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Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Got to Do with It

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Quality of Care and Quality of Life in Nursing Facilities: What’s Regulation Got to Do with It?

Marshall B. Kapp

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I. INTRODUCTION

Religion is mainly an issue of faith. Sound public policy, by contrast, ought to be based on evidence regarding the likely impact of particular governmental actions on the actual lives and well-being of the intended beneficiaries and others affected by such policy. In large part, the environment of pervasive, comprehensive regulation, within which the nursing facility (NF) industry presently operates in the United States, has evolved steadily over the past quarter century as a matter of

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1. Regarding the regulatory environment surrounding the nursing facility industry, see infra Part II. One nationally prominent geriatrician has noted that “[t]he role of regulation and external monitoring is more stringent in nursing home care than in any other type of social service.” Robert L. Kane, Assuring Quality in Nursing Home Care, 46 J. AM. GERIATRICS SOC'Y 232, 232 (1998).

2. In this Article, the terminology nursing facility (NF) is used to match the language employed in the pertinent Medicaid statute, 42 U.S.C.A. § 1396 (West Supp. 1999), and federal regulations. Medicare covers only skilled nursing facilities (SNFs), 42 U.S.C.A. § 1395 (West Supp. 1999).

a political, almost quasi-religious, belief. This belief, by residents’ advocates and their legislative and regulatory allies, has been prodded on and abetted by the popular media. This commitment to direct command and control regulation, as the key to quality of care and quality of life, is often fueled by an ideological fervor predicated on deep and abiding antipathy for any approach to public policy questions faintly sympathetic to a substantial role for free enterprise and the private marketplace in the delivery of health and human services. This Article suggests that, in fact, current and future nursing home residents may best be served by examining the value of regulation with an attitude of healthy skepticism, rather than automatically assuming regulation’s superiority to other potential approaches that are aimed at the same ultimate goals.

Specifically, this Article selectively reviews the relatively sparse, but nevertheless helpful, literature that examines the impact of NF regulation. This search is conducted to identify proof or disproof that such regulation, in practice, has a positive impact on those it is intended to benefit. In this Article, the regulatory approach is subjected to the developing analytic lens of “therapeutic jurisprudence,” which, in other contexts, has asked whether legal “reforms” truly help or hurt when all relevant factors are taken into account. This Article will concentrate on the effects of micro-regulation, that is, statutes and administrative rules that directly attempt to impose precise requirements on particular facets of the quality of care and quality of life for NF residents. Macro concerns about how

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4. Regarding the popular media’s overwhelmingly pro-regulatory bias see, for example, They Didn’t Live So Long for This, N.Y. TIMES, Apr. 26, 1999, at A20 (arguing that “[t]here are signs that the Medicaid and Medicare authorities are beginning to clamp down on nursing home performance, ... [toward a better end].”).

5. See, e.g., Toby S. Edelman, The Politics of Long-Term Care at the Federal Level and Implications for Quality, GENERATIONS, Winter 1997-1998, at 37, 37 (railing against the nursing facility “industry’s ability to exploit the political climate of deregulation and deficit reduction to further its long-standing interest in decreasing public oversight and enforcement”); Iris C. Freeman, Nursing Home Politics at the State Level and Implications for Quality: The Minnesota Example, GENERATIONS, Winter 1997-1998, at 44, 48 (lamenting that, in terms of current nursing facility politics, “[t]he dollar issues dominate. Enforcement is in limbo, and, when all is said and done, the state may prefer to leave nursing home quality to a new stratum of fiscal intermediaries—the managed care organizations whom the state will pay to pay nursing homes.”); Joani Latimer, The Essential Role of Regulation to Assure Quality in Long-Term Care, GENERATIONS, Winter 1997-1998, at 10, 10 (arguing that “[i]n this case [nursing home quality assurance], ... the market mechanism does not fit”).

6. Regarding therapeutic jurisprudence, see generally infra notes 48-77 and accompanying text.

7. Command and control regulation should be contrasted with regulation intended to financially motivate providers to take action to improve the quality of care they provide by linking payment amounts to measured resident outcomes. See Kane, supra note 1, at 232 (arguing that command and control regulation deals with structural and process questions, while regulatory incentives aim at the important goal of improving outcomes); Robert L. Kane, Improving the Quality of Long-Term Care, 273 JAMA 1376 (1995) (arguing that the traditional regulatory approach concentrates on avoiding catastrophes, while an approach that rewards desired outcomes can achieve a positive good); U.S. DEP’T OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION, STUDY OF PRIVATE ACCREDITATION OF NURSING HOMES, REGULATORY INCENTIVES AND NON-REGULATORY INCENTIVES, AND EFFECTIVENESS OF THE SURVEY AND CERTIFICATION SYSTEM (visited July 21, 1998) <http://www.hcfa.gov/medicaid/execvt2.htm> [hereinafter HCPA] (reviewing research linking payment to improved resident outcomes) (copy on file with McGeorge Law Review). Other than incidentally, this Article does not deal with the very important subject of such financial incentives.
regulatory or marketplace\textsuperscript{8} approaches might reform the larger system of long term care financing and delivery\textsuperscript{9} for the better are beyond the scope\textsuperscript{10} of this Article.\textsuperscript{11}

8. Regarding marketplace approaches to reform of the larger long term care system, see Marshall B. Kapp, \textit{Health Care in the Marketplace: Implications for Decisionally Impaired Consumers and Their Surrogates and Advocates}, 24 S. Ill. U. L.J. 1 (1999) (arguing that, among other reasons for enhancing the degree of consumer choice and control in long term care, this will have a positive effect on the quality of services provided).

9. For example, how these approaches might discourage NF placement in favor of home and community-based services, or how they might make long term care more affordable for consumers. \textit{Cf. U.S. DEPT' OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, EARLY EFFECTS OF THE PROSPECTIVE PAYMENTS SYSTEM ON ACCESS TO SKILLED NURSING FACILITIES} (1999) (assessing whether the prospective payment system initiated in 1998 for skilled nursing facilities is causing access problems for Medicare beneficiaries).

10. A thorough examination of private accreditation initiatives in the realm of NF quality assurance is also left to others. \textit{See joint comm'n on accreditation of healthcare organizations, comprehensive accreditation manual for long-term care} (1999) [hereinafter JCAHO MANUAL]. Further, while acknowledging that regulation and litigation frequently are complementary rather than alternative strategies for achieving quality assurance and residents' rights protection objectives, this Article abstains from a careful exegesis of the complicated subjects of tort and contract law and the impact of civil litigation on the well-being of its intended beneficiaries in the NF context. Regarding tort actions in the NF context, see generally Marshall B. Kapp, \textit{Malpractice Liability in Long-Term Care: A Changing Environment}, 24 CREIGHTON L. REV. 1235 (1991) (discussing areas of potential NF liability). Regarding the therapeutic jurisprudence implications of tort law see, for example, Daniel W. Shuman, \textit{The Psychology of Deterrence in Tort Law}, 42 U. KAN. L. REV. 115 (1993) (discussing the prevailing theories of human behavior and analyzing whether tort law deterrence theory is in accord with any of these theories of human behavior); Daniel W. Shuman, \textit{Making the World a Better Place Through Tort Law?: Through the Therapeutic Looking Glass}, 10 N.Y.L. SCH. J. HUM. RTS. 739 (1993) (exploring tort law’s therapeutically driven agenda); Daniel W. Shuman, \textit{Therapeutic Jurisprudence and Tort Law: A Limited Subjective Standard of Care}, 46 SMU L. REV. 409 (1992) (exploring the therapeutic potential of tort law in light of the relationship between mental or emotional problems and accident causation). Regarding contract actions in the NF context, see generally Maureen Armour, \textit{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 (1994). For a look at the impact of civil litigation in the NF context, see generally \textit{nursing home litigation: investigation and case preparation} (Patricia W. Iyer ed., 1999) (educating plaintiffs' attorneys on how to sue nursing facilities). Fear of litigation, as well as of regulatory sanctions, has motivated many NFs to put into place internal risk management programs. \textit{See generally ANDREW D. WEINBERG, RISK MANAGEMENT IN LONG-TERM CARE: A QUICK REFERENCE GUIDE} (1998) (educating nursing home administration and staff how to reduce their likelihood of being sued and held legally liable). The actual impact of such risk management efforts on resident quality of care and quality of life has not been formally evaluated. \textit{See infra} note 107 and accompanying text (setting forth a suggestion that risk management programs may actually work in opposition to the free exercise of residents' rights); \textit{see also Jennifer L. Williamson}, \textit{The Siren Sound of the Elderly: Florida's Nursing Homes and the Dark Side of Chapter 400}, 25 AM. J.L. & MED. 423 (1999) (pointing out other dangers engendered by a climate that allows excessive private litigation against nursing facilities).

II. NURSING FACILITY REGULATION

A. Sources of Regulation

Regulation of the NF industry and the accompanying advocacy network aimed at improving the quality of care and quality of life (including respect for personal rights) for residents are, to grossly understate the situation, multifaceted. The regulatory octopus includes voluntary forms of accreditation dispensed by private agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), internal and external utilization review (UR), quality assurance (QA) mechanisms, malpractice lawsuits based on tortious behavior or breach of contract, and the threat of criminal prosecution. Mandates of the Americans With Disabilities Act and the Rehabilitation Act regarding affirmative obligations to accommodate the disabled are fully applicable to NFs as well.

The most significant influence on provider behavior, and the one on which this Article concentrates, is exerted by mandatory conditions set forth by the federal Department of Health and Human Services (DHHS) through the Health Care Financing Administration (HCFA). The DHHS oversees all NFs that wish to be certified to participate in the Medicare and Medicaid programs. Enforcement of mandatory standards occurs through regular survey and certification by a state administrative agency (usually the state health department) that has been designated by contract between the specific state and the federal government. HCFA provides

14. This author first used this image in 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, 30 (1995).
15. JCAHO MANUAL, supra note 10. Regarding the potential for the federal government approving "deemed status" for the JCAHO or other private accrediting bodies for NFs (i.e., treating that organization’s approval of a NF as sufficient to satisfy Medicare/Medicaid certification standards for Medicare/Medicaid certification purposes), see 58 Fed. Reg. 61816, 61837-61843 (1993); HCFA, supra note 7, at 6-16; see also GENERAL ACCOUNTING OFFICE, GAO/HEHS-99-197R, SELECTION OF MEDICARE DEEMING ORGANIZATIONS (1999) (identifying HCFA’s criteria for granting deemed status to voluntary accrediting bodies and its process for providing ongoing oversight).
20. Id. § 1396.
21. Such a survey must be conducted no less often than once every 15 months at each NF.
the state survey agency with interpretive guidelines, compiled in the Medicaid State Operations Manual,22 and a form for use during NF surveys.23 Frequently, state surveys examine NFs for compliance with both the federal certification standards and state licensure requirements. Violation of federal standards may lead to decertification of the NF from participation in Medicare or Medicaid financing. Moreover, HCFA is empowered under the "look behind" statute24 to conduct its own validation surveys of NFs and to terminate a NF's participation in the Medicaid program despite findings of compliance by the state survey agency.

In addition, failure to fulfill state imposed licensure requirements,25 which are allowed to be more, but not less, demanding than federal standards,26 may result in serious penalties short of decertification. In addition to delicensure from conducting business altogether, sanctions may include a range of intermediate interventions including civil fines, and restrictions on admissions or receivership.

As part of the Omnibus Budget Reconciliation Act of 1987 (hereinafter OBRA 87),27 Congress enacted the Nursing Home Quality Reform Act.28 This Act is modeled on many of the recommendations made in a 1986 Institute of Medicine report that Congress had directed HCFA to commission.29 Passage of the 1987 legislation demonstrated the impatience of Congress and the courts30 with what they
and the public perceived as HCFA's ineffectual regulation of NFs. OBRA 87 amended Titles 18 (Medicare) and 19 (Medicaid) of the Social Security Act to require substantial upgrading in NF quality and enforcement in a number of areas.

To implement this legislation, HCFA published final regulations on February 2, 1989, becoming effective on October 1, 1990. Additional final regulations were published on September 26, 1991. Among the most important requirements imposed by these regulations are those relating to: ensuring resident privacy and decisional rights regarding accommodations, medical treatment, personal care, visits, written and telephone communications, and meetings with others; maintaining confidentiality of personal and clinical records; guaranteeing facility access and visitation rights to persons of the resident's choosing; requiring issuance of notice of rights at the time of admission; ensuring proper use of physical restraints and psychoactive drugs; protecting resident funds being managed in the facility; ensuring transfer and discharge rights, and issuing related notices; requiring minimum staffing levels regarding nursing and social work coverage; requiring comprehensive resident assessments and individualized care plans drawn in accordance with those assessments; requiring state prescreening of all prospective NF admittees; and prohibiting admission of individuals with mental illness or mental retardation unless those individuals are found specifically to need nursing services.

In 1994, HCFA published a final rule governing survey, certification and enforcement of Requirements of Participation for Medicare SNFs and Medicaid

31. The IOM report and resulting legislation and regulation emanated from an atmosphere of highly publicized scandals regarding the atrocious quality of care discovered in many NFs. See generally BRUCE C. VLADEK, UNLOVING CARE (1980) (condemning conditions in most nursing facilities at that time). For a description of the historical background leading to enactment of OBRA 87 and promulgation of implementing regulations see, for example, HCFA, supra note 7, at 1-2; Mary Kathleen Robbins, Nursing Home Reform: Objective Regulation or Subjective Decisions? 11 T.M. COOLEY L. REV. 185, 186-91 (1994); Rebecca Elon & L. Gregory Pawson, The Impact of OBRA on Medical Practice Within Nursing Facilities, 40 J. AM. GERIATRICS SOC'Y 958, 959 (1992).


35. Id. § 483.10(e)(2).

36. Id. § 483.10(k).

37. Id. § 483.10(b).

38. Id. § 483.13(a); see also infra notes 129-48 and accompanying text.


40. Id. § 483.12(a).

41. Id. § 483.15(g).

42. Id. § 483.20(d); see also infra notes 84-93 and accompanying text.


44. 42 C.F.R. § 483.20(f) (2000); see also infra notes 149-60 and accompanying text.
This rule, which became effective July 1, 1995, made significant changes to the survey and certification process and describes the intermediate sanctions that states and the federal government have available to respond to facilities that do not meet federal standards. On March 18, 1999, HCFA published a final rule (with a comment period) that gives states and HCFA new authority to impose civil money penalties in the event of noncompliance.

As this Article is being prepared, the federal appetite for new NF regulations continues unsatiated. For example, on March 25, 1999, President Clinton signed into law the Nursing Home Resident Protection Amendments, which, among other items, protect NF residents from eviction when an NF voluntarily withdraws from participation in the Medicaid program.

B. Therapeutic Jurisprudence Analysis

Many factors, such as ownership type, facility size, mix of payment sources, annual expenditures, and the vagaries of the local labor market, operating singly or in combination, may affect any NF's quality of care. In this Article, however, the variable of interest is the existing set of applicable command and control regulations governing the NF's daily operation. The analytic model through which this variable is examined is that of "therapeutic jurisprudence" (hereinafter referred to as "TJ").

The National Citizens' Coalition on Nursing Home Reform (NCCNHR) has correctly insisted that "the regulatory system should be focused on what we do for the residents who live in nursing homes, not about what we do to providers." Geriatrician Robert Kane observes:

47. See also Charles Grassley, The Resurrection of Nursing Home Reform: A Historical Account of the Recent Revival of the Quality of Care Standards for Long-Term Care Facilities Established in the Omnibus Reconciliation Act of 1987, 7 ELDER L. J. 267, 267 (1999) (explaining that the Chair of the Senate Special Committee on Aging believes new legal initiatives may be necessary to assure that Congressional intent regarding quality of care is carried out). The states' appetite for more expansive NF regulation also continues unabated. See Amy Pyle & Dan Morain, Sweeping Reforms in Nursing Care OK'd, L.A. TIMES, Sept. 9, 1999, at A3 (describing a 1999 California statute).
49. Memorandum from Sarah Greene Burger, Executive Director, The National Citizens' Coalition for Nursing Home Reform to Karen Schoeneman, HCFA (March 12, 1999) (on file with the McGeorge Law Review); see also Charlene Harrington et al., Stakeholders' Opinions Regarding Important Measures of Nursing Home Quality for Consumers, 14 AM. J. MED. QUAL. 124 (1999) (providing that nursing home advocates, administrators, regulators, ombudsmen, and nursing service directors all agree that quality of care and quality of life are the most important yardsticks against which to measure how well nursing facilities are doing their job).
In an area like long-term care, where so little is established about the relationship between process and outcomes, there is a strong argument for concentrating regulatory activities on assuring that satisfactory outcomes are achieved. Such a philosophy is at odds with practice. Often when uncertainty about the best path to follow is greatest, the press for orthodoxy becomes most intense.  

The concept of therapeutic jurisprudence aims to upset that orthodoxy.

In its simplest terms, TJ is a mode of recognizing that every law is an experiment of sorts and insisting that proponents of particular legal interventions, to paraphrase a popular motion picture of the late 1990's, "show us the empirical results." Over a century ago, Henry Ward Beecher remarked that, "[i]t usually takes a hundred years to make a law, and then after it has done its work, it usually takes a hundred years to get rid of it."

As described by Professor David Wexler, one of the original developers—along with Professor Bruce Winick—of the rapidly expanding modern version of the notion that laws' effectiveness should not be taken for granted:

The therapeutic jurisprudence perspective suggests that the law itself can be seen to function as a kind of therapist or therapeutic agent. Legal rules, legal procedures, and the roles of legal actors . . . constitute social forces that, like it or not, often produce therapeutic or antitherapeutic consequences. Therapeutic jurisprudence proposes that we be sensitive to those consequences, rather than ignore them, and that we ask whether the law's antitherapeutic consequences can be reduced, and its therapeutic consequences enhanced . . . .

In other words, TJ "is an interdisciplinary approach to law that builds on the basic insight that law is a social force that has inevitable (if unintended)
consequences for the ... health and ... functioning of those it affects." 57 It embodies an attitude toward the law of legal pragmatism or realism. 58 Although originating specifically in the mental health field, 59 TJ has been expanded vigorously beyond that arena, 60 and there is no good reason why it should not be employed to analyze the law as it affects older persons generally, and NF residents specifically. Indeed, the National Academy of Sciences’ Institute of Medicine, in 1997, established an expert committee to examine the means for assessing, overseeing, and improving the quality of long term care and the practical and policy challenges of achieving a consistent quality of care. Among the questions assigned to this study were:

What is known about the impact of long-term care regulation, especially the Nursing Home Reform Act of 1987, on such matters as: the use of physical and chemical restraints; advance care planning; provision of adequate nutrition; identification of substandard facilities or programs; and public access to information on quality of care? 61

TJ is an “enterprise designed to produce scholarship that is particularly useful for law reform." 62 As the author of this Article suggests elsewhere, “[p]ublic policy making for the elderly ought to be a continuous, iterative process for which improvement in content depends (or ought to depend) on accurate feedback in response to these kinds of inquiry." 63 There are several cogent arguments for pursuing this practical, utilitarian enterprise in the arena of NF regulation.

58. For a modern description of the pragmatic approach to law making, see generally RICHARD A. POSNER, OVERCOMING LAW 4-7 (1995). For a discussion of how TJ relates to other reputable schools of legal analysis, see Bruce J. Winick, The Jurisprudence of Therapeutic Jurisprudence, 3 PSYCHOL., PUB. POL’Y, & L. 184 (1997).
60. See generally LAW IN A THERAPEUTIC KEY: DEVELOPMENTS IN THERAPEUTIC JURISPRUDENCE (David B. Wexler & Bruce J. Winick eds. 1996).
First, in sharp contrast to the prevailing mentality when the Institute of Medicine issued its 1986 report\(^{64}\) on which the OBRA 87 legislation was predicated, there is a widespread contemporary realization that any benefits of regulation must be carefully weighed against the very real economic and social costs imposed by regulatory compliance and oversight.\(^{65}\) In recognition of this reality, in 1994 DHHS issued a "plan for periodic review of rules."\(^{66}\) The review plan, which was initiated in response to Executive Order 12866, calls for a review of all DHHS rules to determine which "should receive early, in-depth review and revisions to reduce regulatory burdens."\(^{67}\)

In the case of NF regulation, the costs to the individual facility are ultimately borne by its residents. For the resident, regulatory costs may take the form of higher monetary fees for services (for privately paying residents), decreased quality of care due to staffing cutbacks made in response to budgetary constraints, or lessened availability of valuable but non-mandated activities.\(^{68}\) Moreover, it is ironic that regulations narrowly prescribing that providers make specific things occur at specific times and in specific ways often may have an unintended consequence for residents’ rights. In effect, regulation can limit residents’ rights rather than empowering them in their choice and freedom.\(^{69}\)

Second, we need to investigate the effectiveness and efficiency of NF command and control regulation in order to weigh this strategy \textit{vis-a-vis} alternative ways of accomplishing the same QA and residents' rights ends.\(^{70}\) Alternative strategies

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64. IOM report, \textit{supra} note 29, at 210 (stating that: [T]he Committee chose not to divert any of its limited time and resources to this purpose [considering the costs of recommended regulation]. It concentrated on developing recommendations that will improve the regulatory system's ability to ensure better quality of care and quality of life for nursing home residents [regardless of the cost entailed].).


67. \textit{Id.} at 3041.


69. \textit{See} Handler, \textit{supra} note 65, at 149-50 (illustrating how long term care consumers may have choices constrained because of the regulatory straightjacket into which providers are placed); Kapp, \textit{supra} note 14, at 32-44 (illustrating how nursing facility residents may have their choices constrained because regulatory requirements prevent nursing facilities from honoring certain resident choices); \textit{see also infra} notes 109-10 and accompanying text.

70. \textit{See generally} Kane, \textit{supra} note 7 (suggesting alternative means).
include market mechanisms, professional education, different payment systems,\textsuperscript{71} private accreditation, and privately initiated QA interventions.\textsuperscript{72} These various QA strategies are not mutually exclusive and combinations of approaches may be conducted simultaneously. Nonetheless, attaining the most efficacious combination (i.e., knowing into which "basket" we should be placing our strategic "eggs") necessitates evaluating the effectiveness and efficiency of each component, including government command and control regulation. It is not enough to simply inquire whether regulation "works;" we must also ask the next question, namely, whether it works better than other possible options. Put differently, do the benefits of pursuing a regulatory strategy outweigh the opportunity costs of foregoing the alternatives?

The questions posed by one set of authors, ordinarily associated with a pro-regulatory stance, are instructive:

[W]hat are the consequences of extensive reforms [in NF regulation] on structure and process? Does the amount of political capital compliance effort associated with these reforms retard efforts to develop more effective outcomes of care measures? Can federal policymakers ever effectively measure the full costs to states of complying with federal standards? If the federal government is not willing to bear the full cost of a program but instead insists that states share in the cost, should Congress be free to dictate standards?\textsuperscript{73}

Evaluating the impact of specific regulations utilizing a TJ model is hardly an easy task, which may explain at least in part why this exercise is done so seldomly. There are some inherent limitations in applicable social science methodologies.\textsuperscript{74} For instance, the effect of regulation on outcomes must be separated out from that of the numerous other variables that may influence NF quality.\textsuperscript{75} In addition, in cases where regulation appears to exert little, if any, positive tangible influence, determining whether the problem lies in weak enforcement rather than in the content of the regulation itself is essential information for plotting future public

\textsuperscript{71} The Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251 (1997), section 4432 required the implementation of a prospective payment system (PPS) for SNFs covering all costs (routine, ancillary and capital) related to covered services furnished to beneficiaries under Part A of the Medicare program. The PPS provides for per diem payment rates adjusted for case mix, or the resource intensity of each resident, and for geographic variation in wages.

\textsuperscript{72} See HCFA, supra note 7, at 5-16 (addressing the private accreditation alternatives in depth).

\textsuperscript{73} RAND E. ROSENBLATT ET AL., LAW OF THE AMERICAN HEALTH CARE SYSTEM 1212 (1997).

\textsuperscript{74} Winick, supra note 58, at 184; Christopher Slobogin, Therapeutic Jurisprudence: Five Dilemmas to Ponder, 1 PSYCHOL., PUB. POL’Y, & L. 193, 204-07 (1995).

\textsuperscript{75} See Catherine Hawes et al., The OBRA-87 Nursing Home Regulations and Implementation of the Resident Assessment Instrument: Effects on Process Quality, 45 J. AM. GERIATRICS SOC’Y 977, 983-84 (1997) (explaining that even the strongest supporters of federal regulation admit the difficulty of proving that positive change should be attributed to new regulation); supra note 48 and accompanying text.
policy directions, but accurately evaluating the respective explanations is usually difficult. Moreover, quality of care and quality of life necessarily remain slippery concepts. In recently announcing a large grant award for a research project entitled Assessing and Improving Nursing Home Quality of Care, the Commonwealth Fund stated, "Reports of poor nursing home quality abound in the media, yet simple measurement tools that could be used to gauge and report the quality of these facilities are lacking."

Despite these challenges, some credible empirical analyses of current NF regulation have been carried out (although not explicitly under the TJ label). The next Part reviews the results that have begun to emerge from these investigations.

### III. The Impact of Regulation

#### A. General Quality of Care and Quality of Life

In terms of OBRA 87's impact on the general quality of care and quality of life within NFs, the overall verdict to date has been largely, although not unanimously, positive. Not surprisingly, past and current HCFA Administrators have given the law (and, not coincidentally, themselves) a glowing endorsement, by pointing to such post-OBRA quality indicators as reduction in resident dehydration, decreased utilization of indwelling urinary catheters, lowering of the hospitalization rate, and an increase in the number of hearing impaired residents who now have hearing aids. Interviews with nursing home employees, regulators, advocates, and representatives of professional associations have yielded favorable perceptions regarding the law's impact. It has also been suggested that physicians are now


77. Commonwealth Fund, Recent Grants Awarded by the Board of Trustees 3 (1999).


80. See Nancy-Ann Min DeParle, Message from the Administrator, HCFA Health Watch, Aug. 1998, at 3; HCFA, supra note 7, at 19-21, 22-35.

81. See Vladeck, supra note 79.

More thoroughly involved in resident care and the QA process in NFs than ever before. 83

Much of the existing empirical research has focused on OBRA's requirement that the NF use a standardized Resident Assessment Instrument (RAI) to collect data, consistent with a mandated Minimum Data Set (MDS) and standardized Resident Assessment Protocols (RAPs), from each new resident to assist with individualized care planning for that resident. 84 The RAI has been praised as an important tool, valuable in this endeavor and contributing to improved results by several research teams. 85 Among the QA improvements cited in favorable evaluations of the RAI are: more accurate information in residents' medical records; 86 greater comprehensiveness of written care plans; 87 reduced use of indwelling urinary catheters; 88 higher rates of residents executing advance medical directives; 89 more resident participation in activities; 90 better use of toileting programs for residents with bowel incontinence; 91 and improvements in specific health conditions (namely, dehydration, falls, decubitus, vision problems, stasis ulcers, poor teeth, and malnutrition). 92 Additionally, advocates for the RAI argue that the information generated through the instrument can be used to evaluate a particular NF's performance according to certain quality indicators, which results in turn can inform both government and private QA initiatives in the future. 93

While the evidence cited in support of OBRA 87's salutary influence on resident outcomes is encouraging, some commentators sagely urge caution before embracing the regulatory strategy too wholeheartedly. According to one noted geriatrician, "[l]ike most clinical studies, there are many potential pitfalls in the interpretation and applicability of the findings." 94 One team of authors found that

83. See Elon & Pawlison, supra note 31; Jonathan M. Evans et al., Medical Care of Nursing Home Residents, 70 Mayo Clinic Proceedings 694 (1995).
86. See Hawes et al., supra note 75, at 979, 981.
87. See id. at 981-82.
88. See id. at 982.
89. See id.
90. See id.
91. See id.
while the RAI may have improved the quality of care of NF residents by reducing overall rates of decline in important areas of resident function, this innovation may have created tradeoffs in that it may have reduced improvement rates in some other areas of function.\textsuperscript{95} A group of NF medical directors suggests that the regulations may even be counterproductive:

Those with the most training are often forced to preoccupy themselves with administrative responsibilities such as required documentation. The documentation required for the minimum data set (MDS), resident assessment protocols (RAPs), and care planning often takes time away from staff supervision, staff education, and direct patient care activities.\textsuperscript{96}

Even if one disagrees with that negative assessment, enthusiasm for the efficacy of regulation certainly ought to be tempered by consistently emerging reminders, coming from credible bodies such as the U.S. General Accounting Office\textsuperscript{97} and the DHHS Office of Inspector General,\textsuperscript{98} of the substantial deficiencies still found in the general quality of care provided by many NFs. According to an experienced advocate, "In spite of extensive regulation, and perhaps in some ways because of [such regulations], for many years serious abuse and neglect of nursing home residents has continued to occur."\textsuperscript{99} Even the then-Administrator of HCFA admitted that, despite the fact that we indisputably can observe improved quality of care and quality of life today as compared with pre-OBRA days, "while we've come a long way, the journey is far from over."\textsuperscript{100} While submitting that, "[n]o one would argue with the desirability of using a systematic, structured approach to assessing measures of how well nursing care is provided").

\textsuperscript{98} U.S. DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, QUALITY OF CARE IN NURSING HOMES: AN OVERVIEW (1999); see also GENERAL ACCOUNTING OFFICE, GAO/HEHS-00-6, NURSING HOME CARE: ENHANCING HCFA OVERSIGHT OF STATE PROGRAMS WOULD BETTER ENSURE QUALITY (1999) (reporting significant failures in the monitoring of nursing home quality of care).
\textsuperscript{99} See Bragg, supra note 26, at 3-4; see also Harriet A. Fields, Closed for Good, WASH. POST, June 22, 1997, at C1 (describing horrible conditions for residents at D.C. Village, the now boarded up nursing home once operated by the District of Columbia).
\textsuperscript{100} Vladeck & Feuerberg, supra note 79, at 9; see also Rebecca J. Coccia & Elizabeth A. Cameron, Caring for Elderly Individuals in Nursing Homes, 25 J. GERONTOLOGICAL NURSING 38, 40 (1999) (lamenting that substandard care continues to be provided in nursing homes more than a decade after the OBRA reforms were enacted).
residents," Kane maintains that, "if one were to argue strongly for an RAI effect, one might be disappointed at the modest results reported."\(^{101}\)

**B. Residents' Rights**

Assuring and enhancing residents' rights has consistently been one of the primary goals of federal and state NF regulation.\(^{102}\) Among other rationales, the creation and enforcement of detailed residents' rights through regulatory mechanisms is predicated on evidence that feelings of having choice and control over important aspects of one's own life produces tangible therapeutic benefits for most individuals.\(^{103}\)

Many persons involved in the long term care field consider OBRA 87's effect of calling greater attention to residents' rights to be its most significant accomplishment.\(^{104}\) In contrast to these general perceptions, the available empirical evidence reveals little about the effect of OBRA 87 on the actual exercise of residents' rights. For instance,

[v]ery little is documented about whether OBRA 87 has had an impact on the resident's right to choose a personal attending physician, the right to receive medical care in privacy, the right to be able to contact the attending physician, the right to be informed of his or her total health status, or the right to refuse treatment.\(^{105}\)

Moreover, at times the current regulatory climate arguably acts as a barrier impeding respect for resident autonomy, as providers believe that paternalistic actions on their part (such as initiating guardianship proceedings that otherwise might have been delayed or avoided)\(^{106}\) are compelled by the providers' need for prudent legal risk management.\(^{107}\) Put differently, many providers act—correctly or not, but in almost every case sincerely—as though respecting residents' decisional rights, especially decisions to take risks, will probably expose the providers to malpractice claims brought by family members or regulatory citations.

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101. Kane, supra note 1, at 233.
102. See supra notes 34-44 and accompanying text.
104. Marek et al., supra note 82, at 31.
106. See Kapp, supra note 14, at 32-35.
and sanctions at the hands of state surveyors in the event that the risks undertaken should materialize.  

The principle of autonomous decision making embodied in the OBRA 87 statute and regulations is supposed to apply with full force in the context of decision making by and for the dying NF resident, and a feeling of being in control is frequently very important to the quality of an individual's end-of-life experience. Each year, approximately half a million NF residents die in the U.S.  

Besides OBRA 87, Congress also enacted as part of the 1990 OBRA the Patient Self-Determination Act (PSDA). Applicable to all NFs that participate in the Medicare or Medicaid programs, the PSDA was passed in the wake of the United States Supreme Court's Cruzan decision to facilitate, indeed encourage, health care consumers to execute advance medical directives in a timely fashion and to encourage health care providers to respect and effectuate those advance directives. Regulations implementing the statute were promulgated shortly thereafter by DHHS.  

The results of these legislative and regulatory forays into better end-of-life care have been, to characterize it charitably, a mixed bag in the NF setting. Referring to OBRA 87 requirements, a nursing professor observes:

"The current MDS and RAPS of the RAI omit important care needs of residents during the living-dying interval, most notably pain, dyspnea, spiritual/religious needs, bereavement, and hospice-type care. In addition to these omissions, the RAPs and care plans triggered by the MDS may not always be appropriate for terminally ill residents. MDS assessments on ..."

112. Id.  
113. Nursing facilities as well as hospitals, home health agencies, health maintenance organizations, preferred provider organizations, and hospices are included. See generally PATIENT SELF-DETERMINATION IN LONG-TERM CARE: IMPLEMENTING THE PSDA IN MEDICAL DECISIONS (Marshall B. Kapp ed., 1994) (discussing application of the PSDA to nursing facilities and home health agencies).  
admission and quarterly thereafter may activate RAP triggers and care plans for nutrition, feeding tubes, or hydration for a terminally ill resident [even if such medical intervention contravenes the resident’s own wishes].

Regarding the PSDA, one large study found that the legislation may have been successful in increasing the use of advance care plans in NFs and in changing the types of residents who use advance care plans; however, that investigation also determined that the use of advance care plans is associated with organizational characteristics, meaning that particular NFs may differ markedly in their willingness and ability to address PSDA mandates. Another set of investigators concluded that there is little evidence that the PSDA has enhanced completion of advance directives by mentally capable residents after admission to the NF, although the PSDA did have the effect of enhancing the documentation of previously executed advance directives. Others acknowledge difficult impediments to implementation of the PSDA, and particularly to expanded use of advance directives in NFs, but are optimistic that those barriers eventually will be overcome.

The task of protecting the detailed residents’ rights enumerated in federal and state law falls largely, though not exclusively, to long-term care ombudsman agencies. A national network of state long term care ombudsmen (ordinarily operating within a state’s department or office of aging), who in turn provide coverage through contracts with either local public agencies or private organizations, has been developed in the United States under the authority of the

118. Nicholas G. Castle & Vincent Mor, Advance Care Planning in Nursing Homes: Pre- and Post-Patient Self-Determination Act, HEALTH SERV. RES., Apr. 1998, at 101; see also Joan M. Teno et al., Changes in Advance Care Planning in Nursing Homes Before and After the Patient Self-Determination Act: Report of a 10-State Survey, 45 J. AM. GERIATRICS SOC’Y 939 (1997) (finding that implementation of the PSDA, as measured by execution of advance directives, varied widely by geographic location). But see Mathy Mezey et al., Implementation of the Patient Self-Determination Act (PSDA) in Nursing Homes in New York City, 45 J. AM. GERIATRICS SOC’Y 43 (1997) (finding that the number of advance directives per bed did not vary significantly by facility size, ownership, religious affiliation, or whether or not the nursing home had a formal ethics committee).
120. For a discussion of potential implementation barriers, see Kapp, supra note 14, at 35-43.
122. See Kayser-Jones & Kapp, supra note 12, at 362-74 (explaining a variety of advocacy possibilities).
Older Americans Act. As a condition of receiving OAA funds, each state is required to establish and operate a program to: investigate and resolve NF resident complaints; monitor laws, regulations, and policies relating to residents' rights; promote citizen involvement concerning protection of residents' rights and provide volunteer training; and inform public agencies of problems in NF care.

Upon Congressional direction, an exhaustive program evaluation conducted by the Institute of Medicine reported:

On the basis of all the information it reviewed, collected, and analyzed, the committee concludes that the ombudsman program serves a vital public purpose. However, in its assessment, the committee identified considerable barriers to effective performance that the ombudsman programs encounter. Significant among these are inadequate funding, resulting staff shortages, low salary levels for paid staff, structural conflicts of interest that limit the ability to act, and uneven implementation within and across states.

This generally positive evaluation of ombudsman programs (albeit not without some reservations) is shared by others, such as social policy commentator Joel Handler:

In general, the presence of an ombudsman program enhances the quality of life and the care of nursing home residents. Apparently the mere presence of concerned outsiders increases the staff's sense of importance and motivation. In addition, attention to the needs of the residents enhances their status in the eyes of the staff, which results in greater respect and better care. This presence also brings home to the staff and the administrators the fact of their accountability.

C. Restraints

Perhaps the most important change intended by supporters of OBRA 87 and its implementing regulations concerned the permissible use of physical and chemical

125. IOM REAL PROBLEMS, supra note 123.
126. Id. at 161.
127. HANDLER, supra note 65, at 154.
restraints on residents in NFs. Unlike the status quo ante, today a resident has the right to be free from any physical restraints imposed for the purpose of discipline or staff convenience, rather than imposed under a physician’s order to treat the resident’s medical problems after less restrictive or intrusive interventions have been considered and attempted unsuccessfully. The same statutory and regulatory restriction applies to psychotropic drugs, which have (in the not very distant past) commonly been administered to NF residents as chemical restraints rather than as a thoughtful, unavoidable piece of the particular resident’s therapeutic plan. Similar provisions restricting the permissible scope of physical and chemical restraints appear in the “Resident Bill of Rights” adopted by each state.

In this context, there is widespread consensus that the government’s “command and control” intrusion has made a powerful, positive difference in provider conduct. Regarding the use of physical restraints in the NF setting, an ambitious study of pre- and post-OBRA ’87 NF resident cohorts found a twenty-five percent decline in the use of restraints as a probable result of the RAI requirement. Most members of the nursing home industry have shown tremendous creativity in developing and implementing suitable alternatives to the use of physical restraints.


130. Id.

131. See, e.g., Jerry Avorn et al., Use of Psychoactive Medications and Quality of Care in Rest Homes, 320 NEW ENG. J. MED. 227 (1989) (regarding the previous prevalence of chemical restraints in NFs); Wayne A. Ray, et al., A Study of Antipsychotic Drug Use in Nursing Homes: Epidemiologic Evidence Suggesting Misuse, 70 AM. J. PUB. HEALTH 485 (1980) (finding drugs often overused as chemical restraints).

132. See Marshall B. Kapp, Nursing Home Restraints and Legal Liability: Merging the Standard of Care and Industry Practice, 13 J. LEGAL MED. 1, 21-22 n.113 (1992) (citing state statutes presenting the permissible use of restraints in NFs).

133. See, e.g., ELON, supra note 105, at 23-28 (concluding that OBRA has led to a reduction in the use of inappropriate restraints in nursing facilities); Robert L. Kane et al., Restraining Restraints: Changes in a Standard of Care, 14 ANNUAL REV. PUB. HEALTH 545 (1993) (reasoning that physical restraint use has fallen because of OBRA). But see Nicholas G. Castle & Vincent Mor, Physical Restraints in Nursing Homes: A Review of the Literature Since the Nursing Home Reform Act of, 55 MED. CARE RES. & REV. 139, 140 (1998) (finding that: implementation of restraint reduction varies widely, and there still is some concern that physical restraints are overused in some facilities. There was significant resistance to reducing restraints, and the majority of facilities are not restraint free. Moreover, isolated examples of facilities abandoning restraint-free care and becoming significant users of physical restraints have been documented.).

in manifold circumstances. In terms of proving a direct cause and effect relationship between regulation and actual practice, an investigative team that interviewed NF administrators in four states reported that:

The participants in our study indicated that complying with OBRA guidelines and satisfying the scrutiny of the state surveyors' inspection was an important reason to reduce restraint use. Indeed, administrators ranked a deficiency-free survey as one of the most beneficial aspects of restraint-free care. Most of the facilities did well with the state surveyors in terms of restraint use and restraint-free alternatives.

Moreover, lower rates of restraint use appear to have been achieved with no increase in serious resident injuries, economic costs, or legal liability exposure for the NF. Further, when restraints have been removed, with independence and rehabilitation encouraged as an alternative, the functional status of many residents—in terms of being capable of carrying out Activities of Daily Living (ADLs)—improves. Thus, the causal connection between improvements in the process of care and improved resident outcomes appears established.

There is convincing evidence from single and multiple institution studies that current federal and state laws limiting allowable prescription of psychotropic drugs in NFs have largely accomplished the policy objective of reducing the number of such prescriptions. It is particularly noteworthy that reductions in the usage of

140. See, e.g., Richard R. Neufeld & Joan M. Dunbar, Restraint Reduction: Where Are We Now?, NURSING HOME ECON., May-June 1997, at 11, 12 (arguing that the ability of residents to participate in daily activities improves when restraints are removed).
141. See, e.g., Nicholas G. Castle, Changes in Resident and Facility Risk Factors for Psychotropic Drug Use in Nursing Homes Since the Nursing Home Reform Act, 18 J. APPLIED GERONTOLOGY 77 (1999) (presenting a multiple institution study showing reduced use of drugs since OBRA); Maria D. Llorente et al., Use of Antipsychotic Drugs in Nursing Homes: Current Compliance with OBRA Regulations, 46 J. AM. GERIATRICS SOC'Y 198 (1998) (same); Melinda S. Lantz et al., A Ten-Year Review of the Effect of OBRA-87 on Psychotropic Prescribing Practices in an Academic Nursing Home, 47 PSYCHIATRIC SERV. 951 (1996) (providing a study in one nursing facility showing a reduced use of drugs since the enactment of OBRA); Judith Garrard et al., The Impact of the 1987 Federal Regulations on the Use of Psychotropic Drugs in Minnesota Nursing Homes, 85 AM.
drugs as chemical restraints has been effected at exactly the same time that physical restraint use has diminished as well, thus negating the early speculation that NFs might simply substitute one form of restraint for another.\textsuperscript{142} Even when OBRA '87 mandates have not been uniformly effective, they have at least increased awareness among caregivers of the proper indications for neuroleptics.\textsuperscript{143}

A precise cause and effect relationship between regulation and drug usage is complicated, though, by the advent of a newer generation of psychotropics which might have influenced professional prescribing patterns even in the absence of a regulatory obligation to rethink customary practice.\textsuperscript{144} Nevertheless, HCFA has concluded:

The magnitude and timing of the trend data in the use of psychopharmacologic medications combined with the results of separate studies designed to assess OBRA '87 impact indicate that the positive changes observed were due to OBRA '87. This is particularly true for some domains; for example, with respect to the utilization of antipsychotic and antidepressant medications drug categories that were specifically targeted in the OBRA '87 regulations and guidelines. [Other factors were important, too.] These other factors, however, were not in and of themselves sufficient to change the general pattern of inappropriate use of psychopharmacologic medications in nursing homes. Only with the implementation of the OBRA '87 was an abrupt change for the better seen. Hence, it appears that regulation was at least a necessary condition for the improvements observed.\textsuperscript{145}

Several sets of authors, while applauding reduced reliance on the prescribing of psychotropic drugs for NF residents as a positive process measure, urge the need to conduct additional research to determine the effects, if any, of this reduction on tangible resident outcomes.\textsuperscript{146} Put accurately, albeit bluntly:

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J. PUB. HEALTH 771 (1995) (detailing the conclusion that nursing facilities in Minnesota have had a reduced use of drugs since OBRA); Todd P. Semla et al., \textit{Effect of the Omnibus Reconciliation Act 1987 on Antipsychotic Prescribing in Nursing Home Residents}, 42 J. AM. GERIATRICS SOC'Y 648 (1994) (explaining a multiple institution study showing reduced use of drugs since OBRA).


143. Id.


145. HCFA, \textit{supra} note 7, at 22.

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Unfortunately, the implementation of these regulations on a national scale was done without concurrent provision for the evaluation of their effect on patient outcomes; thus, it is one of the largest uncontrolled health care experiments of modern times.147

D. Access to Mental Health Care

A section of OBRA '87 requires facility prescreening of all prospective NF admittees and prohibits admission of individuals with mental illness (except for dementia)148 or mental retardation unless they specifically need NF services.149 This provision is referred to as the PASARR requirement, for Preadmission Screening and Annual Resident Review.150 This legislation was enacted largely as a response to the questionable public policy of vigorously deinstitutionalizing patients out of public mental institutions over the previous two decades; by 1980, NFs were caring for ninety-four percent of all institutionalized mentally ill elderly persons.151 PASARR was intended to prevent inappropriate warehousing in NFs of mentally ill and mentally retarded persons (widely believed to be the inevitable fate if government did not intervene),152 and to ensure that previously underserved...
mentally disabled residents\textsuperscript{153} are treated more appropriately, with “specialized services” provided at the state’s expense.\textsuperscript{154}

In the wake of PASARR’s enactment, a number of mental health professionals speculated that the new requirements likely would have the effect of displacing a substantial number of NF residents who would then, literally, have no place to go.\textsuperscript{155} While the scenario of numerous older mentally ill and mentally retarded former NF residents rendered homeless as a result of PASARR requirements does not appear to have developed, appraisals of our experience with this legislation’s actual impact on NF residents’ access to appropriate mental health services are, at best, only mixed.\textsuperscript{156} Indeed, “PASARR has been among the most criticized of all nursing home reforms. It is expensive and intrusive. Most significantly, it appears to have had little effect on the composition of the nursing home population.”\textsuperscript{157} Even the PASARR legislation’s most enthusiastic pro-regulatory fans deplore the “failure to fulfill Congress’ vision” in practice,\textsuperscript{158} lamenting limitations on the class of people protected, harm caused by exempting individuals with dementia, lax enforcement by HCFA, states’ failure to provide community-based alternatives for individuals who do not need NF placement, and HCFA’s narrow definition of “specialized services.”\textsuperscript{159}

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153. See Nancy B. Emerson Lombardo et al., Achieving Mental Health of Nursing Home Residents: Overcoming Barriers to Mental Health Care (1996) (arguing that nursing facility residents are badly underserved when it comes to mental health care).


155. See, e.g., Mary Avellone Eichmann et al., An Estimation of the Impact of OBRA-87 on Nursing Home Care in the United States, 43 HOSP. & COMMUNITY PSYCHIATRY 781 (1992) (expressing concern about widespread homelessness among mentally ill nursing facility residents); Marc P. Freiman et al., Nursing Home Reform and the Mentally Ill, 9 HEALTH AFF. 47 (1990) (same).

156. Kathryn B. McGrew, The Nursing Home as Mental Health Care Provider: The Mixed Message and Impact of Nursing Home Reform, PUB. POL’Y & AGING REP., Winter 1998, at 1, 1 (“Newly emerging research and ongoing public debate suggest that reforms have achieved only mixed success and that we have a long way to go before we have a nursing home system fully responsive to the mental health needs of nursing home residents.”); Clare Collins et al., From Policy to Practice: Mental Health Treatment Received Among Depressed Nursing Home Residents Who Had a Preadmission (OBRA) Evaluation, Special Issue 1, 39 GERONTOLOGIST 366, 366 (1999).

157. McGrew, supra note 156, at 18; accord Mark Snowden & Peter Roy-Byrne, Mental Illness and Nursing Home Reform: OBRA-87 Ten Years Later, 49 PSYCHIATRIC SERV. 229 (1998); Mark Snowden et al., Compliance with PASARR Recommendations for Medicaid Recipients in Nursing Homes, 46 J. AM. GERIATRICS SOC’Y 1132 (1998).

158. Pepper & Rubenstein, supra note 154, at 1449.

159. Id. at 1450-55.
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IV. FUTURE ISSUES AND INQUIRIES

The regulation of NFs is not an end in itself, but only a means to an end. The exact nature and extent of the command and control regulatory environment engulfing NF care ought to be formulated on the basis of evidence about the impact of various governmental interventions on the lives of residents, not as a response to political ideology or bureaucratic convenience. The industry's complaints of "[w]e don't like regulation" should carry no more presumptive weight in public policy formulation than the cries of often self-anointed\textsuperscript{160} resident advocates that "[w]e don't trust the marketplace." An antidogmatic approach will keep the debate going and the inquiry open.\textsuperscript{161} Our ultimate policy objective should be to match, as finely as possible, specific regulatory mandates with desired, beneficial outcomes, while allowing all parties involved maximum flexibility to pursue those goals.\textsuperscript{162}

Some measurement of the impact thus far of current regulations on the quality of NF care, at least in terms of process indicators, has been attempted and available results have been reviewed in this Article. The body of evidence collected is suggestive of some success, but on the whole is quite inconclusive. According to one gerontological researcher, "I also believe that some improvement has occurred. However, the degree of this success is very much open to debate, and paper compliance encouraged by the regulatory system may even be counter-productive to efforts to be innovative in changing resident care."\textsuperscript{163}

Even the leading empirical research team in this arena admits that its work is incomplete. The researchers caution:

\begin{quote}
[O]ur measures do not represent a full range of the processes of care that may be important to the quality of care received by residents and may affect their outcomes. Moreover, they are insufficient to capture adequate indicators of process quality in the area of quality of life. For example, we did not measure such critical aspects of process quality as the nature of staff-resident interactions nor resident satisfaction. Given the goals of the
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\item[160.] Cf. Thomas Sowell, Vision of the Anointed: Self-Congratulation as a Basis for Social Policy (1995) (criticizing unelected individuals and groups who "anoint" themselves to formulate public policy because they have contempt for the wisdom of common people working through the normal democratic processes).
\item[161.] See Posner, supra note 58, at 6 (arguing for an antidogmatic approach to questions about the proper extent of law's involvement in our lives).
\item[162.] Kane, supra note 1, at 236-37.
\item[163.] John F. Schnelle, Can Nursing Homes Use the MDS to Improve Quality? 45 J. AM. GERIATRICS SOC'Y 1027, 1028 (1997); see also John F. Schnelle et al., Policy Without Technology: A Barrier to Improving Nursing Home Care, 37 GERONTOLOGIST 527 (1997) (arguing that standards of care for nursing facilities are written without realistic assessment regarding the existence of an intervention protocol and without determining whether resources are available to meet those standards). Such a situation produces unfair pressure on nursing facilities. Id. The NFs then react with paper compliance strategies, creating barriers to implementing new interventions that do meet care standards once developed. Id.
\end{footnotes}
OBRA nursing home reforms, these aspects of process quality and whether they have improved deserve further study.\textsuperscript{164}

Avorn and Gurwitz remind us of the need to concentrate on outcome measures:

\begin{quote}
[G]iven the proliferation of federal regulations governing drug use in the long-term care setting, research on the optimal mix of regulation, credentialing, and education is needed to improve the outcomes of drug therapy in nursing home residents. It is particularly important to document the clinical consequences of changes in prescribing rather than simply considering the end point of an intervention to be the changes themselves.\textsuperscript{165}
\end{quote}

This Article has suggested the concept of therapeutic jurisprudence as one analytic lens for use in conducting the necessary outcomes-focused inquiry.

The results of such an inquiry are essential to inform, but could never be sufficient to conclude, the formulation of sound public policy, since value choices concerning the acceptable mix of competing benefits and costs must ultimately determine the government's role. Most importantly, whatever government's role and any salutary influence it brings to bear on the quality of care and quality of life for NF residents, regulation by itself will always be inadequate to the task. This author has cautioned elsewhere that, "... [h]uman loving-kindness. . . cannot be legislated in an age of legal minimalism."\textsuperscript{166} Regulatory requirements may be essential to inspire, but can never substitute for, the sense of moral obligation that, in the final analysis, must lie at the heart of protecting and promoting the well-being of our most vulnerable citizens.\textsuperscript{167}

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\footnotetext{164. Hawes, supra note 75, at 983-84.}
\footnotetext{165. Avorn & Gurwitz, supra note 148, at 203; see also William D. Spector & Dana B. Mukamel, Using Outcomes to Make Inferences About Nursing Home Quality, 21 EVALUATION & HEALTH PROFESSIONS 291 (1998) (discussing the need to integrate research with outcome-based quality assurance systems to allow ongoing evaluation and quality improvement in nursing facilities).}
\footnotetext{166. Kapp, supra note 14, at 46.}
\footnotetext{167. Elias Cohen, Legal Obligations/Moral Obligations: Elusive Cross Connections in Long Term Care, 5 CONTEMP. GEROONTOLOGY 39 (1998).}
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