IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF IOWA CEDAR RAPIDS DIVISION

STATE OF KANSAS, et al.,))
Plaintiffs,)
v. XAVIER BECERRA, in his official capacity as Secretary of the Unites States Department of Health and Human Services, et al.,)) Case No. 1:24-cv-00110-LTS-KEM))
Defendants.)

BRIEF OF THE CENTER FOR MEDICARE ADVOCACY, CALIFORNIA ADVOCATES FOR NURSING HOME REFORM, JUSTICE IN AGING, LONG TERM CARE COMMUNITY COALITION, MICHIGAN ELDER JUSTICE INITIATIVE, NATIONAL ASSOCIATION OF LOCAL LONG-TERM CARE OMBUDSMEN, AND NATIONAL CONSUMER VOICE FOR QUALITY LONG-TERM CARE AS AMICI CURIAE IN SUPPORT OF DEFENDANTS

TABLE OF CONTENTS

Table of Authorities	ii
Statements of Interest and Disclosure Statements	1
Introduction and Summary af Argument	4
Argument	5
I. Plaintiffs Cannnot Show a Need for Preliminary Relief.	5
II. Inadequate Staffing Levels Result in Poor Quality Care Outcomes, Injury, Psychological Harm, and Death	7
III. The Staffing Rule Will Save Residents' Lives.	9
IV. Adequate Numbers of Nursing Staff Are Essential to Ensuring Residents' Health, Safety, Welfare, and Rights.	10
V. The Federal Government Has Statutory Authority to Implement a Mandatory Staffing Regulation.	12
VI. The Staffing Rule Ensures That Public Reimbursement is Focused on Resident Care, Not Private Profit	17
VII. The Final Rule Ensures Appropriate Staffing Levels Nationwide, Regardless of Residents' Race and Ethnicity.	19
VIII. Many Nursing Facilities Already Meet Individual Components of the Final Staffing Rule.	19
Conclusion	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
Health & Hosp. Corp. of Marion Cty. v. Talevski, 599 U.S. 166 (2023)	12
Statutes	
42 U.S.C. §1395i-3(d)(4)(B)	13
42 U.S.C. §1395i-3(f)(1)	13
42 U.S.C. §1396r(d)(4)(B)	13
42 U.S.C. §1396r(f)(1)	13
P.L. 101-508, § 4801(17)(B)	14
Regulations	
42 C.F.R. § 483.152(a)(1)	20
42 C.F.R. §§ 483.35(f)-(g)	6
42 C.F.R. § 483.35(h)	6
80 Fed. Reg. 42168 (July 16, 2015)	15
81 Fed. Reg. 68688 (Oct. 4, 2016)	15
87 Fed. Reg. 22720 (Apr. 15, 2022)	8, 12
88 Fed. Reg. 61352 (Sep. 6, 2023)	9
89 Fed. Reg. 40876 (May 10, 2024)	6, 7, 8, 12, 15, 19
Other Authorities	
Abt Associates, Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes. Overview of the Phase II Report: Background, Study Approach, Findings, and Conclusions (Dec. 2001)	14
Abt Associates, Nursing Home Staffing Study, Comprehensive Report (June	2023)19
AHCA, Access to Care Report (Aug. 2023)	16

AHCA & Leading Age, Care for Our Seniors Act17
AHCA, Press Release, Report: Increasing Nursing Home Staffing Minimum Estimated at \$10 Billion Annually (July 19, 2022)
AHCA, Press Release, Updated Report: Additional funding for Workers Needed to Meet a Potential Nursing Home Staffing Minimum Mandate (Dec. 15, 2022)16
ASPE, Office of Behavioral Health, Disability, & Aging Policy, Data Point: Nurse Staffing Estimates in US Nursing Homes, May 2024 (June 28, 2024)
Bliesmer M M, et al., <i>The relationship between nursing staffing levels and nursing home outcomes</i> , J. Aging Health, 1998 Aug;10(3):351-71. doi: 10.1177/089826439801000305. PMID: 10342936
Priya Chidambaram, et al., <i>A Look at Nursing Facility Characteristics Between 2015</i> and 2023 (Jan. 5, 2024)
CMS, Nationwide Expansion of Minimum Data Set (MDS) Focused Survey, S&C: 15-06-NH (Oct. 31, 2014)15
Dorr, D.A., et al., Cost analysis of nursing home registered nurse staffing times. J. of Amer Geriatrics Society, 2005: 53: 840-845
Ashvin Gandhi & Andrew Olenski, <i>Tunneling and Hidden Profits in Health Care</i> , National Bureau of Economic Research (Jul. 13, 2024)
Bill Hammond, Following the Money: An Analysis of "Related Company" Transactions in New York's Nursing Home Industry (Jul. 5, 2022)
Charlene Harrington, et al., <i>United States' Nursing Home Finances: Spending,</i> Profitability, and Capital Structure, 54 Int'l J. Soc. Determinants of Health & Health Servs. 131 (Apr. 2024)
Horn, S.D., et al., <i>The national pressure ulcer long-term care study:</i> Pressure ulcer development in long-term care residents. J. American Geriatrics Society, 2004: 52: 359-367
Horn, S.D., et al., RN staffing time and outcomes of long-stay nursing home residents: pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs. 2005: 105(11): 58-70
Inst. of Medicine, Comm. on Nursing Home Regulation, Improving the Quality of Care in Nursing Homes (1986)

Sushant Joshi, Staffing Shortages, Staffing Hours, and Resident Death in US Nursing Homes During the COVID-19 Pandemic, 24 JAMDA 1114 (2023)10
Kayser-Jones J, et al., Factors contributing to dehydration in nursing homes: inadequate staffing and lack of professional supervision. J Am Geriatr Soc. 1999 Oct; 47(10):1187-94. doi: 10.1111/j.1532-5415.1999.tb05198.x. PMID: 1052295110–11
Leland NE, et al., <i>Falls in newly admitted nursing home residents: a national study</i> , J Am Geriatr Soc. 2012: 60(5):939-45, 10.1111/j.1532-5415.2007.01081.x. PMID: 17341233
Yue Li, et al., COVID-19 Infections and Deaths among Connecticut Nursing Home Residents: Facility Correlates, 68 J. Am. Geriatrics Soc. 1899 (2020)
Min, A., et al., Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A cross-sectional study using the US nursing home compare database, Geriatr. Nurs., 2019: 40 (2):160-165
National Consumer Voice for Quality Long-Term Care, Report, Where Do the Billions of Dollars Go? A Look at Nursing Home Related Party Transactions (2023)
New York State Office of the Attorney General, <i>Nursing Home Response to COVID-19</i> Pandemic (revised Jan. 30, 2021)
Park, J., et al., Effects of state minimum staffing standards on nursing home staffing and quality of care. Health Serv Res. 2009: 44(1):56-78
Phillips, LJ, et al., <i>An observational study of antipsychotic medication use among long-stay residents without qualifying diagnoses</i> , J. Psychiatry Mental Health Nursing. 2018: 25(8):463-474
Simmons, S.F., et al., Resident characteristics related to the lack of morning care provision in long-term care, Gerontologist. 2013: 53(1):151-61
Letter from Tommy G. Thompson, Sec'y of Health & Human Servs., to J. Dennis Hastert, Speaker of House of Representatives 1 (Mar. 19, 2002), reprinted as Appendix 1 in Office of Asst. Sec'y for Planning & Evaluation, Dep't of Health & Human Servs., State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States app. 1 (Nov. 2003)
Uchida-Nakakoji, M., et al., <i>Nurse workforce characteristics and infection risk in VA</i> Community Living Centers: A longitudinal analysis, Medical Care, 2015: 53, 261–26711

U.S. Census Bureau, Press Release, Growth in U.S. Population Shows Early Indication	
of Recovery Amid COVID-19 Pandemic (Dec. 22, 2022)	16
White House, Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care	
in the Nation's Nursing Homes (Feb. 28, 2022)	16

STATEMENTS OF INTEREST AND DISCLOSURE STATEMENTS¹

Center for Medicare Advocacy

The Center for Medicare Advocacy is a national, nonprofit law organization that works to advance access to comprehensive Medicare coverage, health equity, and quality health care for older adults and people with disabilities. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. Founded in 1986, it advocates on behalf of beneficiaries in administrative and legislative forums and serves as legal counsel in litigation of importance to beneficiaries and others seeking healthcare coverage. The Center for Medicare Advocacy is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

California Advocates for Nursing Home Reform

California Advocates for Nursing Home Reform ("CANHR") is a non-profit organization representing the interests of approximately 100,000 California nursing facility residents and their families. Since 1983, CANHR has been advocating for the rights of long-term care residents. CANHR and its 3,000 members have a substantial interest in ensuring that quality care be provided to persons living in nursing facilities. CANHR's efforts include aiding residents and their families in obtaining legal services; working for tougher sanctions on nursing facilities that abuse or neglect residents; providing consumers, attorneys, and social workers with accurate information on long-term care; and continually working to determine the root causes of poor care and developing legislation and policies to address them. CANHR is a non-profit, non-stock

¹ No party's counsel authored the brief in whole or in part. No party nor their counsel contributed money that was intended to fund preparing or submitting the brief. No other person — other than the amici curiae, their members, or their counsel — contributed money that was intended to fund preparing or submitting the brief.

corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Justice in Aging

Justice in Aging is a national non-profit legal advocacy organization that fights senior poverty through law. Justice in Aging was founded in 1972 (originally under the name "National Senior Citizens Law Center") and maintains offices in Washington, D.C. and Los Angeles, California. Justice in Aging advocates for affordable health care and economic security for older adults with limited resources, focusing especially on populations that have traditionally lacked legal protection. Justice in Aging's work includes substantial advocacy on behalf of nursing facility residents, including federal administrative and legislative advocacy. Justice in Aging is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Long Term Care Community Coalition

The Long Term Care Community Coalition ("LTCCC") is a nonprofit organization dedicated to improving quality of care, quality of life and dignity for elderly and disabled people in nursing facilities, assisted living, and other residential settings. LTCCC focuses on systemic advocacy, researching relevant national and state policies, laws, and regulations in order to identify relevant issues and develop meaningful recommendations to improve quality, efficiency, and accountability. LTCCC uses its research and the resulting recommendations to educate policymakers, consumers, and the general public. Consumer, family, and long-term care Ombudsman empowerment are fundamental to its mission. Long Term Care Community Coalition is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Michigan Elder Justice Initiative

Michigan Elder Justice Initiative (MEJI), a project of the Michigan Statewide Advocacy Services, was created in 2011 to protect the rights of and empower low income older adults and adults with disabilities in Michigan. In addition to advocacy on behalf of individuals, MEJI engages in policy advocacy, litigation, education efforts, and collaboration with local, state, and national partners to create systemic reforms. MEJI has a primary focus on long term care and advocates for quality of care, quality of life, access to services, and individual rights. MEJI houses the Michigan State Long Term Care Ombudsman Program as well as ombudsman programs to assist individuals receiving home and community based supports and services. Michigan Statewide Advocacy Services is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

National Association of Local Long-Term Care Ombudsmen (NALLTCO)

The Long Term Care Ombudsman program was created in 1978 by the Federal Older American's Act to serve as advocates for care facility residents. The National Association of Local Long Term Care Ombudsman was formed in 1997 to represent Local Ombudsmen throughout the United States. The mission of NALLTCO is to advocate for the rights and wellbeing of residents in long-term care settings through empowering and supporting local and regional Ombudsmen and promoting excellence in advocacy and service delivery. Members provide Ombudsman services directly to residents in long-term care facilities, particularly skilled nursing facilities, with individual and systemic advocacy, complaint investigation/resolution services, facility monitoring services and information/assistance. NALLTCO is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

National Consumer Voice for Quality Long-Term Care

The National Consumer Voice for Quality Long-Term Care ("Consumer Voice") was formed as NCCNHR (the National Citizens' Coalition for Nursing Home Reform) in 1975 due to public concern for substandard care in nursing facilities. Consumer Voice has since become the leading national voice representing consumers in issues relating to long-term care and is the primary source of information and tools for consumers, families, caregivers, ombudsmen, and other advocates to help ensure quality care for all residents. It is dedicated to advocating for quality care, quality of life, and protection of rights for all individuals receiving long-term services and supports. Consumer Voice is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Amici are organizations that represent the interests of older adults and nursing facility residents. They submit this brief to explain why the Centers for Medicare & Medicaid Services's (CMS's) mandatory minimum nurse staffing rule is critical to protecting nursing home residents' health, safety, welfare, and rights and to promoting the effective and efficient use of public reimbursement. Amici urge this Court to deny plaintiffs' Motion for Preliminary Injunction and to allow the Department of Health and Human Services (HHS) and CMS to implement the final rule.

INTRODUCTION AND SUMMARY OF ARGUMENT

The serious understaffing of nursing homes is a decades-long problem, despite the longstanding requirement that nursing facilities provide "sufficient" staff to meet residents' needs. Although residents, their families and advocates, nursing home staff, and the nursing research community have called for higher staffing levels for many years, the deaths of hundreds of thousands of residents during the coronavirus pandemic made understaffing visible in a way that demanded new and meaningful federal action.

The final staffing rule sets minimum nurse staffing standards (registered nurses (RNs) onsite around the clock and staffing ratios) for facilities nationwide that voluntarily choose to receive Medicare and Medicaid reimbursement. Two important points put these new requirements into context. First, as shown below, many facilities already meet individual parts of the standards in the final rule, and nonprofit and public facilities on average already exceed the staffing ratios. Accordingly, the final rule is a modest, although important, change for nursing facilities. Second, the rule applies only to nursing facilities nationwide that voluntarily choose to receive Medicare and Medicaid reimbursement for providing care to residents. Facilities that do not want to meet federal staffing standards can choose not to seek federal reimbursement.

Researchers estimate that the staffing rule could save 13,000 lives per year. This finding is consistent with experience during the pandemic, finding that higher-staffed facilities had fewer COVID-19 cases and fewer COVID-19 deaths. It is also consistent with decades of academic research documenting that higher staffing levels mean higher quality of care for residents, fewer instances of omitted care, and fewer avoidable negative outcomes.

Finally, the final staffing rule fulfills the federal government's "duty and responsibility" under the 1987 Nursing Home Reform Act to ensure that facilities provide each resident with timely and competent care and services and that the billions of dollars of public reimbursement from the Medicare and Medicaid programs are appropriately spent on residents, and not diverted to excessive profits for nursing home owners and operators.

Plaintiffs' Motion for Preliminary Injunction should be denied. CMS should be allowed to implement the final rule.

ARGUMENT

I. PLAINTIFFS CANNNOT SHOW A NEED FOR PRELIMINARY RELIEF.

Plaintiffs fail to show that preliminary relief is appropriate. As demonstrated below, plaintiffs cannot prevail on the merits of their argument that the final nurse staffing rule is illegal. The federal government has comprehensive statutory authority under the 1987 Nursing Home Reform Act to enact a mandatory staffing rule to ensure that nursing home residents receive the care and services they need, and that federal funds are appropriately spent on care for residents and not impermissibly diverted to excessive private profits for owners and operators.

Plaintiffs also cannot show that they are subject now to any harm from the staffing rule when the rule's specific numerical requirements that they challenge do not go into effect for two to five years, depending on the specific requirement and whether a nursing facility is nonrural or rural.² The rule also recognizes the opportunity for waivers³ and hardship exemptions⁴ for facilities that cannot meet the mandatory staffing requirements. How waivers and exemptions will be applied to any particular facility simply cannot be known at this time. Moreover, a facility cannot even request a hardship exemption unless and until a survey conducted by the state health department determines that the facility violates the requirements of the staffing rule.⁵ No survey will determine whether a facility complies with the staffing rule until the rule's

² The challenged requirements are: 1) registered nurses (RNs) at all times, 24 hours per day, seven days per week, and 2) staffing ratios, 3.48 hours per resident day (HPRD), comprised of 0.55 HPRD of care by RNs, 2.45 HPRD of care by nurse aides, and 0.48 HPRD of care by RNs, licensed practical nurses (LPNs), or aides, at facility discretion. 89 Fed. Reg. 40876, 40913, Table 3 (Implementation Timeframes for Facilities in Rural Areas), Table 4 (Implementation Timeframes for Facilities in Non-Rural Areas) (May 10, 2024).

³ 42 C.F.R. §§ 483.35(f)-(g).

⁴ *Id.* § 483.35(h).

⁵ Id., 89 Fed. Reg. 40876, 40902 (rejecting commenters' objection "to the exemption determination being made after a facility is surveyed and determined to be out of compliance with the HRPD staffing requirement").

numerical requirements are actually in effect – two to five years from now. Moreover, as shown below, Plaintiff Leading Age's affiliates represent many nonprofit facilities that already exceed the staffing ratios required by the final rule.

Finally, the public interest favors prompt implementation of the staffing rule. The public has a compelling interest in having vulnerable nursing home residents – their family members, friends, neighbors – receive appropriate care and in having their tax dollars spent on resident care, not on excessive private profit for owners and operators.

INADEQUATE STAFFING LEVELS RESULT IN POOR QUALITY II. CARE OUTCOMES, INJURY, PSYCHOLOGICAL HARM, AND DEATH.

Among the 46,520⁶ comments received by CMS in response to the proposed rule were comments submitted by family members confirming the dire consequences of inadequate staffing levels for their loved ones. CMS quoted a small sample of the voices in the rule, including the following:

In June 2021 while the day shift nurse was making morning rounds she found my family member aspirating on vomit, having seizures, with a 106 degree temperature which turned in to a case of sepsis. The nurse said she had no idea how long my family member was lying there in that condition as there was only 1 nurse and 1 aide for over 100 residents on the overnight shift. Since that incident my family member has lost the ability to speak and/or respond to questions and or commands. As a result I have personally spent 10 to 12 hours a day, every day, with my family member at the LTC to ensure they are getting the care they need.⁷

They were supposed to check in on him every hour and to help him turn from side to side at least every two hours. Later, when he got better, they were supposed to check on him every four hours, but they didn't. They were supposed to change his clothing and bedsheets regularly. They did none of that often enough, so he developed bedsores/open wounds as big as your hand on his backside because of

⁶ 89 Fed. Reg. at 40883.

⁷ 89 Fed. Reg. at 40884.

a lack of care. How would you like your dad to go through that experience in the last 24 months of his life, after all he'd been through in 90 years?8

Commenters described the lack of dignity suffered by residents in understaffed facilities:

She was a successful Real-estate broker her whole adult life, who suffered a tragic fall that left her with multiple breaks in her leg and landed her in a nursing home for rehab. What she lost in the nursing home was far greater than the break, she lost her dignity and self-worth as she was forced to lay in her own urine on a regular basis and on several occasion her own feces. The staff were caring and capable but there was never enough of them.9

Nursing home staff made similar observations about the consequences for residents of insufficient staffing. A Registered Dietitian wrote:

Nurses so short staffed they declare a 'med holiday' and throw away all the meds for one shift because they don't have time to pass them out. Nursing so understaffed that bedtime snacks, though made and delivered to the nursing station, are not passed out. Resulting in one insulin dependent diabetic resident's blood sugar zeroing out in the wee hours of the night. Patient died. 10

Another staff member wrote:

Recently a resident got skin ulcers after no one was able to see him for the entire 8-hour shift, and who knows how long before that? When you have 14 or 18 or 20 residents to care for, there's simply not enough time for everyone. Feeding them all takes so much time, several hours combined right there. Thats how other basic needs fall by the wayside. When you're doing the job of two CNAs, it really means that half of your residents are going to have to go without.¹¹

In the preamble to the proposed rule, CMS summarized a small fraction of the comments it had received about the consequences of chronic understaffing in nursing facilities in response to its 2022 Request for Information and Listening Sessions regarding staffing: 12

⁸ 89 Fed. Reg. at 40883.

⁹ 89 Fed. Reg. at 40883.

¹⁰ 89 Fed. Reg. at 40884.

¹¹ 89 Fed. Reg. at 40884.

¹² 87 Fed. Reg. 22720 (Apr. 15, 2022).

For example, residents going entire shifts without receiving toileting assistance, which can lead to an increase in falls or the development or worsening of pressure ulcers. Commenters noted that NAs barely have time to get each resident dressed, fed, and bathed; that residents lie for hours in wet and soiled diapers; that residents who need help to eat struggle to feed themselves; and that residents suffer abuse from staff and other residents because no one is watching. Commenters also shared stories of residents wearing the same outfit for a week without a change of clothing or a shower. Commenters highlighted the contribution of facility staff and attributed the lack of quality care to insufficient staffing levels.¹³

III. THE STAFFING RULE WILL SAVE RESIDENTS' LIVES.

In a letter to Senator Elizabeth Warren dated July 8, 2024, researchers at the University of Pennsylvania evaluated the final staffing rule and estimated that "enforcing CMS' new rule on minimum staffing levels would save approximately 13,000 lives per year." The researchers cited "strong evidence that higher levels of nursing staffing in nursing homes improves the outcomes of nursing home residents, including reducing pressure sores and urinary tract infections, improving functional status, and reducing deaths" (citations to research articles omitted).

The researchers' estimate is consistent with research documenting that higher nurse staffing levels saved lives during the coronavirus pandemic. A 2020 study of Connecticut's 215 nursing homes found that 20 additional minutes of RN coverage per resident per day was correlated with 22% fewer COVID cases and 26% fewer COVID deaths. Another study similarly found that facilities that reported staffing shortages had a 10.5% increase in resident

¹³ 88 Fed. Reg. 61352, 61358 (Sep. 6, 2023).

¹⁴ Yue Li, et al., *COVID-19 Infections and Deaths among Connecticut Nursing Home Residents: Facility Correlates*, 68 J. Am. Geriatrics Soc. 1899, 1899-1906 (2020) https://agsjournals.onlinelibrary.wiley.com/doi/abs/10.1111/jgs.16689.

death, from both COVID-19 and non-COVID-19 causes, during the pandemic. ¹⁵ The New York Attorney General's analysis of staffing levels in New York State during the early months of the pandemic found that the highest rates of resident deaths occurred in nursing facilities with the lowest staffing levels. 16

ADEQUATE NUMBERS OF NURSING STAFF ARE ESSENTIAL IV. TO ENSURING RESIDENTS' HEALTH, SAFETY, WELFARE, AND RIGHTS.

The life-saving consequences of appropriate staffing levels during the pandemic are consistent with decades of research confirming that sufficient numbers of nursing staff are the key factor for providing high quality resident care and for preventing avoidable physical and psychological harm to residents.

A 1998 study found that licensed nurses (RNs and LPNs) "were significantly related to improved functional ability, increased probability of discharge home, and decreased probability of death."¹⁷ A 1999 study found that residents with moderate to severe dysphagia, severe cognitive and functional impairment, aphasia or inability to speak English, and a lack of family or friends to assist them at mealtime are at great risk for dehydration when staffing levels are inadequate and supervision is poor.¹⁸

¹⁵ Sushant Joshi, Staffing Shortages, Staffing Hours, and Resident Death in US Nursing Homes During the COVID-19 Pandemic, 24 JAMDA 1114, 1117 (2023), https://www.jamda.com/article/S1525-8610(23)00411-5/pdf.

¹⁶ New York State Office of the Attorney General, Nursing Home Response to COVID-19 Pandemic (revised Jan. 30, 2021), https://ag.ny.gov/sites/default/files/2021nursinghomesreport.pdf.

¹⁷ Bliesmer M M, et al., The relationship between nursing staffing levels and nursing home outcomes, J. Aging Health, 1998 Aug;10(3):351-71. doi: 10.1177/089826439801000305. PMID: 10342936, https://pubmed.ncbi.nlm.nih.gov/10342936/ (abstract).

¹⁸ Kayser-Jones J, et al., Factors contributing to dehydration in nursing homes: inadequate staffing and lack of professional supervision. J Am Geriatr Soc. 1999

Additional studies show that higher staffing levels are associated with reduced incontinence, ¹⁹ reduced urinary tract infections and catheterizations, ²⁰ fewer pressure ulcers, ²¹ less weight loss and dehydration, ²² less use of antipsychotic drugs, ²³ less use of restraints, ²⁴ fewer infections, ²⁵ fewer falls, ²⁶ fewer rehospitalizations and less use of emergency

Oct;47(10):1187-94. doi: 10.1111/j.1532-5415.1999.tb05198.x. PMID: 10522951, https://pubmed.ncbi.nlm.nih.gov/10522951/ (abstract).

¹⁹ Dorr, D.A., et al., *Cost analysis of nursing home registered nurse staffing times*. J. of Amer Geriatrics Society, 2005: 53: 840-845, https://pubmed.ncbi.nlm.nih.gov/15877561/ (abstract). Hereinafter, "Dorr, *Cost analysis*".

²⁰ Horn, S.D., et al., *RN staffing time and outcomes of long-stay nursing home residents: pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care*. Am J Nurs. 2005: 105(11):58-70, https://journals.lww.com/ajnonline/fulltext/2005/11000/rn_staffing_time_and_outcomes_of_long_stay_nursing.28.aspx. Hereinafter, "Horn, *RN staffing*"; Dorr, *Cost analysis*.

²¹ Horn, *RN staffing*; Dorr, *Cost analysis*; Horn, S.D., et al., *The national pressure ulcer long-term care study: Pressure ulcer development in long-term care residents.* J. American Geriatrics Society, 2004: 52: 359-367, https://pubmed.ncbi.nlm.nih.gov/14962149/.

²² Horn, RN staffing.

²³ Phillips, LJ, et al., *An observational study of antipsychotic medication use among long-stay residents without qualifying diagnoses*, J. Psychiatry Mental Health Nursing. 2018: 25(8):463-474, https://onlinelibrary.wiley.com/doi/abs/10.1111/jpm.12488.

²⁴ Park, J., et al., *Effects of state minimum staffing standards on nursing home staffing and quality of care*. Health Serv Res. 2009: 44(1):56-78, https://pmc.ncbi.nlm.nih.gov/articles/PMC2669632/.

²⁵ Uchida-Nakakoji, M., et al., *Nurse workforce characteristics and infection risk in VA Community Living Centers: A longitudinal analysis*, Medical Care, 2015: 53, 261–267, https://pubmed.ncbi.nlm.nih.gov/25634087/ (abstract).

²⁶ Leland NE, et al., *Falls in newly admitted nursing home residents: a national study*, J Am Geriatr Soc. 2012: 60(5):939-45, 10.1111/j.1532-5415.2007.01081.x. PMID: 17341233, https://agsjournals.onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2012.03931.x (abstract).

departments,²⁷ and fewer instances of missed care.²⁸

These studies were among more than 100 studies going back to 1977 cited by Charlene Harrington, the preeminent academic researcher on nurse staffing standards in nursing homes, in comments she submitted to CMS, on behalf of 79 nursing researchers, nursing professors, and organizations, in response to CMS's 2022 Request for Information.²⁹ The studies found better care and fewer poor resident outcomes when facilities are more adequately staffed.

CMS cited multiple studies in the preamble to the final rule, documenting that the consequences of inadequate staffing can mean poor quality care, injury, and death.³⁰

V. THE FEDERAL GOVERNMENT HAS STATUTORY AUTHORITY TO IMPLEMENT A MANDATORY STAFFING REGULATION.

The Supreme Court recognized in Health and Hospital Corporation of Marion Cty. v. Talevski, that the Nursing Home Reform Act enacted by Congress in 1987 effected "a 'seismic shift' in nursing-home quality standards." The Reform Act defined the Secretary's "duty and responsibility," more broadly than ever before, to ensure that requirements of care and their enforcement "are adequate to protect residents' health, safety, welfare, and rights and to promote

²⁷ Min, A., et al., Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A cross-sectional study using the US nursing home compare database, Geriatr Nurs., 2019: 40 (2):160-165, https://pubmed.ncbi.nlm.nih.gov/30292528/ (abstract).

²⁸ Simmons, S.F., et al., Resident characteristics related to the lack of morning care provision in long-term care, Gerontologist. 2013: 53(1):151-61, https://pubmed.ncbi.nlm.nih.gov/22565494/ (abstract).

²⁹ 87 Fed. Reg. 22720 (Apr. 15, 2022).

³⁰ 89 Fed. Reg. at 40880, 40881.

³¹ 599 U.S. 166, 181 (2023) (quoting B. Furrow, T. Greaney, S. Johnson, T. Jost, & R. Schwartz, Health Law 51 (3d ed. 2015)).

the effective and efficient use of public moneys."32 Prior federal law had limited the Secretary's authority to requirements governing health and safety. Nowhere does the 1987 law require the Secretary to keep Requirements of Participation unchanged indefinitely. To the contrary, the law expressly provides that nursing facilities that voluntarily choose to participate in the Medicare and Medicaid programs must "meet such other requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary."33

Inaccurate staffing information reported by nursing facilities hampered past efforts to address the crisis of insufficient staffing. The Institute of Medicine's (IoM) 1986 report, Improving the Quality of Care in Nursing Homes, 34 was a major part of the legislative history of the 1987 Reform Law. The IoM identified the "broad consensus that government regulation of nursing homes, as it now functions, is not satisfactory because it allows too many marginal or substandard nursing homes to continue in operation."35 It found "individuals who are admitted [to many facilities] receive very inadequate – sometimes shockingly deficient – care that is likely to hasten the deterioration of their physical, mental, and emotional health."³⁶ While highlighting the importance of staffing throughout the report,³⁷ the IoM recognized that "[u]ntil standardized resident assessment data become generally available, and some careful empirical studies have

³² 42 U.S.C. §§1395i-3(f)(1), 1396r(f)(1) (Medicare and Medicaid, respectively).

³³ *Id.* §§1395i-3(d)(4)(B), 1396r(d)(4)(B) (emphasis added).

³⁴ IoM, Comm. on Nursing Home Regulation, *Improving the Quality of Care in Nursing* Homes (1986), https://archive.ph/KFNCi.

³⁵ *Id.* at 2.

 $^{^{36}}$ *Id*.

³⁷ *Id.* at 101-103, 200-201.

been completed, prescribing sophisticated staffing standards in the regulations will not be possible."38

In 1990, Congress answered IoM's call for an empirical study and required the federal government to "conduct a study and report to Congress no later than January 1, 1992 [later revised to January 1, 1999, on the appropriateness of establishing minimum caregiver to resident ratios and minimum supervisor to caregiver ratios."39 The Congressionally-mandated report began by describing "Public Concern With Nursing Home Staffing:"

Reports by the U.S. General Accounting Office, the U.S. Office of the Inspector General and the Centers for Medicare and Medicaid Services' (CMS), formerly the Health Care Financing Administration, comprehensive July 1998 nursing home Report to Congress have identified a range of serious problems including malnutrition, dehydration, pressure sores, abuse and neglect. Hearings before the U.S. Senate Special Committee on Aging and CMS' Phase I report have pointed to nurse staffing as a potential root cause of many of the problems observed. In addition, a continuous flow of newspaper articles and television news reports highlighting inadequate care and abuse in nursing homes has heightened public concern with this issue.⁴⁰

The four-volume report, released in 2001, recognized that 4.1 HPRD of nurse staffing time were necessary to meet its two analytical frameworks (staffing levels below which residents suffered avoidable harm and staffing levels needed to meet some Requirements of the Reform Law). HHS Secretary Tommy Thompson rejected the recommendations of the report, in large part because of his "serious reservations about the reliability of staffing data at the nursing home

³⁸ *Id.* at 102.

³⁹ P.L. 101-508, § 4801(17)(B).

⁴⁰ Abt Associates, Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes. Overview of the Phase II Report: Background, Study Approach, Findings, and Conclusions, 1 (Dec. 2001),

https://www.justice.gov/sites/default/files/elderjustice/legacy/2015/07/12/Appropriateness_of_M inimum Nurse Staffing Ratios in Nursing Homes.pdf.

level."⁴¹ In 2001, facilities self-reported their staffing levels at the time of their annual survey. The Government reported these unaudited and unedited staffing levels, although they were known to be inflated.⁴²

In 2016, the Obama Administration revisited the issue of mandating staffing ratios. The proposed rule cited "abundant research that associates increased RN staffing with improved quality of care"43 as well as its authority to impose staffing ratios. Nevertheless, it declined to mandate ratios, recognizing, as had Secretary Thompson, the inadequacy of nursing facilities' self-reported staffing data.⁴⁴ CMS understood that the collection of payroll-based staffing information (called PBJ), which had just begun, could help CMS reevaluate the issues of staffing ratios and RNs around the clock, "once a sufficient amount is collected and analyzed." 45

By 2024, CMS had collected eight years of PBJ data as well as "new evidence from the literature."46 This information provided a strong basis for an enforceable staffing rule. Perhaps most relevant and important, however, were the deaths of hundreds of thousands of nursing

⁴¹ Letter from Tommy G. Thompson, Sec'y of Health & Human Servs., to J. Dennis Hastert, Speaker of House of Representatives 1 (Mar. 19, 2002) ("Thompson Letter"), reprinted as Appendix 1 in Office of Asst. Sec'y for Planning & Evaluation, Dep't of Health & Human Servs., State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States app. 1 (Nov. 2003), https://archive.ph/wip/KQWPt.

⁴² CMS, Nationwide Expansion of Minimum Data Set (MDS) Focused Survey, S&C: 15-06-NH, at 2 (Oct. 31, 2014), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-06.pdf.

⁴³ CMS, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 80 Fed. Reg. 42168, 42200 (July 16, 2015).

⁴⁴ 81 Fed. Reg. 68688, 68754 (Oct. 4, 2016).

⁴⁵ 81 Fed. Reg. at 68756.

⁴⁶ 89 Fed. Reg. at 40880.

home residents during the coronavirus pandemic (accounting for nearly a quarter of the deaths in the United States, although the 1.2 million residents (as of July 2023)⁴⁷ represent just 0.003% of the country's population of 333,287,557 (in 2022)).⁴⁸ These deaths made it impossible for policy-makers and the public to continue ignoring facilities' longstanding crisis in understaffing. They led to President Biden's recognition in his nursing home reform agenda⁴⁹ that resident deaths from COVID-19 made new staffing standards both necessary and the single most critical feature of future regulation and policy to improve the quality of nursing home care for residents.

Throughout the rulemaking process, the nursing home industry's objection to nurse staffing ratios has been an alleged inability to meet them. When CMS published the proposed staffing rule, the trade associations repeatedly argued that facilities could not possibly meet the 4.1 HPRD staffing standard identified in CMS's 2001 report,⁵⁰ not that CMS lacked authority to

⁴⁷ Priya Chidambaram, et al., *A Look at Nursing Facility Characteristics Between 2015 and 2023* (Jan. 5, 2024), https://www.kff.org/medicaid/issue-brief/a-look-at-nursing-facility-characteristics/.

⁴⁸ U.S. Census Bureau, Press Release, *Growth in U.S. Population Shows Early Indication of Recovery Amid COVID-19 Pandemic* (Dec. 22, 2022), https://www.census.gov/newsroom/press-releases/2022/2022-population-estimates.html

⁴⁹ White House, Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes (Feb. 28, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes.

⁵⁰ AHCA, Access to Care Report (Aug. 2023), https://www.ahcancal.org/News-and-communications/Fact-sheets/FactSheets/Access%20to%20Care%20Report%20August%202023.pdf; AHCA, Press Release, Report: Increasing Nursing Home Staffing Minimum Estimated at \$10 Billion Annually (July 19, 2022), https://www.ahcancal.org/News-and-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Press-Releases/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communications/Pages/Updated-Report-Additional-Funding-for-Workers-communication

impose the 4.1 HPRD standard.

The nursing home industry itself supported 24-hour RN coverage. In 2021, Leading Age introduced a legislative proposal along with the American Health Care Association (AHCA), the trade association of primarily for-profit nursing facilities. The "Care for Our Seniors Act, Improving America's Nursing Homes By Learning From Tragedy & Implementing Bold Solutions For The Future," called for RNs 24 hours per day in every nursing facility:

Research shows a positive association between RN hours and overall quality. We support a new federal requirement that each nursing home have a RN on-staff 24 hours a day and will provide recommendations on how to effectively implement this requirement.⁵¹

VI. THE STAFFING RULE ENSURES THAT PUBLIC REIMBURSEMENT IS FOCUSED ON RESIDENT CARE, NOT PRIVATE PROFIT.

The Nursing Home Reform Act also identifies the Secretary's additional duty to "promote the effective and efficient use of public moneys." Many studies document that nursing facilities divert public reimbursement that should be used for staff to private personal gain for owners and operators, often hiding profits in "related party" transactions (nursing homes doing business with entities that they own or control).

For example, "Tunneling and Hidden Profits in Health Care" found that facilities in Illinois hid 62.9% of their profits by paying inflated prices to related parties. ⁵² The study's

<u>Needed-to-Meet-a-Potential-Nursing-Home-Staffing-Minimum-Mandate.aspx.</u> All described the cost of meeting the 4.1 HPRD standard identified in the 2001 CMS report.

⁵¹ AHCA & Leading Age, *Care for Our Seniors Act* at 4, available at https://www.ahcancal.org/Advocacy/Documents/Care%20for%20Our%20Seniors%20Act%20-%20Overview.pdf.

⁵² Ashvin Gandhi & Andrew Olenski, *Tunneling and Hidden Profits in Health Care*, National Bureau of Economic Research (Jul. 13, 2024), https://ucla.app.box.com/v/RelatedParties.

authors calculated that if these hidden profits were spent on staff, staffing ratios would significantly increase – by nearly 0.23 HPRD of RN time, a 28.9% increase, or by 0.47 HPRD of certified nurse aide (CNA) time, a 21.0% increase. Moreover, they reported that if facilities' hidden profits were spent on staff, facilities would be much closer to already complying with the staffing hours identified in the proposed (and now final) staffing rule.

A similar analysis by the Empire Center found that New York State nursing facilities in 2020 spent more than one billion dollars, or 16% of their operating expenses, on payments to related parties.⁵³ Nursing home owners made more of their profit from related-party transactions than from their nursing homes operations. The Empire Center found that facilities that diverted money to related parties spent less of their reimbursement on staff and had lower ratings for the quality of care they provided. Amicus party Consumer Voice has also documented the diversion of public money to private profit through related party transactions.⁵⁴

An analysis of skilled nursing facilities' 2019 Medicare cost reports found that facilities spend more of their revenue on administration, capital, other, and profits (34%) than on nursing (27%). The analysis also found that more than three-quarters of facilities reported \$11 billion in payments to related party organizations, reflecting 9.54% of their net revenue.

Requiring facilities to spend more of the billions of dollars they receive annually from the

⁵³ Bill Hammond, Following the Money: An Analysis of "Related Company" Transactions in New York's Nursing Home Industry (Jul. 5, 2022), https://www.empirecenter.org/publications/following-the-money-2/.

⁵⁴ Consumer Voice, Report, *Where Do the Billions of Dollars Go? A Look at Nursing Home Related Party Transactions* (2023), https://theconsumervoice.org/uploads/files/issues/2023-Related-Party-Report.pdf.

⁵⁵ Charlene Harrington, et al., *United States' Nursing Home Finances: Spending, Profitability, and Capital Structure*, 54 Int'l J. Soc. Determinants of Health & Health Servs. 131, 131 (Apr. 2024), https://journals.sagepub.com/doi/epub/10.1177/27551938231221509.

Medicare and Medicaid programs on higher staffing levels helps fulfill the Secretary's statutory duty "to promote the effective and efficient use of public moneys."

VII. THE FINAL RULE ENSURES APPROPRIATE STAFFING LEVELS NATIONWIDE, REGARDLESS OF RESIDENTS' RACE AND ETHNICITY.

The preamble to the final rule cited multiple studies documenting that "nursing home quality is generally lower in LTC facilities that serve high proportions of minority residents."56 These facilities have lower levels of staffing and higher levels of problems in delivery of care. Mandatory staffing levels applicable nationwide to all facilities and all residents help advance goals of ensuring high quality care for all residents, regardless of their race and where they live.

VIII. MANY NURSING FACILITIES ALREADY MEET INDIVIDUAL COMPONENTS OF THE FINAL STAFFING RULE.

Plaintiffs' argument that facilities cannot comply with the staffing ratios set out in the final rule is simply not true. Most non-profit and publicly-owned nursing facilities already exceed the staffing ratios in the final rule. Many facilities already meet individual components of the final staffing rule.

As found by the 2023 study CMS used in drafting the staffing rule, non-profit and government-operated nursing homes already exceed the 3.48 HPRD of total nursing staff, employing more than 4.2 and 4.1 HPRD, respectively, of nursing staff today.⁵⁷ The study also found that, even during the pandemic, nursing facilities staffed at 3.76 HPRD⁵⁸ and for-profit

⁵⁶ 89 Fed Reg. at 40881 nn. 27-34.

⁵⁷ Abt Associates, Nursing Home Staffing Study, Comprehensive Report at 45 (June 2023), https://www.cms.gov/files/document/nursing-home-staffing-study-final-report-appendixjune-2023.pdf

⁵⁸ *Id.* at 44.

facilities, the most poorly staffed segment of the nursing home industry, staffed at 3.57 HPRD.⁵⁹ Pandemic staffing levels exceeded the 3.48 HPRD mandated by the final rule.

In June 2024, a report by the HHS Assistant Secretary for Planning and Evaluation (ASPE) found that many facilities already exceed the specific components of the staffing rule: 50% of all nursing homes already staff at or above the rule's 0.55 HPRD minimum staffing requirement for registered nurses (RNs); 59% of all nursing homes already staff at or above the rule's 3.48 HPRD total nurse staffing minimum requirement; and 78% of nursing homes provided at least 24 hours of total RN staffing per day, before accounting for facilities that might be eligible for an exemption. ⁶⁰ Although ASPE found that only 30% of nursing homes currently meet the rule's nurse aide requirement of 2.45 HPRD of aide time, the minimal training requirements for nurse aide positions (75 hours are the minimum federal requirement⁶¹) mean that there is considerable time for recruiting and training workers before this requirement goes into effect in three to five years (2027 for nonrural facilities, 2029 for rural facilities).

CONCLUSION

The 1987 Nursing Home Reform Act gives the Secretary comprehensive authority to promulgate the staffing rule, which will both improve and save residents' lives and redirect public reimbursement from excessive provider profits to resident care. Amici urge the Court to deny plaintiffs' Motion for Preliminary Injunction.

⁵⁹ *Id.* at 45.

⁶⁰ ASPE, Office of Behavioral Health, Disability, & Aging Policy, Data Point: Nurse Staffing Estimates in US Nursing Homes, May 2024 at 1 (June 28, 2024), https://aspe.hhs.gov/sites/default/files/documents/8e343af705b07063ad7effcc84ba370a/nursestaffing-estimates-us-nhs.pdf

⁶¹ 42 C.F.R. § 483.152(a)(1).

DATED: December 4, 2024 Respectfully submitted,

> /s/ Toby S. Edelman Toby S. Edelman* (DC Bar #202622) CENTER FOR MEDICARE ADVOCACY PO Box 350 Willimantic, CT 06226 Tel: (202) 293-5760 tedelman@medicareadvocacy.org

AT0010155 Benjamin P. Long RSH LEGAL, P.C. 425 Second Street SE, Suite 1140 Cedar Rapids, IA 52401 Tel: (319) 365-9200 Fax: (319) 365-1114 blong@fightingforfairness.com

*Admitted pro hac vice

CERTIFICATE OF SERVICE

I certify that on December 4, 2024, a copy of the foregoing was filed electronically with the Court and served through the Court's electronic filing system.

/s/ Toby S. Edelman
Toby S. Edelman