses affected by the COVID-19 pandemic (116th Congress Public Law, 2020). The CARES Act specifically provided billions of dollars in funding to healthcare providers, manufacturers and distributors to be allocated for public health programs, adding personal protective equipment (PPE) to the national stockpile, increasing Medicare payments to medical providers, and to cover the costs of COVID-19 testing and vaccination (116th Congress Public Law, 2020). The CARES Act was the largest economic stimulus package in U.S. history, with broad impacts for many areas most impacted by the COVID-19 pandemic (116th Congress Public Law, 2020).

Funds allocated for healthcare purposes were utilized to ensure the protection of wages for front-line healthcare workers in hospitals and in healthcare facilities such as SNFs. Funds were also used to procure PPE for healthcare workers needed to treat patients who were exposed to the virus. CMS was tasked with the distribution of over $178 billion in direct payments to be made via the Provider Relief Fund (Centers for Medicare and Medicaid Services, 2021).

As part of the PRF, $4.5 billion were designated for SNF and Nursing Home Infection Control Relief Fund Payments. These payments were for the diagnosis, testing, or care of individuals with possible or actual cases of COVID-19 (Centers for Medicare and Medicaid Services, 2021). As part of this specific allocation of funds, SNFs were permitted to use funding for reporting COVID-19 test results to appropriate entities, hiring staff to provide patient care or administrative support, improving infection control (including activities such as IPC programs and physical changes to the facility), and providing additional services to patients such as technology for interaction with family members who were not allowed to visit in person (Centers for Medicare and Medicaid Services, 2021).

Due to the continuing nature of the COVID-19 pandemic, additional bills have been passed to supplement the relief provided by the CARES Act. The Consolidated Appropriations Act of 2021 (the spending bill for fiscal year 2021) was passed with $900 billion in stimulus relief for the COVID-19 pandemic including additional support for healthcare industries (116th Congress, 2020). Subsequent to the passage of the Consolidated Appropriations Act of 2021, the American Rescue Plan Act of 2021 was passed, a $1.9 trillion economic stimulus bill to speed up the United States' recovery from the economic and health effects of the COVID-19 pandemic (117th Congress , 2021). The American Rescue Plan Act of 2021 also infused over $160 billion

into direct healthcare-related activities including testing, vaccinations, contact tracing, and workforce development (117th Congress , 2021).

Public Health Emergency

On January 27, 2020, the Secretary of HHS declared the COVID-19 pandemic a national Public Health Emergency (PHE) in the U.S. following confirmation of the first cases, six weeks before the WHO declared it a global pandemic. On March 13, 2020, two days after the WHO declaration, the President declared COVID-19 a national emergency. The declaration of the national emergency activated the authorities available to the President under the Stafford Act, which is utilized to provide federal assistance to state and local governments responding to the emergency, including financial assistance (Public Law 93-288, 1988).

The PHE authorizes the Secretary of HHS to take appropriate actions in response to the emergency consistent with other authorities, including making grants, entering contracts, and conducting and supporting investigations in the cause, treatment, or prevention of the disease or disorder (Office of the Assistant Secretary for Preparedness and Response, 2019). The declaration of a PHE also provides access to PHE funds to rapidly respond to immediate needs resulting from the PHE, including the facilitation and coordination among federal, state, local tribal and territorial entities affected by the PHE (Office of the Assistant Secretary for Preparedness and Response, 2019). Funds can also be utilized to make grants, provide for awards, enter into contracts and conduct investigations including further supporting the Public Health Emergency Preparedness, Hospital Preparedness and Regional Health Care Emergency Preparedness awards; facilitate and accelerate advanced research and development of medical countermeasures; strengthen bio-surveillance and laboratory capacity; support initial emergency operations related to preparation and deployment of National Disaster Medical System teams;

and carry out other activities determined applicable and appropriate by the Secretary (Office of the Assistant Secretary for Preparedness and Response, 2019).

The declaration also enables the CDC to access the Infectious Diseases Rapid Response Reserve Fund to prevent, prepare for, or respond to an infectious disease emergency, either when the Secretary has declared a PHE or when the Secretary determines that the emergency has significant potential to imminently occur and the potential to affect national security or the health and security of U.S. citizens, domestically, or internationally (Office of the Assistant Secretary for Preparedness and Response, 2019). The reserve funding was utilized to combat COVID-19 when the HHS Secretary allowed $105 million to be accessed from the existing balances of the fund (Public Law 116-123, 2020).

Personal Protective Equipment

Through coordination with the Department of Homeland Security (DHS), specifically the Federal Emergency Management Agency (FEMA) and the Attorney General's (AG) office, the President exercised his executive authority through the Defense Production Act (DPA) to collectively coordinate, plan and collaborate for the manufacturing and distribution of PPE (Department of Homeland Security, 2020). The DPA is the primary source of Presidential authorities to expedite and expand the supply of materials and services from the U.S. industrial base needed to promote the national defense (Federal Emergency and Management Agency, 2020).

As part of the DPA, Executive Order (E.O.) 13987 established the White House position of COVID-19 Response Coordinator to manage government-wide public health counter-measures, including coordination of (1) the production of pandemic response supplies using the

DPA, (2) vaccine deployment, (3) school reopening, and (4) intergovernmental and interagency processes (Executive Office of the President, 2021).

E.O. 14001 directed the Secretaries of State, Defense, HHS, DHS, and other relevant agency heads to (1) review and assess availability of "critical materials, treatments, and supplies" to combat COVID-19, (2) examine how DPA and other emergency authorities could address shortfalls; and (3) use DPA authorities necessary for PPE and vaccines (Executive Office of the President, 2021). E.O. 14001 also directed a review of existing scarcity determinations and pricing for pandemic response supplies as well as the development of a long-term manufacturing strategy for "future pandemics and biological threats" (Executive Office of the President, 2021).

The DPA directives were implemented to address supply shortfalls for vaccination supplies, testing supplies, and PPE. The DPA may also be utilized to bolster the public health industrial base and access to critical materials which may involve incentives to expand productive capacity (Executive Office of the President, 2021).

The COVID-19 pandemic presented conditions that posed a direct threat to the national defense of the U.S. and its preparedness programs such that, pursuant to the DPA, an agreement to provide PPE, pharmaceuticals and other critical healthcare resources was deemed necessary for national defense (Department of Homeland Security, 2020). The resources created by invocation of the DPA supplemented the national stockpile and provided PPE and other critical healthcare resources directly to facilities such as SNFs that were severely impacted by the COVID-19 pandemic.

Improving and Expanding Access to Care and Treatments for COVID-19

President Joseph R. Biden's office issued E.O. 13997 on January 21, 2021 aimed at improving and expanding access to care and treatment for COVID-19 in the U.S.. The E.O. was

designed to improve the capacity of the nation's healthcare systems to address COVID-19 and support healthcare workers and patients, to accelerate the development of novel therapies to treat COVID-19, and to improve access to quality and affordable healthcare (Executive Office of the President, 2021). This E.O. authorized several HHS agencies and their heads to work aggressively to meet the goals outlined in the order. This included the identification of barriers that were preventing the effective and equitable access to COVID-19 treatments and coordination with state, local, tribal, and territorial authorities to overcome those barriers (Executive Office of the President, 2021).

In addition to collaboration among the states, the E.O. tasked the Secretaries of Defense, HHS, and Veterans Affairs and the heads of other relevant executive departments and agencies to provide targeted surge assistance to critical care and LTCFs, including nursing homes, SNFs, assisted living facilities, intermediate care facilities for individuals with disabilities, and residential treatment centers in their efforts to combat the spread of COVID-19 (Executive Office of the President, 2021). The intent of this E.O. was to bring much needed federal aid to healthcare facility types most affected by the COVID-19 pandemic.

The preceding findings reflect the applicable federal policies that address prevention and response to communicable disease outbreaks in SNFs. In addition to general communicable disease prevention and response, these findings also describe the applicable federal policies targeted specifically to response to the COVID-19 pandemic in SNFs. Chapter 5 will detail the implications of these findings, the outcomes of the application of CDC's Policy Analysis Framework to the federal policies, gaps between current federal policies and the recommended standards, and policy proposals to address identified gaps.

Table 2. Policy Impact Table

Policy Topic	Current Requirements	Policy Impact Category
Nursing Services	42 C.F.R. § 483.35 - SNFs must have "sufficient nursing staff" with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. "the facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all patients." Required personnel include licensed nurses (LN) and other nursing personnel (including but not limited to nurse aides), that the facility must ensure have the specific competencies and skill sets necessary to care for patients' needs as described in the plan of care. SNFS must also use the services of a registered nurse (RN) for at least 8 consecutive hours a day, 7 days a week.	Prevention

Infection Prevention & Control	42 C.F.R. § 483.80 states that "the facility must establish and maintain an IPC program designed to provide a safe, sanitary, and comfortable environment to help prevent the development and transmission of communicable disease and infections." The IPC program must include at a minimum the following elements: (1) a system for preventing, identifying, reporting, and controlling infections and communicable diseases for all patients, staff, volunteers, visitors, and other individuals providing services to the facility and (2) the IPC program must contain written standards, policies, and procedures for the facilities to follow. Written standards and policies should include surveillance systems that are designed to identify communicable diseases or infections before they can spread to other persons in the facility, policies should also include the reporting structure for communicable diseases, and the standard transmissions-based precautions to be followed to prevent the spread of infections. Standards should also include resident isolation protocol include type and duration of isolation. SNFs must designate one or more individual(s) as the Infection Preventionist (IP) who is responsible for the facility's infection prevention and control program. SNFs must electronically report	Prevention & Response

	information on standardized forms about suspected and confirmed infections among patients and staff, total number of deaths related to COVID-19 among patients and staff, personal protective equipment (PPE) and hand hygiene supplies in the facility, ventilator capacity and supplies in the facility, access to COVID-19 testing, and staffing shortages. SNFs must test patients and facility staff, including individuals providing services under contracts and volunteers for COVID-19. Upon the identification of an individual(s) with symptoms consistent with COVID-19 or who test positive for COVID-19, the facility must take actions in conjunction with their IPs to prevent the transmission of COVID-19	

Training Requirements	42 C.F.R. § 483.95 states that "a facility must develop, implement and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. Training topics must include but are not limited to communication, resident's rights and facility responsibilities, abuse, neglect, and exploitation, quality assurance and performance improvement, infection control, compliance and ethics, required in-service training for nurse aides, required training of feeding assistants, behavioral and health. Trainings on infection prevention and control programs at the facility are mandatory, and should include the written standards, policies, and procedures.	

Quality Assurance & Improvement	42 C.F.R. § 483.75 - each LTCF is required to develop, implement, and maintain an effective comprehensive data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. SNF QAPI programs must maintain documentation and demonstrate evidence of the ongoing QAPI program that meets the outlined requirements. Requirements include systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities	Prevention & Response

Coronavirus Aid, Relief, and Economic Security Act (CARES ACT)	Public Law 116-136 - a $2.2 trillion economic stimulus bill passed in March of 2020, The CARES Act specifically provided billions of dollars in funding to healthcare providers, manufacturers, and distributors to be allocated for public health programs, adding personal protective equipment (PPE) to the national stockpile, increasing Medicare payments to medical providers, and to cover the costs of COVID-19 testing and vaccination. $4.5 billion was designated for SNF Infection Control Relief Fund Payments. These payments were for the diagnosis, testing, or care of individuals with possible or actual cases of COVID-19.	Response
Improving and Expanding Access to Care and Treatments for COVID-19	Executive Order 13997 - designed to improve the capacity of the nation's healthcare systems to address COVID-19 and support healthcare workers and patients, to accelerate the development of novel therapies to treat COVID-19, and to improve access to quality and affordable healthcare. The Executive Order also tasked the Secretary of Defense, The Secretary of HHS, the Secretary of Veterans Affairs and the heads of other relevant executive departments and agencies to provide targeted surge assistance to critical care and LTCFs, including nursing homes, SNFs, assisted living facilities, intermediate care facilities for individuals	Response

	with disabilities, and residential treatment centers in their efforts to combat the spread of COVID-19	
Defense Production Act	As part of the DPA, Executive Order (E.O.) 13987 establishes the White House position of COVID-19 Response Coordinator to manage government-wide public health counter-measures, including coordination of (1) the production of pandemic response supplies using the DPA, (2) vaccine deployment, (3) school reopening, and (4) intergovernmental and interagency processes. E.O. 14001 directs the Secretaries of State, Defense, HHS, DHS, and other relevant agency heads to (1) review and assess availability of "critical materials, treatments, and supplies" to combat COVID-19, (2) examine how DPA and other emergency authorities could address shortfalls; and (3) use DPA authorities necessary for PPE and vaccines. E.O.	Response

	14001 also directs a review of existing scarcity determinations and pricing for pandemic response supplies as well as the development of a long-term manufacturing strategy for “future pandemics and biological threats”	

Public Health Emergency Declaration	On January 27, 2020 the Secretary of HHS upon confirmation of cases of COVID-19 in the U.S., declared a national Public Health Emergency (PHE) in the US The PHE authorizes the Secretary of HHS to take appropriate actions in response to the emergency consistent with other authorities, including making grants, entering contracts, and conducting and supporting investigations in the cause, treatment, or prevention of the disease or disorder (Office of the Assistant Secretary for Preparedness and Response, 2019). The declaration also enables the CDC to access the Infectious Diseases Rapid Response Reserve Fund (when funds are so appropriated) to prevent, prepare for, or respond to an infectious disease emergency,	Response
	Prevention	
	Response	
	Prevention & Response	

Chapter 5: Discussion, Recommendations, and Conclusions

Chapter 5 presents the discussion, policy analyses, identified gaps, and policy proposals based on the relevant policies presented in chapter 4. It is the goal of this chapter to discuss the federal policies researched, their impact on communicable disease prevention and response, and applicable policy proposals that could be leveraged to further prevent and respond to communicable disease outbreaks in SNFs.

The discussion in this chapter directly addresses the primary research questions posited by this dissertation: what are the federal policies aimed at preventing communicable disease outbreaks in SNFs, and what are the federal policies aimed at responding to communicable disease outbreaks in SNFs? Additionally, where applicable, this discussion will illuminate the gaps between current federal policy and current evidence as well as recommendations made by the experts in the field. Experts in the field are defined as individuals or entities with advanced training, knowledge, and publication on SNFs, communicable diseases, epidemiology, federal agencies, and other topics pertinent to this study.

Nursing Services

Per the federal requirements outlined in 42 C.F.R. § 483.35, SNFs must have "sufficient nursing" staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (Code of Federal Regulations, 2016). For nursing services specifically, this means that a facility must have sufficient numbers of RNs, LPNs, and CNAs on a 24-hour basis to provide nursing care to all patients (Harrington & Dellefield, 2020).

This reflects that at the federal level there is no set minimum or maximum defined for "sufficient staff" to which SNFs must adhere. This lack of federal specificity essentially allows

every state and U.S. territory to have their own interpretation for "sufficient staff" requirements, which can have a significant impact on the quality of care that patients receive across regions. While some variation in the level of nursing staffing is expected, the lack of a federal minimum nursing staff definition allows for broad interpretation of "sufficient nursing staff," that is subject to change depending on numerous internal and external factors.

Historically, chronic understaffing and the dangers that it presents to patients has plagued LTCFs, as reflected in the findings from a 2001 study on the Appropriateness of Minimum Nurse Staffing Rations published by CMS (Centers for Medicare and Medicaid Services, 2001). This report highlighted several findings including the relationship between staffing and quality, the appropriateness of minimum nurse-to-staff ratios, and the importance of factors other than staffing numbers/ratios on quality (Centers for Medicare and Medicaid Services, 2001). To emphasize the effectiveness of measures taken to address quality, the CMS star-based rating system was implemented as a tool in SNFs in 2008, primarily used to publicize the overall grade of a facility (Williams, Straker, & et.al, 2016). The star-based rating system issues a quality report card based on state health surveys, quality data from the national minimum data set (MDS), and staffing information (Williams, Straker, & et.al, 2016)

Empirical analysis conducted to determine staffing thresholds below which quality of care was compromised identified that for each quality measure (hospital transfer for potentially avoidable causes and selected quality of care issues for the treatment of long-stay nursing home patients), there was a pattern of incremental benefits of increased nurse staffing with respect to quality of care (Centers for Medicare and Medicaid Services, 2001). More recent studies confirm that higher nurse staffing ratios improve both process and outcome measures of nursing home

quality. Studies show that the impact of RNs are especially positive, however total nursing staff, including LPNs and CNAs, are also important for quality (Harrington & Dellefield, 2020).

Higher RN staffing levels are associated with better patient care in terms of fewer pressure ulcers, lower use of restraints, decreased infections, lower pain, improved activities of daily living (ADLs) independence, less weight loss, less improper and overuse of antipsychotics, and lower mortality rates (Harrington & Dellefield, 2020). In addition to these benefits, studies have shown that there is a strong relationship between higher nurse staffing levels in SNFs and reduced emergency room use and rehospitalizations (Harrington & Dellefield, 2020). The strongest relationships were found to be with higher nurse staff levels and lower deficiencies (violations of federal regulations) for poor quality issued by state surveyors (Harrington & Dellefield, 2020).

The historic nature of nursing staff shortages in SNFs, combined with undefined nursing staff minimums at the federal level, made the introduction of the COVID-19 pandemic a particularly serious health and safety risk for both patients and healthcare workers in SNFs. The longstanding challenges faced by SNFs related to staffing shortages were further compounded by the impacts of the COVID-19 pandemic. Nurses were at an increased risk of contracting COVID-19 in SNFs where patients were already highly susceptible, given the congregate nature of these facilities and the heightened patient acuity (Xu, Intrator, & Bowblis, 2020). Shortages of PPE to prevent the transmission of disease in the early stages of the COVID-19 pandemic placed healthcare workers at increased risk for contracting the virus, with staff suspected of having contracted COVID subject to a mandatory 14-day quarantine period (Xu, Intrator, & Bowblis, 2020).

In addition to mandatory quarantine periods for nurses suspected of having contracted COVID-19, other infection control protocols implemented including the isolation of COVID-19 patients within SNFs and the ban on visitors further increased the need for nursing staff but created an environment where a shortage was inevitable (Xu, Intrator, & Bowblis, 2020). Increasing numbers of healthcare providers unavailable due to quarantine, lack of routine family visitation to provide informal care, and additional societal challenges depleting the availability of qualified healthcare workers contributed to the severe shortage of nurses in SNFs, which in turn affected infection control (Xu, Intrator, & Bowblis, 2020).

Research conducted in June of 2020 from a sample of 11,920 free standing SNFs that self-reported staff shortages indicated that 15.9% of the facilities experienced RN shortages, 18.4% reported shortages of nurse aides, 2.5% reported shortages of clinical staff, and 9.8% reported shortages of other staff (Xu, Intrator, & Bowblis, 2020). Analysis suggested that shortages in RNs and CNAs were more likely in SNFs having any resident or staff member diagnosed with COVID-19 (Xu, Intrator, & Bowblis, 2020). SNFs with a higher proportion of Medicare patients were less likely to experience shortages when compared to SNFs with higher proportions of Medicaid patients (Xu, Intrator, & Bowblis, 2020). Research findings also support the conclusion that SNFs with higher nursing staff levels (RNs, LPNs, & CNAs) before the pandemic were less susceptible to shortages during the pandemic, these higher levels however were not a reflection of shortages for non-clinical staff types (Xu, Intrator, & Bowblis, 2020).

Researchers in Connecticut conducted a study to determine the associations between SNF RN staffing, overall quality of care, and concentration of Medicaid or racial and ethnic minority patients with confirmed cases and deaths from COVID-19 by April of 2020 (Li & Temkin-Greener, 2020). The study was conducted in all 215 SNFs in the state, and the results from

facilities with at least 1 confirmed case (107 facilities) indicated that every 20-minute increase in RN staffing (per resident day) was associated with 22% fewer confirmed cases (Li & Temkin-Greener, 2020).

Compared with one to three-star facilities, four- and five-star facilities had 13% fewer confirmed cases, and facilities with higher concentrations of Medicaid patients or racial/ethnic minority patients had 16% and 15% more confirmed cases, respectively, than their counterparts (Li & Temkin-Greener, 2020).

The results of this study further affirmed the impacts of nursing shortages on COVID-19 outcomes within SNFs. SNFs with higher RN staffing and quality ratings appeared to be better positioned to control the spread of COVID-19 and reduce deaths. SNFs caring predominantly for Medicaid-insured or racial and ethnic minority patients tended to have more confirmed cases and lower RN staffing (Li & Temkin-Greener, 2020).

Nursing Staff Requirements recommended by experts

Several factors have led industry experts to call for more regulation of the nursing staff requirements for LTCFs, including SNFs. These include fewer nursing hours being provided compared to demonstrated need, insufficient number of RNs in SNFs, poor resident outcomes, high nursing staff turnover, lower numbers of RNs resulting in LPNs acting outside their legal scope of practice, and lower RN levels having a negative impact on quality and costs. Most of these are noted in the recommendations from subject matter experts (The Coalition of Geriatric Nursing Organizations, 2014).

In 2014, The Coalition of Geriatric Nursing Organizations (CGNO), made recommendations for minimum nursing staff levels for those working in SNFs and other LTCFs. The CGNO represents nine professional organizations dedicated to nursing and geriatric care,

and over 28,000 nurses who also serve in these spaces. The CGNO is comprised of the American Academy of Nursing, Expert Panel on Aging, American Assisted Living Nurses Association, American Association for Long Term Care Nursing, American Association of Nurse Assessment Coordination, Gerontological Advanced Practice Nurses Association, Hartford Institute for Geriatric Nursing, National Association of Directors of Nursing Administration in Long Term Care, and the National Gerontological Nursing Association (The Coalition of Geriatric Nursing Organizations, 2014). In their report, CGNO lists the unprecedented demands faced by today's SNFs, increasing clinical complexity of patients, pressures to avoid and reduce hospital readmissions among this patient population, and new standards and expectations for quality of life for patients, as the basis for these recommendations (The Coalition of Geriatric Nursing Organizations, 2014). In addition to these challenges, research data related to patient quality of care and its direct relation to nursing staff ratios also served as catalysts for the organization's professional recommendations.

In the recommendations, CGNO calls for specific changes to the minimum nursing staff requirements in SNFs to be adopted, funded, implemented, and publicly reported for SNFs at the state and federal levels. CGNO proposes that a registered nurse be present in the SNF at all times for oversight of resident care, resident assessment, and supervision of LPNs and CNAs, CGNO also proposes that the Director of Nursing (DON) be prepared either at the baccalaureate level or certified in nursing administration (The Coalition of Geriatric Nursing Organizations, 2014). Additionally, they propose that the hours of direct nursing care for each resident be at least 4.1 hours per resident day with a minimum 30% of that consisting of licensed nurses (The Coalition of Geriatric Nursing Organizations, 2014). CGNO also proposes that administrative RN positions such as the DON and Assistant DON, not be counted towards direct nursing hours for

resident care and that SNFs have licensed staff based on clinical acuity, which may necessitate more than the 4.1 hours per resident minimum (The Coalition of Geriatric Nursing Organizations, 2014).

Expert organizations including the American Academy of Nursing (ANA) have endorsed the recommended nursing staff minimum requirements as part of CGNO, and separately, as the leading nursing organization in the U.S. While these recommendations were made almost seven years ago, the ANA and CGNO continue to advocate for state implementation and federal adoption of these proposed requirements, citing the same ongoing challenges in SNFs as when the recommendations were first made (American Association of Colleges of Nursing, 2020) .

While CGNO as an organization has not prescribed exact recommendations for adjusting minimum nursing staff requirements based on acuity, other experts in the field have recommended a five-step method for individual SNFs to determine whether their facility has adequate and appropriate nursing staff.

The first step is to determine the collective resident acuity, by evaluating resident assessment data and overall resident care plans, the second step is to determine the facilities current staffing levels using payroll data, the third step in the process is to determine the staffing levels needed based on the peer-reviewed studies and professional recommendations on minimum staffing levels (Harrington & Dellefield, 2020). The fourth step is to examine empirical evidence such as survey deficiencies, complaints, adverse events, and other care problems (Harrington & Dellefield, 2020). The final step is to compare the facility staffing to the appropriate nursing staffing levels based on collective acuity, to identify areas for improvement ensuring adequate nursing staff levels to protect patient safety and well-being (Harrington & Dellefield, 2020).

There are obvious gaps between current federal policy related to nursing services and staffing requirements, and the recommendations proposed by subject matter experts in the field, including CGNO and reports by CMS. The most glaring of these is the lack of a clear definition regarding "sufficient staff." This lack of federal clarity can have a significant impact on the quality of care that patients receive. This is in clear contrast to the CGNO, which clearly defines minimum nursing staff requirements as at least 4.1 hours per resident day, with a minimum of 30% of care being provided by LPNs and RNs.

A clear federal definition of minimum nursing staffing requirements would provide all SNFs with the standards they must meet to participate under CMS requirements. This would set a minimum standard for nursing services provided at SNFs that is much less open to state and territorial interpretation. Additionally, clearly identifying appropriate staff levels based on the collective resident acuity of the facility, is important to ensuring that quality care is always provided.

Expert Nursing Staff Recommendation Policy Analysis

Applying CDC's Policy Analysis Framework to the proposed nursing staff policy change helps to determine the benefit of this policy's adoption and implementation, compared to current standards. A policy analysis of this proposal addresses the overall public health impact, the feasibility of implementation and the economic impact that its implementation would have (Centers for Disease Control and Prevention, 2019).

Based on current evidence, the overall public health impact of defining "sufficient nursing staff" at or above the limits proposed by CGNO would be expected to improve patient outcomes and the quality of care in SNFs. Higher nurse staffing improves both process and outcome measures of nursing home quality. While the impact of RNs is especially positive, total

nursing staff including LPNs and CNAs are also important for quality care (Harrington & Dellefield, 2020). In terms of infection prevention, studies also showed that SNFs with higher RN staffing and quality ratings have the potential to better control the spread of COVID-19 and reduce deaths (Li & Temkin-Greener, 2020).

The feasibility of implementing a policy change of this nature is two-fold. First, federal regulators would have to initiate the process to update current federal regulations by announcing the proposed rule change. Assuming that a proposed policy recommendation is made to change current federal policy, the federal rule-making process would be initiated by the authorizing agency. Specifically, for nursing standards in SNFs, CMS would develop a draft proposed rule, the Office of Information and Regulatory Affairs (OIRA) would review the draft proposed rule, CMS would then publish the proposed rule and make any changes based on public comments received, the OIRA would review the final draft, and then CMS would publish the final rule (Congressional Research Service, 2021). While the federal rulemaking process is clearly outlined, the process can be lengthy and involve many stakeholders. However, the process is already carried out for many rules on a regular basis.

The second part of feasibility for this policy change is the availability of nursing staff to meet the demands that this new policy would create. This will be more challenging than rulemaking due to a national nursing shortage that dates to the early 2000's (American Association of Colleges of Nursing, 2020). Per the American Association of Colleges of Nursing, nursing shortages are will continue to intensify as Baby Boomers (those born between 1946 and 1964) age, the need for healthcare continues to grow, and nursing schools struggle to expand capacity to meet the rising demand for care (American Association of Colleges of Nursing, 2020). This shortage creates even more difficulty for an industry that is currently facing

nursing staff shortages, with a pandemic that is creating even more challenges for staffing. In addition, research from the Paraprofessional Healthcare Institute (PHI) estimates turn-over rates across the long-term care industry (pre-COVID) ranging from 45% to 66% by conservative estimates (Scales, 2018).

In the U.S., becoming a RN generally takes between 2-4 years for an associate degree or bachelor's degree respectively (Nurse Journal, 2021). While the associate degree is the minimum requirement to take the RN licensure exam, many employers and states are only hiring nurses with bachelor's degrees, thus further complicating the nursing shortage (Nurse Journal, 2021). To help mitigate this barrier, many employers and nursing schools are offering incentives for nurses to continue their education to the bachelor's degree level, including financial assistance for continuing education and bridge programs to help nurses with associate degrees complete the requirements for a bachelor's degree (Nurse Journal, 2021). Despite these incentives projected nurse shortages are expected to continue because of a rapidly aging population.

As a result of these challenges, the demand for nurses remains high. The implementation of quality recruiting and retention processes across the senior care industry is important for helping to meet current and future demands created by a potential policy change. The Center for Aging Research and Education from the University of Wisconsin-Madison outlined steps for long-term care organizations to effectively retain employees. Steps outlined include administrative agreement on the needs of nurses in the work environment, creating a residency program for new nurses, starting new nurses with lower caseloads that increase gradually, designating experienced nurses as mentors, and fostering a supportive culture for learning and growth that includes continuing education (Center for Aging Research and Education, 2017).

Economically, the impact of such a policy change would create additional expenditures for both CMS and SNFs themselves, requiring them to hire more staff to meet appropriate staffing levels and higher rates of reimbursement to facilities, but based on historic and current data, not an undue burden that would preclude the adoption of minimum nursing staff requirements. In 2001, CMS published its most recent report on the appropriateness of minimum nurse staffing ratios in SNFs. The report indicated that by 2001 standards, direct nursing care for fewer than 2.8 hours per day per patient was associated with reductions in the quality of care provided (Centers for Medicare and Medicaid Services, 2001).

Using 2.8 hours as a minimum standard at the time of the report, those standards would have required SNFs across the nation to hire approximately 137,000 RNs, 27,000 LPNs, and 300,000 nursing aides (Centers for Medicare and Medicaid Services, 2001). Despite these increases, the report concluded that there will be an increased need for RNs and CNAs in SNFs, and that while setting minimum nurse staffing ratios would cost CMS additional funds, the costs would not preclude the feasibility of implementation (Centers for Medicare and Medicaid Services, 2001).

As of 2019, the U.S. (through CMS) spent $172.2 billion on SNFs, an increase of 3.3% from the $167.2 billion spent in 2018 (Martin, Hartman, Lassman, & Catlin, 2020). This increase while substantial, still pales in comparison to the 7.7% ($8 billion) increase paid by CMS for home health services and the increase of 6.2% for hospitals to a total of $1.2 trillion in CMS expenditures (Martin, Hartman, Lassman, & Catlin, 2020). This suggests that there is an imbalance between where funds are being allocated within the healthcare service delivery system, especially in an area where there is a clear and evident need.

The impact of COVID-19 on SNFs drew national attention and necessitated a large infusion of funding from CMS to help mitigate illness and death among patients and healthcare workers. By November of 2020, CMS had directed over $20 billion to SNFs to combat COVID-19, suggesting that some of the funds that become available for emergency use, may be better utilized to improve public health infrastructure which could help prevent emergencies in the first place.

Policy Proposal

Based on available research, the recommendations made by expert stakeholders in the field, and the application of CDC's Policy Analytical Framework; it is the conclusion of this analysis that federal regulators should adopt expert recommendations to define a minimum standard for "sufficient nursing staff" for SNFs, as sufficient staff to provide 4.1 hours of nursing care per resident day with a minimum 30% of that consisting of licensed nurses. In addition to the minimum standards, federal regulators should also provide nursing staff requirements to SNFs in categories based on higher acuity case-mix weights.

Adopting the proposed requirements would help to increase the number of CNAs, LPNs, and RNs in SNFs across the country, which is important as higher nurse staffing levels have been proven to be associated with better resident quality of care and patient outcomes. (Harrington & Dellefield, 2020). Additional policy solutions may be necessary to ensure the proper implementation of this policy proposal given the ongoing nursing shortage. While the current growth rate of RNs seems to be on track to end the current shortage, current projects are subject to potentially unforeseen developments such as the economic and noneconomic effects of the COVID-19 pandemic (National Academy of Medicine, 2021).

Infection Prevention & Control

Per the federal requirements outlined in 42 C.F.R. § 483.80, SNFs "must establish and maintain an IPC program designed to provide a safe, sanitary, and comfortable environment to help prevent the development and transmission of communicable disease and infections" (Code of Federal Regulations, 2020). The IPC program must include at a minimum the following elements: "(1) a system for preventing, identifying, reporting, and controlling infections and communicable diseases for all patients, staff, volunteers, visitors, and other individuals providing services to the facility and (2) the IPC program must contain written standards, policies, and procedures for the facilities to follow" (Code of Federal Regulations, 2020).

42 C.F.R. § 483.80 also requires SNFs to "designate one or more individual(s) as the Infection Preventionist (IP) who is responsible for the facility's infection prevention and control program The IP must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field, must be qualified by education, training, experience, or certification, must work at least part-time at the facility, have completed specialized training in IPC, and must be a part of the quality assessment and assurance committee and report on the IPC activities on a regular basis" (Code of Federal Regulations, 2020).

This federal requirement means that SNFs that participate in Medicare and Medicaid programs must have an IPC program in their facility. These programs are to ensure a safe environment for patients and healthcare workers where infections and communicable disease transmissions are prevented and adequately responded to in the event of an outbreak. Furthermore, the IPs responsible for IPC programs within SNFs must be designated by the

facility and undergo training in infection prevention. Having well-trained IPs in a SNF further ensures the prevention and appropriate response to communicable disease outbreaks.

These federal requirements provide SNFs with the guidance on the areas that must be addressed in a compliant infection control and prevention programs. As previously discussed, SNFs are especially susceptible to the spread of communicable diseases due to the communal nature of nursing homes, and the populations they serve, primarily elderly patients, those with chronic illnesses, and patients with disabilities (Centers for Disease Control and Prevention, 2020).

IPs are an important resource for preventing and responding to infections in SNFs. IPs work in various parts of the healthcare delivery system, including SNFs, to eliminate infections, improve patient safety, quality of care, and reduce cost burden (Crist & Murphy, 2019). While the importance of IPC and IPs in SNFs is evident, this has been particularly highlighted by the COVID-19 pandemic.

In addition to ongoing IPC concerns, proposed regulatory changes to IP requirements by CMS set to be implemented at the beginning of Fiscal Year 2022 (October 1, 2021), have also raised concerns about the stability of IPC in SNFs. The regulatory changes soon to be in effect, will remove the requirement for facilities to designate one or more individuals as IPs responsible for the facilities IPC program and simply require SNFs to have one or more designated contacts for the program (Centers for Medicare and Medicaid Services, 2019). Removing the requirement that facilities to appoint a designated IP who is responsible for IPC can undermine the strength of the program and create situations where IPC protocols are not being properly developed, monitored, or enforced.

These upcoming changes also remove the requirement for IPs to work in the facility part-time and requires that the designated contact person(s) instead have "sufficient time" at a facility to achieve their IPC program objectives (Centers for Medicare and Medicaid Services, 2019). This change, defaulting to "sufficient time" as the standard can allow facilities to have personnel that never report physically to the facility as a point of contact for the program.

To effectively manage the program, these individuals should work at least part-time in the facility. This will allow them to understand the individual challenges faced by the facility, tailor policies and procedures accordingly, and ensure they are readily accessible to respond to emerging infection control concerns such as detection of new antibiotic resistant organisms (Personal Communication with CDC Experts, 2019). Their on-site presence also signals to residents and staff that prevention of infections is a priority for the facility and provides an accessible point of contact to address questions and interact with partners including public health programs, quality improvement organizations, and referring providers in the community (Personal Communication with CDC Experts, 2019).

While the evidence on the impact of IPs and IPCs in SNFs remains limited, available studies indicate that IPs play a critical role in the prevention and management of healthcare-associated infections in SNFs, especially in the areas of influenza vaccination and pressure ulcer prevention among high-risk SNF patients (Wagner, Roup, & Castle, 2014). Research also suggests that there continue to be areas of needed improvement in IPC in SNFs across the U.S. These include the need for an increase in the provision of training materials on infection reduction, focused trainings on specific infections and pathogens, and SNF re-engagement in collaboratives aimed at infection reduction (Dorritie, Quigley, & et.al, 2020).

The need for quality training has direct implications for IPs and IPC in SNFs and the areas of improvement recommended by experts in the field. 42 C.F.R. § 483.95 outlines the federal requirements for training that SNFs must maintain for their personnel. 42 C.F.R. § 483.95 states that "a facility must develop, implement and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles (Code of Federal Regulations, 2016). These federal requirements also provide guidance to SNFs on the topics that should be covered in training for staff and personnel, but do not provide a detailed guidance or curricula that SNFs or states must follow. This lack of clear guidelines, standards, and requirements inevitably leads to variation in training across states and facilities, which can affect the quality of care received by patients.

Researchers have shown that standardized training results in the standardization of skills, aids in the identification of skill gaps, helps to reduce errors and improve retention, creates easier measures to test training efficacy, and ensures consistency across locations (Juozitis, 2019). These are all factors that are important for ensuring quality of care for patients in SNFs that are not addressed by current federal regulations.

Expert Recommendations

Due to growing concerns related to infection control issues in SNFs, the CDC, in conjunction with CMS, created a free online training course, Specialized Infection Prevention and Control Training for Staff in LTCFs, to help facilities meet the IPC program elements outlined in 42 C.F.R. § 483.80. This course provides 19 hours of training that covers information about the core activities of an infection prevention and control program, recommended practices to prevent pathogen transmission, and practices to reduce healthcare-associated infections and

antibiotic resistance in SNFs (Centers for Medicare and Medicaid, 2019). The course was designed for individuals responsible for IPC in SNFs, those designated as IPs, or other staff that participate in IPC activities. The course also introduces how to use IPC program implementation resources, including policies and procedures, templates, audit tools, and outbreak investigation tools (Centers for Disease Control and Prevention, 2020).

This structured training program developed by the nation's federal public health agency, and the federal agency responsible for the quality of care provided in SNFs, demonstrates that training elements can be developed, produced, and implemented for all SNFs wishing to participate in the Medicare and Medicaid programs. There is, however, no requirement that facilities use these training materials or demonstrate relevant competencies.

IPC and Training Policy Analysis

Providing standardized mandatory trainings created by CMS and CDC that SNFs must utilize to participate in Medicare and Medicaid programs would help to ensure that all IPs and personnel involved in IPC have standardized training that would not vary from facility to facility, or state to state. Research has indicated that the use of clinical pathways as a training mechanism for standardizing care processes for a well-defined group of patients helps ensure continuous healthcare quality and overall improvement within facilities (Lavelle, Schast, & Keren, 2015). Clinical pathways are tools used to guide evidence-based healthcare, with the aim of translating clinical practice guidance into the process of care within the environment of a healthcare delivery setting (Busse, Klazinga, & et.al, 2019) While currently being applied in hospital settings to various patient populations, the pathways approach can be applied to SNFs, where patients require complex levels of treatment, and there is a clear need for standardization of process.

To ensure that patients are receiving high quality care in CMS-certified facilities, standardizing the training information and processes for IPC and other topics as outlined in 42 C.F.R. § 483.80, will remove uncertainty around the information and training that healthcare workers are receiving, and make the application of CMS standards more equally enforceable. Standardized trainings provided by public health and healthcare experts will help ensure that providers within SNFs are adequately prepared for providing the highest possible level of care for patients.

The feasibility of implementing standardized mandatory trainings created and provided by CMS and CDC for SNFs would require the allocation of resources, both time and money. The development of online training programs varies based on length, the level of detail provided in training, and the modes of teaching utilized (Defelice, 2021). Experts in the field on average recommend anywhere from six to twelve months from inception to delivery for an in-depth training course (Defelice, 2021).

In addition to the time resource, developing programs at this scale can come with a significant economic impact. Current projections suggest that the full development of an online educational platform could cost between $200 and $900 per minute of content (Roundtable Learning, 2021). Based on these numbers, the cost to produce and maintain a full suite of training and educational resources would be in the millions. Without developing these courses, Medicare programs could continue to spend $208 million treating preventable infections that occurred in SNFs like they did between 2008 and 2012 (Department of Health and Human Services, 2014).

Given that many training databases have been created by CMS and other federal partners, the work required to update, maintain, and continue to offer further trainings as mandatory to

SNFs would neither be infeasible nor cost-prohibitive. Investing the resources needed to produce, maintain, update, and distribute these trainings to SNFs across the nation will work to improve the quality of care that is provided to patients, and in turn will reduce the costs associated with adverse events such as preventable infections in SNFs.

Policy Proposal

Based on available research, the impact that communicable disease outbreaks such as COVID-19 have had on SNF patients and healthcare workers, the recommendations made by expert stakeholders in the field, and the application of CDC's Policy Analytical Framework; it is recommended that federal regulators adopt the standardized IPC training course produced by CMS and CDC as a federal requirement for all personnel involved in IPC in SNFs, and publicly report the compliance of training. In addition to IPC training, federal regulators should provide and update, as needed, a repository of standardized trainings that SNFs must have their employees take as an ongoing condition of participation in Medicare and Medicaid. As part of this policy change, CMS should also evaluate the impact these standardized trainings have on reducing infections in SNFs, to support continual process improvement. Finally, CMS should reverse the decision that would both remove designated IPs in SNFs and reduce the time spent in SNFs by IPs to "sufficient time."

Given the lack of federal standards related to IPC training and the current spending to address preventable infections, and outbreaks of communicable diseases such as COVID-19, the implementation of this policy proposal could significantly improve the quality of training that healthcare providers in SNFs receive, and in turn the quality of care that patients receive in these facilities. Removing the arbitrary nature of current training processes that vary by facility and state, will help ensure the quality of training for healthcare workers.

Quality Assurance and Performance Improvement

The regulations outlined in 42 C.F.R. § 483.75, provide the current federal rules on quality assurance and performance improvement (QAPI) programs that LTCFs must maintain. The regulation states that "each LTCF is required to develop, implement, and maintain an effective comprehensive data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life" (Code of Federal Regulations, 2017).

QAPI is the coordinated application of two mutually-reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, comprehensive, and data-driven approach to maintaining and improving safety and quality in nursing homes while involving all nursing home caregivers in practical and creative problem solving (Centers for Medicare and Medicaid Services, 2016). SNFs must maintain documentation and demonstrate evidence of an ongoing QAPI program that meets the outlined requirements. Requirements include systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities (Code of Federal Regulations, 2017).

QAPI programs are intended to focus on healthcare providers' care of patients, the overall performance of the facility, and the impacts of treatment provided by the facility on the health status of patients (Centers for Medicare and Medicaid Services, 2016). QA focuses on the standards of quality for services and their outcomes, and it is the overall process through which a SNF demonstrates that care is being provided at an acceptable level in relation to the standards (Centers for Medicare and Medicaid Services, 2016). PI focuses on improvement of the facility with the overall intent of improving patient outcomes and preventing problems by identifying

areas of opportunity and testing new approaches to address underlying problems and barriers (Centers for Medicare and Medicaid Services, 2016).

Expert Recommendations

QAPI programs are necessary for providing safe care environments for patients and healthcare workers, and require development and input from staff, patients, and family members serviced by SNFs (Adkins, 2018). To have an effective program, five core elements should be considered for inclusion (1) design & scope, (2) governance and leadership, (3) feedback, data systems, and monitoring, (4) performance improvement projects, and (5) systematic analysis and systematic action (Adkins, 2018).

The design and scope of QAPI programs works to address all services that are provided by the facility, it incorporates an evidence-based approach for assessing areas for improvement and includes the development of a facility-wide QAPI plan (Adkins, 2018). Governance and leadership require that QAPI plans incorporate all members of the team, direct allocations of resources for QAPI initiatives, and create a non-punitive environment for challenging the status quo (Adkins, 2018).

Feedback, data systems, and monitoring require that SNFs are ready to make meaningful changes related to the data they receive, that various data points are utilized for QAPI initiatives, and that data are utilized to set benchmarks to monitor progress (Adkins, 2018). Performance improvement should be based on areas of concerns illuminated by the data and requires full staff participation for overall improvement. Performance improvement initiatives should also be meaningful to the types of services being provided by the facility (Adkins, 2018).

Lastly, systematic analysis and systematic action are the approaches needed to determine where more data or analysis are needed for decision making. It should also include feedback loops that promote continual learning and improvement at the facility level (Adkins, 2018).

These core elements provided by experts in the field directly mirror the standards published in a 2011 guidance document by CMS for SNFs. CMS identified these five strategic elements as the foundation of effective and efficient QPAI programs in SNFs (Centers for Medicare and Medicaid Services, 2011). In addition to the core elements listed, CMS provided additional action steps that are recommended for SNFs to implement their QAPI program.

The first step is leadership responsibility and accountability; support from the top is an essential part of an effective QAPI program and needed to foster the active participation of every caregiver. The second step is to develop a deliberate approach to teamwork with a clear purpose, defined roles, and active engagement from each team member. The third step is to conduct a self-assessment which helps to evaluate the extent of which components of QAPI are in place, and which areas would need additional development (Centers for Medicare and Medicaid Services, 2011).

The fourth step is to identify the facility's guiding principles; this step helps to establish the foundation for the work, guide decision making and set priorities. Step five is the development of a QAPI plan, this will assist in the achievement of the identified purpose, guiding principles and scope for QAPI (Centers for Medicare and Medicaid Services, 2011). Step six of the guidance is to conduct an awareness campaign to let everyone know about the QAPI plan – often and in multiple ways, the goal is to achieve widespread awareness of QAPI initiatives. Step seven is to develop a strategy for collecting and using QAPI data, and step eight

is to use the data to identify gaps and opportunities (Centers for Medicare and Medicaid Services, 2011).

Step nine is to prioritize quality opportunities and charter process improvement projects; this prioritization is a key step in the process of translating data into action. Step ten is to plan, conduct, and document process improvement projects. This step requires identifying improvement areas, planning a process to achieve identified improvements, conducting the improvement project, and documenting the results of the improvement (Centers for Medicare and Medicaid Services, 2011). Step eleven requires getting to the root of the problem, a root cause analysis is suggested as a systematic process for identifying contributing causal factors that underlie variations in performance. The final step, taking systematic action requires the cyclical implementation of the outlined steps to ensure sustainability, efficiency, and efficacy (Centers for Medicare and Medicaid Services, 2011).

The core elements and action steps described in this section, if properly implemented, would satisfy the SNF QAPI program requirements outlined in 42 C.F.R. § 483.75. The degree of variability among SNFs, even within the same state, necessitates the use of structures that allow SNFs to create QAPI plans that address specific facility and patient population needs.

Policy Proposal

Based on available research, the role of QAPI programs in preventing communicable disease outbreaks in SNFs, and the recommendations made by experts in the field, CMS should dedicate resources to evaluating the impact of QAPI programs in SNFs. While the current federal regulations provide a sufficient overarching framework to achieve their intended goals, there is little evidence to support the program's impact on a national level.

The current federal requirements for QAPI in SNFs work to ensure that patients receive quality care and that facilities are constantly assessing ways that patient outcomes could be improved. QAPI needs vary vastly by facility and patient populations served, which makes the degrees of freedom allowed in the current federal regulations appropriate.

Federal COVID-19 Response Policies

The impact of COVID-19 specifically on SNFs across the U.S., necessitated a federal response to provide aid and resources to facilities struggling to combat the pandemic. Federal COVID-19 response policies varied significantly, from updates to existing regulations regarding qualified personnel and communicable disease reporting, to large infusions of funding and the leveraging of Presidential executive authority to have federal agencies work together on a plan.

While the complete impact of these policies in response to COVID-19 won't be fully assessed for several years, the federal actions in this section reflect policies created in response to the pandemic, some of which occurred early when federal action was most critical. These federal response policies were focused on preventing new cases and loss of life from COVID-19 among patients and healthcare workers in SNFs.

Coronavirus Aid, Relief, and Economic Security Act

The 2020 CARES Act specifically provided billions of dollars in funding to healthcare providers through the Pandemic Relief Fund (PRF), of which $4.5 billion was designated for SNF and Nursing Home Infection Control Relief Fund Payments. These payments were for the diagnosis, testing, or care of individuals with possible or actual cases of COVID-19 (Centers for Medicare and Medicaid Services, 2021). As part of this allocation of funds, SNFs were permitted to use funding for reporting COVID-19 test results to appropriate entities, hiring staff to provide patient care or administrative support, improving infection control (including activities such as

IPC programs and physical changes to the facility), and providing additional services to patients such as technology for interaction with family members who were not allowed to visit in person (Centers for Medicare and Medicaid Services, 2021).

HHS, through the Health Resources and Services Administration (HRSA), allocated $2 billion in incentive payments to nursing home facilities that reduced COVID-19 infection rates relative to their county and mortality rates against a national benchmark (Centers for Disease Control and Prevention, 2021). These payments to SNFs were accompanied by federal eligibility criteria 1) the nursing homes infection rate must be lower than that of the infection rate in their county, and 2) the nursing home's mortality rate for residents must be less than 10% for all residents in their facility that contracted COVID-19 (Centers for Disease Control and Prevention, 2021).

These incentive payments help to incentive SNFs' IPC programming, with the focus on hitting benchmarks prescribed by HHS. It is important to acknowledge that these incentive payments which help to bolster facility IPC programs may adversely penalize facilities who were already under-resourced before COVID-19. Facilities who serve a higher proportion of low-income patients or facilities that serve a higher proportion of Black and Hispanic patients, may be unjustly penalized in not receiving incentive payments for new COVID benchmarks that they were functionally unable to meet, due to longstanding healthcare delivery issues.

Personal Protective Equipment

In response to pleas from SNFs regarding the lack of the basic PPE needed to ensure the safety of patients and healthcare workers, in coordination with the Department of Homeland Security (DHS), the Federal Emergency Management Agency (FEMA), and the U.S. Attorney General's (AG) office, the President announced the formation of a voluntary agreement under

Section 708 of the Defense Production Act (DPA) to collectively coordinate, plan and collaborate for the manufacturing and distribution of PPE (Department of Homeland Security, 2020). The signing of Executive Order (E.O.) 13911 authorizing the DPA in March of 2020 was an important step at the federal level in the response to the pandemic as it directed the heads of several key federal agencies to formulate response plans to combat the spread of COVID-19 in SNFs.

The DPA allows the President to provide for the formation of voluntary agreements by the private sector to help expedite and expand the supply of materials and services from the U.S. industrial base needed to promote the national defense (Federal Emergency and Management Agency, 2020). FEMA was activated under the White House COVID Task Force to provide SNFs across the nation with PPE and HHS also allocated $4.9 billion to SNFs on May 21, 2020 to assist in restocking the much-needed PPE (Whoriskey, Cenziper, & et.al, 2020).

The COVID-19 pandemic presented conditions that posed a direct threat to the national defense of the U.S. and its preparedness programs such that, pursuant to the DPA, an agreement to provide PPE, pharmaceuticals, testing supplies and other critical healthcare resources was necessary for national defense (Department of Homeland Security, 2020). The resources created by the invocation of the DPA supplemented the national stockpile and provided PPE and other critical healthcare resources directly to facilities such as SNFs that were severely impacted by the COVID-19 pandemic.

Qualified Persons & Expanded Diagnostic Testing

One of the measures implemented as a result of the declaration of a Public Health Emergency (PHE) for COVID-19 was the expansion of categories of Qualified Persons authorized to prescribe, dispense, and administer covered medical countermeasures for COVID-

19, such as the ordering and administering of vaccines (Department of Health and Human Services, 2020). Qualified Persons included pharmacist interns and healthcare providers, including physicians, advanced practice registered nurses, registered nurses, or practical nurses, who held an active license or certification to prescribe, dispense, or administer vaccines under the law of any state within the last five years, that was inactive, expired, or lapsed (Department of Health and Human Services, 2020). Persons could be covered to prescribe, dispense, or administer COVID-19 vaccines if their license was in good standing prior to its expiration, they completed a CDC COVID-19 vaccine training, and they had confirmation of competency by a practicing healthcare professional (Department of Health and Human Services, 2020). The expansion of qualified personnel to provide COVID-19 countermeasures was aimed at addressing the shortage of healthcare workers due to the pandemic. In areas severely affected, extending eligibilities to other qualified persons was also intended to help mitigate illness and death in healthcare facilities (Department of Health and Human Services, 2020).

In addition to expanding qualified personnel, federal policies were updated in response to COVID-19 to help protect the safety of patients, and the timely administration of care. One such revision was made by CMS as an interim-rule to amend several Medicare policies to allow any healthcare professional authorized to do so under state law to order COVID-19 diagnostic laboratory tests, and to bill for specimen collection fees for COVID-19 testing under the Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS) during the public health emergency (PHE) (Department of Health and Human Services, 2020). Existing requirements mandated that all diagnostic tests paid under the PFS and OPPS must be furnished under a specified minimum level of supervision by a physician. Given the urgency surrounding the COVID-19 pandemic, the waiver of this requirement allowed for more rapid testing to

mitigate the additional spread of COVID-19 in hospitals, outpatient settings, and LTCFs (Department of Health and Human Services, 2020).

Additionally, CMS added reporting requirements, specifically for LTCFs, mandating that as part of the Quality Reporting Program (QRP), LTCFs were required to report information on COVID-19 incidence among patients and staff to the CDC (Department of Health and Human Services, 2020). This addition was made without the traditional notice-and-comment process because it was believed that informing patients, their families, and the public of the incidence of COVID-19 in LTCFs would assist public health officials in detecting outbreaks and saving lives (Department of Health and Human Services, 2020).

Requirements for Notification of Confirmed COVID-19 (or Persons Under Investigation) Among Patients and Staff in SNFs

Due to heightened concerns regarding the rapid increase of cases and deaths of patients and healthcare workers in SNFs in the early months of the pandemic, CMS increased their communicable disease reporting requirements to include that SNFs must report information on COVID-19 cases and deaths among patients and staff to the agency (Whoriskey, Cenziper, & et.al, 2020). The communicable disease reporting requirements worked to ensure the appropriate tracking, response, and mitigation of COVID-19, requiring facilities to report patients or staff with confirmed cases of COVID-19 and Persons Under Investigation (PUI) to CDC in a standardized format and frequency defined by CMS and CDC (Centers for Medicare and Medicaid Services, 2020). This action resulted in the first look at nationwide case totals in SNFs and subsequently the continuous tracking of COVID-19 in SNFs.

The tracking of case and death data by CMS and CDC enabled the federal government to understand the true impact of COVID-19 in SNFs, and the forms of assistance that states needed

to better support SNFs. While initial estimates indicated that SNFs were heavily impacted, the reporting of case and death data to federal agencies illuminated just how dire the situation was. By June of 2020, SNFs accounted for only 10% of all U.S. COVID-19 cases, but between 33% and 50% of all COVID-related deaths in the U.S. (Yourish, Lai, & et.al, 2020).

The public reporting of just how seriously the COVID-19 pandemic was impacting SNFs across the nation, propelled many historic challenges facing SNFs into the national spotlight. Challenges related to nursing staff shortages, infection control, and the overall quality of care that patients received in these facilities were called into question (University of Rochester Medical Center, 2020). Patients and healthcare workers alike were extremely vulnerable due to the nature of these facilities, and the case and death data reported on a weekly basis to CDC and CMS were a cause for concern and more federal action (University of Rochester Medical Center, 2020).

CMS converted data received by SNFs through CDC's reporting mechanism into an electronic dashboard that provided weekly case and death counts for the nation (Centers for Medicare and Medicaid Services, 2021). Some states, on the other hand, published their own data and produced similar reports by facility level, redacting personally identifying information (Kaiser Family Foundation, 2020). While some states reported their data before federal requirements made reporting mandatory, other states were delayed in their reporting. By April 2020, only 36 states were reporting their LTCF COVID-19 cases and deaths among patients and healthcare workers, which was a barrier to fully understanding the full national impact of COVID-19 in these facilities (Kaiser Family Foundation, 2020).

Improving and Expanding Access to Care and Treatments for COVID-19 & Personal Protective Equipment

Adding to the federal response policies already in place, E.O. 13997, was signed into effect on January 21, 2021 by President Biden, designed to highlight the policy of his administration to improve the nation's response to COVID-19, to accelerate the development of novel therapies to treat COVID-19, and to improve access to quality and affordable healthcare (Executive Office of the President, 2021).

The E.O. also tasked the HHS Secretary and Director of the National Institutes of Health with developing plans to support large-scale randomized trials to identify optimal clinical management strategies, alternative treatments for COVID-19 and future high consequence public health threats that could be easily manufactured, distributed, and administered (Executive Office of the President, 2021). The E.O. tasked the Secretary of Defense, The Secretary of HHS, the Secretary of Veterans Affairs and the heads of other relevant executive departments and agencies to provide targeted surge assistance to critical care and LTCFs, including nursing homes, SNFs, assisted living facilities, intermediate care facilities for individuals with disabilities, and residential treatment centers in their efforts to combat the spread of COVID-19 (Executive Office of the President, 2021). The E.O. also requires the HHS Secretary to issue recommendations for how states and healthcare providers can increase the capacity of their healthcare workforces to address COVID-19, and to expand access to programs and services designed to meet long-term health needs of patients recovering from COVID-19 (Executive Office of the President, 2021).

Combined Impact of Federal Response Policies

While the full impact of the federal policies issued in response to the COVID-19 pandemic remain to be seen, it is already clear that they helped to expand capacity levels required to mitigate the disease impact. Through federal policy action across HHS and FEMA, SNFs were able to receive PPE that was needed to more safely treat patients and protect healthcare workers (Flynn, 2020).

The changes to regulations by CMS also helped to provide more transparent data to federal agencies and the public regarding the situation in SNFs across the nation. These data were important to inform federal action and to ensure that facilities most heavily impacted received priority supplies. Cross-agency collaboration at the federal level was also important for providing needed assistance to SNFs. A CMS report commissioned by the Coronavirus Commission for Safety and Quality in Nursing Homes confirmed that over $21 billion was distributed directly to SNFs at an average of $1.5 million per facility (Centers for Medicare and Medicaid Services, 2020).

In addition to direct funding needed to aid in response capacity, more than 15,000 SNFs received emergency 14-day supplies of PPE when the supply shortage was at its peak, over 13,850 point-of-care testing devices were provided to SNFs, and federal task forces were deployed to SNFs in states where particularly affected facilities were identified (Centers for Medicare and Medicaid Services, 2020).

As the response continues to evolve and scientists work to assess the impacts of federal response policies, it is the conclusion of this analysis that these federal policy actions were needed and without them there would likely have been more illness and death in SNFs across the nation.

Equity-Based Implications

The policy proposals presented reflect the current scientific evidence and an approach to improving the overall quality of care and safety for all patients and healthcare workers in SNFs. Despite the intent of these policies, there are potential equity-based implications of these policy proposals.

For rural and underserved populations, defining the minimum standards of nursing can prove to be a significant challenge to facilities currently experiencing staffing shortages because of their geographical area. Requiring more nursing staff to treat patients safely and adequately, could result in the closure of facilities who are unable to comply with this regulation change, potentially negatively impacting access to healthcare for patients in that region.

In addition to geographic challenges, trends in nursing which include employers preferring candidates with bachelors' degrees, can impact the availability of staff to fill these positions for routine nursing care and even more so for specialized roles such as an IP.

Challenges with staffing also can negatively impact retention rates for healthcare workers. Understaffing has already been linked to higher rates of burn out and turn over, changing policies to require additional staff that a facility might not be able to provide could further exacerbate the issue.

Finally, many of the caregivers and patients who utilize these facilities are not aware of the open public comment period where their concerns could be heard related to proposed changes to federal regulations that govern SNFs. Making more changes to policies without ensuring that the affected populations, especially those who are most disadvantaged, have an opportunity to voice their opinion is of great concern. These equity-based implications reflect a

need for comprehensive and cross-collaborative policy efforts that work to mitigate as many adverse outcomes as possible, especially for individuals who are facing disparities.

Conclusion

COVID-19 is the greatest public health crisis to impact the U.S. and the world in over a century (Farzan, Hassan, Bellware, & et.al, 2020). As of May 30, 2021, CMS confirmed 655,110 cases and 132,608 deaths in patients, and 583,756 confirmed cases and 1,931 deaths in healthcare workers in SNFs in the U.S. because of COVID-19 (Centers for Medicare and Medicaid Services, 2021). The impact of this global pandemic on vulnerable populations such as older adults in SNFs, especially those from communities of color, has once again shone the spotlight on areas of the U.S. public health infrastructure and healthcare delivery system that require immediate attention. As more of the U.S. population ages, the demand for long-term care will continue to grow. As part of this expansion, the federal government will need to provide a stronger policy framework to prioritize patient health, safety, and quality of care.

While there are current federal policies designed to prevent and respond to communicable disease outbreaks in SNFs, there are evident gaps between existing policies and current evidence regarding best policies and practices. One of these gaps exist between current federal policy related to nursing services and staffing requirements, and the recommendations proposed by experts. The lack of a clear definition regarding "sufficient staff" allows every state and U.S. Territory to have different interpretations which can impact on the quality of care that patients receive.

The proposed policy solution is that federal regulators adopt recommendations to clearly define a minimum standard for "sufficient nursing staff" for SNFs. This would include sufficient staff to provide 4.1 hours of nursing care per resident day with a minimum 30% of that

consisting of licensed nurses. In addition, there should also be clear staffing requirements based on higher acuity case-mix weights. Adopting the proposed requirements would also help to increase the number of CNAs, LPNs, and RNs in SNFs across the country, which is important given the strong association between higher nurse staffing levels and better resident quality of care and patient outcomes. (Harrington & Dellefield, 2020).

Other gaps exist between current policies and best practices regarding infection prevention and control (IPC). Current requirements do not require standardized training that would ensure consistency and quality in the training that providers receive, and upcoming regulatory changes will also weaken requirements for IPs in facilities, despite concerns among experts about the impact this would have on IPC programs as well as patient health and safety.

This study proposes that federal regulators adopt standardized IPC training courses produced by CMS and CDC as a requirement for all personnel involved in IPC in SNFs, publicly report the compliance of training, and provide and update as needed a repository of standardized trainings that SNFs must have their employees take. In addition, CMS should evaluate the impact of these trainings on reducing infections in SNFs and reverse the decision that would remove designated IPs in SNFs while also reducing the time spent in SNFs by IPs to "sufficient time."

Despite some of limitations of this study, including the exclusive focus on federal policies, the lack of evidence-based data that assesses the impact of QAPI programs in SNFs, and the lack of data regarding the impact of federal COVID-19 response policies, the gaps identified here require federal action for the overall improvement of SNFs. The policy solutions proposed by this research highlight the current knowledge and recommendations of scientists and subject matter experts across relevant areas. The areas identified as limitations are important to

understanding all aspects of federal policies as they relate to communicable disease prevention and response in SNFs and should be evaluated in future research and analysis.

Personal Reflections

COVID-19 has illuminated many of the major gaps in both healthcare and public health infrastructure. Every aspect of our healthcare delivery system from healthcare professionals and the supply of critical PPE, to hospital and intensive care unit capacity and LTCFs was significantly impacted by this pandemic. Not only were infrastructure gaps highlighted, the pervasive health disparities experienced by racial and ethnic minority communities in the U.S. were also brought back to the forefront.

Amid this global pandemic, a long overdue racial awakening also seemed to be happening in the U.S. after the murder of George Floyd. Black and Brown people and their allies showed up during the largest public health crisis of the past century, to protest police brutality and racism in this country. I would admit that the risk of protesting during a global pandemic caused the public health professional in me to be deeply concerned about the spread of the disease among already disproportionately affected communities, but as a Black man, I knew that this moment was desperately needed.

When I think about all the ways that COVID-19 has impacted this country, I can't help but think about the many ways that this could have been prevented, or the impacts significantly mitigated. If it weren't for the politicizing of basic scientific principles, the constant contradiction of scientific experts with decades of experience, the need for constant attention by elected officials, and the lack of investment in public health, many more lives could have been saved. This country has done its people a great disservice with the way that COVID-19 has been handled, especially the vulnerable patients and healthcare workers in SNFs.

Despite the many challenges that COVID-19 has presented, one of the things I am most proud of is the tenacity, professionalism, and excellence that has been exhibited by health

professionals of all backgrounds. Those whose work has gone unnoticed in the public eye for a long time, are finally getting the praise they deserve for the hard work that they do night and day to ensure the health and safety of U.S. citizens. I am hopeful that the momentum for public health readiness will continue even when COVID-19 is a thing of the past, and that the proper investments are made to ensure our preparedness and response capabilities in the future are up to par.

Table 3. Policy Proposal Table

Policy Topic	Current Requirements	Policy Gaps (Yes/No)	Policy Proposal (Yes/No)	Policy Impact Category
Nursing Services	42 C.F.R. § 483.35 - SNFs must have "sufficient nursing staff" with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.	Yes- Discrepancy identified between current federal requirements for "sufficient nursing staff" and expert recommendations for quality patient care	Yes - Federal regulators adopt recommendations to define a minimum standard for "sufficient nursing staff" for SNFs, as sufficient staff to provide 4.1 hours of nursing care per resident day with a minimum 30% of that consisting of licensed nurses. In addition to the minimum standards, federal regulators should also provide nursing staff requirements to SNFs in categories based on higher acuity case-mix weights.	Prevention

Infection Prevention & Control/Training Requirements	42 C.F.R. § 483.80 - SNFs "must establish and maintain an IPC program designed to provide a safe, sanitary, and comfortable environment to help prevent the development and transmission of communicable disease and infections." The IPC program must include at a minimum the following elements: "(1) a system for preventing, identifying, reporting, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services to the facility and (2) the IPC program must contain written standards, policies, and procedures for the facilities to follow. SNFs must "designate one or more individual(s) as	Yes- Lack of federally standardized training materials for SNF personnel needed to provide the same quality of care for patients.	Yes – Federal regulators should adopt the standardized IPC training course produced by CMS and CDC as a federal requirement for all personnel involved in IPC in SNFs, and publicly report the compliance of training. In addition to IPC training, federal regulators should provide and update as needed a repository of standardized trainings that SNFs must have their employees take as an ongoing condition of participation in CMS programs. As part of this policy change, CMS should also evaluate the impact that the standardization of these trainings has had on reducing infections in SNFs, for the purpose of continual process improvement.	Prevention & Response

	the Infection Preventionist (IP) who is responsible for the facility's infection prevention and control program The IP must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field, must be qualified by education, training, experience, or certification, must work at least part-time at the facility, have completed specialized training in IPC, and must be a part of the quality assessment and assurance committee and report on the IPC activities on a regular basis			

Quality Assurance & Improvement	42 C.F.R. § 483.75 - each LTCF is required to develop, implement, and maintain an effective comprehensive data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. SNF QAPI programs must maintain documentation and demonstrate evidence of the ongoing QAPI program that meets the outlined requirements. Requirements include systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities	N - QAPI needs vary vastly by facility and patient populations served, which makes the degrees of freedom allowed in the federal regulations appropriate in this context.	Y - CMS should dedicate resources to evaluating the impact of QAPI programs in SNFs. While the current federal regulations provide a sufficient overarching framework to achieve their intended goals, there is little evidence to support the programs impact on a national level.	Prevention & Response

Coronavirus Aid, Relief, and Economic Security Act (CARES ACT)	Public Law 116-136 - a $2.2 trillion economic stimulus bill passed in March of 2020, The CARES Act specifically provided billions of dollars in funding to healthcare providers, manufacturers, and distributors to be allocated for public health programs, adding personal protective equipment (PPE) to the national stockpile, increasing Medicare payments to medical providers, and to cover the costs of COVID-19 testing and vaccination. $4.5 billion was designated for SNF Infection Control Relief Fund Payments. These payments were for the diagnosis, testing, or care of individuals with possible or actual cases of COVID-19.	No - CARES Act funding was a vital component to the response of COVID-19 in SNFs. Funding was used to provide PPE, diagnostic testing, and care for individuals confirmed or suspected to have COVID-19.	No recommended policy change for Public Law 116-136 (CARES ACT).	Response

Requirements for Notification of Confirmed COVID-19 Among Residents and Staff in SNFs	QSO-20-26-NH – CMS is requiring facilities to report cases of residents or staff who have confirmed COVID-19 and Persons Under Investigation (PUI) to CDC in a standardized format and frequency defined by CMS & CDC.	No - The reporting of confirmed and suspected COVID-19 cases to CMS and CDC was a necessary component for publicly transparency and to ensure an adequate and measured response.	No recommended policy change for QSO-20-26-NH.	Response
Improving and Expanding Access to Care and Treatments for COVID-19	E.O. 13997 - designed to improve the capacity of the nation's healthcare systems to address COVID-19 and support healthcare workers and patients, to accelerate the development of novel therapies to treat COVID-19, and to improve access to quality and affordable healthcare. The Executive Order also tasked the Secretary of Defense, The Secretary of HHS, the Secretary of Veterans Affairs and the heads of other relevant executive departments and agencies to provide targeted surge assistance to	No - The establishment of an Executive Order directed to formulating surge assistance for SNFs to combat the spread of COVID-19 is an appropriate federal response.	No recommended policy change for Executive Order 13997.	Response

	critical care and LTCFs, including nursing homes, SNFs, assisted living facilities, intermediate care facilities for individuals with disabilities, and residential treatment centers in their efforts to combat the spread of COVID-19			
Personal Protective Equipment	The COVID-19 pandemic presents conditions that pose a direct threat to the national defense of the US and its preparedness programs such that, pursuant to the DPA, an agreement to provide PPE, pharmaceuticals and other critical healthcare resources is necessary for national defense	No - The provisions of the Defense Production Act are in alignment with the declaration of a Public Health Emergency in the United States. Utilizing available resources to ensure the health and safety of patients in SNFs is an appropriate federal response	No recommended policy change for the Defense Production Act	Response
Regulatory Response to COVID-19	Qualified Persons: Expanded Diagnostic Testing:	No - The regulatory response to COVID-19 including updates to Qualified Persons and Expanded Diagnostic testing are critical to an	No recommended policy changes to Regulatory Responses	Response

		effective response. These updates are an appropriate federal response.		

References

116th Congress. (2020, December 27). H.R. 133; Public Law 116-260. *Consolidated Appropriations Act, 2021*. District of Columbia, United States of America.

116th Congress Public Law. (2020, March 27). Coronavirus Aid, Relief, and Economic Security Act (CARES Act). *CARES ACT*. District of Columbia, United States of America.

117th Congress . (2021, March 11). H.R. 1319. *American Rescue Plan Act of 2021*. District of Columbia, United States of America .

Adkins, J. (2018). Infection Prevention & Performance Improvement. Pennsylvania, United States of America: Pennsylvania Patient Safety Authority. Retrieved from Alliant Quality.

Alfarah, Z., & Walker, M. e. (2019). Skilled Nursing Facility Utilization Management in a Risk-Sharing Environment in the Community. *The Journal of Post Acute and Long Term Care Medicine*, 1052-1053.

American Association of Colleges of Nursing. (2020, September). *Nursing Shortage*. Retrieved from aacunursing.org: aacnnursing.org/news-information/fact-sheets/nursing-shortage

American Health Care Association. (2020, May). *STATE BY STATE BREAKDOWN: COVID-19 TESTING FOR NURSING HOMES Testing every US nursing home resident and staff once would cost $440 million*. Retrieved from American Health Care Association: https://www.ahcancal.org/facility_operations/disaster_planning/Documents/State%20by%20State%20Breakdown_COVID%20Testing%20for%20Nursing%20Homes%205.20.20.pdf

Arons, M., Hatfield, K., & Reddy, S. e. (2020). Presymptomatic SARS-CoV-2 Infections and Transmission in a Skilled Nursing Facility. *New England Journal of Medicine*.

Association for Professionals in Infection Control and Epidemiology. (2020, December). *Who are Infection Preventionists?* Retrieved from APIC: https://apic.org/monthly_alerts/who-are-infection-preventionists/

Board of Governors of the Federal Reserve System. (2018, June 29). *What is a regulation and how is it made?* Retrieved from Federal Reserve : https://www.federalreserve.gov/faqs/what-is-a-regulation.htm#:~:text=In%20general%2C%20a%20federal%20agency,that%20respond%20to%20the%20comments.

Borrayo, E. e. (2002). Utilization Across the Continuum of Long-Term Care Services. *The Gerontologist* , 603-612.

Burke, R., & Juarez-Colunga, E. (2015). Rise of Post-Acute Care Facilities as a Discharge Destination of U.S. Hospitalizations. *Journal of the American Medical Association Internal Medicine*, 295-297.

Busse, R., Klazinga, N., & et.al. (2019). Clinical Pathways as a Quality Strategy. In R. Busse, N. Klazinga, & et.al, *Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies.* Copenhagen: European Observatory on Health Systemsand Policies.

California Health Information Association. (2013, January). *Sequela (Late Effects)*. Retrieved from California Health Information Association:

https://californiahia.org/sites/californiahia.org/files/docs/resources/ICD10/Oct-2013-sequela-late-effects.pdf

Center for Aging Research and Education. (2017, December 18). *The Secrets of Success for Nursing Staff Retention in Long-Term Care*. Retrieved from CaRE at the UW-Madison School of Nursing: https://care.nursing.wisc.edu/2017/12/18/the-secrets-of-success-for-nursing-staff-retention-in-long-term-care/

Centers for Disease Control and Prevention. (2014). *Using Evaluation to Inform CDC's Policy Process.* Atlanta : Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention. (2015, November 5). *Management of Multidrug-Resistant Organisms in Health Care Settings*. Retrieved from CDC: https://www.cdc.gov/infectioncontrol/guidelines/mdro/background.html

Centers for Disease Control and Prevention. (2019, January 2). *Policy Analytical Framework.* Retrieved from CDC: https://www.cdc.gov/policy/polaris/index.html

Centers for Disease Control and Prevention. (2019, January 2). *Policy and Strategy*. Retrieved from Office of the Associate Director for Policy and Strategy: https://www.cdc.gov/policy/polaris/policyprocess/policy_analysis.html

Centers for Disease Control and Prevention. (2020, June 10). *Infection Prevention Training* . Retrieved from Nursing Homes and Assisted Living (Long-term Care Facilities [LTCFs]): https://www.cdc.gov/longtermcare/training.html#anchor_1591649197937

Centers for Disease Control and Prevention. (2020, November 13). *Late Sequelae of COVID-19*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/late-sequelae.html

Centers for Disease Control and Prevention. (2020, June 25). *Nursing Homes and Long-Term Care Facilities*. Retrieved from Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

Centers for Disease Control and Prevention. (2020, October 16). *Testing Residents* . Retrieved from CDC.gov: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

Centers for Disease Control and Prevention. (2021, May 5). *Provider Relief Fund COVID-19 Nursing Home Quality Incentive Program*. Retrieved from CDC.gov: https://data.cdc.gov/Administrative/Provider-Relief-Fund-COVID-19-Nursing-Home-Quality/bfqg-cb6d

Centers for Disease Prevention and Control. (2020, May 18). *About CDC*. Retrieved from Centers for Disease Control and Prevention : https://www.cdc.gov/about/organization/cio.htm

Centers for Medicare & Medicaid Services. (2020, March 24). *National Health Expenditure Data*. Retrieved from CMS.gov: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet

Centers for Medicare and Medicaid. (2019, March 11). Specialized Infection Prevention and Control Training for Nursing Home Staff in. Batlimore , Maryland: Centers for Medicare and Medicaid.

Centers for Medicare and Medicaid Services. (2016, September 20). *QAPI Description and Background*. Retrieved from CMS.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapidefinition

Centers for Medicare and Medicaid Services. (2020, February 14). *Legacy Medicare Provider Utilization and Payment Data: Skilled Nursing Facilities*. Retrieved from CMS.gov: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/SNF

Centers for Medicare and Medicaid Services. (2021, January 19). *CMS Program Statistics*. Retrieved from CMS: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/index

Centers for Medicare and Medicaid Services. (2001). *Report to Congress: Appropriateness of Minimum Nurse Staffinf Ratios in Nursing* . Baltimore: Department of Health and Human Services.

Centers for Medicare and Medicaid Services. (2001). *Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes Phase 2 Final Report.* Baltimore: CMS.

Centers for Medicare and Medicaid Services. (2011). *QAPI at a Glance: A Step by Step Guide to Implementing QAPI in Your Nursing HOme.* Baltimore : Centers for Medicare and Medicaid Services.

Centers for Medicare and Medicaid Services. (2012, November 14). *Minimum Data Set*. Retrieved from CMS.gov: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports

Centers for Medicare and Medicaid Services. (2016, September 20). *QAPI Description and Background*. Retrieved from CMS.gov: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapidefinition

Centers for Medicare and Medicaid Services. (2019, July 18). *Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency*. Retrieved from Federal Register: https://www.federalregister.gov/documents/2019/07/18/2019-14946/medicare-and-medicaid-programs-requirements-for-long-term-care-facilities-regulatory-provisions-to

Centers for Medicare and Medicaid Services. (2019, October 1). *Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities; Regulatory Provisions to Promote Efficiency, and Transparency.* District of Columbia: Department of Health and Human Services.

Centers for Medicare and Medicaid Services. (2020, September 16). *Independent Nursing Home COVID-19 Commission Findings Validate Unprecedented Federal Response*. Retrieved from CMS.gov: https://www.cms.gov/newsroom/press-releases/independent-nursing-home-covid-19-commission-findings-validate-unprecedented-federal-response

Centers for Medicare and Medicaid Services. (2020, April 19). *Requirements for Notification of Confirmed COVID-19 Among Residents and Staff in Nursing Homes*. Retrieved from CMS.gov: https://www.cms.gov/files/document/qso-20-26-nh.pdf

Centers for Medicare and Medicaid Services. (2021, May 25). *CARES Act Proider Relief Fund*. Retrieved from HHS.gov: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html

Centers for Medicare and Medicaid Services. (2021, May 30). *COVID-19 Nursing Home Data.* Retrieved from Data.CMS.Gov: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/

Centers for Medicare and Medicaid Services. (2021, May 30). *COVID-19 Nursing Home Data* . Retrieved from CMS.gov: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Chidambaram, P., Neuman, T., & Garfield, R. (2020, October 27). *Racial and Ethnic Disparities in COVID-19 Cases and Deaths in Nursing Homes*. Retrieved from Kaiser Family Foundation : https://www.kff.org/coronavirus-covid-19/issue-brief/racial-and-ethnic-disparities-in-covid-19-cases-and-deaths-in-nursing-homes/#:~:text=Deaths%20and%20Cases%20by%20Resident%20Race%2FEthnicity&text=Nationwide%2C%2063%25%20of%20nursing%20homes,of%20Black%

CMS. (2020, May 19). *Conditions for Coverage & Conditions of Participation*. Retrieved from CMS: https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs

Code of Federal Regulations. (2016, November 28). Requirements for Long Term Care Facilities . *Nursing Services*. District of Columbia: Centers for Medicare and Medicaid Services .

Code of Federal Regulations. (2016, November 28). Requirements for States and Long Term Care Facilities . *Training Requirements*. District of Columbia: Centers for Medicare and Medicaid Services.

Code of Federal Regulations. (2017, July 13). Quality assurance and performance improvement. *Requirements for Long Term Care Facilities*. District of Columbia, United States of America.

Code of Federal Regulations. (2020, September 2). Title 42. Public Health . *Infection Control* . District of Columbia: Centers for Medicare and Medicaid Services .

Commission on California State Government Organization and Economy. (1983). *The Bureaucracy of Care: Continued Policy Issues for Nursing Home Services & Regulation* . Sacremento : State of California .

Congressional Research Service. (2021, March 19). An Overview of Federal Regulations and the Rulemaking Proces. Congressional Research Service .

Congressional Research Service. (2021, February 5). *New Presidential Directives on the Defense Production Act (DPA) and the COVID-19 Pandemic*. Retrieved from Congressional Resaerch Service: https://crsreports.congress.gov/product/pdf/IN/IN11593

Crist, K., & Murphy, D. e. (2019). The Role of the Infection Preventionist in a Transformed Healthcare System: Meeting Healthcare Needs in the 21st Century. *American Journal of Infection Control*, 352-357.

Defelice, R. (2021, January 13). *How Long Does it Take to Develop Training? New Question, New Answers*. Retrieved from Association for Talen Development: https://www.td.org/insights/how-long-does-it-take-to-develop-training-new-question-new-answers

Department of Health and Human Services. (2014). *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beenficiaries.* Baltimore: Inspector General.

Department of Health and Human Services. (2020, April 28). Centers for Medicare and Medicaid Services. *Additional Policy and Regulatory Revisions in Response to the COVID-19*

Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. District of Columbia, United States of America.

Department of Health and Human Services. (2020, May 19). Countermeasures Against COVID-19. *Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19* . District of Columbia , United States of America.

Department of Homeland Security. (2020, August 14). Voluntary Agreement under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. *Federal Emergency Management Agency*. District of Columbia, United States of America.

DeWalt, D., Oberlander, J., & Carey, T. (2005). Significance of Medicare and Medicaid Programs for the Practice of Medicine. *Health Care Financing Review*, 79-90.

Division of Healthcare Quality Promotion. (2015). *Outpatient Settings Policy Options for Improving Infection Prevention.* Atlanta: Centers for Disease Control and Prevention.

Dorritie, R., Quigley, D., & et.al. (2020). Support of nursing home infection management varies by US State Departments of Health. *Journal of Hospital Infection*, 258-264.

Dumyati, G., Stone, N., & Nace, D. (2017). Challenges and Strategies for Prevention of Multidrug-Resistant Organism Transmission in Nursing Homes. *Current Infectious Disease Reports*, 18.

Executive Office of the President. (2021, January 25). Executive Order 13987. *Organizing and Mobilizing the United States Government to Provide a Unified and Effective Response to Combat COVID-19 and to Provide United States Leadership on Global Health and Security*. District of Columbia: Executive Office of the President. Retrieved from Congressional Resaerch Service: https://crsreports.congress.gov/product/pdf/IN/IN11593

Executive Office of the President. (2021, January 21). Improving and Expanind Access to Care and Treatments for COVID-19. *Executive Order 13997*. District of Columbia, United States of America: Federal Register.

Farzan, A., Hassan, J., Bellware, K., & et.al. (2020, August 14). *US was 'unprepared' for 'greatest public health crisis' in a century, CDC director says*. Retrieved from The Washington Post: 2020

Federal Emergency and Management Agency. (2020, November 23). *Defense Production Act*. Retrieved from FEMA.gov: https://www.fema.gov/disasters/defense-production-act

Flynn, M. (2020, November 19). *PPE Supplies Mostly Holding Steady for Nursing Homes, But So Much Hinges on their Suppliers*. Retrieved from Skilled Nursing News: https://skillednursingnews.com/2020/11/ppe-supplies-mostly-holding-steady-for-nursing-homes-but-so-much-hinges-on-their-suppliers/

Gebelopff, R. e. (2020, May 21). *The Striking Racial Divide in How COVID-19 Has Hit Nursing Homes*. Retrieved from The New York Times: https://www.nytimes.com/article/coronavirus-nursing-homes-racial-disparity.html

Harrington, C., & Dellefield, e. (2020). Appropriate Nurse Staffing Levels for US Nursing Homes. *Health Services Insights*, 1-14.

Harrington, C., Dellefield, M., E, H., & al., e. (2020). Appropriate Nurse Staffing Levels for US Nursing Homes. *Health Services Insights Volume 13*, 1-14.

Harrington, C., Schnelle, J., & Margaret, M. (2016). The Need for Higher Minimum Staffing Standards in US Nursing Homes. *Health Services Insights*, 13-19.

Juozitis, C. (2019, February 28). *Imrpove Training Effectiveness with Standardization*. Retrieved from Solid Professor: https://www.solidprofessor.com/blog/improve-training-effectiveness-with-standardization/

Kaiser Family Foundation. (2020, April 23). *State Reporting of Cases and Deaths Due to COVID-19 in Long-Term Care Facilities*. Retrieved from Kaiser Family Foundation: https://www.kff.org/coronavirus-covid-19/issue-brief/state-reporting-of-cases-and-deaths-due-to-covid-19-in-long-term-care-facilities/

Lavelle, J., Schast, A., & Keren, R. (2015). Standardizing Care Processes and Improving Quality Using Pathways and Continuous Quality Improvement. *Current Treatment Options in Pediatrics*, 347-358.

Lee, M., Lee, G., Lee, S., & Park, Y. (2019). Effectiveness and Core Components of Infection Prevention and Control Programmes in Long-Term Care Facilities: A Systematic Review. *Journal of Hospital Infection*, 377-393.

Li, Y., & Temkin-Greener, H. e. (2020). COVID-19 Infections and Deaths among Connecticut Nursing Home Residents: Facility Correlates. *Journal of the American Geriatrics Society*, 1-26.

Martin, A., Hartman, M., Lassman, D., & Catlin, A. (2020). National Health Care Spending in 2019: Steady Growth for the Fourth Consecutive Year. *Health Affairs*, 14-24.

Mendelson, M. A. (1974). *Tender Loving Greed.*

Montoya, A., & Mody, L. (2012). Common infections in nursing homes: a review of current issues and challenges. *Aging and Health* , 889-899.

Montoya, A., Cassone, M., & Mody, L. (2016). Infections in Nursing Homes: Epidemiology and Prevention Programs. *Clinical Geriatric Medicine*, 585-607.

Mor, V., & Zinn, J. e. (2004). Driven to Tiers: Socioeconomic and Racial Disparities in the Quality of Nursing Home Care. *The Milbank Quarterly*, 227-256.

Morbidity and Mortality Weekly Report. (2020). *COVID-19 in a Long-Term Care Facility - King County, Washington, February 27 - March 9 2020.* Atlanta : Centers for Disease Control and Prevention.

National Academy of Medicine. (2021). *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equiry.* District of Columbia: The National Academies Press.

National Council of State Boards of Nursing. (2020). *Definition of Nursing Terms*. Retrieved from National Council of State Boards of Nursing: https://www.ncsbn.org/nursing-terms.htm

National Institute of Health . (2017, May 1). *National Insitute on Aging*. Retrieved from Residential Facilities, Assisted Living, and Nursing Homes: https://www.nia.nih.gov/health/residential-facilities-assisted-living-and-nursing-homes

National Law Review. (2020, June 2). *Pandemic Highlights Existing Problems in Nursing Home System*. Retrieved from National Law Review: https://www.natlawreview.com/article/pandemic-highlights-existing-problems-nursing-home-system

Nurse Journal. (2021, May 20). *How to Become a Registered Nurse*. Retrieved from Nurse Journal: https://nursejournal.org/registered-nursing/how-to-become-a-rn/

Office of Inspector General. (2018). *Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased* . District of Columbia : US Department of Health and Human Services.

Office of Management and Budget. (2020, November 20). *OMB*. Retrieved from whitehouse.gov: https://www.whitehouse.gov/omb/

Office of the Assistant Secretary for Preparedness and Response. (2019, November 26). *Publicd Health Emergency Declaration*. Retrieved from US Department of Health and Human Services: https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx

Office of the Associate Director for Policy and Strategy. (2015, May 29). *Definition of Policy*. Retrieved from CDC: https://www.cdc.gov/policy/analysis/process/definition.html

Personal Communication with CDC Experts. (2019, July). Changes to Centers for Medicare and Medicaid Services Changes to IP Requirements for Conditions of Participation. Atlanta , Georgia , United States: Unpublished Conversation.

Public Health Law Center. (2015, March). *Laws, Polciies, and Regulations: Key Terms and Concepts*. Retrieved from Public Health Law Center:

https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-laws-policies-regs-commonterms-2015.pdf

Public Health Ontario. (2020, December 10). *Infection Prevention and Control* . Retrieved from Public Health Ontario: https://www.publichealthontario.ca/en/health-topics/infection-prevention-control

Public Law 93-288. (1988). Robert. T. Stafford Disaster Relief and Emergency Assistance Act. *Stafford Act*. United States Government Prining Office .

Roundtable Learning. (2021, Janurary). *Cost of a Custon eLearning Program 2021*. Retrieved from Roundtable Learning : https://roundtablelearning.com/cost-of-elearning-2021/

Scales, K. (2018, June 8). *Staffing in Long-Term Care Is a National Crisis*. Retrieved from Paraprofessional Healthcare Insitute: https://phinational.org/recruitment-retention-long-term-care-national-perspective/

Senior Justice Law Firm. (2018, August 13). *What is a CMS RUG Score, and can it show fraud?* Retrieved from Senior Justice Law Firm: https://seniorjustice.com/what-is-a-cms-rug-score-and-can-it-show-fraud/

Solon, J., D, R., D.E., K., & Baney, A. (1957). *Nursing Homes, Their Patients and Their Care: A study of Nursing Homes and Similar Long-Term Care Facilities in 13 States.* District of Columbia: US Public Health Services.

Stausbaugh, L., & Joseph, C. (2000). The Burden of Infection in Long-term Care. . *Infection Control Hospital Epidemiology*, 674-679.

Stone, P., & Herzig, C. e. (2015). Understanding Infection Prevention and Control in Nursing Homes: A Qualitative Study. *Journal of Geriatric Nursing* , 267-272.

Temple University Center for Public Health Law Research. (2017, January). *Theory & Methods*. Retrieved from Temple University: http://publichealthlawresearch.org/theory-methods#introduction

The Coalition of Geriatric Nursing Organizations. (2014). *Nursing Staffing Requirements to Meet the Demands of Today's Long Term Care Consumer* . The Coalition of Geriatric Nursing Organizations .

Thomson Reuters Legal. (2020). *How to do Legal Research in 3 Steps*. Retrieved from Thomson Reuters Legal: https://legal.thomsonreuters.com/en/insights/articles/basics-of-legal-research-steps-to-follow

US Department of Commerce, Economics, and Statistics Administration. (2016). *The Population 65 Years and Older in the United States: 2016.* District of Columbia: US Census Burearu.

US Department of Health and Human Services. (2013). *National Action Plan to Prevent Healthcare-Associated Infections: Road Map to Elimination.* District of Columbia: US Department of Health and Human Services.

US Department of Health and Human Services. (2020, May 22). *HHS Announces Nearly $4.9 Billion Distribution to Nursing Facilities Impacted by COVID-19*. Retrieved from HHS.gov: https://www.hhs.gov/about/news/2020/05/22/hhs-announces-nearly-4.9-billion-distribution-to-nursing-facilities-impacted-by-covid19.html

US Department of Health, Education, and Welfare. (1958). *Report on National Conference on Nursing Homes and Homes for the Aged* . District of Columbia: US Public Health Service.

US Department of Health, Education, and Welfare. (1971). *Report on Skilled Nursing Home Certification Project.* District of Columbia: US Department of Health, Education, and Welfare.

US Senate (91st Congress). (1970). *Medicare and Medicaid: Problems, Issues and Alternatives.* District of Columbia: US Government Printing Office.

US Senate. (1957). *Recommendations of the Commission on Chronic Illness on the Care of the Long-Term Patient.* District of Columbia: Committee on Labor and Public Welfare.

US Senate Special Committee on Aging. (1974). *Nursing Home Care in the United States.* District of Columbia: US Government Printing Office. Retrieved from US Senate Special Committee on Aging. 1974. Nursing Home Care in the United States: Failure in Public Policy. Washington, D.C.: US Government Printing Office.

US Senate Subcommittee on Long-Term Care, Special Committee on Aging. (1970). *Nursing Home Care in the United States: Failure in Public Policy, An Introductory Report* . District of Columbia : US Senate .

US Senate Subcommittee on Problems of the Aged and Aging. (1960). *The Condition of American Nursing Homes.* District of Columbia : US Senate Committee on Labor and Public Welfare.

United States Census Burearu. (2018, March 13). *The Graying of America: More Older Adults than Kids by 2035*. Retrieved from US Census bureau : https://www.census.gov/library/stories/2018/03/graying-america.html#:~:text=Starting%20in%202030%2C%20when%20all,add%20a%20half%20million%20centenarians.

United States Senate. (2020). *Laws and Regulations*. Retrieved from United States Senate: https://www.senate.gov/reference/reference_index_subjects/Laws_and_Regulations_vrd.htm

University of Rochester Medical Center. (2020, June 18). *COVID-19 Toll in Nursing Homes Linked to Staffing Levels and Quality*. Retrieved from University of Rochester Medical Center: https://www.urmc.rochester.edu/news/story/covid-19-toll-in-nursing-homes-linked-to-staffing-levels-and-quality

Wagner, L., Roup, B., & Castle, N. (2014). Impact of Infection Preventionists on Centers for Medicare and Medicaid Quality Measures in Maryland Nursing Homes. *American Journal of Infection Control*, 2-6.

Walshe, K. (2001). Regulating US Nursing Homes: Are We Learning From Experience . *Journal of Health Affairs: Chronic Care in America*, 128-144.

Werener, R., & Konetzka, T. (2018). Rends in Post-Acute Care Use Among Medicare Beneficiaries: 2000 to 2015. *Journal of the American Medical Association*, 1616-1617.

Whoriskey, P., Cenziper, D., & et.al. (2020, June 4). *Hundreds of nursing homes ran short on staff, protective gear as more than 30,000 residents died during pandemic*. Retrieved from The Washington Post:

https://www.washingtonpost.com/business/2020/06/04/nursing-homes-coronavirus-deaths/

Williams, A., Straker, J., & et.al. (2016). The Nursing Home Five Star Rating: How Does It Compare to Resident and Family Views of Care. *The Gerontologist*, 234-242.

World Health Organization. (2018). *Noncommunicable diseases*. Retrieved from WHO: http://www.who.int/nmh/countries/chn_en.pdf.

World Health Organization. (2020, January). *Health Policy*. Retrieved from World Health Organization: https://www.who.int/topics/health_policy/en/

World Health Organization. (2020, January). *Infection Prevention and Control*. Retrieved from WHO: https://www.who.int/infection-prevention/about/ipc/en/

Xu, H., Intrator, O., & Bowblis, J. (2020). Shortages of Staff in Nursing Homes During COVID-19 Pandemic: What are the Driving Factors? *Journal of the American Medical Directors Association*, 1371-1377.

Yanchus, N., Ohler, E., & Crowe. (2017). 'You Just Can't Do It All': A Secondary Analysis of Nurses' Perceptions of Teamwork, Staffing, and Workload. *Journal of Research in Nursing*, 313-325.

Yourish, K., Lai, R., & et.al. (2020, May 11). *One-Third of All US Coronavirus Deaths Are Nursing Home Residents or Workers*. Retrieved from The New York Times: https://www.nytimes.com/interactive/2020/05/09/us/coronavirus-cases-nursing-homes-us.html