IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND NORTHERN DIVISION

CONNOR, et al.,))
Plaintiffs,)
v.	
MARYLAND DEPARTMENT OF HEALTH, et al.,) Civil Action No. 1:24-cv-01423-MJM)
Defendants.))
)

BRIEF OF AMICUS CURIAE TOBY S. EDELMAN IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTEREST OF AMICUS CURIAE¹

Toby S. Edelman is a senior policy attorney at the Center for Medicare Advocacy.² Ms. Edelman has been representing older people who live in long-term care facilities at the federal level since 1977. She has testified before Congress and served on federal task forces, technical expert panels, and working groups on nursing home issues. She worked closely with staff of the chief sponsors of the Federal Nursing Home Reform Act, and testified in support of the Reform Act at one of the three Congressional hearings on the bills, the House Ways and Means Committee, Subcommittee on Health, on June 1, 1987.

Since 1977, Ms. Edelman has been involved in key litigation to protect the rights of nursing home residents. She participated in early litigation to enforce federal transfer and discharge protections guaranteed by federal Bill of Rights provisions (*Fuzie v. Manor Care*, 461 F. Supp. 689 (N.D. Ohio 1977)), co-wrote an *amicus* brief in litigation filed by nursing home residents challenging the survey and enforcement system for nursing homes (*Estate of Smith v. Heckler*, 747 F.2d 583, 590 (10th Cir. 1984)), wrote *amicus* briefs in two Supreme Court cases addressing nursing home residents' rights (*O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773 (1980), and *Blum v. Yaretsky*, 457 U.S. 991 (1982)), wrote an amicus brief supporting the nursing home survey and enforcement system in litigation brought by a nursing facility to challenge the system (*Beverly Health & Rehab. Servs., Inc. v. Thompson*, 223 F. Supp. 2d 73 (D.D.C. 2002)), and wrote an amicus brief in her own name in *Health and Hospital Corp. of*

¹ Pursuant to Local Rule 105.12(b), amicus certifies that her counsel has conferred with all parties regarding consent to file this brief. Counsel for Plaintiffs has consented to this filing; counsel for Defendants opposes Ms. Edelman's request. Ms. Edelman further certifies that no counsel for any party authored this brief in whole or in part; and that no party or party's counsel contributed money to fund its preparation or submission.

² Ms. Edelman appears in her personal capacity. Her organizational affiliation is provided for identification purposes only.

Marion County v. Talevski, 599 U.S. 166 (2023) (holding that nursing home residents may sue under Section 1983 to enforce their rights secured by the Federal Nursing Home Reform Act). Ms. Edelman was the lead attorney in the successful effort of a statewide class of nursing home residents in California to require their state to implement the Federal Nursing Home Reform Act, when the state publicly refused to implement the law (Valdivia v. Cal. Dep't of Health Servs., No. S-90-1226EJG EM, 1991 WL 80896 (E.D. Cal. Feb. 25, 1991); No. S-90-1226EJG/PAN, 1992 WL 554299 (E.D. Cal. Aug. 11, 1992).

INTRODUCTION

The federal Nursing Home Reform Act, enacted in 1987, refocused federal law for nursing homes participating in the Medicare or Medicaid program, or both—nearly every nursing home in the country. The law set comprehensive standards for quality of care, quality of life, and residents' rights. It created survey and enforcement procedures to ensure that these standards are met and that deficiencies are corrected for all residents and appropriately sanctioned. The federal survey process, most often implemented by state departments of health, is the mechanism for determining whether facilities are providing care to residents and respecting residents' rights in compliance with federal standards. Annual surveys (also known as standard surveys) and complaint investigations must be timely to ensure that problems are identified and promptly corrected. Survey information is also reported on the federal government's website: Care Compare. People choosing a nursing home for a friend or relative use Care Compare to identify facilities that could provide appropriate care and then, once a placement is made, to identify and understand facility problems. If survey information reported on Care Compare is untimely and inaccurate, it is misleading and does a disservice to residents, families, and the public at large.

I. The Nursing Home Reform Act of 1987 Reframed Federal Nursing Home Law to Focus on Residents' Need for High Quality of Care, Quality of Life, and Residents' Rights.

In May 1982, the U.S. Department of Health and Human Services proposed a rule that sought to privatize and weaken survey practices for nursing homes.³ The proposed rule made facilities eligible for Medicare and Medicaid reimbursement if they met standards of a private accrediting organization (avoiding a publicly-conducted survey). The rule also permitted less frequent public surveys. Congress' opposition to the drastic reduction in public oversight and accountability was swift. In two legislative moratoria, first in the Tax Equity and Fiscal Responsibility Act of 1982⁴ and then in the continuing budget resolution enacted in late 1982, Congress expressly prohibited implementation of the proposed rule. As a third moratorium was under consideration, Congress and the Administration reached a compromise: the Administration could not make any changes in federal nursing home regulations until the Institute of Medicine ("IoM") at the National Academy of Sciences undertook and released a study.⁵ The study was begun in 1983⁶ and completed in March 1986.

³ 47 Fed. Reg. 23403, 23403-23414 (May 27, 1982), https://www.govinfo.gov/content/pkg/FR-1982-05-27/pdf/FR-1982-05-27.pdf. These are the so-called "Subpart S regulations."

⁴ Pub. L. No. 97-248, § 135, 96 Stat. 324, 325 (1982), https://www.govinfo.gov/content/pkg/STATUTE-96/pdf/STATUTE-96-Pg324.pdf.

⁵ Comm. on Nursing Home Regulation, Inst. of Med., *Improving the Quality of Care in Nursing Homes* (1986) (hereinafter: "IoM, *Improving the Quality of Care in Nursing Homes*"), https://www.ncbi.nlm.nih.gov/books/NBK217556/pdf/Bookshelf_NBK217556.pdf; *Nursing Home Care: The Unfinished Agenda (Vol. I): Hearing Before the Special Comm. on Aging, U.S. Sen.*, 99th Cong. 6 (1986) (statement of Sen. John Glenn), https://www.aging.senate.gov/imo/media/doc/publications/5211986.pdf.

 $^{^6}$ Nursing Home Care: The Unfinished Agenda (Vol. I), at 6.

The IoM's comprehensive report described 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." A key recommendation was refocusing both the standards that facilities must meet (now called Requirements) and the survey process used to determine compliance with those standards. The IoM proposed adding quality of life to regulatory standards of care and strengthening residents' rights in the regulatory hierarchy (including identifying multiple enumerated rights). In addition, instead of evaluating the potential capacity of facilities to meet residents' needs, the IoM committee called for the survey process to determine whether residents' needs were actually being met. The enforcement system, the third prong of the federal regulatory system, would require correction of problems for all residents affected by a facility's deficient practices and a range of remedies for deficiencies.

The IoM's detailed and specific recommendations are a key part of the legislative history of the Nursing Home Reform Act ("NHRA") and were enacted 21 months later, generally as recommended, in the NHRA. 42 U.S.C. §§ 1395i-3(a)-(h), 1396r(a)-(h) (addressing Medicare and Medicaid, respectively). The law established the regulatory structure envisioned by IoM, with requirements for facilities, 42 U.S.C. §§ 1395i-3(b)-(d), 1396r(b)-(d) (including quality of life, the first reference to quality of life in a federal health care law) and residents' rights; the

⁷ IoM, *Improving the Quality of Care in Nursing Homes*, at 2.

⁸ *Id.* at 70.

⁹ *Id.* at 107.

¹⁰ *Id.* at 85-88.

¹¹ *Id.* at Chapter 5, 146-170.

survey process, 42 U.S.C. §§ 1395i-3(g), 1396r(g); and the enforcement system, 42 U.S.C. §§ 1395i-3(h), 1396r(h).

Critically, NHRA defines the general "duty and responsibility" of the Secretary of the Department of Health and Human Services "to assure that requirements which govern the provision of care in nursing facilities under this subchapter, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents." 42 U.S.C. §§ 1395i-3(f)(1), 1396r(f)(1). "Welfare and rights" were new mandates for federal nursing home law, which, earlier, addressed a federal role only for health and safety concerns. NHRA also requires facilities to "provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 U.S.C. §§ 1395i-3(b)(2), 1396r(b)(2). The statutory language emphasizes that *each* resident must receive high quality care and high quality of life, not just residents in the aggregate. As the Supreme Court recognized in *Health and Hospital Corporation of Marion County v. Talevski*, NHRA effected "a 'seismic shift' in nursing-home quality standards." 12

With respect to the survey process, which determines whether facilities are providing care to residents and honoring residents' rights in compliance with federal standards, NHRA mandates a comprehensive set of requirements for both federal and state governments, 42 U.S.C. §§ 1395i-3(g), 1396r(g). The Secretary must develop, test, and validate survey protocols for annual surveys and for extended surveys (at facilities providing substandard quality of care). Federal law establishes the content and frequency of annual surveys (a 9 to 12-month cycle, with a 12-month average) and the qualifications and testing requirements for surveyors.

¹² Health & Hosp. Corp. of Marion Cty v. Talevski, 599 U.S. 166, 181 (2023) (quoting B. Furrow, T. Greaney, S. Johnson, T. Jost, & R. Schwartz, Health Law 51 (3d ed. 2015)).

Under contracts with the federal government, states are tasked with conducting surveys using the federal survey protocols. Usually, State Health Departments conduct the NHRA's federally-mandated surveys. States report their survey findings to the Centers for Medicare & Medicaid Services ("CMS") with recommendations about which deficiencies to cite and which remedies to impose. Relying on state findings, CMS sends official notice of deficiencies to facilities and imposes remedies for noncompliance. State-conducted surveys are critical to assuring that residents receive care and have their rights respected, as federally mandated.

Public disclosure of survey results is also central to NHRA. The Secretary and states must disclose the results of surveys to the public (as discussed below) and must notify state long-term care ombudsman programs of state findings of facilities' noncompliance with standards of care and enforcement actions taken against facilities. States must also provide notice to physicians and skilled nursing facility administrator licensing boards about facilities that provide substandard quality of care.

The survey process is the essential first step in identifying problems in resident care, quality of life, and residents' rights that facilities must correct. States conduct two types of surveys. Annual surveys provide a comparatively comprehensive view of a facility's baseline performance in meeting residents' needs. Complaint investigations, in contrast, focus on a specific, but usually more limited, issue affecting a particular resident. Both types of surveys are needed to determine facilities' compliance with federal standards, although complaint surveys, which are more unpredictable in their timing, as well as unannounced, often lead to identification, and formal citing, of many of the most serious deficiencies.

The resident-focus of the survey process is apparent in guidance for surveyors in how to conduct surveys and complaint investigations. If surveyors cite a deficiency at a nursing facility,

the facility must submit a plan of correction for each deficient practice. 42 C.F.R. §488.408(d). Section 7317 of CMS's State Operations Manual sets out detailed requirements for an acceptable plan of correction. A plan of correction must:

- "Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice";
- "Address how the facility will identify other residents having the potential to be affected by the same deficient practice";
- "Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur";
- "Indicate how the facility plans to monitor its performance to make sure that solutions are sustained"; and
- "Include dates when corrective action will be completed. The corrective action completion dates must be acceptable to the State. If the plan of correction is unacceptable for any reason, the State will notify the facility in writing. If the plan of correction is acceptable, the State will notify the facility by phone, e-mail, etc. Facilities should be cautioned that they are ultimately accountable for their own compliance, and that responsibility is not alleviated in cases where notification about the acceptability of their plan of correction is not made timely." ¹³

In short, the plan of correction process ensures that facilities make specific changes for each resident affected by their deficient practice and take actions to ensure that the poor care practice will not recur for that resident or any other resident. The federal survey process requires

¹³ CMS, State Operations Manual, Pub. # 100-07, Chapter 7, § 7317. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c07pdf.pdf.

state agencies to verify that corrections are actually and successfully made (State Operations Manual Ch. 7 §7317.1), usually through state surveyors' on-site (in-person) revisits (*id*. §7317.2).

The devastating consequences to residents of annual and complaint surveys that are untimely or never performed were the subject of a hearing entitled "Residents at Risk: The Strained Nursing Home Inspection System and the Need to Improve Oversight, Transparency, and Accountability," held by the U.S. Senate Special Committee on Aging on May 18, 2023. 14

Describing state survey agencies as the "front lines for protecting nursing home residents from substandard care and unsafe conditions," Erin Bliss of the HHS Office of Inspector General said in her written testimony, "The importance of State Agencies' roles in identifying and correcting poor care by nursing homes cannot be overstated in light of the longstanding and persistent problems that affect resident health and safety." 15 She testified about the critical need for timely surveys, better verification of the correction of deficiencies, and improved accuracy of deficiency data reported on *Care Compare*. Colorado's state ombudsman Leah McMahon's written testimony described the consequences for residents of delayed surveys. She described a family member who filed a complaint with the state agency about physical and verbal abuse that a relative suffered in a nursing home—a staff member "pulled their hair, physically shook the

¹⁴ Residents at Risk: The Strained Nursing Home Inspection System and the Need to Improve Oversight, Transparency, and Accountability: Hearing Before the Special Comm. on Aging, U.S. Senate, 118th Cong. (2023) (hereinafter "Residents at Risk"), https://www.congress.gov/118/chrg/CHRG-118shrg52564/CHRG-118shrg52564.pdf. Witnesses' testimony and transcript available at https://www.aging.senate.gov/hearings/residents-at-risk-the-strained-nursing-home-inspection-system-and-the-need-to-improve-oversight-transparency-and-accountability.

¹⁵ Residents at Risk at 33, 35.

resident, and left the resident in the bathroom after assisting them to the toilet." When the State investigated the complaint a full year later, the resident had already moved out in order to avoid further abuse and neglect. The delayed complaint investigation left other residents vulnerable to abuse.

II. States Must Conduct Annual Surveys Using Federal Survey Protocols.

The Federal NHRA requires that states use the federal survey protocols that the Secretary develops, tests, and validates when conducting surveys of facilities' compliance with federal standards of care. However, on October 1, 1990, the effective date of NHRA, California issued a press release defiantly claiming it would not implement the Act. California insisted, instead, that it would continue to use the federal survey process that predated NHRA. ¹⁷ The IoM had described multiple shortcomings in that prior survey process, including its focus on "theoretical facility capability rather than actual performance," use of "record reviews rather than direct observations," and insensitivity to resident needs. ¹⁸

A statewide class of nursing home residents sued the state. ¹⁹ The court granted the class a preliminary injunction, rejecting the argument that California's own laws were sufficient to meet the requirements of the new federal law. The injunction was incorporated into a final settlement in April 1993 that required the state, among other actions, to conduct nursing home surveys using the federal survey protocols.

¹⁶ *Id*. at 7.

¹⁷ California Dep't of Health Servs., Departmental Appeals Board, Appellate Division, Decision No. 1490 (Aug. 12, 1994) (hereinafter "Cal. Decision No. 1490"), https://www.hhs.gov/sites/default/files/static/dab/decisions/board-decisions/1994/dab1490.html.

¹⁸ IoM, *Improving the Quality of Care in Nursing Homes*, at 107.

¹⁹ Valdivia v. Cal. Dep't of Health Servs, No. S-90-1226EJG EM, 1991 WL 80896, *3 (E.D. Cal. Feb. 25, 1991).

Meanwhile, in response to California's refusal to use the federal survey protocol for annual surveys, the Health Care Financing Administration ("HCFA," now CMS) disallowed federal funding for nursing home surveys conducted in California for the quarters ending December 31, 1990 and March 31, 1991, the period when the state refused to use the new federal survey process. The disallowance, totaling \$4,557,921, was upheld.²⁰

HCFA's disallowing federal funding for California when it refused to conduct surveys using the new federal survey process underscores that the federal survey protocols are a mandatory part of NHRA that states are not free to ignore. States must conduct surveys using the federal survey protocols to determine whether nursing facilities meet federal standards of care. No other survey process is permitted.

III. The Federal Public-Facing Website with Information about Nursing Homes, *Care Compare*, Highlights the Importance of Survey Information.

In November 2002, CMS developed *Nursing Home Compare* (now called *Care Compare*), a public-facing website to provide information about nursing homes that residents and families could rely on, both to help choose a nursing home and to monitor care provided by a nursing home. Over the years, CMS has added information to the website to provide more comprehensive information about nursing home surveys (results of public surveys and how deficiencies are classified; penalties imposed for noncompliance), staffing levels (numbers of nursing hours provided, by category of nurse), and quality measure (resident assessment) information. For example, in 2018, recognizing that self-reported unaudited staffing information is unreliable, CMS began reporting staffing levels based on auditable payroll-based

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²⁰ Cal. Decision No. 1490.

information.²¹ In 2023, CMS began posting more detailed ownership information, with links to information about facilities with a common affiliation.²²

On December 18, 2008, CMS added a Five-Star Rating System to the federal website in order to help the public understand the comprehensive information on *Care Compare*.²³

Facilities are rated on a five-point scale (with one the lowest, and five, the highest) on three separate domains: public surveys, staffing levels, and quality measures (*i.e.*, resident assessment data) and are given an overall five-star rating.

CMS's "Design for *Care Compare* Nursing Home Five-Star Quality Rating System: Technical Users' Guide" (Apr. 2024), ²⁴ like previous versions of the Guide, explains the Five-Star scoring system. Each of the three domains (survey, staffing, quality measures) is separately scored on a five-point scale. The survey domain is the most important component. The overall rating for each facility begins with the survey rating. A facility with five stars in the staffing or quality measures domain increases its overall rating by one star; a facility with one star in the staffing or quality measure domain decreases its overall rating by one star. Typically, facilities' overall rating reflects their survey score.

²¹ CMS, Transition to Payroll-Based Journal (PBJ) Staffing Measures on the Nursing Home Compare tool on Medicare.gov and the Five Star Quality Rating System, QSO-18-17-NH (Apr. 6, 2018), https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/qso18-17-nh.pdf.

²² CMS, *Posting of Nursing Home Ownership/Operatorship Affiliation Data on Nursing Home Care Compare Website and data.cms.gov*, QSO-23-18-NH (June 28, 2023), https://www.cms.gov/files/document/qso-23-18-nh.pdf.

²³ CMS, *Nursing Homes – Launching of Five Star Rating System on the Nursing Home Compare Website*, S&C-09-17 (Dec. 5, 2008), https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/scletter09-17.pdf.

²⁴ CMS, *Design for* Care Compare *Nursing Home Five-Star Quality Rating System: Technical Users' Guide* (Apr. 2024), https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf.

The Care Compare website and the Five-Star Quality Rating System are intended to provide accurate, comprehensive, and timely information about each nursing facility in the country that receives federal reimbursement. If the information is inaccurate and out-of-date, it is misleading to residents and families, who may make placement or monitoring decisions based on what the federal website reports.

Maryland's failure to conduct timely standard and complaint surveys means that the publicly available information about surveys on the federal website may reflect survey information that is many years old and, therefore, inaccurate and misleading. Residents, families, and the public cannot reasonably use or rely on such dated information.

CONCLUSION

The Court should grant Plaintiffs' Opposition to Defendants' Motion to Dismiss that this action can ensure that residents' rights are protected. Annual surveys and complaint investigations are the methods mandated by NHRA to assure that residents' care and rights, guaranteed by the NHRA, are recognized and respected.

DATED: September 12, 2024 Respectfully submitted,

Anthony J. May (Bar No. 20301) amay@browngold.com Brown, Goldstein & Levy, LLP 120 E. Baltimore Street, Suite 2500 Baltimore, Maryland 21202

Tel: (410) 962-1030

Fax: (410) 385-0869

Attorney for Amicus Curiae Toby S. Edelman