Methods for Managing Risk and Promoting Resident-Centered Care in Nursing Homes

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Risk prevention is a central concept in long-term care settings — both skilled-care and assisted-living settings. Risk allocation varies by care setting, with skilled-care administrators being the most risk averse and those in assisted living, a more social and homelike environment, being more lenient. The challenge for such administrators is to find the balance between risk prevention — avoiding injury from falls, choking, or other safety risks — and the individual's quality of life and right to self-determination. Confronted with regulatory and common-law liability, facilities of all types implement policies that shield them from risk — often at the expense of practices that would facilitate higher quality of life for residents. This is especially the case in skilled-care settings (such as nursing homes), which are subject to stricter regulations than are assisted-living facilities. Some regulations have improved quality of life in nursing homes, but, in practice, government regulations produce a level of risk aversion that diminishes quality of life for residents. This Note considers the effects of the current legal regime on risk allocation in skilled-care facilities. These facilities may be better able to care for residents — thereby improving quality of life for skilled-care residents — via the extension of the Culture Change movement along with specific tools like Negotiated Risk Agreements, which are currently acceptable in assisted living.

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I. INTRODUCTION

In 1900, 4.1 percent of the American population was 65 or older.[1] The U.S. Department of Health and Human Services Administration on Aging estimates seniors (65 or older) will number above 70 million, representing 20 percent of the population, by 2030.[2] This simple numerical reality indicates the importance of developing sound elder care policy, and recent discussions of long-term care have identified an important characteristic of smart policy: It should facilitate both quality of care and quality of life for long-term care residents.[3]

As the American population ages, policymakers are receiving increasing signals that they must revise their ideas about how providers of long-term care should operate. In the mid-1980s, landmark nursing home policy reform marked a significant shift in how regulators assess the quality of healthcare provided in long-term care facilities.[4] The Nursing Home Reform Act (NHRA), which passed as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA),[5] altered enforcement requirements and reformed care standards in two ways: First, it revised regulations related to quality of medical care, and, second, it added new consideration for quality of life among nursing home residents.[6] Taken together, these reforms introduced a change in the overall approach to nursing home regulation:

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1. ADMINISTRATION ON AGING, U.S. DEPT. OF HEALTH & HUMAN SERVICES, A PROFILE OF OLDER AMERICANS: 2001 1 (2001).

2. *Id.* at 2.

3. *See, e.g.*, Sheryl Zimmerman et al., *Transforming Nursing Home Culture: Evidence for Practice and Policy*, 54 GERONTOLOGIST S1 (2014) (presenting several discussions regarding transforming nursing home culture in order to facilitate both quality of care and quality of life).

4. *See, e.g.*, Celia Berdes, *Balancing Patient Safety and Person-Centered Care in Nursing Homes*, ANN. REPORT 2009 (Buehler Center on Aging, Health & Society, Chicago, Ill.), at 3. For a detailed history of long-term care in the U.S., see David A. Bohm, *Striving for Quality Care in America's Nursing Homes: Tracing the Trajectory of Nursing Homes and Noting the Effect of Recent Federal Government Initiatives to Ensure Quality Care in the Nursing Home Setting*, 4 DEPAUL J. HEALTH CARE L. 317 (2001).

5. Authors cite alternatively to OBRA and NHRA. This Note will cite to OBRA, as it appears to be more common in citations to this law.

6. For a summary of OBRA and its effects, see JOSHUA M. WIENER ET AL., NURSING HOME CARE QUALITY: TWENTY YEARS AFTER THE OMNIBUS BUDGET RECONCILIATION ACT OF 1987 (2007). *See generally* Maureen Armour, *A Nursing Home's Good Faith Duty "To" Care: Redefining a Fragile Relationship Using the Law of Contract*, 39 ST. LOUIS U. L.J. 217, 248 (1994) ("[Q]uality of care and quality of life are the focal points of the statutory scheme.").

> This [was] the first time the federal government [had] ever expressed the certification and participation obligations under Medicaid and patients' rights under Medicaid in terms of "quality of life." In doing so, OBRA explicitly rejected the narrow, instrumental and process oriented medical and custodial care paradigm that defined quality care under the old regulatory scheme.[7]

Under OBRA, "[a] skilled nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident."[8]

Over time, quality of life has taken on increased significance in the eyes of skilled-care providers. In 1986, the National Academy of Sciences' Institute of Medicine (IOM) released a seminal report on nursing home reform, "Improving Quality of Care in Nursing Homes," which translated directly into the provisions passed by Congress as part of OBRA.[9] In name and the majority of the substance, the report and subsequent legislation emphasized "quality of care," defined as the clinical healthcare outcomes achieved by each provider.[10] The legislation overhauled the regulatory scheme, introducing new surveying practices[11] and raising standards of care,[12] though it retained some of the previous regulatory regime's focus on the "nursing" component of nursing homes — the clinical measures by which regulators assess resident health and safety.[13] Thus, despite recognizing the im-

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7. Armour, *supra* note 6, at 248.

8. Codified at 42 U.S.C. § 1395i-3(b)(1)(A). *See, e.g.*, Armour, *supra* note 6, at 249.

9. COMM. ON NURSING HOME REGULATION, INST. OF MEDICINE, IMPROVING THE QUALITY OF CARE IN NURSING HOMES (1986); Philip C. Aka et al., *Political Factors and Enforcement of the Nursing Home Regulatory Regime*, 24 J.L. & HEALTH 1, 11 (2011) (indicating that the study's recommendations "formed the basis for the preparation and passage of the NHRA in 1987").

10. *See, e.g.*, Bohm, *supra* note 4, at 331–32.

11. This Note occasionally refers to "surveyors," the common term for state agents that conduct the periodic facility reviews required for the receipt of Medicare and Medicaid funding. This Note also refers to "regulators," which includes both policymakers and enforcement agents.

12. *See, e.g.*, WIENER ET AL., *supra* note 6, at 5–8.

13. *See, e.g.*, Bohm, *supra* note 4, at 331–32 ("OBRA 87 changed the focus of standards for nursing homes enrolled in the Medicare and Medicaid programs. Prior to the passage of this legislation, the program participation standards focused merely on the nursing home's ability to provide care to its residents, not on the quality of the care that was actually rendered. Accordingly, OBRA 87 refocused the federal program standards upon: (1) the actual delivery of care and (2) the results of such care.").

portance of quality of life in nursing homes, the law increased facilities' focus on medical outcomes rather than committing to significant quality-of-life improvements.[14]

Still, the regulatory foundation was laid for increased focus on quality of life in skilled-care facilities, leading to what the Pioneer Network[15] and other reform leaders have labeled "Culture Change."[16] The Culture Change movement, which began in full in the late 1990s, calls for a shift in thinking among providers and regulators, with an emphasis on fostering a home-like atmosphere in long-term care.[17] As the Culture Change movement has recognized, the medical model of care (an approach that views nursing homes as more similar to hospitals than to homes) cannot fulfill the goals of long-term care: While hospital operators can and should focus mostly on clinical outcomes for short-term medical problems, nursing homes seek to offer, in essence, new homes for their residents. In long-term care settings, as Professor Maureen Armour has asserted, "quality of life is very important for its own sake (that is, as an outcome goal) and because it is intimately related to quality of care in nursing homes."[18]

However, efforts to implement Culture Change — and the resident-centered care[19] objectives that this movement entails — have been slowed by regulatory and civil liability risks. Gerontologist Celia Berdes describes the conflict as such: "In the daily life of nursing home patients and those who care for them, keeping them safe and simultaneously respecting their autonomy,

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14. E. Foy White-Chu et al., *Beyond the Medical Model: The Culture Change Revolution in Long-Term Care*, 10 J. AM. MED. DIRECTORS ASS'N 370 (2009).

15. The Pioneer Network is an organization of advocates, researchers, regulators, and administrators that has been influential in guiding nursing home reform discussion since the group's inception in 1997. *See, e.g.*, Mary Jane Koren, *Person-Centered Care for Nursing Home Residents: The Culture-Change Movement*, 29 HEALTH AFF. 312, 313 (2010).

16. *Id.* at 312–13. *See also* CULTURE CHANGE IN LONG-TERM CARE (Audrey S. Weiner & Judah L. Ronch eds., 2003); Anna N. Rahman & John F. Schnelle, *The Nursing Home Culture-Change Movement: Recent Past, Present, and Future Directions for Research*, 48 GERONTOLOGIST 142 (2008). While most authors do not capitalize the term "Culture Change," this Note uses such capitalization to emphasize Culture Change as a recognized movement in long-term care.

17. Koren, *supra* note 15, at 313 ("Today the movement's overarching goals are to individualize care for residents, making facilities more homelike and less 'institutional.'").

18. Armour, *supra* note 6, at 244–45.

19. In order to interface with existing gerontological literature, this Note utilizes several terms of art common in nursing home discussions. Here, "resident-centered care" (sometimes called "person-centered care") stands for the idea that each individual resident should receive services "to attain or maintain the highest practicable physical, mental, and psychosocial well-being," as stated at 42 U.S.C. § 1395i-3(b)(2).

dignity, and privacy can be goals that are difficult to reconcile."[20] This tension emerges in two related ways: First, efforts to improve quality of life may subject care providers to regulatory sanctions if the resident is (or could be) injured because of the facility's decision to allow greater autonomy, and in order to avoid such sanctions, some facilities opt for interventions that oppose resident-centered care.[21] As an oft-cited example, care providers frequently seek to prevent falls by reducing residents' mobility generally, such as by using wheelchairs or placing other restrictions on unassisted movement.[22] Residents, living in a theoretically home-like setting, lose the ability to move freely, a significant detriment to their personal autonomy. Second, the risk of civil liability exposure gives rise to some of the same restrictive policies that are used to avoid regulatory sanctions. When residents assume greater autonomy the potential for accidents increases, leading both to litigation and to higher costs for liability insurance coverage.[23]

The recent reform movement targets a change in the culture of nursing homes, but this Note will argue that the movement's goals cannot be achieved without legal and regulatory recognition of quality of life as a valuable objective.[24] Several possibilities exist for initiating this shift in perspective. First, lawmakers and regulators might build more recognition of quality-of-life outcomes into nursing home assessments, both in specific nursing home survey standards and in the underlying philosophy guiding enforcement.[25] Such a change in mentality may lead regulators

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20. Berdes, *supra* note 4, at 3.

21. *Id.* at 4–5.

22. Joshua R. Wilkins, *Consumer Directed Negotiated Risk Agreements*, 6 NAELA STUDENT J. 1 (2011), https://www.naela.org/app_themes/public/PDF/Library%20Tab/03_Joshua_Wilkins.pdf [perma.cc/72D4-MTBE].

23. Allen A. Lynch, II, & Sarah A. Teachworth, *Risky Business: The Enforceability and Use of Negotiated Risk Agreements*, 10 SENIORS HOUSING & CARE J. 3, 4 (2002).

24. Other authors have advanced similar arguments, focusing on the need for changes in the relationship between nursing homes and regulators. *See, e.g.*, Berdes, *supra* note 4, at 6; Mary Jane Koren, Assistant Vice President, The Commonwealth Fund, Moving To A Higher Level: How Collaboration And Cooperation Can Improve Nursing Home Quality, Invited Testimony Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce (May 15, 2008) (providing recommendations "to ensure that the survey process itself is not a barrier to innovation"), *in* COMMONWEALTH FUND PUB. NO. 1137.

25. *See, e.g.*, ROBYN I. STONE ET AL., SUPPORTING CULTURE CHANGE: WORKING TOWARD SMARTER STATE NURSING HOME REGULATION 1 (2009) (Commonwealth Fund Pub. 1328 Vol. 68) (describing a "partnership model aimed at promoting high performance," with a focus on supporting Culture Change reforms).

to reward Culture Change through enforcement discretion, which could lead to changes in the written regulations; alternatively, lawmakers and executive officials could begin with regulatory reform, which would necessitate changes on the part of enforcers. Relatedly, federal policymakers should consider regulations governing the use of Negotiated Risk Agreements (NRAs) in nursing homes to foster greater person-centered facility policies. Long-term care facilities routinely grapple with improving both quality of care and quality of life for their residents. Because of countervailing regulatory pressures, these considerations can seem to be a zero-sum game for care providers: In attempting to emphasize the "home" part of the equation, providers fear that regulators will issue citations for inadequate "nursing." This Note seeks to analyze the balance and co-existence of quality-of-care and quality-of-life measures in nursing homes, with a focus on the effects of the legal and regulatory regime governing this field. Part II proceeds by documenting the state of nursing home regulation and recent trends toward resident autonomy in these facilities. Part III asserts that the current legal regime prioritizes resident safety to the detriment of personal autonomy and discusses the current role of NRAs in long-term care risk prevention. Part IV suggests that changes to regulations and the enforcement process can better facilitate quality-of-life improvements and argues for federal standards for NRAs in nursing homes. Part V concludes by highlighting issues for further analysis, including the problem of providing additional funding to proliferate Culture Change.

II. THE STATE OF NURSING HOME REGULATION AND OPERATIONS

Nursing homes are notoriously heavily regulated.[26] In addressing the contours of nursing home care, it is thus important to understand the lay of the regulatory land. While a concise description of nursing home regulation will be insufficient to explain the full processes by which federal and state regulators hold facilities accountable, the broad strokes will help inform this Note's discussion of potential reform to facilitate resident choice and quality of life in nursing homes. Part II.A describes the most

26. *See, e.g.*, Robert L. Kane, *Assuring Quality in Nursing Home Care*, 46 J. AM. GERIATRICS SOC'Y 232, 232 (1998).

significant regulatory structures and their place in long-term care oversight. Part II.B examines current nursing home practices, with emphasis on the recent Culture Change movement that has emphatically pressed for quality-of-life improvements.

A. MAPPING THE LONG-TERM CARE REGULATORY STRUCTURES

The regulatory landscape for long-term care is defined by parallel federal and state requirements for nursing homes,[27] along with an adversarial atmosphere that emerges from negative care outcomes in such facilities.[28] While some facilities are exclusively for private-paying residents, approximately 96 percent of nursing homes are certified to accept Medicaid reimbursements,[29] and facilities that are so certified must abide by the regulations set forth by the Centers for Medicare and Medicaid Services (CMS).[30] Because federal funding plays such a significant role in the long-term care field, national regulations are most significant in determining how care providers must operate.[31] Enforcement of these regulations takes place at the state level, which also incorporates various licensing requirements for these facilities.[32] In conjunction with regulation enforcement, the plaintiff's bar seeks to hold facilities to common-law and statutory standards of care.[33]

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27. For an overview of federal regulation and the states' roles within the regulatory scheme, see Kieran Walshe & Charlene Harrington, *Regulation of Nursing Facilities in the United States: An Analysis of Resources and Performance of State Survey Agencies*, 42 GERONTOLOGIST 475 (2002).

28. *See, e.g.*, STONE ET AL., *supra* note 25, at 1 ("The traditional nursing home regulatory approach, which uses survey and enforcement to achieve performance improvement, has created tensions between providers and surveyors.").

29. David C. Grabowski et al., *Nursing Home Quality as Public Good* (Nat'l Bureau of Econ. Research Working Paper, Paper No. 12361, 2006), http://www.nber.org/papers/w12361.pdf [perma.cc/GYM7-L2VE]. While these facilities have discretion over resident admission, "Medicaid is the dominant purchaser of nursing home services accounting for roughly 50% of all nursing home expenditures and 70% of all bed days." *Id.*

30. Promulgated by 42 U.S.C. § 1396r; regulations codified at 42 C.F.R. § 483.

31. *See, e.g.*, WIENER ET AL., *supra* note 6, at 1 ("Given the financial dominance of Medicaid and Medicare, it is not surprising that federal quality assurance standards, mandated inspections, and enforcement processes dominate the formal quality assurance system for nursing homes.").

32. *Id.* ("In order to receive Medicaid and Medicare reimbursement, nursing homes must be licensed by the state in which they are located and certified as meeting the federal quality standards for nursing homes. While the standards are federal, almost all of the actual inspections and most enforcement are conducted by state Departments of Health, giving states a major stake and responsibility in the quality assurance process.").

33. *See, e.g.*, David M. Studdert & David G. Stevenson, *Nursing Home Litigation and Tort Reform: A Case for Exceptionalism*, 44 GERONTOLOGIST 588, 589 (2004).

Understanding the spectrum of long-term care options is an important first step in assessing standards for quality of care and quality of life. Nursing homes and assisted-living facilities fill this spectrum, which bridges independent living and end of life. While providing generally similar services (care for the elderly), these types of facilities are governed in significantly different ways, emerging from the history and function of each type. They diverge most significantly in their historic and ongoing inclusion or exclusion of a medical model of care.[34] Long-term care facilities evolved in the nineteenth century from almshouses that provided shelter and (generally low-quality) service to the poor.[35] Over time, these almshouses came to be populated mostly by the elderly.[36] The modern nursing home began to emerge when, in 1935, the Social Security Act provided a new model of federal reimbursement for facilities providing elder care.[37] This law contributed significantly to the privatization of elder care, as only private facilities were eligible for federal matching funds.[38] Shortly thereafter, in the 1940s, market competition led to improved standards of care, largely based on a medical model.[39] In 1965, the federal government further entrenched its significant role in nursing home oversight with the Social Security Act amendments that produced Medicaid and Medicare.[40]

Since their emergence in the 1980s, assisted-living facilities have avoided extensive regulation on the strength of residents' contentions for autonomy and flexibility, along with market de-

34. *See, e.g.*, Stephanie Edelstein, *Assisted Living: Recent Developments and Issues for Older Consumers*, 9 STAN. L. & POL'Y REV. 373, 376 (1998) (suggesting the related question of whether the increase in medical care in assisted living facilities demands a parallel increase in regulation).

35. Bohm, *supra* note 4, at 324–27.

36. *Id.* at 327. Specifically, during the second half of the nineteenth century, "reformers moved specific groups into separate institutions. The young went to orphanages, the insane to mental institutions, the physically handicapped to special schools, and the able-bodied to workhouses. By stripping away one group after another and leaving the elderly in place, these reformers unintentionally, but nonetheless effectively, transformed the almshouse into a residence for older, poor people. . . ." Martha Holstein & Thomas R. Cole, *The Evolution of Long-Term Care in America*, *in* THE FUTURE OF LONG-TERM CARE: SOCIAL AND POLICY ISSUES 26 (Robert H. Binstock, Leighton E. Cluff, & Otto von Mering eds., 1996).

37. Bohm, *supra* note 4, at 329.

38. Aka et al., *supra* note 9, at 7.

39. Bohm, *supra* note 4, at 330.

40. Aka et al., *supra* note 9, at 15.

sires for varying levels of care and cost.[41] Nursing homes, on the other hand, are regulated most significantly by Federal Medicaid provisions, as the federal government seeks to "promote uniform standards across the nation in a key service area."[42] Professor Robert Kane, reflecting a widely-held view among care providers,[43] has expressed this in the extreme: "The role of regulation and external monitoring is more stringent in nursing home care than in any other type of social service."[44] Today, assisted living is governed almost exclusively at the state level, with varying interpretations of appropriate governance.[45]

The assisted-living model evolved specifically as an alternative to the medical model of skilled care.[46] Assisted living developed in the 1980s in response to the market demand for long-term living facilities in which residents could maintain greater autonomy than in nursing homes.[47] Marketization of long-term care represents a distinct difference between nursing homes and assisted living: The federal government — and the states, following suit — have opted for regulation over market-based techniques in order to raise standards in nursing homes.[48] The nursing home field lies largely outside the free market, both because of active political decisions[49] and because of the inherent qualities

41. Edelstein, *supra* note 34, at 374–76 (indicating that assisted living facilities have evolved "in response to a call for alternatives to the high cost and institutional setting of nursing homes [and] demands for more personal autonomy," among other reasons).

42. Aka et al., *supra* note 9, at 15.

43. *See, e.g.*, David G. Stevenson & David M. Studdert, *The Rise of Nursing Home Litigation: Findings from a National Survey of Attorneys*, 22 HEALTH AFF. 219, 219 (2003) ("The legal system's traditional response to concerns about the quality of long-term care has been regulation, rendering nursing homes among the most highly regulated entities in American health care.").

44. Kane, *supra* note 26, at 232 ("Any private industry that uses substantial public funds is likely to be regulated. When the private organizations are largely proprietary and often without sophisticated operational structures, the role of regulation becomes even more dominant. Because catastrophes catalyze regulation, the notoriety that came from state and federal commissions that uncovered gross instances of flagrant exploitation fanned the flames of stringent regulation.").

45. WIENER ET AL., *supra* note 6, at 32–33 ("States have almost total responsibility for non-nursing home residential care. As a result, there is no standardization across states in terms of definition of various types of residential care, and state regulatory requirements vary greatly.").

46. Edelstein, *supra* note 34, at 374–76.

47. *Id.* at 376. Several related factors were also relevant, including: the high cost of care in nursing homes, the aging of the American population (seeking affordable care), and the desire for the elderly to "age in place." *Id.* at 374.

48. *See* Aka et al., *supra* note 9, at 25–28.

49. Multiple administrations and Congresses have considered deregulation of the nursing home industry since the early 1980s. Under the Reagan administration, calls for

of skilled-care demand.[50] In selecting nursing homes for older family members, most consumers prioritize location, demonstrating a significant barrier to the proper functioning of the market, and thus for the use of market-based improvement techniques.[51] In fact, one study of the selection process suggested that residents and their families tend to place more emphasis on location, amenities, and cleanliness than on quality of care.[52]

In addition, regulatory differences correspond with functional qualities in assisted-living and nursing homes. For example, assisted living can be viewed as occupying any location in the "continuum of care" between independent living and nursing home care. As such, assisted living can include "both a 200-bed facility that provides extensive health care services, and a six-bed facility that provides only room, board, and minimal assistance with activities of daily living."[53] Nursing homes are, again, quite different. To function as a certified nursing home under federal law, a facility must meet specific definitions in the Social Security Act and abide by the standards for nursing homes set forth in the Federal Code and any pertinent state standards. Recent patterns suggest a greater role for nursing care in assisted living,[54] but the highest standards still apply to nursing homes.

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deregulation were eventually curtailed in favor of improving the existing regime. Under Bill Clinton's administration, the President vetoed efforts to deregulate nursing homes and the executive established new measures for improving regulatory enforcement. Aka et al., *supra* note 9, at 11–13.

50. In some industries, the market forces of supply and demand are sufficient for bolstering self-regulation. Long-term care is different. Consumers rarely have the same choices for quality and price when selecting a residence for an elder. Alexander D. Eremia, *When Self-Regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care*, 11 ANNALS HEALTH L. 93, 100–01 (2002).

51. David C. Grabowski et al., *Who Are the Innovators? Nursing Homes Implementing Culture Change*, 54 GERONTOLOGIST S65, S74 (2014).

52. Nicholas G. Castle, *Searching for and Selecting a Nursing Facility*, 60 MED. CARE RES. & REV. 223, 241 (2003).

53. Eric M. Carlson, *Protecting Rights or Waiving Them? Why 'Negotiated Risk' Should Be Removed from Assisted Living Law*, 10 J. HEALTH CARE L. & POL'Y 287, 290 (2007).

54. *See, e.g.*, Brandy Harris-Wallace et al., *The Emerging Role of Health Care Supervisors in Assisted Living*, 19 SENIORS HOUSING CARE J. 97 (2011) (considering the need for organizational changes in light of assisted living facilities "increasingly provid[ing] medical as well as social care"). *See also* Eunice Park-Lee et al., *Residential Care Facilities: A Key Sector in the Spectrum of Long-Term Care Providers in the United States*, National Center for Health Statistics Data Brief No. 78, 4 (2011) (showing that nearly forty percent of assisted living residents received skilled nursing care in 2010), http://www.cdc.gov/nchs/data/databriefs/db78.pdf [perma.cc/9YAB-Y73Q].

B. CULTURE CHANGE AS AN ENGINE FOR QUALITY-OF-LIFE REFORM

This Note approaches risk management with the goal of building quality-of-life considerations into nursing home best practices to a greater extent, a goal advocated by the Culture Change movement. Culture Change represents greater emphasis on policies that treat residents as individuals, seeking to improve quality of life and quality of care in nursing homes through both substantive and procedural principles.[55] The substantive principles include guidelines on the types of services provided to each resident; the procedural principles inform nursing home organizational structures and management.[56] As an overarching philosophy of care, Culture Change can help move the long-term care field toward improvements in quality of life, and changes to the applicable legal and regulatory structures can help facilitate these improvements.

The Culture Change movement can be understood as a continuation of reformers' efforts at the junction of nursing home quality and the law over the past several decades. As mentioned in the previous Part, regulators undertook to revise long-term care oversight with the Social Security Act of 1935, which provided new federal grants to private long-term care providers.[57] In the 1960s, a set of elder care scandals partially shaped the Social Security Act amendments of 1965 (including the creation of Medicare and Medicaid).[58] Further coverage of elder abuse and neglect led to calls for reform in the mid-1970s, which — after the development of a new regulatory framework, a reverse shift toward deregulation under the Reagan Administration, and subsequent backlash toward such proposals — eventually led to OBRA and the Nursing Home Reform Act in 1987.[59]

The 1986 IOM report introduced quality of life as an important focus for new regulatory measures, but this development

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55. *See generally* Koren, *supra* note 15. *See also* Zimmerman et al., *supra* note 3, at S3 ("Embracing the central role of organizational culture in care delivery, the nursing home culture change movement aims to improve resident quality of life and quality of care by emphasizing the deinstitutionalization of nursing home culture and focusing on person-centered care.").

56. *See, e.g.*, Koren, *supra* note 15, at 313.

57. Aka et al., *supra* note 9, at 7.

58. *Id.* at 9.

59. *Id.*

seems rooted more deeply in the history of long-term care facilities.[60] Almshouses — once developed as punitive environments for the poor and eventually evolving into the main setting for elder care — began to account for quality of life as early as the beginning of the twentieth century, when the New York Commissioner of Charities recommended that the city's almshouse be renamed "the Home for the Aged and Infirm" in order to project resident dignity.[61] After a century of regulatory revisions, the Culture Change movement carries the torch of quality of life that was reignited in the IOM report.

Relatively new as a cohesive philosophy of long-term care, the contours of Culture Change are still developing.[62] A recent issue of *The Gerontologist* focused on Culture Change and summarized the movement as such: "The nursing home culture change movement aims to improve resident quality of life and quality of care by emphasizing the deinstitutionalization of nursing home culture and focusing on person-centered care."[63] More specifically, scholars and care providers attribute a number of qualities to Culture Change. In her oft-cited article on the movement, Dr. Mary Jane Koren identifies several interrelated factors as characterizing Culture Change: a homelike atmosphere; close relationships among residents and other members of the long-term care community; staff empowerment; collaborative decision making among staff and management; and continuous quality improvement procedures.[64] Broadly, Koren describes Culture Change as "espous[ing] a set of principles, instead of offering a prescriptive set of practices or dictating conformance to a model."[65]

Importantly, Culture Change is not *synonymous* with quality-of-life or resident-centered care, but those factors are central to the movement's goals.[66] In addition, Culture Change does not

60. COMM. ON NURSING HOME REGULATION, *supra* note 9, at 79 (explaining that the previous regulatory structure "[did] not explicitly recognize the importance of quality of life").

61. Holstein & Cole, *supra* note 36, at 28.

62. *See, e.g.*, Christine E. Bishop & Robyn Stone, *Implications for Policy: The Nursing Home as Least Restrictive Setting*, 54 GERONTOLOGIST S98 (2014).

63. Zimmerman et al., *supra* note 3, at S1.

64. Koren, *supra* note 15, at 313.

65. *Id.*

66. *See id.* at 313–14 (explaining that Culture Change "strives to honor residents' individual rights, offering them quality of life and quality of care in equal measure" and describing several features of Culture Change).

conjure a fully concrete set of particular practices, at least in its current form.[67] The underlying concept is that, by emphasizing resident choice and resident-centered care, efforts to improve quality of life can be made consistent with efforts to optimize safety.[68] This Note approaches Culture Change as a hybrid of ends and means, as the term includes some specific procedural and substantive techniques[69] and also broadly seeks to achieve improvements in quality of life and resident autonomy, the foci of this discussion.[70] In the following Parts, this Note thus utilizes Culture Change as a vehicle for these ideas and considers the impact of regulation on the objectives of the movement.

III. CURRENT APPROACHES TO RISK MANAGEMENT FOR QUALITY OF LIFE

Even as quality of life becomes a more significant component of care standards in the abstract, the law — including both regulations and civil suits — presents a barrier to progress toward a pragmatic approach to care that fully encompasses quality of life considerations. This Part focuses on the manner in which long-term care facilities attempt to consider these factors in light of the current landscape. Part III.A posits that existing enforcement mechanisms stifle innovation in quality-of-life practices by encouraging overly-cautious risk management techniques, and Part III.B introduces an important tool in managing risk — Negotiated Risk Agreements.

A. THE EFFECT OF RISK MANAGEMENT ON QUALITY OF LIFE

The current regulatory framework has important effects on Culture Change and, more generally, the development of quality-of-life policies. In exploring the possibility of improving quality of life in nursing homes, accepting resident autonomy even in

67. Rahman & Schnelle, *supra* note 16, at 142 ("The concept has defied easy definition (even to today), in part because the movement encompasses diverse and sometimes contradictory components. Consequently, culture change is more often described in the literature than defined in it.").

68. Victoria Shier et al., *What Does the Evidence Really Say About Culture Change in Nursing Homes?*, 54 GERONTOLOGIST S6, S7 (2014).

69. *See infra* Part III.B.

70. Rahman & Schnelle, *supra* note 16, at 142–43. ("Culture-change proponents aim to create caring communities where both empowered frontline staff and residents can flourish, and where residents experience enhanced quality of life.").

skilled-care settings is an important starting point. Legal perspectives on each type of facility seem to take certain levels of autonomy for granted, with important effects on approaches to risk management. In assisted living, flexibility and lack of stringent regulation have allowed some space for scholars and care providers to consider the best measures for guaranteeing resident rights, including both care and autonomy. In nursing homes, many authors seem to have concluded that "risk taking is very limited because of a predominance of frailty, regulation, and . . . the medical model of long term care itself."[71] However, a similar desire for autonomy can exist in nursing homes and, in fact, has taken root in the Culture Change movement.[72]

For nursing homes, risk prevention is inherently related to federal standards of care. In analyzing the effect of care standards, the "Quality of Care" section of the Federal Code is particularly significant: "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."[73] The Department of Health and Human Services (DHHS), through the Health Care Financing Administration, compiles guidelines on care standards in the Medicaid State Operations Manual (SOM),[74] and state surveyors assess facilities according to standards commonly referred to as "F Tags."[75] F Tag 240 nominally builds quality of life into facility assessments.[76] However, other sections push back: F Tag 323 ("Accidents and Supervision"), for example, is particularly important for the balance of quality of care and quality of life — and particularly demanding for nursing homes.[77] There, surveyors seek to enforce the regulatory provision indicating: "The facility must ensure that — (1) The resident environment remains as free from accident hazards as is possible; and (2) Each resident receives ade-

71. Lynch & Teachworth, *supra* note 23, at 4.

72. *See supra* Part II.A.

73. 42 C.F.R. § 493.25.

74. Marshall B. Kapp, *Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Go to Do with It?*, 31 MCGEORGE L. REV. 707, 711 (2000).

75. *See, e.g.*, Berdes, *supra* note 4.

76. CTRS. FOR MEDICARE & MEDICAID SERVS. STATE OPERATIONS MANUAL app. F240 (2015) ("A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.").

77. Berdes, *supra* note 4, at 3.

quate supervision and assistance devices to prevent accidents."[78] As a result of this provision's high but hazy standard, the response from many nursing homes has been to reduce resident choice regarding activities as simple as walking.[79]

In providing guidance to providers and surveyors, the SOM indicates a natural tension inherent in this F Tag, demonstrative of the regulatory regime more generally. To explain this provision, the SOM describes requirements related to quality of life, including "respecting residents' rights to privacy, dignity and self determination, and their right to make choices about significant aspects of their life in the facility."[80] Four paragraphs later, however, the SOM instructs providers to "commit to safety and implement systems that address resident risk and environmental hazards to minimize the likelihood of accidents."[81]

From a policy perspective, that this regulation is somewhat self-contradictory is not, in itself, troubling. As the SOM[82] and the scholarly literature[83] recognize, the challenge for nursing homes is to develop an atmosphere in which *both* quality of care and quality of life are emphasized. Presenting more of a difficulty is the fact that the regulations explicitly indicate this tension but regulators have done little to actively encourage solutions in the form of resident-centered care. The adversarial relationship between providers and regulators gives rise to an overly cautious atmosphere in which providers are hesitant to push Culture Change forward.[84] When NRAs first entered the long-term care lexicon in the 1990s, experts identified a "permeating aura of legal anxiety" related to negligence litigation and regulatory sanc-

78. CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app. F323 (2015).

79. Berdes, *supra* note 4, at 4.

80. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 78.

81. *Id.*

82. *Id.*

83. *See, e.g.*, Bishop & Stone, *supra* note 62, at S99 (recognizing that nursing homes could improve clinical outcomes by running like a "mini hospital; but such a setting is rather far from the ideals of . . . homelike").

84. *See, e.g.*, STONE ET AL., *supra* note 25, at 1–2 ("Some argue that the regulatory approach, which they view as primarily legalistic and enforcement-based, creates an environment in which administrators are afraid to pursue culture change activities that they believe may put them in jeopardy. Others indicate that specific regulations actually get in the way of culture change, particularly those that prevent necessary changes to the physical environment, staffing patterns, and training requirements."); Kieran Walshe, *Regulating U.S. Nursing Homes: Are We Learning From Experience?*, 20 HEALTH AFF. 128, 133 (2001) (addressing the ongoing role of "formal, legalistic, punitive, and sanction-oriented" regulation of nursing homes).

tions.[85] A decade later, another influential article described providers as "suffering a comparative nervous breakdown."[86]

The plaintiff's bar represents a separate means of oversight that seeks to hold skilled-care facilities to certain quality standards. In some respects, litigation is related to regulatory standards, as low quality of care (or, a prevalence of regulatory deficiencies) increases the risk of accidents that give rise to litigation.[87] Seemingly working in conjunction with regulatory enforcement, nursing home litigation spiked in the 1990s.[88] Previously, the legal system approached nursing home oversight legislatively; litigation was uncommon because of lack of access to civil representation for nursing home residents.[89] In the late 1990s, however, nursing home litigation became "one of the fastest-growing areas of health care litigation."[90]

Nursing home litigation does not speak directly to the existing regulatory structure, though it is certainly related. When a facility receives a regulatory citation, courts may find negligence under an expansive view of negligence per se, which is the "unexcused violation of a legislative enactment or an administrative regulation, which is designed to prevent injury to a class of persons of which the injured party is a member."[91] Statutory, regulatory, and common-law standards of care are closely related, though significant litigation also emerges from state resident rights laws and common-law causes of action.[92] Regardless of the source of claims, the interconnected roles of regulation and litigation are important to consider. On one hand, regulation frequently informs the standard of care to which nursing homes are held

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85. Marshall B. Kapp & Keren Brown Wilson, *Assisted Living and Negotiated Risk: Reconciling Protection and Autonomy*, 1 J. ETHICS L. & AGING 5, 8 (1995).

86. Lynch & Teachworth, *supra* note 23, at 4.

87. *See, e.g.*, David M. Studdert et al., *Relationship between Quality of Care and Negligence Litigation in Nursing Homes*, 364 N. ENGL. J. MED. 1243, 1249 (2011).

88. Stevenson & Studdert, *supra* note 43, at 219.

89. *Id.* ("This view holds that the elderly are not attractive clients to plaintiffs' attorneys, because the lack of associated economic losses makes the damages (and fees) recoverable for their injuries relatively small.").

90. *Id.*

91. Jennifer N. Phan, *The Graying of America: Protecting Nursing Home Residents by Allowing Regulatory and Criminal Statutes to Establish Standards of Care in Private Negligence Actions*, 2 HOUS. J. HEALTH L. & POL'Y 297, 312–13 (2002) (quoting Niece v. Emlview Group Home, 929 P.2d 420, 423 (1997)).

92. Stevenson & Studdert, *supra* note 43, at 221 (indicating that state statutes accounted for forty-nine percent of nursing home claims and common-law causes of action accounted for thirty-six percent).

in court.[93] On the other, litigation affects the role of law enforcers. The prevalence of litigation has made nursing home quality assurance a highly adversarial matter, and, as Professor Kane has explained, "the role of the regulatory agent has become exclusively external lest any efforts to offer suggestions for improving care compromise the potential for enforcement."[94]

However, policymakers have not been explicitly unfriendly to the Culture Change movement. Federal regulators have responded to Culture Change positively over the past decade.[95] In particular, CMS has produced multiple documents in support of Culture Change as a broad goal of long-term care.[96] At some level, then, the "face validity"[97] of Culture Change is being recognized by federal regulators. A few characteristics of the current legal landscape, however, continue to inhibit innovation toward quality-of-life improvements. First, the survey process remains highly adversarial because of the structure of quality assurance efforts.[98] CMS's recognition of the value of Culture Change is thus a step toward improvements in quality of life, but it does not fundamentally alter the terrain on which regulations takes place. Second, the safety of the resident has continued to quality-of-life considerations, making it less likely for nursing homes to innovate. The above discussion of the frictional intersection between regulation and Culture Change indicates an inherent uncertainty in quality-of-life standards. In the presence of such uncertainty, "the press for orthodoxy becomes most intense."[99] In practice, this has held true: A recent study identified several thousand non-adopters in 2004 and concluded that only 1.7% had implemented Culture Change by 2011.[100]

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93. Phan, *supra* note 91, at 317.

94. Kane, *supra* note 26, 232.

95. Rahman & Schnelle, *supra* note 16, at 143 (observing the intuitive rationality supporting certain components of Culture Change).

96. In 2006, for example, CMS released a new self-study tool emphasizing Culture Change — the Artifacts of Culture Change Tool — along with launching a new quality-improvement campaign that featured measures to improve resident-centered care. *Id.* at 144. In 2009, CMS further emphasized resident autonomy in its Interpretive Guidelines for nursing home surveyors. Grabowski et al., *supra* note 51, at S66.

97. Shier et al., *supra* note 68, at S16.

98. Kane, *supra* note 26, at 232.

99. *Id.* at 234.

100. Grabowski et al., *supra* note 51, at S72 (with implementation assessed by a team of Pioneer Network Directors and other Culture Change experts).

Still, that the Culture Change movement has gained significant traction in the long-term care community[101] indicates the potential for this philosophy to drive improvements in nursing-home care. Even without a facilitative regulatory atmosphere, the movement has encouraged greater consideration of quality of life, and facilities have begun to explore necessary risk management techniques in conjunction with expanding resident autonomy.

B. THE ROLE OF NEGOTIATED RISK AGREEMENTS IN LONG-TERM CARE

In addition to the philosophical approach embodied by the Culture Change movement, long-term care providers have adopted certain risk management tools to facilitate better quality of life. Specifically, assisted-living facilities have turned to NRAs in order to expand resident choice with an allocation of risk that is acceptable to both residents and providers. To date, NRAs have appeared almost exclusively in assisted living,[102] but a legal regime allowing this tool in nursing homes may allow for greater consideration of quality of life. This Part considers the current implementation of NRAs, followed by objections to their use in certain long-term care settings.

1. *Background on Negotiated Risk Agreements*

NRAs represent the product of a negotiation process between provider and resident that authorizes the resident to engage in behavior contrary to provider advice or policy.[103] Theoretically, provider reluctance to allow certain exercises of resident autono-

101. Susan C. Miller et al., *Culture Change Practice in U.S. Nursing Homes: Prevalence and Variation by State Medicaid Reimbursement Policies*, 54 GERONTOLOGIST 434 (2013) (reporting in a study of directors of nursing in skilled care, eighty-five percent of responders indicated some measure of Culture Change in their facilities).

102. *See, e.g.*, Joseph L. Bianculli & Keren Brown Wilson, *Negotiated Risk in Assisted Living: An AAHSA Technical Assistance Brief* (Am. Ass'n of Homes & Servs. for the Aging, Washington, D.C. 1996), at 1 (describing the term as "a buzzword specific to assisted living"). This Note uses the term "negotiated risk agreements" as synonymous with "managed risk agreements" and "shared responsibility agreements," terms used by some authors and lawmakers for the same concept.

103. *See, e.g.*, *id.* at 12 (describing negotiated risk as "a reasonably good process to deal with the exceptions to the service planning process for individuals who are moderately impaired, either cognitively, physically or medically").

my[104] can be addressed through documentation that the facility has met its duty of care through the negotiation process.[105] This contractual tool was developed for assisted living,[106] though its structure seems to offer nursing homes similar opportunities for managing risk.

NRAs were first developed in the 1990s, as assisted-living facilities sought to advance a social model of living for the elderly, including "privacy, independence, choice, and the maintenance of a normal lifestyle."[107] In 1995, one early article characterized the term as "the first buzzword unique to assisted living."[108] Of the 41 states with regulations governing assisted living, 14 states and the District of Columbia have some provisions pertaining specifically to NRAs or a similar risk allocation apparatus.[109] In the absence of national data regarding their implementation, some smaller scale surveys have indicated fairly infrequent use,[110] perhaps reflective of the fact that NRAs are meant to be drafted as an exception to normal care plans for long-term residents.[111]

There is no universally accepted definition of NRAs, a point of critique on the part of opponents.[112] In exploring regulatory interpretations of NRAs, one influential article identifies three perspectives for understanding this tool: contractual, procedural, and as a hybrid of contract and procedure.[113] The first concept views an NRA as an agreement that grants a resident permission to engage in conduct against the advice of the facility.[114] The final document is the focus of this conception. Some have identi-

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104. *See supra* Part I.

105. ROBERT JENKENS ET AL., A STUDY OF NEGOTIATED RISK AGREEMENTS IN ASSISTED LIVING: FINAL REPORT 1 (2006).

106. *See, e.g.*, Joseph L. Bianculli, *Negotiated Risk — An Operational Issue*, PROVIDER, Nov. 1995, at 32.

107. JENKENS ET AL., *supra* note 105, at iii.

108. Bianculli, *supra* note 106, at 32.

109. JENKENS ET AL., *supra* note 105, at iv.

110. *Id.* at 6.

111. *See, e.g.*, Wilkins, *supra* note 22, at 8 ("The negotiated risk agreement . . . should not be used for outlining the entire relationship between the resident and facility, but only used for exceptional circumstances where the facility determines that the desired resident choice is too risky.").

112. Carlson, *supra* note 53, at 287–88.

113. Lynch & Teachworth, *supra* note 23, at 5.

114. *Id.* (quoting Bruce Vignery & Zita Dresener, *Troubling Assisted Living Facility Issues: Negotiated Risk Agreements*, ELDER LAW FORUM, Nov.–Dec. 1995, at 10 ("Residents agree to absolve facilities of liability for injury that may result from their inability to provide some service or accommodation to protect them.")).

fied this conception as problematic, allowing for the characterization of NRAs as invalid exculpatory clauses;[115] rather than standing merely as liability waivers, NRAs are important largely for the exchange of information that takes place during the negotiation process.[116] This latter benefit lies at the center of the procedural conception.

Still, reducing liability remains a significant objective in the negotiation of such agreements. From the provider's perspective, however, the specific waiver of liability may be less important and less effective for protection than the procedural components of the negotiation process.[117] Aside from explicitly shielding a provider from civil liability, the NRA may be valuable for educational and, if need be, evidentiary purposes, allowing residents and decision-makers to understand the implications of their choices and documenting the process of discussion in a clear manner.[118]

2. *Critiques of Negotiated Risk Agreements*

To date, NRAs have not been implemented in nursing homes due to several inhibiting factors. Eric Carlson, a directing attorney with Justice in Aging (formerly known as the National Senior Citizens Law Center), has issued broad critiques of NRAs in assisted living.[119] According to Carlson, NRAs can be used in ways that exploit residents in favor of shielding providers from liability.[120] This argument identifies NRAs as a source of exploitation, as nursing homes may use NRAs to unfairly restrict residents from bringing meritorious negligence claims and to challenge

115. For a discussion of such critiques, see *infra* Part III.B.2.

116. *Id.*

117. *See, e.g.*, Lynch & Teachworth, *supra* note 23, at 10 (recognizing that the NRA may not be an enforceable contract). *See also* Wilkins, *supra* note 22, at 8 ("[T]he exchange might not be an absolute waiver of liability, but simply a shifting of a certain amount of liability or responsibility from the facility to the resident . . . .").

118. JENKENS ET AL., *supra* note 105, at ix ("Most experts agreed that the availability of a signed document recording formal discussions between the facility and the resident regarding risky choices . . . could be comparable in protection to a formal waiver of liability in the event of a law suit.").

119. Carlson, *supra* note 53, at 288 ("Assisted living law should be rewritten across the country to eliminate any mention of negotiated risk."). *See also* Eric M. Carlson, *Negotiating for Resident-Centered Care*, 10 MARQ. ELDER'S ADVISOR 21 (2008).

120. Carlson, *supra* note 53, at 288–89 ("Due to the term's vagueness and misuse, it can be used as justification for an inadequate quality of care. Negotiated risk endangers the health and safety of elderly assisted living residents across the country.").

regulatory sanctions.[121] Even if the facility is aware that an agreement is unenforceable on policy grounds, it may implement such a contract in order to discourage plaintiffs from bringing suit in the first place.[122] A related concern is the problem of facilities contracting out of the duty to provide necessary services to residents who sign NRAs.[123]

A further criticism emerges from the varying interpretations of NRAs among the states that recognize them. The statutory definition and implementation of NRAs lacks consistency, this argument asserts, because the states apply varying models in their NRA laws, such as: resolving disputes based on the resident's acceptance of risk; care planning with an emphasis on the acceptance of risk; care planning with limited references to risk; care planning to reduce probability of negative clinical outcomes; and consenting to lower levels of care.[124] Critics charge that experts similarly discuss NRAs in varying terms that complicate and confuse their implementation.[125] As discussed above, some advocates view NRAs as "empower[ing] resident[s] to exercise choice regarding service delivery," thereby contributing to the goals of resident-centered care.[126] On the other hand, critics view NRAs as a potential "Trojan horse," allowing providers to improperly shield themselves from liability, provide substandard care, and revoke residents' rights under the guise of autonomy and choice.[127]

These challenges to the implementation of NRAs are important, and any effective implementation in nursing homes would address the full range of difficulties that NRAs may present. One significant difficulty is exploitation of resident inexperience.[128] As indicated above, providers may attempt to block even meritorious cases simply by discouraging potential plaintiffs using NRAs. As a related matter, NRAs may be used in an overly

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121. *Id.* at 297.

122. *See generally* NATALIE M. DUVAL & CHARLES MOSELEY, NEGOTIATED RISK AGREEMENTS IN LONG-TERM SUPPORT SERVICES (2001).

123. *See, e.g.*, Carlson, *supra* note 53, at 295 ("Negotiated risk was proposed as a means for a facility to avoid liability for a lack of medical services and expertise, or for a relatively low level of supervision.").

124. *Id.* at 302.

125. *See, e.g.*, *id.* at 294.

126. Bianculli & Wilson, *supra* note 102, at 2.

127. Carlson, *supra* note 53, at 294.

128. *See, e.g.*, Bianculli & Wilson, *supra* note 102 (supporting NRA implementation but recognizing inherent bargaining power inequality between resident and provider).

broad manner, with facilities applying them in situations that merit changes in care plans or moves to different care settings.[129] This issue emerges when facilities diverge from the intended goals of NRAs; rather than specifically negotiating each party's responsibility regarding particular conduct, facilities may seek to use NRAs in a blanket fashion, effectively forcing residents to negotiate for aspects of care to which they would otherwise be entitled.[130] A central component of Carlson's critique relates to pre-existing resident rights. He asserts that residents should not have to negotiate for personalized care because such rights are already guaranteed by a federal regulation,[131] which states: "A resident has the right to . . . [r]eside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered."[132]

Perhaps the most controversial aspect of NRAs is the potential for them to include improper waivers of liability, rather than addressing specific deviations from resident care plans.[133] This concern of experts and lawmakers emerges from the aforementioned possibility for exploitation of residents. Carlson has argued in several articles that liability waivers in this context qualify as invalid exculpatory contracts and should draw the same "jaundiced eye" that courts have applied to such contracts in other contexts.[134] In line with this philosophy, Vermont, Delaware, New Jersey, and Washington specifically prohibit NRAs as liability waivers.[135] One assessment of NRAs summarized the limitation of this tool for shielding care providers: "Unless state laws are changed, the liability waivers won't insulate providers from negligence claims."[136]

If characterized as exculpatory contracts, NRAs might be assessed according to the standards set forth in *Tunkl v. Regents of University of California*,[137] the most commonly cited case for such contracts.[138] In that case, the California Supreme Court identi-

129. Wilkins, *supra* note 22, at 8.
130. Carlson, *supra* note 53, at 23.
131. *Id.*
132. 42 C.F.R. § 483.15(e)(1).
133. *See, e.g.*, Wilkins, *supra* note 22, at 12–13.
134. Carlson, *supra* note 53, at 325.
135. JENKENS ET AL., *supra* note 105, at 11.
136. DUVAL & MOSELEY, *supra* note 122, at 13.
137. 383 P.2d 441 (Cal. 1963).
138. Carlson, *supra* note 53, at 326.

fied a set of six factors that can justify a finding that an exculpatory clause is invalid on policy grounds:

> [1] It concerns a business of a type generally thought suitable for public regulation. [2] The party seeking exculpation is engaged in performing a service of great importance to the public, which is often a matter of practical necessity for some members of the public. [3] The party holds himself out as willing to perform this service for any member of the public who seeks it, or at least for any member coming within certain established standards. [4] As a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possesses a decisive advantage of bargaining strength against any member of the public who seeks his services. [5] In exercising a superior bargaining power the party confronts the public with a standardized adhesion contract of exculpation, and makes no provision whereby a purchaser may pay additional reasonable fees and obtain protection against negligence. [6] Finally, as a result of the transaction, the person or property of the purchaser is placed under the control of the seller, subject to the risk of carelessness by the seller or his agents.[139]

Given this set of factors, the observation that broad waivers of liability are unenforceable is justified — though, as the *Tunkl* Court acknowledged, case-by-case analysis would be required under this standard — but neither proponents nor opponents of this tool make claims to the contrary.[140] The *Tunkl* factors provide a strong indication that facilities cannot use NRAs wholesale and without active contributions from residents or advocates, an important limitation on the use of such contracts but not an absolute bar.

A final source of difficulty pertains to resident decision-making capacity.[141] Among the skilled-care community, this issue is distinctly important because of the portion of the resident population affected by cognitive impairment. In 2012, DHHS reported that 37.7 percent of all nursing home residents exhibit

139. *Tunkl*, 383 P.2d at 444–46.
140. JENKENS ET AL., *supra* note 105, at vi.
141. *See, e.g.*, *id.* at ix.

severe cognitive impairment, with another 25.7 percent showing moderate impairment.[142] However, formal determinations of decision-making capacity are rare.[143] While most states do offer the ability to transfer decision-making authority to a guardian via health care power of attorney documentation, most long-term care residents do not take these steps.[144] Alternatively, the courts can issue an order of guardianship on the basis of the resident's cognitive incapacitation.[145]

General practice among long-term care providers depends to a greater extent on informal determinations of incapacitation, as formal guardianship over long-term care residents is uncommon.[146] Here, a further tension emerges. Formal guardianship would afford all parties involved greater clarity regarding the legal status of any decision reached.[147] On the other hand, the displacement of guardianship is inherently a significant blow to personal autonomy for the resident, as legal decision-making capacity is perhaps the most significant formal manifestation of autonomy.[148] A potential solution would include the adoption of new quasi-guardianship standards for the elderly, allowing for a greater role for advocates without requiring findings of incapacity. Such a plan, however, would likely mark a paradigmatic change to elder advocacy and is outside the scope of this Note. For the purpose of assessing NRAs, though, it is important to note the sometimes-uncertain enforceability of agreements entered into by frail residents.

IV. LEGAL FACILITATION OF QUALITY-OF-LIFE IMPROVEMENTS

The previous Part should indicate some of the effect that the law has on nursing home care, in general, and resident autonomy within nursing homes, in particular. If legislators and regulators are to recognize the full value of resident autonomy in nursing

142. CTRS. FOR MEDICARE & MEDICAID SERVS., NURSING HOME DATA COMPENDIUM 2013, at 192 (10th ed. 2013).

143. JENKENS ET AL., *supra* note 105, at vii.

144. DUVAL & MOSELEY, *supra* note 122, at 9.

145. *Id.* ("Persons found to be lacking in capacity are stripped of the legal right to represent themselves in designated matters in some states").

146. *Id.* at 11.

147. Marshall B. Kapp, *Medical Decisionmaking for Older Adults in Institutional Settings: Is Beneficence Dead in an Age of Risk Management?*, 11 ISSUES L. & MED. 29, 33 (1995–1996).

148. *Id.*

homes and build consideration of quality of life into care models, several changes may be helpful. Part IV.A proceeds with a consideration of how the law might shift in supporting the Culture Change movement. Part IV.B will return to NRAs and examine their most beneficial role in nursing homes.

A. LEGAL DEVELOPMENTS TO BOLSTER CULTURE CHANGE

Culture Change in skilled-care facilities has evolved from proposal to (albeit still-developing) reality. In other words, "the 'culture change' train has left the station,"[149] even as researchers continue to gather evidence documenting the effectiveness of this philosophy toward resident satisfaction and quality of care.[150] Beyond widespread acceptance and approval of the movement by providers and long-term care experts, though, policymakers should view resident-centered care as a necessary component of the law governing skilled-care facilities, requiring a shift in how they understand quality-of-life measures within the regulatory structure.

Two potential avenues seem to exist for shifting the regulatory paradigm. First, enforcers might move away from the "intrusive regulatory climate" that currently exists[151] in favor of a more collaborative approach, using something akin to prosecutorial discretion. Such a shift in mindset may in turn result in explicit regulatory acknowledgment of Culture Change values, though the "aura of apprehension" among providers would likely remain until the letter of the law changed.[152] As a second possibility, CMS and state regulatory agencies could add further clarity to provisions regarding quality of life in instructions to enforcers, such as through changes to the SOM. Instead of merely recognizing a "challenge" posed to facilities regarding the development of quality of life while retaining high standards of medical care, regulators could foster a greater atmosphere for Culture Change innovation by clarifying the value of active resident-centered care measures.[153]

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149. Zimmerman et al., *supra* note 63, at S3.
150. Bishop & Stone, *supra* note 62, at S99.
151. Marshall B. Kapp, *Making Patient Safety and a "Homelike" Environment Compatible: A Challenge for Long Term Care Regulation*, 12 WIDENER L. REV. 227, 244 (2005).
152. *Id.*
153. Koren, *supra* note 15, at 316.

Because of widespread acceptance of Culture Change as valid — with support from both care providers and regulatory bodies like CMS — policy reform that would improve quality of life in nursing homes likely depends on both procedural and substantive developments. The SOM itself demonstrates the substantive differences in requirements that regulators apply for quality of care versus quality of life. F Tag 323, which documents a variety of quality-of-care requirements to minimize the risk of accident, occupies 30 pages of the SOM and includes complete discussions of hazards, interventions, and investigative protocol for surveyors.[154] F Tag 240, which prompts surveyors to consider quality-of-life measures, is three sentences of the 731-page SOM.[155] While some variation is likely necessary — F Tag 323 includes some quite technical discussions of safety standards — in its current form, the SOM places inappropriate emphasis of quality of care over quality of life.

A simple initial step in policy reform would be the inclusion of specific guidelines for quality of life in the SOM. One challenge to this change is that quality of life measures are necessarily less specific than clinical care standards. Thus, while F Tag 323 can include water temperature requirements, it may be that no substantive equivalent is appropriate for F Tag 240. Still, the SOM (at least nominally) already acknowledges resident choice in other sections.[156] The current quality of life provision fails in two ways: First, it fails to provide facilities with almost *any* direction regarding quality of life, as it does so extensively for quality of care. F Tag 241 provides several examples of proper appreciation for resident dignity;[157] without requiring an exhaustive list, the SOM might include some examples of practices or principles in support of quality of life. Second, the SOM fails to provide surveyors with any procedure for assessing quality of life at each facility, whereas, for example, F Tag 309 ("Quality of Care") does include such instructions despite being a similarly broad re-

154. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 78.

155. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 76.

156. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app. F279 (2015) (requiring surveyors to "[c]orroborate information regarding the resident's goals and wishes for treatment in [his or her care] plan by interviewing residents. . . .").

157. CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app. F241 (2015).

quirement for care providers.[158] Building more quality-of-life content into the SOM would mark an important initial step in the reform process.

In addition, regulators must seek a fundamental shift in approach to the survey process, away from the adversarial quality that exists today. The safety standards are, of course, sensible as a set of protections for a highly vulnerable population. When regulators target facilities through aggressive enforcement, however, they impute a level of sterility that turns long-term care facilities into hospitals by another name.[159] The adversarial surveying model may be effective for the worst actors, but those facilities at the other end of the spectrum — those seeking to improve the homelike qualities of nursing homes — must face the same lack of cooperation from surveyors.[160] This leads to an atmosphere in which experimentation, a necessity if Culture Change is to move forward, is impossible.

In light of Professor Kane's argument on the relationship between regulators and litigation,[161] progress in nursing home regulation would include a reduced emphasis on litigation. Studies indicate that nursing home litigation is relatively ineffective at improving nursing home quality.[162] In response, reform in support of Culture Change might seek to de-emphasize litigation both directly — by further specifying quality of life considerations within the duty of care owed to residents — and indirectly — such as through approval of such tools as NRAs.

Challenging the effectiveness of nursing home litigation does not imply that such suits always lack merit. Lack of access to the courtroom may still be a problem, and, in fact, the frequency of

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158. CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app. F309 (2015).

159. *See* STONE ET AL., *supra* note 25.

160. *See, e.g.*, Walshe, *supra* note 84 (describing reformers' assertions that "regulation should be simplified and reduced, focusing mainly on a smaller number of 'problem' nursing homes"). One possibility for this type of reform is to allow nursing homes to achieve "deemed status," under which a facility would be considered compliant without further surveys for a longer period. The IOM report rejected "deemed status" for nursing homes. COMM. ON IMPROVING QUALITY IN LONG-TERM CARE, INST. OF MEDICINE, IMPROVING THE QUALITY OF LONG-TERM CARE 178 (2001). Still, as certain nursing homes adopt innovative and beneficial care practices, reconsideration of "deemed status" for nursing homes may be appropriate.

161. *See* Part II.A.

162. *See, e.g.*, Studdert et al., *supra* note 87, at 1243 ("The best-performing nursing homes are sued only marginally less than the worst-performing ones. Such weak discrimination may subvert the capacity of litigation to provide incentives to deliver safer care.").

litigation dropped in the first half of the 2000s (although expenses are still significant).[163] Still, a litigious atmosphere may not contribute to positive developments in nursing home care, as litigation creates the same disincentives to Culture Change as do stringent regulations. Considering the lack of a significant relationship between litigation and quality, reform in this area is appropriate, and some of observed that the distinct qualities of long-term care litigation may make broad-based tort reform ineffective for addressing the issue of excessive liability for nursing homes.[164] While a full consideration of litigation reform is outside the scope of this Note, recognizing the role of litigation in limiting nursing home innovation is important for structuring regulations and enforcement practices.

B. IMPLEMENTATION OF NEGOTIATED RISK AGREEMENTS FOR IMPROVING QUALITY OF LIFE

NRAs might feature significantly in the aforementioned changes to nursing home regulation. The panoply of challenges to the adoption of NRAs in long-term care (including both assisted living and skilled care) indicates that this tool requires further consideration regarding its construction, but this should not prevent federal policymakers from utilizing the tool at all. Rather, the above discussion can inform effective federal regulation of NRAs in nursing homes. As stated, one of the central critiques of NRAs in assisted living is the lack of a uniform definition and interpretation of NRAs by the various states that regulate them. A federal standard would remedy this potential source of difficulty, and, as discussed, nursing homes are far more suitable for federal regulation than are assisted-living facilities.

Effective federal regulation must positively define the scope, contents, and implementation process of NRAs with a high level of clarity. A federal standard might build on the similarities that many NRAs already demonstrate (as not every instantiation of this device is entirely unique and inconsistent with others).[165] Several states currently require six components as part of valid NRAs: (1) a clear description of the service at issue; (2) a description of the choices made available to the resident; (3) a descrip-

163. *Id.* at 1245.
164. *See* Studdert & Stevenson, *supra* note 33, at 591–93.
165. Lynch & Teachworth, *supra* note 23, at 11.

tion of the risks and benefits involved in each option; (4) a description of the resident's choice; (5) identification of the option agreed upon by the parties; and (6) a description of each party's responsibilities.[166] Commentators have provided several additional components from a normative viewpoint.[167]

To be effective, this model must address or work within each of the concerns and constraints discussed in the previous Part. Resident exploitation, for example, is vital for regulators to consider, though the proper checks can help ensure that providers do not use NRAs for the wrong reasons. In particular, the scope of NRAs must be limited to specific deviations from pre-established care plans,[168] which federal regulation can and should describe. In addition, federal regulation would answer the substantial concern of critics regarding inconsistencies in how NRAs are defined; rather, a single standard would clarify each party's rights and responsibilities using this type of contract.

The application of a federal standard for NRAs in nursing homes must also address the issues of avoiding the provision of service and contracting with legally capable parties. Each of these concerns is distinct for skilled-care providers as compared to assisted-living facilities. The first concern appears to be a non-issue in nursing homes, as facilities *cannot* contract out of the provision of medical care that is required by the federal regulations,[169] whereas assisted living is defined by the presence of a spectrum of service levels.[170]

The second matter — legal capacity for decision-making — is distinct for skilled care as well, though in the opposite direction.

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166. *Id.* at 17. The jurisdictions that require these features include Delaware, the District of Columbia, Illinois, Kansas, New Jersey, Oregon, and Wisconsin. *Id.* at 17 & 28 n.116.

167. *See, e.g.*, DUVAL & MOSELEY, *supra* note 122, at 14–17 (identifying eleven suggestions for NRA components, including, without limitation: a statement of perspective from the resident's support term; acknowledgment that the resident understands the risks and alternatives; sunset provisions; and interim review requirements based on circumstantial changes). For a list of enforceability assessments based on policy considerations, contract law, and torts, see Lynch & Teachworth, *supra* note 23.

168. *See, e.g.*, Bianculli & Wilson, *supra* note 102, at 15 (suggesting the implementation of NRAs only in exceptional cases).

169. DUVAL & MOSELEY, *supra* note 122, at 12 ("Providers cannot use a negotiated risk contract to escape state health and safety prohibitions. By extension, courts may not permit providers to absolve themselves of liability for negligence when the standard of care arises from licensing regulations.").

170. Carlson, *supra* note 119, at 32 ("Under flexible regulations, a facility has significant discretion over the services it will provide and the care practices that it will follow.").

Whereas assisted living tends to serve more capable residents, skilled care is defined by the frailty of its consumers.[171] Rather than rendering skilled-care NRAs categorically unenforceable and useless, two possibilities exist for integrating NRAs into the existing regulatory framework for nursing homes. First, regulators might recognize the negotiation process as an outgrowth of care planning. Under the current SOM, facilities must develop care plans with significant participation from the resident and the resident's family.[172] F Tag 280 guarantees the resident the right to participate in care planning and treatment.[173] To assess this process, surveyors ask, among other questions, whether the facility "attempt[s] to make the process understandable to the resident/family."[174] An effective NRA structure could mirror the features of the current care planning process but with greater specificity for instances in which residents seek to deviate from recommended care measures. The same level of participation is already allowed for residents in developing care plans; an NRA provision would include specific steps for facilities when residents desire to depart from the established plan.

A second possibility for regulators would be to add competence requirements before allowing residents to enter into NRAs. The current care plan model allows resident participation "unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State."[175] Durable power of attorney, however, is fairly uncommon and includes significant judicial barriers.[176] As commentators have noted, informal arrangements are most common in this setting, but they do not offer legal protection for facilities.[177] Carlson and others recognize the potential for exploitation when contracting with a cognitively impaired resident, and federal regulators could emphasize the need for legal capacity before allowing skilled-care facilities to enter NRAs with residents. With this added requirement — perhaps with greater enforcement than the current care plan requirement of competence

171. *See, e.g.*, Lynch & Teachworth, *supra* note 23, at 4.
172. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL apps. F279–F282 (2015).
173. CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app. F280 (2015).
174. *Id.*
175. *Id.*
176. *See, e.g.*, DUVAL & MOSELEY, *supra* note 122, at 10.
177. *Id.* at 11.

— residents might also be more likely to produce end-of-life documents, facilitating greater clarity beyond the scope of this Note's proposals.

Finally, federal regulators should explicitly prohibit broad waivers, allowing either highly narrow liability releases or doing away with such waivers entirely. The *Tunkl* factors and other conceptions of improper exculpatory contracts clearly encompass NRAs that include broad waivers of liability protecting care providers.[178] The value of NRAs, however, is not constrained to the availability of such a waiver; rather, the procedural components of this tool should allow the facility to achieve some security in pursuing resident-centered practices.[179] To harness this value, an effective federal standard would emphasize the educational and evidentiary benefits of NRAs, conforming to the procedural characterization of NRAs rather than to the contractual characterization.

With such a construction, NRAs could help facilitate quality of life improvements in multiple ways. Most directly, facilities and residents could tap their potential for expanding autonomy with reduced fear of sanction or suit. Because of this reduction, front-end quality assurance — achieved through the procedure of negotiating these agreements — could reduce the impact of litigation. Without exaggerating the potential for NRAs to shift risk prevention measures entirely, this could also facilitate a greater collaborative role for regulators, if litigation occupies a smaller role in attempts to maintain care standards.

V. CONCLUSION

The objective of this Note has been to review the effects of regulation on quality of life and Culture Change in nursing homes, and also to introduce some new considerations for facilitating resident-centered care through law and regulation. In continuing to regulate nursing homes heavily, federal and state policymakers must add methods for encouraging quality-of-life measures, in addition to the significant existing body of quality-of-care regulations.[180] NRAs have the potential for encouraging

178. Carlson, *supra* note 53, at 326.

179. JENKENS ET AL., *supra* note 105, at 9.

180. CMS has already taken some other steps in this direction, focusing to a greater extent on resident satisfaction in facility assessments and encouraging organizational

the proliferation of resident-centered care practices, though this tool will only be effective if accompanied by shifts in the regulatory approach to quality-of-life matters.[181] Ingraining Culture Change into the law is a difficult challenge for policymakers, given the historical need for standards focusing on medical care, but such a development is necessary if this country's millions of older people are to maintain high quality of life into their later years. Such a project will require input from policymakers, providers, and regulatory enforcers, and it will require emphasis on effectively balancing clinical care standards and the components of quality of life.

Of course, a diverse set of further considerations remain as policymakers and providers seek to improve skilled-care models. One factor that demands further consideration from the long-term care community is the manner in which Culture Change can be spread from early adopters to less innovative facilities.[182] Because Culture Change involves a high level of organizational competency,[183] predicate steps are necessary for ensuring organizational improvement before low-quality homes adopt Culture Change measures.[184] In addition to questions of how to set facilities up for improving resident-centered care, more research is necessary in order to understand the full effects of Culture Change (for both quality of life and quality of care) before policymakers can develop sound standards for implementing it.[185] Specifically, the research is as yet underdeveloped in terms of particular measures to implement Culture Change.[186] Recent reviews of the existing literature have emphasized the need for clear evidence regarding specific Culture Change measures,[187] though the

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transformation through the Eighth Statement of Work. Bishop & Stone, *supra* note 62, at S98.

181. Koren, *supra* note 15, at 316 (emphasizing the need for a "policy environment conducive to innovation" for Culture Change to spread).

182. For a study on the factors that make a facility more likely to adopt Culture Change, see Grabowski et al., *supra* note 51.

183. *Id.* at S72 ("At baseline, nursing homes implementing culture change had fewer health-related survey deficiencies, more nurse aides (NAs), and a lower debt relative to assets.").

184. *Id.* at S73.

185. *See, e.g.*, Bishop & Stone, *supra* note 62, at S99 (2014) ("[T]he evidence base about culture change . . . cannot yet be used to choose the most effective practices from a culture change toolbox . . . .").

186. Shier et al., *supra* note 68, at S7.

187. *Id.*

policy changes discussed here can help to develop a more innovative atmosphere as a whole.

Perhaps the most significant hurdle is the matter of funding. Examining Culture Change across the various states, studies indicate that states with higher Medicaid reimbursement rates have better scores based on quality-of-life factors.[188] Commentators have intuitively and statistically concluded that funding is directly connected with facility quality, with one scholar going so far as to say that "[p]erhaps the greatest obstacle to the quality improvement approach is that . . . favored strategies call for substantial investments."[189] To date, Culture Change has largely been confined to facilities that already perform well;[190] even with the proposed reforms to regulatory approach and, specifically, to NRAs within skilled care, increased funding will likely be necessary for spreading the benefits of resident-centered care.

The question of funding returns to the specific content of Culture Change practices, which is beyond the scope of this Note. Instead, this Note seeks to emphasize the role of the law (through legislation, regulation, and civil suits) in supporting improvements in resident autonomy and quality of life in nursing homes. The 1987 reforms recognized that the purely medical model was far outdated. Today, however, safety continues to outstrip resident choice because of the overly cautious atmosphere created by stringent regulations and frequent litigation. Legal reforms facilitating Culture Change and exploring specific measures for collaboration between residents and facilities can produce an environment in which residents retain appropriate levels of autonomy as they age.

188. Miller et al., *supra* note 101, at 443.
189. Stevenson & Studdert, *supra* note 43, at 227.
190. Carlson, *supra* note 53, at 49.