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# Quality-Control Regulation of Home Health Care

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# QUALITY-CONTROL REGULATION OF HOME HEALTH CARE

Sandra H. Johnson\*

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## I. INTRODUCTION

"Image" has an impact on the regulation of health care. Newspaper exposés of "warehoused" and abused elderly residents, for example, have frequently preceded new thrusts in the regulation of nursing homes. Similarly, our image of home as a place of loving care colors our ability to investigate and analyze dispassionately

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the quality and impact of home care. The family, however, does not always provide an idyllic community with the physical, financial, and emotional resources necessary to care for a very sick person at home. The problems that generally exist in health care settings do not disappear simply because care is provided in the home.

The assumption arises, however, that learning gathered from substantial experience with external quality-control regulation in institutions such as hospitals and nursing homes can simply transfer to the home health care organization. The apparent similarities between nursing homes and home health organizations generate potentially fruitful comparisons. These similarities include, for example, their patient<sup>1</sup> populations<sup>2</sup> and the common influence of federal payment systems in both nursing homes and home care.<sup>3</sup> An analogy between the quality-control regulation of nursing homes and of home health care is attractive because of the rich experience with quality control regulation of nursing homes.<sup>4</sup> Appropriate application of that experience to home health care promises shortcuts in experimentation and testing.

This Article examines the comparability of nursing homes and

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1. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation standards for home health care refers throughout its text to the recipients of the care as patients/clients. JCAHO, STANDARDS FOR THE ACCREDITATION OF HOME CARE (1988) [hereinafter JCAHO HOME CARE STANDARDS]. The Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 100 Stat. 1330 (1987) (codified as amended in scattered sections of 42 U.S.C.A. (West Supp. 1989) [hereinafter OBRA of 1987] refers throughout the relevant sections of its text to the recipients as individuals. This nomenclature may reveal an assumption that persons receiving home health care are not "patients" in the same sense as acutely ill persons in the hospital are "patients." It is not unusual that the names chosen for persons receiving health care convey a message. For example, the Committee on Nursing Home Regulation of the Institute of Medicine preferred to call persons receiving nursing home care "residents" instead of patients because "it more clearly conveys the idea that most people admitted to nursing homes, live in them for many months or years." COMMITTEE ON NURSING HOME REGULATION, INSTITUTE OF MEDICINE, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 215 n.28 (1986) [hereinafter IOM STUDY].

2. Refer to text accompanying notes 111-29 *infra* for a discussion concerning the characteristics of the two populations.

3. Refer to note 17 *infra* for a discussion concerning federal programs that reimburse for home care. Federal programs, including Medicaid, pay for approximately 60% of nursing home care. IOM STUDY, *supra* note 1, at 6.

4. See generally IOM STUDY, *supra* note 1; Symposium Issue on Nursing Home Law, 24 ST. LOUIS U.L.J. 617, 618 (1981); Jost, *Enforcement of Quality Nursing Home Care in the Legal System*, 13 LAW, MEDICINE & HEALTH CARE 160, 161 (1985); Johnson, *State Regulation of Long-Term Care: A Decade of Experience with Intermediate Sanctions*, 13 LAW, MEDICINE & HEALTH CARE 173, 183 (1985).

home health care with respect to the quality-control effects of private litigation and state licensure. This Article focuses on the choice of a regulatory model for state licensure of home health care and on the transferability of intermediate sanctions<sup>5</sup> from nursing home licensure to the licensure of home health agencies. This focus becomes particularly appropriate in light of the authorization in the Omnibus Budget Reconciliation Act of 1987<sup>6</sup> of intermediate sanctions for the enforcement of Medicare standards for home health agencies.<sup>7</sup>

Nursing homes and home health care share strong similarities with respect to private litigation and state licensure. The enterprises differ significantly, however, foreclosing the possibility of borrowing lessons learned in the context of nursing homes and applying them without reflection to home health care.<sup>8</sup> The false assumption of a broad comparability between nursing homes and home health care could hamper effective regulation of quality in the delivery of home health care.

This Article has two main sections—one on private litigation and the other on state licensure and enforcement tools. Each section discusses first the current status of the regulatory mechanism in the nursing home setting and in the home health care setting and then examines the points of comparability and dissimilarity. Finally, each section includes recommendations for development or further exploration.

### A. *Background*

Health care provided in the home goes beyond the sort of palliative care that may be provided best in familiar settings. In fact, home health care often is, and will increasingly be in the future, technologically sophisticated and complex care. Virtually the full panoply of medical care available in the hospital may be provided in the home, including ventilators, dialysis, and nasogastric feeding. Home care frequently becomes not a short-term, though intense, experience, but rather a long-term commitment in which the chronic nature of the illness often denies the reward of cure for

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5. Refer to note 173 *infra* and accompanying text.

6. OBRA of 1987, *supra* note 1, at § 4023.

7. *Id.* There are similar provisions for intermediate sanctions for nursing homes (at 42 U.S.C.A. §§ 1395aa & 1396r (West Supp. 1989)) and for Providers of Clinical Diagnostic Lab Tests (at 42 U.S.C.A. § 1395l (West Supp. 1989)).

8. Refer to notes 90-93 *infra* and accompanying text.

care well-given. The frustrations of both family and paid caregivers can interfere with their capacity to care for the patient.

The increasing reliance on home care as a major health care delivery system acting in the relative isolation of individual residences challenges assumptions based on images of home and family. In 1986, 1.7 million Medicare beneficiaries received home care totaling 45 million visits.<sup>9</sup> Medicare spending on home health care totaled \$2.91 billion in 1987.<sup>10</sup> In 1976, Medicare paid \$287 million for home health services and in 1982, \$1.146 billion.<sup>11</sup> In 1967, fewer than 2,000 home health agencies were certified for participation in Medicare. In 1981, there were about 3,000 Medicare-certified home health agencies.<sup>12</sup> By 1987, there were 5,794 home health agencies participating in Medicare and, additionally, an estimated 3,700 not participating in the program.<sup>13</sup>

Currently, commercially provided home health care responds to only a portion of the need. A 1982 survey reported that 2.2 million individuals provided unpaid assistance to 1.2 million noninstitutionalized elderly. One-third of these caregivers were over sixty-five, and 72% were women. The increase in the very elderly population and the decrease in the number of women available to provide care for elderly family members supports projections of continued growth for the home health industry.<sup>14</sup> In addition, Congress increased coverage and reimbursement of home health care in the Medicare Catastrophic Coverage Act of 1988,<sup>15</sup> and pri-

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9. NATIONAL ASS'N FOR HOME CARE, 1988 NAHC BLUEPRINT FOR ACTION, at 44 (1988) [hereinafter BLUEPRINT].

10. *Id.*

11. U.S. GENERAL ACCOUNTING OFFICE, REPORT NO. GAO-IPE-83-1 REPORT TO THE CHAIRMAN OF THE COMM. ON LABOR & HUMAN RESOURCES, U.S. SENATE, at 1 (1982) [hereinafter GAO REPORT]. Other federal programs providing home health services experienced similar growth. For example, in 1973, Medicaid paid \$25.4 million, and \$263.6 million in 1979. *Id.*

12. K. ANDERSON & D. KASS, CERTIFICATE OF NEED REGULATION OF ENTRY INTO HOME HEALTH CARE, 21 (Bureau of Economics Staff Report to the Federal Trade Commission, 1986) [hereinafter FTC REPORT].

13. BLUEPRINT, *supra* note 9, at 44. One study estimates that there are 12,000 home health agencies, of which only half are Medicare certified or accredited. SPECIAL COMM. ON AGING, HOME CARE AT THE CROSSROADS, 100TH CONG., 2D SESS. 4 (Comm. Print 1988) [hereinafter CROSSROADS].

14. Etheredge, *Private Foundations, Government, and Social Change: Home and Community-Based Care for the Elderly*, 6 HEALTH AFF. 176, 179 (1987).

15. Pub. L. No. 100-360, 102 Stat. 683 (codified as amended in scattered sections of 42 U.S.C.).

vate insurers have begun to offer coverage of home health care.<sup>16</sup>

During this period of rapid growth, the attention paid to home health care focused primarily on the establishment, financing, and public<sup>17</sup> and private<sup>18</sup> reimbursement of home care organizations. Obviously, questions of financing and reimbursement have a significant effect on the quality of health care. The adequate capitalization of any health care organization directly affects its capacity to provide adequate staff, equipment, and supplies without serious disruption. Organizational structure determines lines of ultimate responsibility and couples responsibility with control. Thus, organizational structure can affect both the ability of direct care providers and patients to influence institutional decisionmaking related to care, and the impact of incentives and disincentives on the quality of care. The focus, however, only recently has shifted from birthing an industry to direct and intentional monitoring of the quality of the services delivered.<sup>19</sup>

A number of private and public regulatory mechanisms now exist for quality-control regulation of freestanding home health care. In 1988 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued its first set of standards<sup>20</sup> for the voluntary accreditation of home care organizations;<sup>21</sup> it has since

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16. There are currently more than 70 companies offering long-term-care insurance. Approximately half of them include some degree of home care within their coverage. See, *Who Can Afford a Nursing Home?*, CONSUMER REPS. 300, 305-07 (May 1988).

17. Medicare (42 U.S.C.A. §§ 1395-1395ccc (West Supp. 1989)) and Medicaid (*id.* at §§ 1396c-1396s) are the primary sources of public funds for home health care. Other federal payment sources include Title XX of the Social Security Act (*id.* at §§ 1397-1397f) and Title III of the Older Americans Community Service Employment Act (*id.* at §§ 3056-3056f). States also fund home health care. Refer to note 18 *infra*. The GAO REPORT noted that the total governmental cost of home health care is probably seriously "underestimated" because analysts fail to take account of government supports such as housing and food stamps. GAO REPORT, *supra* note 11, at 26. Furthermore, "in terms of cost, support of noninstitutional care services shifts much of the burden of costs from the public sector to private individuals." *Id.*

18. Several states have insurance regulations that require insurance companies to include home care within certain insurance offerings. See, e.g., MONT. CODE ANN. § 33-22-1002 (1987).

19. This is not to say that quality concerns within the industry arose for the first time only within the past few years. Some steps were taken earlier. The National Homecare Council, for example, first began accreditation of home care in 1962.

20. See JCAHO, *supra* note 1. The JCAHO had earlier established standards for hospital-based home health agencies. JOINT COMMISSION ON THE ACCREDITATION OF HOSPITALS, ACCREDITATION MANUAL FOR HOSPITALS 47 (1978). As of July 1, 1988, 300 freestanding home health agencies had submitted applications for the accreditation process.

21. The organizations eligible for accreditation are those that provide either home

begun to accredit these organizations. In 1986 the American Nurses Association published standards developed by a task force of home care and nursing associations for home health nursing practice.<sup>22</sup> The National League for Nursing, which accredited home health agencies for twenty years, is in competition with the newer accreditation efforts.<sup>23</sup> The National Homecoming Council developed a training program and curriculum for home health aides in 1978 that has been incorporated within the licensure requirements of several states.<sup>24</sup>

Litigation by patients against providers for injuries suffered due to deviations from accepted standards of care offers an additional significant, though "private," tool for quality control in health care. The regulatory effect of the malpractice system lies in its capacity to deter poor care and encourage voluntary quality assurance activities.<sup>25</sup> Unlike hospitals and nursing homes, home health agencies have not yet experienced a high incidence of malpractice or negligence litigation by patients, but this situation is expected to change.<sup>26</sup> Apparently, liability insurance carriers have anticipated the change by decreasing the availability and coverage of liability insurance and increasing the information required of home health agencies in application for liability insurance. The higher volume of home care services, the increase in the number of patients receiving more complicated, intensive services at home, and technological advances that require more invasive care, such as

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health services, personal care and support services, pharmaceutical services or equipment management. JCAHO, *supra* note 1, at xi-xii.

22. AMERICAN NURSES ASSOCIATION, STANDARDS OF HOME HEALTH NURSING PRACTICE, at xi-xiii (1986). The National League for Nursing also has developed criteria for home health nursing. See NAT'L LEAGUE FOR NURSING, ACCREDITATION OF HOME HEALTH AGENCIES AND COMMUNITY NURSING SERVICES (1976).

23. Weinstein, *Assessing the Quality of Care Given at Home*, 9 OBSERVER 5 (Jan. 1989) (monthly newsletter of the American College of Physicians).

24. See, e.g., N.D. CENT. CODE § 23-3-02 (1987).

25. The existence of quality-assurance programs in hospitals indicates that medical malpractice liability is probably resulting in safer medical behavior; however, some commentators doubt its deterrence value in the medical field because of the widespread reliance on malpractice insurance. See, e.g., P. DANZON, *MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY* 17 (1985); Bell, *Legislative Intrusions into the Common Law of Medical Malpractice: Thoughts About the Deterrent Effect of Tort Liability*, 35 SYRACUSE L. REV. 939, 943 (1984).

26. See, e.g., Lehrman & West, *Special Issues for Hospital Affiliated Home Care Companies*, in NAT'L HEALTH LAW ASS'N PROC. ON HOME CARE LEGAL ISSUES § J, at 19 (1988).

intravenous treatments and chemotherapy, may increase claims.<sup>27</sup>

The federal government, primarily through Medicare certification,<sup>28</sup> and the states, primarily through licensure,<sup>29</sup> control the public regulation of home health care. The federal Omnibus Budget Reconciliation Act of 1987 included amendments to the Social Security Act.<sup>30</sup> The amendments specifically addressed the enforcement of quality standards in home health agencies certified to receive reimbursement through Medicare.<sup>31</sup> At least thirty-eight states and the District of Columbia now require at least some home health agencies to obtain licenses.<sup>32</sup>

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27. See Pyles, *Identifying and Minimizing the Risk of Legal Liability in Home Care*, in NAT'L HEALTH LAW. ASS'N PROC. ON HOME CARE LEGAL ISSUES § B, at 1-3 (1988).

28. 42 U.S.C.A. §§ 1395-1395ccc (West Supp. 1989). Peer Review Organizations (PRO), created by Congress in 1982 as part of its enactment of the prospective payment system (42 U.S.C. § 1320(c)(13) (1982)), also review the quality of care provided by home health agencies. Congress mandated PRO review of care provided by home health agencies under the Omnibus Budget Reconciliation Act of 1986, 42 U.S.C.A. §§ 1320(c)(12) (West Supp. 1989)). Under this Act, home health agencies were required to contract with PROs by October 1, 1987 for the review of written complaints of patients/clients of the agency. *Id.* In addition, as part of their charge to review hospital readmissions, the PROs were to "determine if . . . the post-hospital services meet professionally recognized standards of health care." *Id.*

29. State and local governments typically contract with home health agencies for home health services in rural areas and for indigent persons. This contracting role presents an opportunity for quality control in standards applied as a condition of eligibility for contracting.

30. Codified as amended in scattered sections of 42 U.S.C.A. (West Supp. 1989).

31. OBRA of 1987, *supra* note 1, at §§ 4021-27.

32. See ARIZ. REV. STAT. ANN. § 36-425 (1986); CAL. HEALTH & SAFETY CODE § 1725 (West 1987); CONN. GEN. STAT. ANN. § 19a-490 (West 1986); DEL. CODE ANN. tit. 16, § 122 (1986); D.C. CODE ANN. § 32-1302 (1988); FLA. STAT. ANN. § 400.461 (West 1986); GA. CODE ANN. § 31-7-151 (1985); HAW. REV. STAT. § 321-11 (1987); IDAHO CODE § 39-1303 (1985); ILL. REV. STAT. ch. 111.5, para. 2801 (1988); IND. CODE § 16-10-2.5-2 (Burns 1983); KAN. STAT. ANN. § 65-5102 (1985); KY. REV. STAT. ANN. § 216B.105 (Baldwin 1987); LA. REV. STAT. ANN. § 40:2009.32 (West 1988); ME. REV. STAT. ANN. tit. 22, § 2143 (1988); MD. HEALTH-GEN. CODE ANN. § 19-401 (1987); MICH. COMP. LAWS § 14.15 (1987) (allows regulations to be promulgated but does not provide for licensure); MINN. STAT. ANN. § 144A.46 (West 1989); MISS. CODE ANN. § 41-71 (Supp. 1988); MO. REV. STAT. § 197.405 (1988); MONT. CODE ANN. § 50-5-201 (1987); NEB. REV. STAT. § 71-2018 (1986); NEV. REV. STAT. § 449.030 (1987); N.H. REV. STAT. ANN. § 151:2 (1988); N.J. STAT. ANN. § 30:4E-2 (West 1981) (authorizes a task force to recommend regulations, which have since been promulgated.); N.M. STAT. ANN. § 24-1-5 (1988); N.Y. PUBLIC HEALTH LAW § 3605 (McKinney 1985); N.C. GEN. STAT. § 131E-138 (1988); N.D. CENT. CODE § 23-17.3 (Supp. 1987); OR. REV. STAT. § 443.015 (1987); PA. STAT. ANN. tit. 35 § 448.801 (Purdon 1988); R.I. GEN. LAWS § 23-17-4 (1988); S.C. CODE ANN. § 44-69-30 (Law. Co-op. 1985); TENN. CODE ANN. § 68-11-202 (1987); TEX. REV. CIV. STAT. ANN. § 4447u (Vernon 1976 & Supp. 1989); UTAH CODE ANN. § 26-21-8 (1989); Vermont provides for contract regulation but does not require licensure. See VT. STAT. ANN. tit. 18 § 2502 (Equity Publishing Supp. 1988); VA. CODE ANN. § 32.1-162.9 (Supp. 1989); WASH. REV. CODE § 70.127.020 (Supp. 1989) (requires home health agencies to be certified in order to provide



Although each of these mechanisms—private accreditation, private litigation, Medicare certification and state licensure—currently operates in the home health care setting, the experience with their application to home health care is limited. This holds true particularly for private litigation and state licensure.

## II. PRIVATE LITIGATION

Private litigation against health care institutions for malpractice or negligence often has been credited with a positive impact on the quality of health care. Not all commentators, however, subscribe to this characterization of the impact of malpractice litigation.<sup>33</sup> To the extent that such litigation has a beneficial regulatory effect on the quality of health care,<sup>34</sup> an analysis of private litigation against home health providers can be relevant to a consideration of quality-of-care regulation.<sup>35</sup>

### A. *Barriers to Private Litigation in Long-Term Care*

The malpractice litigation system does not favor patients who require long-term care. Their age and medical condition create problems in proving the cause of injuries, thereby limiting or decreasing damage awards. The frailty of some of these patients, for example, prevents their physical presence for courtroom testimony. Other elderly patients may suffer from mental confusion that makes their testimony unreliable or creates the appearance of unreliability. Long-term health care patients who at the time of the incident are already in poor health or are particularly susceptible to injuries such as fractures, bruises, and infections have difficulty proving that the source of their injury was the negligence of the health care provider. Such patients may not survive to trial. Recent state malpractice reform statutes, which require pretrial procedures such as tribunals, can exacerbate this problem.<sup>36</sup> In some states the death of the plaintiff eliminates certain causes of action,

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home health care services, but requiring licensure after July 1, 1990); WIS. STAT. § 141.15 (1989).

33. See, e.g., Bell, *supra* note 25, at 973; P. DANZON, *supra* note 25, at 118.

34. Another purpose of the tort system of liability is to provide compensation to those injured as a result of the negligence of others. See, e.g., P. DANZON, *supra* note 25, at 3.

35. For a more complete analysis of private litigation and principles of liability for home health agencies, see Johnson, *Liability in High Tech Home Health Care*, in HIGH TECHNOLOGY HEALTH CARE IN THE HOME (to be published in 1989 by Nat'l Law Publishing).

36. See, e.g., N.Y. JUD. LAW § 148-a(1) (McKinney 1989).

such as invasion of privacy. In addition, for those causes of action that do survive the death of the plaintiff, juries may be unwilling to award damages to family members, especially those who were not "devoted enough" to the patient.<sup>37</sup> Patients receiving long-term health care usually are not wage earners and, therefore, do not suffer lost wages, a major source of damages in personal injury cases. The effect on the jury of a general perception of an elderly, chronically ill, and incompetent individual as "not having much of a life anyway" cannot be discounted. These factors affect the likelihood and amount of a damage award and also influence the willingness of private attorneys, who often work on a contingency basis in personal injury litigation, to take such cases.<sup>38</sup>

Despite these obstacles, plaintiffs have achieved some notable successes in recovering substantial damage awards in litigation against nursing homes.<sup>39</sup> These successful plaintiffs were able to prove outrageous circumstances in the treatment of the patient, a pattern of poor care, or inadequate staffing by the defendant facility.<sup>40</sup>

The testimony of current or former employees, and inspection reports of government agencies, can prove the existence of patterns of poor care or other aggravated circumstances necessary to sustain

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37. Juries may look with disdain on the claims of relatives who rarely, if ever, visited the deceased. McNath, *The Nursing-Home Maltreatment Case*, 21 TRIAL 52 (Sept. 1985).

38. For a general discussion of the difficulties of litigating on behalf of elderly nursing home patients and strategies that respond to these factors, see Butler, *Nursing Home Quality of Care Enforcement: Part I—Litigation by Private Parties*, 14 CLEARINGHOUSE REV. 622 (1980); Johnson & Dodson, *Decreasing Exposure to Liability in Long-Term Care*, 67 HEALTH PROGRESS, Oct. 1986, at 18; McNath, *supra* note 37, at 52; Nemore, *Protecting Nursing-Home Residents*, TRIAL, Dec. 1985, at 54, 56-57. For a review of private litigation against nursing homes, see S. Johnson, N. Terry & M. Wolff, *NURSING HOMES AND THE LAW: STATE REGULATION AND PRIVATE LITIGATION* §§ 3-1 to 3-6 (1985) [hereinafter JOHNSON, TERRY & WOLFF].

39. A lawyer in Arkansas, for example, reported "eleven results in excess of \$100,000 and one of \$450,000" over the course of two years. McNath, *supra* note 37, at 52. The National Senior Citizens Law Center reported several cases with jury awards or settlements of \$50,000 to \$1.35 million. Nemore, *supra* note 38, at 57. For a discussion of damages in private litigation against nursing home cases, see JOHNSON, TERRY & WOLFF, *supra* note 38, at ch. 6.

40. In *Payton Health Care Facilities, Inc. v. Estate of Campbell*, 497 So. 2d 1233, 1235-40 (Fla. Dist. Ct. App. 1986), for example, the court of appeals upheld, in a wrongful death case, a jury award in favor of the plaintiff (decendent's estate) amounting to \$8,958.15 in compensatory damages; \$500,000 in compensatory damages to the surviving spouse; \$900,000 in punitive damages against the management company; and \$800,000 in punitive damages against the corporate owner of the facility. A settlement of \$50,000, paid to the plaintiff by the attending physician, was deducted from the compensatory damages.

a claim for punitive damages.<sup>41</sup> Although this strategy has proven successful in suits against nursing homes, plaintiffs may have a more difficult time proving patterns of poor care in the context of home health care. The difficulty arises because the patients, and thus the actual delivery of care, are much more dispersed geographically. These circumstances make patterns of poor care for a significant proportion of the agency's clients much less observable and much harder to prove. With no possibility of punitive damages, clients and attorneys may find suing for negligent home health care too costly in light of the minimal financial loss that will be recognized at law.

Proving causation of injuries in frail, elderly clients may create difficulties as well. Again, some plaintiffs in recent litigation against nursing homes have overcome this problem.<sup>42</sup> Although proving the cause of injury poses a challenge to any frail individual with multiple illnesses, the plaintiff in a nursing home case has an advantage over the plaintiff in a home health care case. The nursing home exercises nearly complete custody and control over the resident. Typically, the only persons physically caring for the individual are employees of the facility. This control can support inferences that the facility staff caused the injuries attributable to negligent care or intentional abuse.<sup>43</sup> Within a facility, the staff clearly holds responsibility for cleaning the patient, changing dressings, supervising the patient's activity, and monitoring the physical condition of the patient and the performance of any medical equipment in use. In contrast, when a patient is cared for at home, much of the actual care often is rendered by family members or by several paid agency- or self-employed caregivers. The plaintiff harmed in this situation may be unable to persuade the jury to place liability on one particular provider.<sup>44</sup>

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41. See, e.g., *Hutton v. Willowbrook Care Center, Inc.*, 79 N.C. App. 134, 338 S.E.2d 801, 803 (1986) on the admissibility of such reports. Nursing homes have attempted to use inspection reports as a defense to claims of negligence as well. See, e.g., *Golden Villa Nursing Home, Inc. v. Smith*, 674 S.W.2d 343, 349 (Tex. App.—Houston [14th Dist.] 1984, writ ref'd n.r.e.); *Kujawski v. Arbor View Health Care Ctr.*, 139 Wis. 2d 455, 407 N.W.2d 249 (Wis. 1987).

42. See, e.g., *McGillivray v. Rapides Iberia Management Enterprises*, 493 So. 2d 819, 823-24 (La. Ct. App. 1986).

43. But see *Lemoine v. Insurance Co. of North America*, 499 So. 2d 1004, 1007 (La. Ct. App. 1986), where there was some belief that the resident was abused by a family member during visitation.

44. Plaintiffs receiving care within an institution may attempt to use the doctrine of *res ipsa loquitur* to assist in proving negligence against the facility in cases where the plain-

### B. Institutional Liability

Legal theories of institutional (as opposed to individual) liability for negligence and malpractice influence the success and attractiveness of litigation on behalf of patients. Health care enterprises usually have a greater capacity to pay damages than do individual health care providers. This is especially the case when the negligent health care provider is a nurse, an allied health professional, or an aide rather than a physician. These health care providers frequently are uninsured or underinsured against liability. Furthermore, juries may exhibit more reluctance to award damages against an individual nurse or aide than against an organization in the business of providing health care.

Generally, under the theory of vicarious liability, an employer is liable for injuries caused by the negligent acts of its employees. A patient harmed through the negligence of an employee of a health care organization—whether hospital, nursing home, or home care agency—may recover against the organization by proving that the direct caregiver who caused the injury was an employee of the organization, and acted within the course and scope of his or her employment.<sup>45</sup>

When direct-care providers are independent contractors, rather than employees, as is often the case in home health care, the agency may not have vicarious liability for damages to the patient.<sup>46</sup> The hospital-physician relationship provides a useful ana-

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tiff cannot prove which individual, among those providing care within the facility, actually rendered the negligent care. The plaintiff must prove that the event ordinarily would not occur without someone's negligence; that the event was caused by an agent or instrument within the exclusive control of the defendant; and that the event must not have been caused by any voluntary action on the part of plaintiff. For a discussion of the use of this doctrine in nursing home cases, see JOHNSON, TERRY & WOLFF, *supra* note 38, at §§ 3-21, 4-2. The obstacles facing nursing home plaintiffs attempting to use *res ipsa* discussed in that material are even more serious for home health patients due to the circumstances discussed in the text.

45. See JOHNSON, TERRY & WOLFF, *supra* note 38, at § 5-6.

46. There is a well established general rule that there is no vicarious liability for the acts of an independent contractor. See *Johns v. New York Blower Co.*, 442 N.E.2d 382, 384 (Ind. Ct. App. 1982) (generally, one is not liable for acts or negligence of another unless relation of master and servant exists between them); *Clark v. Young*, 692 S.W.2d 285, 289 (Ky. Ct. App. 1985) (negligence of independent contractor was not imputable to principal). In general, an independent contractor contracts for particular work to be done and controls the manner in which the work is done. The independent contractor typically controls his or her own hours and is responsible for travel and other business expenses. The independent contractor may work for more than one company.

logue. Theories developed in malpractice litigation against hospitals may prove applicable to patients litigating against home health care agencies.<sup>47</sup>

Although vicarious liability does not extend to providers that hire independent contractors, the doctrine of ostensible agency may apply. Under ostensible agency theory, the negligence of independent contractors would subject a home health agency to liability if the patient reasonably believed, because of actions of the home health agency, that the independent contractor was authorized to act on behalf of the agency.<sup>48</sup> Because this theory focuses on the actions of the home health agency rather than the subjective belief of the patient, the home health agency can control liability by giving prominent notice that the caregivers are not agents or employees of the agency.<sup>49</sup> Industry standards may provide a

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47. When a doctor employed directly by the hospital commits an act of malpractice, the hospital may be derivatively liable under doctrine of respondeat superior. *Baker v. Werner*, 654 P.2d 263, 267 n.5 (Alaska 1982). The law typically regards physicians over whom the hospital does not exercise control as independent contractors and does not hold hospitals vicariously liable. *Reed v. Good Samaritan Hosp. Ass'n, Inc.*, 453 So. 2d 229, 230 (Fla. Dist. Ct. App. 1984); *see also Hale v. Sheikholeslam*, 724 F.2d 1205, 1207-08 (5th Cir. 1984) (where doctor at county hospital was clearly independent contractor, hospital could not be held liable for his actions); *Lurch v. United States*, 719 F.2d 333, 337-38 (10th Cir. 1983) (V.A. hospital not liable where it did not have traditional employer-employee relationship with physician); *Harnish v. Children's Hosp. Medical Center*, 387 Mass. 152, 439 N.E.2d 240, 245 (1982) (hospital could not be held vicariously liable absent proof that the hospital had power of control over physician's professional conduct). Although these are generally accepted rules of law, exceptions exist. *See Hedding v. Ashford Memorial Community Hosp.*, 734 F.2d 81, 86 (1st Cir. 1984) (even if physicians who attended patient were independent contractors, rather than employees of hospital, risk of negligent treatment was clearly foreseeable by hospital such that hospital could be held liable for physicians' actions); *Darling v. Charleston Comm. Mem. Hospital*, 33 Ill. 2d 326, 211 N.E. 2d 253 (1965) (hospital has duty to know qualifications and standard of performance of physicians who practice on its premises); *Elam v. College Park Hosp.*, 183 Cal. Rptr. 156, 157, 132 C.A.3d 332, 335 (Cal. Ct. App. 1982) (a hospital is liable to a patient under the doctrine of corporate negligence for negligent conduct of independent physicians and surgeons who, as members of the hospital staff, avail themselves of the hospital facilities, but who are neither employees nor agents of the hospital); *Gregg v. National Medical Health Care Services, Inc.*, 145 Ariz. 51, 699 P.2d 925, 929 (Ariz. Ct. App. 1985) (a hospital that has significant control over the practice of a physician will be held liable for the negligence of the physician).

48. For example, a California appellate court applied ostensible agency to a chiropractic college where a negligent roentgenologist operated an independent radiology unit. *Stanhope v. Los Angeles College of Chiropractic*, 54 Cal. App. 2d 141, 146, 128 P.2d 705, 708 (Cal. Dist. Ct. App. 1942). *But see Porter v. Sisters of St. Mary*, 756 F.2d 669 (8th Cir. 1985) (patient's subjective conclusion that the emergency room physician was an employee of the hospital did not create an ostensible agency).

49. The agency's disclaimer of an employment relationship will not determine the question of whether the caregiver was actually the employee of the agency. The court will examine the relationship itself. Refer to note 46 *supra*.

source of liability beyond the limitations of the common law theory of ostensible agency if the standards require home health agencies to monitor the quality of care delivered by independent contractors. Nevertheless, an explicit duty to monitor (or other similar structural duties) provides a much narrower basis for liability than does the liability provided by ostensible agency.<sup>50</sup>

Difficulty in identification of the organization that appropriately holds liability creates an additional issue that will arise in home health care litigation. Home health care agencies frequently maintain formal relationships with other health care institutions, such as hospitals. In such a relationship, for example, the agency may act as a subsidiary corporation, joint venturer, or franchisee.<sup>51</sup> The corporate structure of the agency has a significant impact on the determination of the party ultimately responsible for compensating an injured plaintiff.<sup>52</sup>

Further obscuring the liability issue, other organizations often act as contractors to home health agencies. It is very common for home health agencies to contract with other providers for durable medical equipment or for staff.<sup>53</sup> Extensive contracting, especially for staff, can create problems in the quality of care given to the patient.<sup>54</sup> Home health agencies remain responsible for monitoring the quality of care provided by agencies with which they contract. These responsibilities are delineated in state<sup>55</sup> and federal regula-

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50. Refer to notes 66-77 *infra* and accompanying text.

51. For a discussion of the corporate structure of home health agencies, see generally Kelly, *Franchising Home Health Agencies*, and Roth, *Corporate Reorganization of the Home Care Company*, 1986 NAT'L HEALTH LAW. ASS'N PROC. ON HOME HEALTH CARE LEGAL ISSUES; T. Therrill & C. Evashwick, *MANAGING THE CONTINUUM OF CARE*, ch. 7 (1987); Teplitzky & Janson, *HOME HEALTH AND HOSPICE MANUAL: REGULATIONS AND GUIDELINES* § IV (1985 & Supps. 1986 & 1987); Caesar & Kelly, *Joint Ventures and Acquisitions—Capital Formation and Market Acquisition*, 1988 NAT'L HEALTH LAW. ASS'N PROC. ON HOME CARE LEGAL ISSUES § K.

52. For further analysis, refer to JOHNSON, *supra* note 35.

53. "In 1985, [six] of the 16 sample [home health agencies] in three Eastern States contracted with 18 vendors for all or part of the nearly 150,000 home health aide visits provided to Medicare patients. Of those total visits, 72[%] were made by vendor aides the six [home health agencies] did not recruit, hire, train or assign to patient cases." U.S. DEP'T HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, *HOME HEALTH AIDE SERVICES FOR MEDICARE PATIENTS*, Sept., 1987 at 6 [hereinafter OIG REPORT].

54. *Id.* at 6 & 15.

55. See, e.g., N.D. CENT. CODE § 23-17.3-05(1)(f) (Supp. 1987), which provides: "If services are to be provided by arrangement with other agencies or organizations, the home health agency must ensure that the other agencies or organizations furnish qualified and trained personnel."

tions.<sup>56</sup> Private accreditation standards also address contracting. JCAHO standards for home health care, for example, require a written agreement defining the nature and scope of the services provided.<sup>57</sup> The agreement must specify the services to be provided and the rights and responsibilities of the two contracting parties for supervision and evaluation of care, among other items.<sup>58</sup> The standards also require that the accredited agency's internal quality assurance program address all home care services "whether provided directly or through a written contract."<sup>59</sup> The framework relating to vicarious liability, discussed previously, offers an approach for determining whether injured patients may use these provisions to establish the appropriate standard of care for home health agencies contracting for services.<sup>60</sup> There remains a need for states to clarify by statute the ultimate responsibility and liability for injuries to patients caused by substandard care. The ultimate obligation to maintain standards of care should fall on the agency responsible for the patient's plan of treatment.

### C. *Setting the Standard of Care*

In 1965 the Illinois Supreme Court, in *Darling v. Charleston Community Memorial Hospital*,<sup>61</sup> held a hospital directly liable for the failure of administrators and staff to monitor and supervise the delivery of health care within the hospital even when the care was provided by nonemployees. The court relied on the Standards for Hospital Accreditation (now the JCAHO), state licensing regulations, and the hospital's own by-laws as proof of the standard of care owed by hospitals.<sup>62</sup>

As in *Darling*, plaintiffs in nursing home cases have attempted to use government and accreditation standards as proof of the standard of care required in a particular situation. In *Stogsdill v. Manor Convalescent Home, Inc.*<sup>63</sup> the trial court directed a verdict

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56. See, e.g., OBRA of 1987, *supra* note 1, at § 4021 (codified at 42 U.S.C.A. 1395bbb (West Supp. 1989)).

57. JCAHO, *supra* note 1, at 29. (Standard MA. 10 and Required Characteristic MA. 10.1.).

58. *Id.*

59. *Id.* at 21. Standard QA. 1 and Required Characteristic QA. 1.3.

60. Refer to text accompanying notes 45-50 *supra*.

61. 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966).

62. 211 N.E.2d at 256-58.

63. 343 N.E.2d 589 (Ill. App. 1976).

in favor of the nursing home and submitted the question of the liability of the plaintiff's physician to the jury. The case involved a patient who suffered amputation of her leg due to negligent treatment of a decubitus ulcer.<sup>64</sup> The appellate court affirmed the trial court's directed verdict in favor of the facility, and held that the plaintiff had failed to establish the standard of care. The plaintiff had introduced the state nursing home licensure regulations as proof of the standard of care required of the facility.<sup>65</sup>

The appellate court examined in particular two provisions of the regulations. The first provision required the facility to notify the family immediately of "anything unusual happening to the resident such as a sudden illness or disease."<sup>66</sup> While the court noted that the facility had not fully complied with this regulation, it found that the plaintiff's children had not relied on the lack of notice from the facility, would not have acted differently had they been notified, and were, in fact, aware that the ulcer was growing larger and causing their mother pain.<sup>67</sup>

The second set of regulations discussed by the court included a requirement that no patient requiring skilled nursing care be kept in an intermediate care facility such as the defendant facility.<sup>68</sup> The court termed this requirement "too vague to be [a] sufficient indicator of the standard of due care required of nursing homes by themselves."<sup>69</sup> The court relied on the participation of

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64. The jury awarded the plaintiff \$40,000 in general damages and \$80,000 in punitive damages against the physician. *Id.* at 592. The physician appealed the judgment against him, and the plaintiff appealed the directed verdict against her and in favor of the facility. The appellate court reversed the punitive damages award against the doctor but let stand the \$40,000 award for general damages. *Id.* at 613.

65. *Id.* at 610.

66. *Id.* at 611.

67. *Id.* at 611. The court also held, concerning the nurses' failure to notify the plaintiff's physician at the time the ulcer occurred, that "there [was] no evidence that [the physician] would have acted any differently had he been more closely informed." *Id.* at 612. Current Medicare regulations for home health agencies require that the agency alert the physician to any changes in the patient's condition that might require alteration of the patient's care. 42 C.F.R. § 405.1223(b) (1988).

68. 343 N.E.2d at 611. Medicare regulations for home health agencies require that the agency accept patients "on the basis of a reasonable expectation that the patient's medical, nursing and social needs can be met adequately by the agency in the patient's place of residence." 42 C.F.R. § 405.1223 (1988). This provision may be subject to the same question raised in *Stogsdill*, i.e., whether the agency is entitled to rely on the patient's physician for this determination.

69. 343 N.E.2d at 611. The National Academy of Sciences nursing home study recommended that the distinction between skilled nursing facilities and intermediate care facilities in Medicare be eliminated because the distinctions between the two had "blurred," and



the plaintiff's personal physician in her care to relieve the nursing home of liability under this standard, even though it had found the evidence sufficient to hold the physician liable for negligence in his care of the plaintiff.

In *Makas v. Hillhaven, Inc.*<sup>70</sup> the plaintiff claimed that the resident, her great-grandmother, had been intentionally abused and had been otherwise injured by the negligence of the facility. The plaintiff refused to produce an expert to testify on the standard of care required of the nursing home. Instead, the plaintiff relied solely on the North Carolina statutory Nursing Home Patients' Bill of Rights.<sup>71</sup> Specific provisions of this statute require that residents "be treated with consideration, respect, and full recognition of personal dignity and individuality . . . to receive care, treatment, and services which are adequate [and] appropriate and to be free from mental and physical abuse."<sup>72</sup>

The court held that photographs of the resident showing extensive bruising on her face and hands were sufficient evidence of abuse to allow the jury to apply "its own common knowledge and experience . . . to understand and judge whether the defendant's nursing care was negligent and outside the standard of care."<sup>73</sup> As to the harm suffered from the alleged negligence in caring for the resident, the court held that "[t]he question of when the time period between intervals [of cleaning a patient without bladder or bowel control] becomes unreasonable is beyond the realm of common knowledge of the Court or the jury. Evidence from one who is familiar with the standards of practice or care is required."<sup>74</sup>

At least one case considered the use of governmental regula-

because the two types of facilities "do not in practice display clear differences in the residents they serve." IOM STUDY, *supra* note 1, at 71, 73. The OBRA of 1987 eliminated this distinction for Medicaid. OBRA of 1987, *supra* note 1.

70. 589 F. Supp. 736 (D.N.C. 1984).

71. N.C. GEN. STAT. § 131 E-117 (1988). Several states have a statutory patients' bill of rights applicable to home health agencies, usually within the state's general statute on health facility licensure. See NEB. REV. STAT. §§ 71-2017, 71-2024 (1988); CAL. WELF. & INST. CODE §§ 15600, 15721 (West 1989); and NEV. REV. STAT. §§ 449.700 to .730 (1988). In addition, the OBRA of 1987 amends the Social Security Act to add a bill of rights for home health patients/clients as a new condition for participation in the Medicare program. OBRA of 1987 at § 1395bbb (West Supp. 1989). The JCAHO standards also have provisions concerning patients' rights. JCAHO HOME CARE STANDARDS, *supra* note 1, at 3-6 (Patient/Client Rights and Responsibilities).

72. *Makas*, 589 F. Supp. at 741.

73. *Id.* at 743.

74. *Id.* at 743. The court suggested that an administrator, director of patient services, registered nurse, or experienced licensed practical nurse could serve as the required expert.

tions in setting the standard of care in cases claiming recovery from a home health agency. In *Roach v. Kelly Health Care, Inc.*<sup>75</sup> the plaintiff sought damages for personal injuries that Edna Tuson sustained in her home while under the care of individuals provided by the Visiting Nurse Association and by Kelly Health Care. The trial court directed the verdict in favor of defendant Kelly Health Care on several of the plaintiff's claims.<sup>76</sup> The Oregon Court of Appeals reversed the trial court's directed verdict in favor of Kelly Health Care, holding that the plaintiff had sufficiently established the standard of care due from the agency and that the trial court should have submitted the issue to the jury.<sup>77</sup>

Mrs. Tuson was eighty-seven years old, living alone, and becoming confused. Her daughter arranged for the Visiting Nurse Association to provide home nursing visits several times a week. After Mrs. Tuson suffered a stroke, her daughter called Kelly Health Care to arrange for twenty-four-hour live-in care. Kelly sent certified nurse assistants rather than home health aides. Certified nurse assistants (CNAs) receive sixty hours of training with an emphasis on institutional care, whereas home health aides (HHAs) receive an additional sixty hours of training with an emphasis on home care.<sup>78</sup> Both the trial court and the appeals court concluded that the state licensure law in Oregon required Kelly to provide home

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75. 87 Or. App. 495, 742 P.2d 1190 (1987). This was the only reported case discovered that involved a personal injury claim by a patient against a home health agency. In addition, staff members of ten state licensure enforcement agencies and the National Senior Citizen's Law Center reported that they were unaware of any other similar litigation. Telephone interviews with officials from: Arizona: Bonnie James, Health Surveyor, Department of Health Care Institutions (Apr. 22, 1988); California: Constance Clayton, Specialist, Home Health Agencies Referral Center, Adult Day Health Care, Department of Health Services (Apr. 11, 1988); Illinois: Don Gunther, Program Consultant, Office of Health Regulations, Department of Public Health (Mar. 29, 1988); Iowa: Ann Drake, Iowa Department of Inspections & Appeals (Apr. 19, 1988); Minnesota: Julianne Johnston, Office of Quality Assurance and Review (Apr. 19, 1989); Missouri: Lois Kollmeyer, Chief of Bureau, Home Health Licensing and Certification (Mar. 28, 1988); New Jersey: Dr. Solomon Goldberg, Director of License and Certification Standards for Health Facilities (Apr. 12, 1988); New York: Debra Hanson, Consultant Nurse, Community Nursing Service, Bureau of Home Health Services (Mar. 31 1988); Pennsylvania: Jan Staloski, Health Facility Quality Examiner, Division of Primary Care (Apr. 12, 1988); Texas: Becky Buchinor, Program Administrator, Health Facilities Licensure and Certification, Department of Health (Apr. 19, 1988); and National Senior Citizens Law Center: Toby Edelman, Attorney (Apr. 19, 1989).

76. 742 P.2d at 1193. There is no mention in the case of a claim by plaintiff against the Visiting Nurses Association.

77. *Id.* at 1195. The Court of Appeals also reversed the trial court for deficiencies in its instructions to the jury on the claim it did allow to be submitted to the jury. *Id.*

78. *Id.* at 1192.

health aides as opposed to certified nurse assistants for Mrs. Tuson.<sup>79</sup>

In addition, the plaintiff claimed that Kelly violated a requirement that the home care organization clearly set forth in writing lines of authority, and not delegate administrative and supervisory functions to another agency or organization. The appeals court stated that "[t]here was evidence that the Kelly CNAs were confused about whether they were responsible to their Kelly supervisor or to the VNA nurses for Tuson's care and that the Kelly supervisors thought that VNA had primary responsibility for nursing care, including instructing the Kelly CNAs."<sup>80</sup> The court went on to hold that "[t]he jury could have found that, with more frequent supervision,"<sup>81</sup> Mrs. Tuson's injury could have been avoided, and therefore, that the jury could have found Kelly liable for the injuries.<sup>82</sup> The ruling of the appeals court reversed the trial court's ruling, which had prevented the jury from considering the plaintiff's claim of liability on the negligent delegation point. The appeals court did not hold Kelly liable; rather, the court held that the jury must be allowed to consider that question.<sup>83</sup>

Home health care agencies fall subject to a variety of standards that plaintiffs might offer as proof of the standard of care owed to patients by home care providers. In addition to regulations developed by state and federal enforcement agencies, at least four national associations have developed standards for home care, including the National Association for Home Care, the Joint Commission on Accreditation of Healthcare Organizations, the National League for Nursing, and the American Nurses Association.<sup>84</sup>

Although the *Darling* court relied in part on the JCAHO standards,<sup>85</sup> neither the nursing home cases nor *Roach*<sup>86</sup> discussed pri-

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79. *Id.* at 1193. The appeals court reported that the testimony of defendant's expert was based on "the difficulty of finding HHAs willing to do 24-hour in-home care and on the extra costs to the agency and to the family for using HHAs." *Id.* The court stated that "[t]hose matters are for legislative consideration . . . . The trial court did not err in concluding that the law required Kelly to provide HHAs to Tuson." *Id.* Although the trial court had correctly concluded that the statute proved the standard of care, it failed to correctly instruct the jury concerning plaintiff's claim on this point. *Id.* at 1193-95.

80. *Id.* at 1194.

81. *Id.* at 1195.

82. *Id.*

83. *Id.*

84. Refer to text accompanying notes 20-24 *supra*.

85. Refer to notes 57-62 *supra* and accompanying text.

86. Refer to notes 75-83 *supra* and accompanying text.

vate accreditation standards. Private accreditation for nursing homes has never been as widely accepted as it has been for hospitals.<sup>87</sup> In fact, patient advocacy groups strenuously opposed a Reagan administration proposal to allow substitution of Joint Commission accreditation for Medicare certification for nursing homes.<sup>88</sup> It is unlikely that the courts will accept as evidence of the *customary* standard of care accreditation standards that are not well accepted by the particular industry.<sup>89</sup>

Acceptance of state regulations as proof of the standard of care in *Roach* and rejection of this strategy in *Stogsdill*<sup>90</sup> and *Makas*<sup>91</sup> may be explained by differences between home health care agencies and nursing homes. The distinction drawn by the court in *Stogsdill* between nursing homes and hospitals<sup>92</sup> does indicate that judges may pay close attention to differences among types of health care providers.

The *Stogsdill* court commented:

It must be remembered that this is a nursing home and not a hospital. It may be that what would be negligence in a hospital because of its greater control over physicians and its more extensive facilities would not be negligence in a nursing home. Since the regulations do not clearly set forth the standard of care required, expert testimony was still required in this case . . . .<sup>93</sup>

A more helpful analysis of these cases, however, focuses on the type of regulation involved in each case, especially the specificity of the regulation and the fit between the regulation and the incident. For example, when offered evidence of the standard of care applicable to health care facilities, courts may be more receptive to regulations concerning structural measures for quality control, which tend to be within the expertise of the administration of the institution. Standards falling within this category include the establishment and implementation of procedures and policies that concern training and placement of caregivers, maintaining records,

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87. The JCAHO has accredited nursing homes since 1966. As of 1985, only approximately 1400 nursing homes were accredited. IOM STUDY, *supra* note 1, at 185-86.

88. IOM STUDY, *supra* note 1, at 1-2.

89. Refer to text accompanying notes 104-15 *infra* for a discussion about the acceptance of private accreditation within home health care.

90. Refer to notes 63-69 *supra* and accompanying text.

91. Refer to notes 70-74 *supra* and accompanying text.

92. 343 N.E.2d at 612.

93. *Id.* at 612. The appellate court found the testimony of plaintiff's expert witness equivocal on the issue of the negligence of the nurses and the facility. *Id.*

and monitoring of the care given and the incidents that arise during the course of that care. Structural standards concerning personnel assignment and supervisory responsibility were used in *Roach*. In contrast, the issues resolved against the plaintiffs on the question of proof of the standard of care in both *Stogsdill* and *Makas* primarily concerned the adequacy of the nursing or medical care itself. In the context of malpractice or negligence litigation, these cases contain important judicial explanations of the relationship of state licensure regulations and private accreditation standards to the standard of care owed to the individual patient.

#### D. *Statutory Private Rights of Action*

To overcome some of the obstacles to successful litigation of claims by persons injured within nursing homes, several states have enacted statutory private rights of action.<sup>94</sup> These statutes typically provide enhanced damages for violations of state licensure standards. The state legislatures enacting these statutes intended to improve the quality of care provided in nursing homes by creating "private attorneys general" for the enforcement of state standards.<sup>95</sup> Although only a few reported cases involve these statutes, these few cases illustrate the significance of the statutory private rights of action in litigation against health care providers.

In *Stiffelman v. Abrams*<sup>96</sup> the Missouri Supreme Court considered the claims of the estate of a nursing home resident who died from physical abuse by an employee of the facility. The court allowed the resident's estate to bring an action against the facility under the state's statutory private right of action rather than as a claim for wrongful death.

The court held that the facility had breached the Missouri nursing home residents' bill of rights provision, which requires that the facility "insure" that each resident "is free from mental and physical abuse."<sup>97</sup> Characterizing the abuse as a breach of the bill of rights brought the employee's act within the reach of the private right of action. More importantly, the statutory action in this case

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94. See N.Y. PUB. HEALTH LAW §§ 2800-2813 (Consol. 1988); MO. ANN. STAT. § 198.088 (Vernon Supp. 1989).

95. See generally Hoffman & Schreier, *A Private Right of Action Under Missouri's Omnibus Nursing Home Act*, 24 ST. LOUIS U.L.J. 661 (1981) (examining the private right of action under Missouri law).

96. 655 S.W.2d 522 (Mo. 1983).

97. *Id.* at 526.

allowed the award to the resident's estate of punitive damages and damages for the pain and suffering of the resident, despite the death of the resident. The action also required the facility to pay the plaintiff's attorney's fees.

In *Harris v. Manor Healthcare Corp.*,<sup>98</sup> the plaintiff, a nursing home patient, suffered a decubitus ulcer on her heel that became infected and required the amputation of her leg. The plaintiff sued the facility based on several theories, including the Illinois private right of action statute.<sup>99</sup> In claiming punitive damages under common-law negligence theory, the plaintiff must prove aggravated circumstances, as discussed previously.<sup>100</sup> The Illinois statutory private right of action, however, provides for treble damages on proof of negligence alone, without further evidence of aggravated circumstances.<sup>101</sup> The defendant facility in *Harris* argued that the statute violated the constitutional guarantees of due process. The Supreme Court of Illinois upheld the statute because it was intended to create a "private attorney general" for the enforcement of nursing home standards.<sup>102</sup>

Patients of home health care face obstacles to successful litigation of their claims for negligent care or malpractice similar to those faced by nursing home patients.<sup>103</sup> In fact, in a few instances discussed previously, home health patients are in an even worse position.<sup>104</sup> Even more so than in nursing homes, the regulation of home health care must rely on the capacity of the patients themselves to identify and pursue breaches of standards of care. For these reasons, full effectiveness of regulating home health care through litigation awaits statutory private rights of action that include provisions for enhanced damages and attorney's fees for prevailing plaintiffs.

Private litigation can exert significant influence on quality control by health care providers,<sup>105</sup> but litigation by private parties cannot replace government regulation. Private litigation, in con-

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98. 111 Ill. 2d 350, 489 N.E.2d 1374 (1986).

99. ILL. REV. STAT. ch. 111 ½, para. 4153-602 (1988).

100. Refer to note 41 *supra* and accompanying text.

101. ILL. REV. STAT. ch. 111 ½, para. 4153-602 (1988).

102. 489 N.E.2d at 1382-83.

103. Refer to text accompanying notes 36-38 *supra*.

104. Refer to text accompanying notes and 42-44 *supra*.

105. There has been an increasing interest in alternative dispute resolution techniques for malpractice and negligence claims. The impact of these methods on elderly health care patients has not been thoroughly analyzed and falls outside the scope of this article.

trast to government regulation, places the largest proportion of the cost of quality control on the individual choosing to sue and may have a negative discriminatory effect against elderly persons.<sup>106</sup> Private litigation has a limited proactive effect on quality through deterrence of substandard behavior. Private litigation, unlike government regulation related to reimbursement or licensure, can operate effectively only when substandard care has caused compensable injury. Legal limitations narrow the realm of compensable injury, as a subset of all forms of injury, when they require, for example, the survival of the patient and measurable physical injury. Private litigation, then, can play only a part in an overall regulatory scheme.<sup>107</sup> State government remains a potentially important source of quality-of-care regulation and enforcement in long-term care.

### III. STATE LICENSURE AND ENFORCEMENT MECHANISMS

Both the federal and state governments regulate long-term care. In the regulation of nursing homes, the federal and state governments have each played significant roles: the federal government as payor-regulator in the federal Medicare program and the state-federal Medicaid program, and the state as partner in Medicaid and as licensor. A strong interplay between the federal and state regulatory systems, especially in regard to enforcement, has created a dynamic in relation to regulatory standards, methods, and practice. This dynamic is illustrated by the adoption of intermediate sanctions by the United States Congress for use in Medicare and Medicaid enforcement after more than a decade of development and implementation of sanctions used by the states in licensure.<sup>108</sup>

Similarly, home health agencies are subject to both federal and state regulation through Medicare and Medicaid and through licensure. Unlike state licensure of nursing homes, however, licen-

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106. "Claim frequency and severity are unrelated to the percentage of the population over age 65. Since hospital admission rates for the elderly are roughly twice as high as for persons under 65, and the rate of negligent injury per admission is roughly twice as high for the elderly, the absence of any significant difference in claim frequency implies that the probability of an elderly person's filing a claim, given a potentially actionable injury, is roughly one-fourth that of persons under 65." P. DANZON, *supra* note 25, at 74.

107. See generally Jost, *The Necessary and Proper Role of Regulation To Assure the Quality of Health Care*, 25 Hous. L. Rev. 525 (1988).

108. Refer to notes 176, 179-84 *infra* and accompanying text.

sure of home health agencies rests on an undeveloped, bare-bones system. State licensure of home health care providers remains very narrow in coverage and falls among the lowest of priorities for state enforcement agencies. In light of the contributions state licensure has made to the regulatory scheme applicable to nursing homes, the nature of licensure of home health agencies merits examination. Additionally, as with nursing homes, federal regulation of home health care applies only to organizations participating in Medicare or Medicaid. By some estimates, fewer than half of the organizations providing home health care participate in these programs.<sup>109</sup>

This section examines state licensure for home health care, beginning with a discussion of the appropriate regulatory model for home health care using governmental regulation of hospitals and nursing homes as alternative models. It then provides a brief overview of the status of licensure for home health care providers, and identifies the coverage of the state statutes, the intermediate sanctions currently available, and the experience of several states in the licensure of home health agencies. Finally, the rationale and experience supporting intermediate sanctions for nursing homes are analyzed, with a view toward applying these sanctions to home health care, and preliminary conclusions are drawn concerning the use of intermediate sanctions in home health care.

#### A. *Regulatory Models*

The structure or definition of a regulatory model involves a number of descriptors. Prominent factors include the locus of control (whether governmental or professional); the nature of standards (whether structure, process or outcome); the balance in the standards between regulatory control and provider discretion; and the character of the enforcement relationship (whether consultative or adversarial). In each of these factors, nursing home regulation has differed markedly from the regulation of hospitals. The contrast between the regulatory models of nursing homes and hospitals has become less defined as a result of recent developments in cost-containment and quality-control mechanisms operating in acute care. The traditional dichotomy remains useful, however, as a framework that relates regulation to its institutional context and

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109. See BLUEPRINT, *supra* note 9, at 44.



thereby raises relevant questions about the regulatory model appropriate to home health care.

For purposes of the following discussion, a rough dichotomy of public regulation and private regulation provides a shorthand method of comparing nursing home and hospital regulation. As with all analytical dichotomies, this analysis emerges from a partially false assumption because few, if any, regulatory systems are entirely public or entirely private. Furthermore, generalizations about public versus private regulation may reflect only customary rather than immutable distinctions. For example, it is common to place public regulatory programs in the enforcement or adversarial category and to place private regulatory programs, including private accreditation and internal quality assurance, in the consultative or collegial category.<sup>110</sup>

Nursing homes differ from hospitals in terms of patient population, history of development, and intrainstitutional role of the medical and nursing professions. Each of these characteristics influences the form and role of government regulation.

Unlike hospital patients, patients in nursing homes face chronic rather than acute illness. The chronic nature of the illness contributes to an "overriding sense [on the part of caregivers] that the clientele are in inevitable decline" and leads to "therapeutic nihilism" and a "poor self-image" on the part of providers.<sup>111</sup> The average length of stay for nursing home patients far exceeds the average length of stay for patients in acute-care hospitals. A study on nursing home utilization conducted by the Institute of Medicine in 1976 found that 63% of new residents either died or were discharged within three months of admission; but 70% of all residents in a nursing home at any one time had been there at least eighteen months.<sup>112</sup> Although 13% of nursing home residents have no visitors in the course of a year, approximately 62% of nursing home residents receive weekly or daily visits.<sup>113</sup> The 1985 report of the National Center for Health Statistics reported that 88.7% of nursing home residents were dependent in bathing; 75.4% in dressing;

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110. The placement of regulatory systems into customary models remains debateable, but the debate lies outside the scope of this discussion.

111. Kane & Kane, *Long-Term Care: Variations on a Quality Assurance Theme*, 25 *INQUIRY* 132, 132 (Spring 1988).

112. IOM *Study*, *supra* note 1, at 47.

113. *Id.* at 46.

51.9% in continence; and 39.3% in eating.<sup>114</sup>

Characteristics of this population limit the population's ability to bring suit to remedy harms suffered as a result of breaches of established duties of care. Private litigation, therefore, plays a smaller role in nursing home quality assurance than in hospital quality assurance. The comparative isolation of nursing home residents requires that the state take an active role in monitoring the quality of care they receive. Their isolation also diminishes their ability to seek services, such as legal assistance, for themselves. The long-term nature of their confinement heightens sensitivity to the impact of failures in quality of care and quality of life.<sup>115</sup>

Physicians ordinarily control the operation of a hospital, especially where treatment decisions are concerned.<sup>116</sup> Reinforced by external organizations such as the JCAHO, the medical staff structure plays a critical role in the governance of the hospital.<sup>117</sup> The traditional rationale for physician power in the hospital rests on the assumption that the physician's primary concerns focus on quality of care and the best interests of the patient.<sup>118</sup> Although this view may not accurately reflect physician behavior in some instances,<sup>119</sup> the implicit underlying respect and trust may affect the nature of the regulation of the traditionally physician-dominated hospital in comparison with the nursing home. Physicians still do not exert a significant degree of control in the management of

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114. NATIONAL CENTER FOR HEALTH STATISTICS, U.S. DEPT. OF HEALTH & HUMAN SERVICES, THE NATIONAL NURSING HOME SURVEY OF 1985, at 34 (1989) [hereinafter NURSING HOME SURVEY].

115. IOM STUDY, *supra* note 1, at 47-48.

116. See generally P. Starr, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982); Thompson, *The Uneasy Alliance*, in PHYSICIANS & HOSPITALS (1985); Havighurst, *Doctors and Hospitals: An Antitrust Perspective on Traditional Relationships*, 1984 DUKE L.J. 1071.

117. The Joint Commission's standards for hospital accreditation require that there be "a single organized medical staff that has overall responsibility for the quality of the professional services provided by individuals with clinical privileges, as well as the responsibility of accounting therefore to the governing body." JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS. MANUAL FOR HOSPITALS Standard MS. 1 (1989). The medical staff generally controls the granting, monitoring and revocation of admitting privileges (although the governing board makes the final decision), participates in the hospital's governing board and controls committees that review the quality of medical treatment in the hospital. The Joint Commission's standards further require that the medical staff develop its own by-laws and adopt them with the approval of the hospital's governing board, placing significant power in the hands of the medical staff as against the hospital. *Id.* at Standard MS. 2.

118. INSTITUTE OF MEDICINE, FOR-PROFIT ENTERPRISE IN HEALTH CARE 172 (B. Gray ed. 1986).

119. *Id.* at 173.

nursing homes, which have no organization comparable to the hospital's medical staff. Although physicians in hospitals generally see patients on a daily basis, physicians in nursing homes typically visit patients on an irregular basis, usually when the staff identifies a need.

Because physicians self-regulate their own practices and because physicians control hospitals, the tradition of self-regulation has transferred to some extent to the regulation of hospitals. The extraordinarily wide acceptance of private accreditation and the domination of the JCAHO as the primary private accreditation agency for hospitals has reinforced the practice of self-regulation for hospitals.<sup>120</sup> With no such tradition to borrow from, nursing homes fall subject to a more intrusive public regulatory model.

In the area of professionalism, the role of the nursing staff in hospitals contrasts with the nursing role in nursing homes. While professional nurses dominate direct patient care in hospitals, the role of the registered nurse in the majority of long-term care institutions is that of supervisor with most of the direct patient care rendered by nurses' aides.<sup>121</sup> The modern self-concept of professional nursing requires independent judgment and advocacy on behalf of the patient.<sup>122</sup> Through professional nurses, the hospital patient acquires another daily caregiver who has been socialized through professional education with the interest and capacity to assure quality care.

Nursing homes typically experience a turnover rate of 70% to

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120. The American Medical Association, American Hospital Association, American College of Surgeons, and the American College of Physicians are member organizations of the Joint Commission on Accreditation of Healthcare Organizations. The American College of Surgeons established a private accreditation program in 1919, to which the JCAHO is a successor. Eighty percent of acute care hospitals in the United States are accredited by the JCAHO. Nearly all hospitals with more than 25 beds are JCAHO accredited. For a thorough discussion of the history and influence of the JCAHO, see Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. REV. 835 (1983).

121. "About 15% of the nursing personnel in the nation's nursing homes are registered nurses, 14% are licensed practical nurses, and 71% are nurse's aides. 'Aides . . . provide six times as much care in nursing homes as do registered nurses, and five times as much care as do licensed practical nurses.'" IOM STUDY, *supra* note 1, at 101, quoting Weisfeld, *Accreditation, Certification and Licensure of Nursing Home Personnel: A Discussion of Issues and Trends* (background paper prepared for the Committee on Nursing Home Regulation, Institute of Medicine, National Academy of Sciences, 1984).

122. See, e.g., Winslow, *From Loyalty to Advocacy: A New Metaphor for Nursing*, HASTINGS CENTER REP., June 1984, at 32.

100% each year in the persons who provide direct patient care.<sup>123</sup> High turnover of caregivers in nursing homes adversely affects the level of training of the facility's staff and the quality of care provided to patients. Unlike the hospital nursing staff, all of whom hold at least nursing school diplomas and many of whom hold college degrees, nurses' aides typically train on the job.<sup>124</sup>

At the time when more aggressive licensure systems developed for nursing homes, the demand for nursing home beds was very high. The National Center for Health Statistics reported that in 1985 occupancy rates in nursing homes continued to be high, averaging well over 90%.<sup>125</sup> The strong demand for nursing home spaces leaves a potential nursing home resident or the resident's family with little or no choice among facilities once certain essential factors are considered. Those factors include the source of payment (if Medicare, Medicaid or other public assistance) and level of care required (especially if of a level not reimbursed by public assistance). Choice is further limited by the short length of time available for placement and the stress accompanying a severe change. Such constraints on consumer choice limit the power of the market over quality and strengthen the argument for quality-control regulation. The shortage of nursing home beds also led to a demand for enforcement alternatives to decertification and revocation that would result in the closing of a needed, even if substandard, facility.<sup>126</sup>

Similarly, the long stay of the majority of nursing home patients makes it difficult to close and empty a facility by attrition. By contrast, if hospital admissions are discontinued even for a very short time, the hospital's census ordinarily declines precipitously. In addition, some evidence supports claims that the transfer of frail, elderly nursing home patients causes physical and emotional injury and perhaps death.<sup>127</sup> The prospect of transferring, and perhaps injuring, the residents of a nursing home discouraged enforcers from using sanctions that would result in closing the facility.

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123. IOM STUDY, *supra* note 1, at 11.

124. OBRA of 1987 mandates training for nurses' aides. OBRA of 1987, *supra* note 1, at § 4021 (codified as amended at 42 U.S.C. A. § 1395 (West Supp. 1989)).

125. NURSING HOMES SURVEY, *supra* note 114, at 8.

126. See, e.g., Note, *The Need to Change Traditional Entitlement Doctrine Analysis in Decertification of Nursing Homes*, 59 N.C.L. REV. 943, 964 (1981).

127. See generally Comment, *Involuntary Relocation of Nursing Home Residents and Transfer Trauma*, 24 ST. LOUIS U.L.J. 758 (1981) (applying different legal theories to prevention of harmful or unnecessary patient transfers).

Finally, the nursing home industry has been the subject of many locally and nationally publicized scandals concerning patient abuse and poor patient care.<sup>128</sup> For the most part, hospitals have escaped such publicity. The scandals have influenced the course of nursing home regulation, whether they actually revealed a significant problem in the nursing home industry that justified aggressive regulation or simply created a political atmosphere that would support the efforts of state legislatures in passing strict nursing home statutes.<sup>129</sup>

The distinctions between nursing homes and hospitals may not be as bright as commonly portrayed. Some of the traditional assumptions may change, for example, as nursing homes move even more toward a medical model and provide care that is increasingly complex and technologically sophisticated. The distinctions between nursing homes and hospitals, whether real or constructed, have resulted in very different regulatory models. Hospitals have followed a path largely, though not entirely, of self-regulation. Nursing homes, in contrast, are highly regulated by both the state and federal governments.

Advocates of increased regulation of home health care should ask whether home health providers fit more in the hospital self-regulation model or in the nursing home public regulatory model. Answers to this question will influence such policies as the acceptance of private accreditation as a substitute for certification or licensure,<sup>130</sup> the level of funding for the quality-control regulatory process, and the identification of the role of the regulators as either consultants or enforcers.<sup>131</sup>

Like nursing homes, home health agencies present several characteristics that support a greater degree of public regulation. Home health agencies predominantly serve long-term patients—a

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128. See, e.g., F. MOSS & V. HALAMANDARIS, *TOO OLD, TOO SICK, TOO BAD—NURSING HOMES IN AMERICA* (1977); M. MENDELSON, *TENDER LOVING GREED* (1974).

129. For a discussion of the relationship between nursing home reform and nursing home reformers/legislators, see Johnson & Hoffman, *Missouri's Omnibus Nursing Home Act*, 26 ST. LOUIS B. J. 4 (Winter 1980).

130. The Health Care Financing Administration has proposed that hospital-based home health agencies accredited by the JCAHO and freestanding agencies accredited by the National League for Nursing be deemed to have met standards for participation in Medicare. 52 Fed. Reg. 49,510-16 (to be codified at 42 C.F.R. pt. 405) (proposed Dec. 31, 1987).

131. For a criticism of enforcers as consultants in the nursing home enforcement process, refer to Jost, *supra* note 4, at 162-63. For an analysis of the consultant/enforcer roles on a comparative basis, see Day & Klein, *The Regulation of Nursing Homes: A Comparative Perspective*, 65 MILBANK Q. 303-47 (1987).

chronically and seriously disabled population. In light of demand, a shortage of home health agencies may arise, especially for patients relying on public payor sources, and this shortage may diminish the operation of the market. Unlike hospitals, home health care has only a weak tradition in private accreditation. Finally, although accreditation and regulatory standards currently applicable to home health care require the participation of health care professionals in certain structural capacities, daily caregivers are predominantly nonprofessional or paraprofessional.

The typical long-term patients of home health care tend to be physically debilitated. A New York study of case mix in home health care found that the majority of the patients of certified home health agencies in New York State were "physically impaired with skilled care needs."<sup>132</sup> These patients required assistance with medications, nursing monitoring, ostomy care, range of motion exercises, tracheostomy care, and wound care.<sup>133</sup> Certified home health agencies also served large numbers of patients requiring rehabilitation, special care (including patients with grade four decubitus, dialysis, and nasogastric feeding and patients who were comatose or quadriplegic), and complex management (including patients with dehydration, terminal illness, internal bleeding, hemiplegia, intravenous transfusions, and ventilators).<sup>134</sup>

Home health patients experience some degree of isolation because they are at least partially, if not totally, confined to their residences because of chronic illness. Unlike nursing home patients, however, patients receiving home health care are not within the complete custody of an institution.

Transfers from one home health agency to another can cause stress to the patient and family, but there would seem to be little probability of severe physical harm caused by the transfer itself except when care is actually interrupted. Knowledge about what actually happens to the patients of home health agencies that do close, however, remains sparse.<sup>135</sup> The process and costs, both financial and personal, of transferring patients from one agency to

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132. EXECUTIVE SUMMARY, DEVELOPMENT OF A SURVEY, CASE MIX MEASUREMENT SYSTEM, AND ASSESSMENT INSTRUMENT TO RATIONALIZE THE LONG TERM CARE HOME CARE SYSTEM 6 & 12 (Oct. 1986).

133. *Id.* at 6.

134. *Id.* at 12.

135. The state agency staff interviewed for this project did not know what happened to patients when a home health agency closed. Refer to note 75.

another must be analyzed as a foundation for planning an appropriate regulatory system applicable to home health care.

The supply of regulated health care will have an impact on the costs of transfer and on the willingness of regulators to enforce standards. In part, certificate-of-need requirements caused the shortage of nursing home beds that occurred during the development of the "reformed" nursing home statutes.<sup>136</sup> In many states, home health agencies are subject to certificate-of-need requirements as well.<sup>137</sup> Requiring a certificate of need limits the entry of new firms into the health care market and constricts the supply of health care.<sup>138</sup> The Federal Trade Commission, in a study concerning the application of certificate of need to home health care, found no justification for the certificate of need in home health.<sup>139</sup> The report commented that "by retarding or preventing entry of new firms, [certificate-of-need] regulation of home health markets may be denying consumers the benefits of innovative or low-cost services that could lower the cost or improve the quality of health care."<sup>140</sup> Hospital discharge planners report difficulty in placing patients with home health agencies for postdischarge treatment.<sup>141</sup> A shortage of home health care capacity or a failure in the availability of information needed by patients for access to home health care<sup>142</sup> could limit the ability of consumers to move freely among

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136. Rango, *Nursing-Home Care in the United States: Prevailing Conditions and Policy Implications*, 14 NEW ENG. J. MED. 883, 883-84 (1982).

137. As of June 1985, thirty-four states required certificate of need for home health agencies. A certificate-of-need program requires that certain health care facilities prove to a state agency that the services they seek to provide are needed by the community in which they propose to operate and requires the facilities to obtain a certificate authorizing their operation. Anderson & Kass, *supra* note 12 at 19.

138. *See id.* at 24-34.

139. *Id.* at 14-15 & 105-07.

140. *Id.* at 15. The study based its conclusion in part on the fact that, unlike other health care facilities, entry into the home health market was relatively inexpensive, typically requiring fixed costs of only \$15,000. *Id.* at 7.

141. In a 1987 General Accounting Office survey of hospital discharge planners, 86% reported problems with home care placements for Medicare beneficiaries; 52% of that group cited Medicare rules and regulations as the most important barrier to placement. *Home Care: The Agony of Indifference, The Role of the Older Americans Act in Assuring Access to Quality Home Care: Hearings Before the Senate Special Comm. on Aging*, 100th Cong., 1st Sess. 111 (1987) (statement of Ann Mootz, representative of the National Association for Home Care) [hereinafter *Home Care Hearings*].

142. *See, e.g.,* Heinen, Gorski & Roe, *Quality of Care Research and Projects in Progress*, 7 HEALTH AFF. 145, 148 (1988) for a brief description of projects on consumer health care choice information (representative projects include the JCAHO, the American College of Physicians, the American Medical Association, and the Health Care Quality Alliance).

providers on the basis of quality and will require more aggressive regulation.

Although JCAHO has had tremendous subscription to its hospital accreditation program, through which it accredits 80% of the hospitals in the United States, its program for nursing homes is not nearly as well accepted.<sup>143</sup> Home health providers themselves generally do not support private accreditation, although the National Association for Home Care supports the proposal of the Health Care Financing Administration to substitute private accreditation for the Medicare certification process. In 1985 the Association surveyed 1500 home health agencies for their attitudes toward private accreditation. Approximately 71% of those responding said that they did not believe that there should be a "separate accreditation process besides the state survey."<sup>144</sup> When asked how much they would be willing to pay for the accreditation process, the majority of those responding selected \$100 to \$500.<sup>145</sup> JCAHO accreditation for home care requires a downpayment of \$1000 for a survey.<sup>146</sup> Only 30.9% of those responding to the survey reported that they were accredited.<sup>147</sup> The majority of the accredited agencies were institution-based agencies most of which were probably accredited as part of the institution's accreditation.<sup>148</sup> Of course, this attitude could change if private accreditation exempted the agency from annual Medicare surveys as proposed by the Health Care Financing Administration.

Finally, the highest proportion of home health care is provided by nonprofessional or paraprofessional staff. As in nursing home care, registered nurses serve mostly, though not solely, supervisory functions. Again, as in nursing homes, physicians responsible for the patient's care are infrequently on site, if ever, to observe the care provided by agency staff, although under Medicare a physician must approve the patient's plan of care.<sup>149</sup> Internal quality assurance under the JCAHO's standards for accreditation of free-standing home care agencies must be conducted by representatives of each type of service provided "and/or those also involved in the

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143. Refer to note 21 *supra*.

144. NAT'L ASS'N FOR HOME CARE, HOMECARE QUALITY ASSURANCE SURVEY 9 (1985) [hereinafter *QUALITY SURVEY*].

145. *Id.* at 9.

146. JCAHO HOME CARE STANDARDS, *supra* note 1, at xii.

147. *QUALITY SURVEY*, *supra* note 144, at 17.

148. *QUALITY SURVEY*, *supra* note 144, at 2.

149. 42 C.F.R. § 405.1223 (1977).



patient's care, including, as appropriate, patients/clients' physicians."<sup>150</sup> Medicare does require that the policies of certified agencies be "established by a group of professional personnel . . . including one or more physicians and one or more registered professional nurses."<sup>151</sup>

Home health agencies and nursing homes share characteristics relating to population, market failure, lack of a well-established private accreditation system, and the limited involvement of health care professionals in direct patient care. In addition, the impact of private litigation has been even more limited in home health care than in nursing homes. These conditions would seem to set the stage for active public regulation of home health care.

Political factors may have a much greater impact on the nature of regulation of health care facilities, however, than do factors relating to the particular characteristics of those facilities. For nursing homes, the scandals revealing abuse and mistreatment of elderly nursing home residents formed a negative public perception of nursing homes at a time when protective legislation for the elderly was generally quite popular. For home health care, the absence of such negative publicity and the image of someone being cared for in their "home sweet home" with the assistance of their "loving family" may influence its regulation.

Although this discussion has focused on comparing the regulation of nursing homes with that of hospitals for the purpose of raising questions concerning the appropriate model for home health care, it may be that neither of these models fit home health care. Unlike nursing homes and hospitals, home health care is not institutional care. Visitation of the site of care, in this case private homes, will be time consuming and expensive.

Further investigation and analysis should be conducted to test the assumption that a system designed for health care institutions provides the best model for regulating and monitoring home health care agencies. Alternative models may rely more heavily on the licensure, certification, or registration of the nonprofessional or paraprofessional providers themselves.<sup>152</sup> These schemes are cer-

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150. JCAHO HOME CARE STANDARDS, *supra* note 1, at 22 (Required Characteristic, QA.1.4.5.). The standards do not identify this as a "key standard" for accreditation.

151. 42 C.F.R. § 405.1201(a) (1977).

152. See, e.g., Goldman & Puro, *Decertification of Police: An Alternative to Traditional Remedies for Police Misconduct*, 15 HASTINGS CONST. L.Q. 45 (1987) (thirty-seven states require police officers to be certified and will decertify officers to deter misconduct).

tainly subject to criticism, particularly because they increase the cost of care and would seriously impair informal care systems that rely on hiring friends and acquaintances.<sup>153</sup> Furthermore, such schemes cannot serve as the only regulation for home health care. An appropriate regulatory system would not relieve the agency of due care in the hiring process or in monitoring the care actually provided. Licensure, certification or registration, however, may give the regulatory process the capacity to more directly affect the qualifications and performance of the caregivers themselves.

A focus on the individual caregivers, as a supplement to regulation of home health organizations, would effectively address the structure of home health care delivery as generally practiced. Regulation must assess the degree of control that the regulated provider has over the desired outcome. The institutional control over the quality of individual providers in hospitals (through staff privileges, the employment relationship and collegial observation of practices) and in the nursing home (through the employment relationship and direct supervision) is largely absent in home health care. The caregivers themselves frequently have only very brief contact with the main site of the agency or with other caregivers, limiting the agency's capacity to monitor their performance and to socialize them to the expectations of the agency.<sup>154</sup> A regulatory system focusing on the individual caregiver, if accompanied by effective public disclosure, can, in fact, honor the recruiting by the patient's family that has been a part of home health care delivery. Even if such parallel or complimentary regulation does exist, however, regulation of the agencies themselves will continue in some form.

### B. State Licensure of Home Health Care

At least thirty-eight states license organizations that provide

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153. At least one study has commended the quality of family recruited personal care providers. Refer to note 207 *infra*.

154. A study of home health aides listed the absence of a "collegial atmosphere in a contained work unit" leading to a lack of "regular peer support" as a factor contributing to the unattractiveness of personal care as an occupation. Other factors cited include low wages, variable and often undesirable work environment, lack of guaranteed work hours, low prestige, and demanding and unrealistic clients. *Home Care Hearings, supra* note 141, at 111 (the statement of Ann Mootz, representing National Association for Home Care, quoting *Enhancing Aide Service in the Home: Recommendations for Action*, Report of the Long Term Care Coordinating Committee, Rensselaer County, N.Y. (1985)).

home health care.<sup>155</sup> The coverage of these licensing statutes varies among the states. Several state statutes use a definition similar to that used by Medicare for purposes of reimbursement of home health care costs to describe a home health agency for purposes of licensure.<sup>156</sup> This definition, as it appears in the Medicare regulations,<sup>157</sup> requires that a certified home health agency provide "[p]art-time or intermittent skilled nursing services and at least one other therapeutic service."<sup>158</sup> Borrowing the Medicare definition of home health agencies eligible to receive reimbursement for the definition of agencies required to be licensed results in an imperfect fit. The definition of home health care in the Medicare statute is one developed for the purpose of limiting coverage of home health care and with a view toward funding a less expensive alternative to the care available in nursing homes.

The definition of home health care for purposes of licensure ideally should relate to risks presented by health care delivered in the home. The Medicare definition, of course, does not attempt to do this. Fortunately, home health agencies sometimes provide a variety of services,<sup>159</sup> which would bring them coincidentally within this definition. The use of the Medicare definition of reimbursable home health care reflects the continued reliance on the Medicare certification system as the primary, if not sole, public regulatory scheme for home health care. The role of Medicare reimbursement in the genesis of state licensure of home health care also explains

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155. Refer to note 32 *supra*. The state of Washington only requires certification of home health agencies. WASH. REV. CODE ANN. § 70.126.040 (Supp. 1989), amended by § 70.127.020 (Supp. 1989) (requires home health agencies to be licensed after July 1, 1990). This system is the equivalent of licensure.

156. See, e.g., ARIZ. REV. STAT. ANN. § 36-151(5) (1986) and MISS. CODE ANN. § 41-71-1(a) (Supp. 1988) (both use the definition of home health agency included in the Medicare statute). CAL. HEALTH & SAFETY CODE § 1727(b) (West 1979 & Supp. 1989); GA. CODE ANN. § 31-7-150(3) (1985); ILL. ANN. STAT. ch. 111 ½ para. 2802.04 (Smith-Hurd 1988); and NEB. REV. STAT. § 71-2017.01(21) (1986) (uses a definition identical to that in the Medicare regulations). IDAHO CODE § 39-1301(e) (1985) and MONT. CODE ANN. § 50-S-101(13) (1987) use the definition in the Medicare regulations, with the exception of "intermittent or part-time."

157. The definition in the statute differs from that in the regulations. The statute provides that a certified home health agency is a public or private organization "primarily engaged in providing skilled nursing services and other therapeutic services." 42 U.S.C. § 1395x(o)(1) (1982).

158. 42 C.F.R. § 405.1221(a) (1986). The regulation requires that the agency provide at least one of these services directly and allows the agency to provide the second under contract. *Id.*

159. See, e.g., FTC REPORT, *supra* note 12, at 10.

the continued use of the Medicare definition.

Until the enactment of the Omnibus Reconciliation Act of 1980,<sup>160</sup> for-profit corporations offering home health care were not eligible for Medicare reimbursement unless they were licensed by the state.<sup>161</sup> The influence of Medicare requirements on the initial enactment of state home health agency licensure statutes is found in the legislative history of the statutes of several states. Pennsylvania, for example, enacted licensure to allow proprietary agencies Medicare reimbursement.<sup>162</sup> Once proprietary agencies were made eligible for Medicare absent licensure, the Pennsylvania licensing agency recommended repeal or modification of its licensure statute for several years following the change.<sup>163</sup> Florida originally licensed only those home health agencies that received Medicare.<sup>164</sup> Idaho licenses proprietary home health agencies only.<sup>165</sup>

Several states define home health agencies in terms distinguishable from the definition used in Medicare reimbursement.<sup>166</sup> Some agencies are generally excluded from the requirement of licensure. Providers most commonly exempt from licensure include

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160. Pub. L. No. 96-499, § 930(n)(2), 94 Stat. 2599 (codified at 42 U.S.C. § 1395(0)(7) (1982)).

161. Medicare currently requires that home health agencies certified for Medicare be licensed in states with licensure. 42 C.F.R. § 405.1220 (1986).

162. "A primary reason for including home healthcare agencies under the licensure provisions of the Health Care Facilities Act was to accommodate a Federal Medicare provision, which excluded private profitmaking agencies from Medicare participation, unless the certifying state had a licensure program. To a large degree, the State licensure statute was, therefore, written to include home health care agencies so that they could obtain medical reimbursement." *Rules and Regulations, Title 28 Health and Safety, Home Health Care Agencies*, 16 PA. BULL. 4067 (October 25, 1986).

163. "In 1981, 1982 and 1983, the Department attempted, through legislative action, to eliminate or modify State licensure requirements for home health agencies . . . . The Department believed that adequate protection was provided by the Medicare standards. However, since some agencies remain outside of the Federal program, and, thus, the protection afforded by Federal requirements, the Pennsylvania legislature retained the State licensure provisions for home health agencies." *Id.*

164. Florida amended its home health licensure statute to include all home health agencies in 1985. FLA. STAT. ANN. § 400.462(2) (West 1986 & Supp. 1989).

165. IDAHO CODE § 39-1301(e) (1985). Wisconsin licensed only proprietary agencies until 1981. WIS. STAT. ANN. § 141.15(1)(a) (West 1989).

166. See, e.g., the District of Columbia, which defines a home care agency for purposes of licensure as "an agency, organization, or distinct part thereof, other than a hospice, that provides, either directly or through a contractual arrangement, a program of health care, habilitative or rehabilitative therapy, personal care services, homemaker services, chore services, or other supportive services to sick or disabled individuals living at home or in a community residence facility." D.C. CODE ANN. § 32-1301(a) (1986).

agencies relying on spiritual healing,<sup>167</sup> individuals providing home health care independent of an agency,<sup>168</sup> nursing registries,<sup>169</sup> and agencies operated by the state or local government.<sup>170</sup> Some states exempt Medicare certified agencies from licensure.<sup>171</sup> The exclusion of individuals independently providing home health care, of nursing registries, and of state agencies creates difficulties because these providers have been cited as the source of some quality problems.<sup>172</sup>

### C. *Intermediate Sanctions*

In the regulation of health care providers, intermediate sanctions fall between license revocation, which is the most severe sanction available in a licensure system, and no action in response to violations of the requirements for licensure. Intermediate sanctions include suspension of admissions, public monitors, receiverships, and civil fines, among others.<sup>173</sup>

The development of intermediate sanctions for use in nursing home licensure in the mid-1970s was hailed as a watershed for the activation of state enforcement. The enthusiasm for the use of intermediate sanctions in nursing home enforcement has not waned. In fact, a recent study by the Institute of Medicine (IOM) of the quality of care in nursing homes confirmed the judgment that these enforcement tools contribute significantly to the effectiveness

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167. See, e.g., MINN. STAT. ANN. § 144A.43(4)(1) (West 1989 & Supp. 1989). TEX. REV. CIV. STAT. ANN. § 4447u(6)(12) (Vernon Supp. 1989).

168. See, e.g., KAN. STAT. ANN. § 65-5101(b) (1985); MO. ANN. STAT. § 197.460(1) (Vernon Supp. 1989).

169. See, e.g., MD. HEALTH-GEN. CODE ANN. § 19-401(c)(2)(i) (1987 & Supp. 1988); NEB. ADMIN. R. & REGS. § 175-010.03 (1987).

170. See, e.g., KAN. STAT. ANN. § 65-5101(b) (1985); ME. REV. STAT. ANN. tit. 22 §§ 2147(9), (12) (Supp. 1988).

171. See, e.g., VA. CODE ANN. § 32.1-162.8(2) (Supp. 1988).

172. BLUEPRINT, *supra* note 9. The exclusion of nursing registries is based in part on the notion that such registries operate as employment agencies with the ultimate decision to hire, fire and monitor credentials and performance left to the employer. At least one case has held that a nursing registry could not be held vicariously liable for the negligence of a private duty nurse it had assigned to a patient because the nurse was not an employee of the registry and the registry had not done anything to support a claim for ostensible agency. *Robison v. Faine*, 525 So. 2d 903, 906 (Fla. 1987).

173. For a discussion of the full variety of intermediate sanctions available under nursing home licensure, see A.B.A., MODEL RECOMMENDATIONS: INTERMEDIATE SANCTIONS FOR ENFORCEMENT OF QUALITY OF CARE IN NURSING HOMES (1981) [hereinafter MODEL RECOMMENDATIONS].

of quality-control regulation.<sup>174</sup> The IOM study recommended the adoption of intermediate sanctions by the federal government and by the states,<sup>175</sup> and Congress adopted the recommendation in the Omnibus Budget Reconciliation Act of 1987.<sup>176</sup>

The 1987 budget reconciliation act also authorized intermediate sanctions for home health care.<sup>177</sup> Some observations support the need for intermediate sanctions for home health care.<sup>178</sup> Ten states have intermediate sanctions available for home health care.<sup>179</sup> These sanctions include injunctions,<sup>180</sup> civil fines,<sup>181</sup> and criminal penalties.<sup>182</sup> Whether intermediate sanctions will have a beneficial effect in the regulation of home health care remains an open question. Absent intermediate sanctions, however, enforcement of home health standards by state licensure agencies surely will remain less than effective.

Interviews with staff members of enforcement agencies in ten states provided some information on the experience of the states with licensure. The state agencies interviewed were located in Arizona, California, Illinois, Iowa, Minnesota, Missouri, New Jersey, New York, Pennsylvania, and Texas. Most of these states were chosen because their enforcement of nursing home licensure had been studied as part of the National Academy of Sciences project on nursing home enforcement.<sup>183</sup> Arizona, California, Illinois, Missouri, and New York have no sanctions available beyond denial, revocation, and suspension of the agency's license. The absence of

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174. IOM STUDY, *supra* note 1, at 2.

175. *Id.* at 146-68.

176. OBRA of 1987, *supra* note 1, at §§ 4023 (codified as amended at 42 U.S.C.A. § 1395 bbb (West Supp. 1989)).

177. OBRA of 1987, *supra* note 1, at §§ 4203 & 4213 (codified at 42 U.S.C.A. §§ 1395a, 1396r (West Supp. 1989)).

178. *See, e.g.*, OIG REPORT, *supra* note 47, at 9 which states "[t]he only enforcement power to assure correction of specific deficiencies by non-compliant agencies is an involved decertification process which is rarely used."

179. This conclusion is based on a review of state statutes. State regulations may provide intermediate sanctions not specified in the statute.

180. ILL. REV. STAT. ch. 111.5, para. 2814 (1986); MONT. CODE ANN. § 50-5-221 (1987); PA. STAT. ANN. tit. 35, § 448.817 (1988); TENN. CODE ANN. § 68-11-213 (1987); and TEX. REV. CIV. STAT. ANN. § 4447u(12) (Vernon Supp. 1989).

181. D.C. CODE ANN. § 32-1309(a) (1988); MINN. STAT. ANN. § 144A.45(2) (West 1989); MONT. CODE ANN. § 50-5-221 (1967); PA. STAT. ANN. tit. 35, § 448.817 (1988); TEX. REV. CIV. STAT. ANN. § 4447u(12) (Vernon Supp. 1989).

182. Violations are usually classified as Class A or Class B misdemeanors. *See, e.g.*, FLA. STAT. ANN. § 400.501 (West 1986); KAN. STAT. ANN. § 65-5114 (1985); MO. REV. STAT. § 197.475 (1988).

183. IOM STUDY, *supra* note 1.

intermediate sanctions for home health care in these states contrasts with the situation regarding nursing homes. Each of these states has statutes specifically authorizing intermediate sanctions for nursing homes.<sup>184</sup>

New Jersey, Pennsylvania, and Texas each have at least one intermediate sanction available. The New Jersey Department of Health has the authority to impose fines in addition to revoking or suspending the license.<sup>185</sup> The Pennsylvania Department of Health has the following sanctions: suspension and revocation of license, conditional license, civil fines, injunctions, and appointment of a master to assume operation of the agency until violations are corrected.<sup>186</sup> The Texas Department of Health may use civil penalties and injunctions in addition to revocation and suspension of the license.<sup>187</sup>

Iowa and Minnesota do not yet license home health care agencies. A staff member of the Iowa Department of Inspections and Appeals reported that the Department received very few consumer complaints regarding home health services. Of the few complaints received, most involved fraudulent billing for services not actually provided. Although Minnesota does have a home health licensure statute,<sup>188</sup> regulations implementing that statute are not due until January of 1990.

An effective survey and inspection process serves as a critical prerequisite to effective licensure enforcement. In a 1985 Quality Assurance Survey, the National Association for Home Care asked home health agencies<sup>189</sup> for information concerning the frequency and length of inspections under the Medicare, Medicaid, and state licensure systems. Approximately 78% of the providers reported that Medicare certification on-site "visits" occurred annually; 75% reported annual Medicaid on-site visits; and 71% reported annual "non-Medicare/Medicaid" visits. Of the remaining responses, 2.5%

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184. For a list of the intermediate sanctions for nursing homes available in these states as of 1981, refer to MODEL RECOMMENDATIONS, *supra* note 173, at 57-71.

185. Interview with New Jersey enforcement agency. Refer to note 75 *supra*.

186. PA. STAT. ANN. tit. 35, § 448.817 & .814(b) (1988).

187. TEX. REV. CIV. STAT. ANN. §§ 4447u(11)-(12) (Vernon Supp. 1989).

188. MINN. STAT. ANN. § 144A.46 (West 1989).

189. The Association mailed the survey to over 7000 home care agencies and received 1505 responses. QUALITY SURVEY, *supra* note 144, at 1. Among the agencies responding, 95% were Medicare certified, 87% provided services reimbursed by Medicaid, and 72% provided non-reimbursed services. Only 29% of the respondents were institution-based agencies, and 71% were freestanding agencies. *Id.* at 2.

reported that surveys in all three categories took place at least every six months; 4.2%, every eighteen months; 5.9%, every two years; and 6.4% reported on-site surveys less frequently than every two years.<sup>190</sup>

Eighteen percent responded that Medicare services were sometimes monitored through a written survey without an on-site visit. As for Medicaid services, 20.3% reported written surveys without on-site visits, and for non-Medicare/Medicaid services, 25.4%.<sup>191</sup>

Medicare surveys lasted five hours or less for 24.3% of the providers and six to ten hours for 38%. Medicaid surveys lasted five hours or less for 23.7% of the providers and six to ten hours for 36.3%. Non-Medicare/Medicaid service surveys lasted five hours or less for 24% of those reporting and six to ten hours for 33.5%. Because of the subsequent institution of required home visits under Medicare, the length of on-site inspections should have increased substantially after the Quality Assurance Survey was conducted.<sup>192</sup>

The Quality Assurance Survey also asked home health providers to evaluate the adequacy of the inspection process in assuring quality of care. For overall agency functioning, 80% reported that surveys for Medicare services were sufficient; 78.2%, for Medicaid services; and 73.8%, for non-Medicare/Medicaid services. For skilled professional services, 73.3% reported that surveys for Medicare services were sufficient; 72%, for Medicaid services; and 66.6%, for non-Medicare/Medicaid services. For paraprofessional and homemaker- or home-health aide services, 70.5% reported that surveys were sufficient for Medicare services; 69%, for Medicaid services; and 67.1%, for non-Medicare/Medicaid services. The significant difference in perceptions of "sufficiency" of government

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190. *Id.* at 15.

191. *Id.* at 15-16. The Program Administrator of the Department of Health, Health Facilities Licensure and Certification in Texas reported in an interview for this project that Class B agencies (those agencies that are not Medicare certified) are allowed to complete a self-survey if the state has not inspected the agency in the twelve months prior to the date of licensure renewal. Refer to note 75 *supra*.

192. QUALITY SURVEY, *supra* note 144, at 15. The Office of Inspector General, however, reported that home visits required under a directive from the Health Care Financing Administration in November 1985 were not being made as of 1987. OIG REPORT, *supra* note 53, at 14. Several state agencies in the interviews conducted for this article reported conducting interviews with patients only in limited circumstances. Arizona, for example, interviews patients when the agency has had high staff turnover or a number of complaints. Refer to note 75 *supra*.



inspection processes between "overall agency functioning" on the one hand and direct care services on the other reflects the emphasis of the inspection process on visitation of the site of the agency and review of records rather than observation of patient care.

A report of the Office of Inspector General on home health aide services does not support the findings of the Quality Assurance Survey concerning the frequency of Medicare on-site visits. This report found that "[Medicare] certified home health agencies are not usually resurveyed annually. Among the 16 home health agencies visited by the inspection team in 1986, 1 was last resurveyed in early 1986, 5 in 1985, 7 in 1984, 1 in 1983 and 2 in 1981. In fact, in most sample States, resurveys are backlogged 1 to 4 years."<sup>193</sup> The report noted that branch offices of home health agencies were not usually visited on resurveys.<sup>194</sup> Often the branch offices are located far from the parent office and sometimes in two different state regional survey offices.<sup>195</sup>

Predictably, the inadequacies in the survey and inspection process cited by the Inspector General are attributed to inadequate budget allocations.<sup>196</sup> The agencies responsible for inspecting home health agencies also inspect other health care providers. These agencies apparently have identified home health recertifications as low priority.<sup>197</sup> The Health Care Financing Administration (HCFA) in testimony before the Senate Special Committee on Aging in April 1987 stated that HCFA had significantly increased its budget for home health agency surveys in fiscal year 1988 in order to increase the frequency of surveys.<sup>198</sup> Most states conduct the Medicare and licensure inspections at the same time.<sup>199</sup>

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193. OIG REPORT, *supra* note 53, at 12.

194. *Id.* at 13.

195. *Id.*

196. *Id.* Of the state agencies interviewed for this article, Arizona, Illinois and Texas identified lack of staff or lack of financial resources as the most difficult aspect from the state's point of view regarding enforcement of the home health statute. Refer to note 75 *supra*.

197. OIG REPORT, *supra* note 53, at 12-13.

198. *Home Care Hearings*, *supra* note 141, at 57 (statement of Louis Hays, Associate Administrator, Ops., Health Care Financing Administration). OBRA of 1987 requires that surveys take place no later than 15 months after the date of the previous standard survey and that the state's average interval between surveys not exceed 12 months. OBRA of 1987, *supra* note 1, at § 4022(a) (codified as amended at 42 U.S.C.A. § 1395bbb (West Supp. 1989)).

199. Arizona, California and New Jersey reported that their licensure inspection is generally done in conjunction with the Medicare survey. Refer to note 75 *supra*. New York inspects for licensure every two years but conducts the Medicare certification and licensure

The Inspector General's report noted that because of surveyors' failure to cite violations, Medicare's only available tool at that point was "an involved decertification process which is rarely used."<sup>200</sup> This all-or-nothing approach to violations is exactly the problem that intermediate sanctions are intended to resolve.<sup>201</sup>

There is some evidence that enforcement of standards in nursing home licensure has increased with the introduction of intermediate sanctions.<sup>202</sup> The states with access to intermediate sanctions for home health care, however, report that they have not yet actually used those sanctions. Texas reported that the state's Attorney General handles sanctions and that there was a case pending within that office. Pennsylvania reported that no intermediate sanctions had been used. New Jersey reported one nonrenewal of license, but no other sanctions levied against any home health facilities in that state.

Several factors may explain the general lack of enforcement action on the part of the states, including states with intermediate sanctions. Nonenforcement certainly may be attributable to lack of budget for inspections and enforcement, to the relatively recent availability of intermediate sanctions for home health care, or to lack of commitment to home health regulation as compared to regulation of other health care providers.<sup>203</sup> An additional justification for nonenforcement exists in the case of home health, however, that does not generally apply to nursing homes.

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surveys simultaneously in the year in which they both occur. *Id.* Illinois reported that there was only one inspection for both Medicare certification and licensure except for the initial survey in which the agency must be surveyed for licensure before it is able to admit any Medicare patients. *Id.* Texas has two classifications for licensure. Class A agencies are certified for Medicare. TEX. REV. CIV. STAT. ANN. art. 4447u (Vernon Supp. 1989). Class B agencies are not Medicare certified. *Id.* For Class A agencies, the Medicare and licensure surveys are completed simultaneously. Interview, *supra* note 66. Class B agencies are allowed to perform a self-survey if the state agency has not surveyed in the previous twelve months. Pennsylvania reported that although Medicare surveys and licensure surveys are conducted by the same office, Medicare inspections are conducted independently. *Id.*

200. OIG REPORT, *supra* note 53, at 9. Agencies interviewed for this article confirmed this finding and reported very few revocations and decertifications. Of the eight states with licensure, only three (Illinois, Missouri and Texas) reported a single license revocation in the past year; five (Arizona, California, New Jersey, New York and Pennsylvania) states reported no license revocations. Refer to note 75 *supra*. Five states reported no decertifications during the same time span. *Id.* Missouri reported that the agency whose license had been revoked had also been decertified. Illinois reported six decertifications. *Id.*

201. MODEL RECOMMENDATIONS, *supra* note 173, at 2-3.

202. Jost, *supra* note 4, at 160.

203. OIG REPORT, *supra* note 53, at 9-14.

Many persons familiar with home health care maintain that the home health industry in general does not have a problem with the quality of care delivered to patients. Several sources report the scarcity of complaints from families or patients concerning the quality of care provided by home health agencies.<sup>204</sup> A representative of the National Association for Home Care testified before the Senate Special Committee on Aging that "[w]e are proud of a record of outstanding service to the ill, elderly, and disabled in this country . . . . In its 101 year history, home care has enjoyed . . . a largely unblemished reputation. The vast majority of patients have been very pleased with the services they received, and the quality of those services."<sup>205</sup> These comments suggest a high degree of confidence in the quality of health care services provided in the home.

Other observations do not support this perception. For example, there is evidence that home health agencies "dump" patients who no longer can pay for services but who still require care. This can result in a harmful disruption of medical care.<sup>206</sup> The National Association for Home Care cites serious quality problems with individuals providing paraprofessional services, such as homemaker-home health aide services, independent of agencies.<sup>207</sup> The Office of Inspector General reports that home aides providing services under contract between home health agencies and vendors "did not perform the majority of extensions of skilled care tasks assigned to them; subjected Medicare patients to substandard practices; [and] make visits which were unnecessarily time consuming, frequent and costly."<sup>208</sup> Witnesses before the Senate Special Committee on Aging reported instances of abuse, retaliation, ignorance of the use of machinery necessary for the patients, and poor training.<sup>209</sup>

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204. For example, staff members of the state health facility agencies in Iowa and Arizona reported receiving very few complaints. Refer to note 75 *supra*.

205. *Home Care Hearings*, *supra* note 141, at 109. A lawyer with the National Senior Citizen's Law Center commented in an interview that the home health industry has been very clean in regard to quality issues. Refer to note 75 *supra*.

206. Browning, *Home Health Care: The Nurse's Perspective*, HOME NURSING CARE FOR THE ELDERLY Ch. 5 (Hogstel, ed., 1985).

207. BLUEPRINT, *supra* note 9, at 9. A National Long-Term Care Channeling Demonstration, however, found that "high quality personal care services can be given by persons carefully recruited by family members." *Home Care Hearings*, *supra* note 141, at 49 (statement of Charles Wells, Deputy Commissioner, Commission on Aging).

208. OIG REPORT, *supra* note 53, at 19.

209. *Home Care Hearings*, *supra* note 141, at 113-18 (statement of Witnesses on Panel # 1).

The question whether there is a problem with the quality of home health care today remains unanswered, although research has begun.<sup>210</sup> The American Bar Association stated in a 1986 report that "the quality of care being provided to older and disabled persons in their homes today is a virtual black box . . . an unknown both to consumers and to policymakers."<sup>211</sup> External mechanisms for assuring quality care, such as private accreditation, are too new and too undersubscribed by providers to furnish a response.<sup>212</sup> The inspection system used in Medicare and for state licensure has been underfunded and has not yet begun to actually observe the care provided to home health patients in significant numbers.

#### D. *Developing Effective Enforcement*

An effective monitoring system, which is absent in home health care, provides one of three essential elements of a successful quality control regulatory system.<sup>213</sup> Intermediate sanctions for state licensure may play a role in stimulating an inspection and survey process, as they did with nursing homes, that will adequately monitor the quality of home health care. A second critical element is the identification and development of standards to be applied through the regulatory process.<sup>214</sup> Regulatory standards must accurately identify problems and must encourage consistency and predictability.<sup>215</sup> Intermediate sanctions make an additional demand on regulatory standards. The success of intermediate sanctions requires a reconceptualization of the standards applied during the process, in a fashion that allows the agency to draw distinctions among violations. Intermediate sanctions require the

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210. A number of studies of quality assurance in home health care were completed in 1988 reflecting increased interest in the issue. See BUTLER & PROUDFOOT, *QUALITY ASSURANCE IN HOME HEALTH CARE* (1988) (a study of home health care quality & cost under capitated & fee-for service payment systems); GRANT & HARRINGTON, *QUALITY OF CARE IN LICENSED & UNLICENSED HOME CARE AGENCIES: A CALIFORNIA CASE STUDY*, INST. FOR HEALTH AND AGING, (1988); and HARRINGTON, GRANT, INGMAN & MILDNER, *THE STUDY OF REGULATION OF HOME HEALTH CARE AGENCIES IN TWO STATES: CALIFORNIA & MISSOURI*, INST. FOR HEALTH AND AGING (1988).

211. House Select Comm. on Aging, *The 'Black Box' of Home Care Quality*, 99th Cong., 2d Sess. prepared by the A.B.A., Comm. Pub. No. 99-573, p. 1. (1986).

212. Refer to notes 143-48 *supra* and accompanying text.

213. IOM STUDY, *supra* note 1, at 12.

214. *Id.*

215. See generally Jost, *supra* note 4, at 161; Johnson, *supra* note 4, at 174 (1985).

enforcement agency to classify standards in groups organized hierarchically according to the impact of the standards on the quality of care received by the patients and according to the severity of the harm suffered because of violations. A classification scheme also makes the relationship between violation and penalty more predictable.<sup>216</sup> Current Medicare home health care standards do not provide predictability.<sup>217</sup>

Effective enforcement completes the triad of a successful regulatory system.<sup>218</sup> Intermediate sanctions are more effective than revocation or decertification simply because enforcement agencies are more likely to use them and the courts are more likely to uphold them. Enforcers and courts hesitate to close a business and a person's livelihood, except in the most egregious circumstances, and even then only after extensive procedural protections have been exhausted.<sup>219</sup> Not only do patients remain at risk while procedures are followed; state enforcement personnel suffer low morale and a sense of futility.<sup>220</sup> An enforcement system relies upon the deterrence of violations; sanctions that are abandoned do not deter violations. These factors support the use of intermediate sanctions both in nursing homes and in home health care because they relate to the enforcement process rather than the characteristics of the particular type of health care provider.

Two additional factors supporting intermediate sanctions for nursing home enforcement are not applicable to home health care. First, patients transferred from closed facilities might suffer transfer trauma. Second, the nursing home system could not easily afford the loss of a facility, because of the shortage of nursing

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216. For a more complete discussion of classification of violations and legal issues arising under classification, see Johnson, *supra* note 4, at 174.

217. The Office of Inspector General reported that "[t]he decision by State surveyors as to whether agencies meet the [federal guidelines for] overall Condition of Participation [in Medicare] is largely left to the surveyor's subjective judgment. Consequently, while elements of the Condition . . . or standards . . . may be out of compliance, surveyors may still determine that the Condition is met." OIG REPORT, *supra* note 53, at 9.

218. IOM STUDY, *supra* note 1, at 12.

219. MODEL RECOMMENDATIONS, *supra* note 173, at 2. License revocation typically requires substantial and time-consuming procedures which take place while the substandard operator remains in business. A 1973 report by the California Deputy Attorney General indicated that license revocation had been taking as long as five to seven years. Cohen, *Long-Term Care: A Challenge to Concerted Legal Techniques*, 2 OHIO N.U.L. REV. 642, 667 (1975).

220. See Jost, *supra* note 4, and Johnson, *supra* note 4.

homes.<sup>221</sup> As previously discussed, the transfer trauma syndrome probably does not occur in home health care, though the extent and nature of the injury that patients do suffer when a home health agency closes is unknown.<sup>222</sup> The "shortage" of home health agencies may have more to do with certificate-of-need requirements and restrictions on public reimbursement than with profitability of home health agencies. Absent the barrier created by certificate of need, a home health agency that closes would normally be replaced in the market by another agency, as long as home health care remains profitable, fixed costs remain relatively low,<sup>223</sup> and on-site development needs such as construction or equipment remain few.

The experience with intermediate sanctions in nursing home enforcement has indicated that each sanction also requires particular systematic elements. In a survey on the use and effectiveness of intermediate sanctions, state survey agencies responsible for nursing home enforcement reported that sanctions seem to be effective when they affect the income of the provider and can be implemented quickly.<sup>224</sup> The design of the particular intermediate sanctions can achieve or thwart these goals.

Of the sanctions developed for nursing home care, those that have received the most attention are the civil fine, the suspension of admissions, and the receivership. The Omnibus Budget Reconciliation Act of 1987 authorized the Secretary of the Department of Health and Human Services to use those types of sanctions by imposing civil fines, suspending all or part of the payments to which the agency would otherwise be entitled, and appointing temporary management.<sup>225</sup>

Although the Secretary of Health and Human Services will have access to these sanctions, state licensing agencies must also have access to intermediate sanctions. The federal government can

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221. MODEL RECOMMENDATIONS, *supra* note 173, at 2.

222. Refer to text accompanying note 135 *supra*.

223. FTC REPORT, *supra* note 12, at 7.

224. Nineteen agencies also reported obstacles to effective enforcement, eleven of which identified administrative and legal delays as an obstacle to enforcement. IOM STUDY, *supra*, note 1, at 164.

225. OBRA of 1987, *supra* note 1, at § 4023(a) (codified as amended at 42 U.S.C.A. § 1395bbb (West Supp. 1989)). The temporary management described in COBRA bears some similarity to receivership except that the temporary management is administratively appointed and the receivership is court-appointed. The implications this difference may have for the scope and powers of the temporary management remedy have not been explored.

reach only those agencies that are Medicare certified, while licensure can have a broader scope. Participation in Medicare is voluntary, but licensure is mandatory. In addition, the state may choose a more aggressive enforcement plan than does the federal government, even if the standards to be applied are identical. At this early stage in the development of quality-control enforcement in home health, the independent state development of intermediate sanctions provides for the testing of a variety of models in a setting that is in some significant ways very different from nursing homes.

States should provide their licensing agencies with the authority to impose civil fines and to suspend admissions to home health agencies. Because the transfer trauma and supply shortage arguments may not apply as strongly, if at all, to home health care,<sup>226</sup> the receivership as designed for nursing homes need not be developed, unless there is evidence of a shortage of agencies such that alternative services will not be available to patients. A substitute designed for the special need for patient protection upon closure of home health agencies is recommended.

1. *Civil Fines.* As of 1983 twenty-six states had authority to impose civil or administrative fines against nursing homes; thirteen reported using civil fines during 1983; and there were 900 such actions taken in those states.<sup>227</sup> At least five states have authority to levy fines against home health agencies.<sup>228</sup> To the extent that economics motivate substandard care, fines can increase the cost and decrease the benefit of the violations. With an appropriate range, the amount of the fine can be sensitive to the severity of the particular violation and to the economic incentives for the particular behavior.<sup>229</sup> Fines are also particularly well-suited to violations that are serious but involve few patients and show little likelihood of recurring. States can avoid significant delays in the imposition of civil fines if the administrative agency rather than the courts holds the authority to impose fines and if administrative proceedings are not too elaborate. Administrative handling of disputes,

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226. Refer to text accompanying notes 125-27 & 135-42 *supra*.

227. IOM STUDY, *supra* note 1, at 163.

228. Refer to note 181, *supra* and accompanying text.

229. For a complete discussion of the necessary elements of a successful civil fine system, see IOM STUDY, *supra* note 1, at 166; Johnson, *supra* note 4, at 175-76; MODEL RECOMMENDATIONS, *supra* note 173, at 8-16, 72-83; Butler, *Nursing Home Quality of Care Enforcement Part II—State Agency Enforcement Remedies*, CLEARINGHOUSE REV. 665, 676-82. (Oct. 1980).

rather than court enforcement, will more likely yield a positive experience with the implementation of civil fines. Although access to judicial appeals should not be limited unreasonably, states should not adopt statutory or regulatory structures that actually encourage recourse to the courts. The administrative procedures for the imposition of the fine should provide for an informal conference, if flexibility in the imposition of fines is desired, and a full hearing on the demand of the provider. A complete record of the hearing should be produced so that if the provider appeals to a court, judicial review of the action is limited to the record before the administrative agency, excluding as evidence any subsequent improvements in the home health agency.

It is common that licensure and certification procedures focus on the condition of the agency at the time of the survey and do not explicitly consider the past compliance record of the agency. In contrast, a civil fine system should make the past compliance record relevant to the amount of the fine. The agency should levy higher fines for repeat violations.

Finally, a civil fine system works best if it deters noncompliance. A civil penalty system in which the state abandons a fine if challenged decreases the risk that facilities assume when violating standards. It also rewards those providers that invest in contesting fines. The enforcement agency, or the assistant attorney general representing the agency in court, may incorrectly view the amount of the fine as the amount in controversy, thereby undervaluing the contest. What is often in controversy is the reputation of the facility, especially if sanctions are disclosed to the public, and the facility's record of compliance, if relevant to the severity of further sanctions.

2. *Suspension of Admissions.* As of 1983 thirty-two states had authority to suspend admissions to nursing homes; fifteen reported using the sanction in thirty-two actions in 1983.<sup>230</sup> Suspension of admissions is particularly well-suited to licensure because through its licensure authority the state may regulate both Medicare-certified and non-Medicare-certified agencies and may suspend the admission of private-pay as well as public-pay patients.<sup>231</sup>

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230. IOM STUDY, *supra* note 1, at 165. The authority extended to all admissions in some states and only to Medicaid admissions only in others. *Id.* at 163.

231. *Id.* at 165.



Suspension of admissions<sup>232</sup> works well because it combines a *de facto* fine with adverse publicity and prevents the agency from beginning a relationship with new patients at a time when its operation falls below the required standards.<sup>233</sup> It also allows the agency to continue providing care to current patients on the assumption that the violations at issue are not a serious threat to their well-being.<sup>234</sup> In addition, a state may choose to suspend admissions as an added incentive when the facility has correctable deficiencies that do not justify the revocation of its license.

In the nursing home context, this distinction between new patients and current patients is justified by the belief that the injury likely to be caused by the transfer of a current resident is greater than any injury likely to be suffered by remaining in the substandard facility.<sup>235</sup> Although the identical calculation of relative harms does not apply to home health care, there is surely some cost in changing agencies. One advantage of the suspension of admissions is that it can be put in place while administrative procedures to contest its imposition are proceeding. The financial effect of suspension of admissions is cumulative in that the patient census of the agency will decline over time.<sup>236</sup> For nursing homes suspension of admissions represent a significant financial penalty because they are not easily able to shrink their costs with a decline in patient census. In contrast, home health agencies, especially those relying on part-time or contractor staff, may find that much easier to accomplish. What impact this may have on the value of suspension of admissions as an enforcement tool in home health must be explored further.

If the state imposes a suspension of admissions on a home health provider, it should notify the current patients of the agency and their attending physicians. This notification should include a hotline at the state agency for these individuals to call for further information. The state must make available to those patients deciding to switch agencies some provision for discharge planning. Relying on the home health provider to provide discharge planning

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232. For a complete discussion of suspension of admissions, see Johnson, *supra* note 4, at 183; IOM STUDY, *supra* note 1, at 165-166; MODEL RECOMMENDATIONS, *supra* note 173, at 21-22; Butler, *supra* note 229, at 683.

233. IOM STUDY, *supra* note 1 at 165.

234. *Id.* at 165-66.

235. *Id.* at 166.

236. *Id.* at 165-66.

may itself discourage patients from changing agencies. The enforcement agency may have to establish alternative resources. At a minimum, the state agency should monitor the home health agency's handling of inquiries and requests for transfer of records.

3. *Receivership.* The nursing home receivership places custody and control of the nursing home in the hands of an individual appointed by a court, generally at the recommendation of the state enforcement agency.<sup>237</sup> The agency is most likely to request a receivership when the facility is in danger of closing without an appropriate plan that protects patients who must be transferred, or when the facility has seriously violated the standards and shows little inclination or capacity to correct the violations.<sup>238</sup> The court may appoint the receiver either to govern the facility while it closes and to safely transfer the residents, or to correct the violations and facilitate the transfer of the nursing home to another owner.<sup>239</sup> Nursing home receiverships have been successful in both functions.<sup>240</sup>

The primary factors supporting receiverships for nursing homes are the avoidance of trauma to the residents due to transfer and the preservation of salvageable facilities for an undersupplied nursing home industry.<sup>241</sup> Because these factors do not seem to exist for home health agencies, the receivership remedy, which can be a serious intrusion upon the interests of the owner, may not be required for home health enforcement in the same form. The only exception to this conclusion would occur in rural areas where there may be only a single home health agency. Instead, the state should have in place a standard notice for the closing agency to send to patients and their attending physicians, should monitor the transfer of records, and should maintain a list of home health agencies willing to accept transfers. It may be possible to publicize and use placement on this list as an incentive for establishing a good com-

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237. *Id.* at 166-67.

238. MODEL RECOMMENDATIONS, *supra* note 173, at 17-18.

239. IOM STUDY, *supra* note 1 at 166-67.

240. For a more complete discussion of nursing home receiverships, see Johnson, *supra* note 4, at 177-79; MODEL RECOMMENDATIONS, *supra* note 173, at 16-21, 84-91; IOM STUDY, *supra* note 1, at 166-68; Butler, *supra* note 230, at 668-75; Johnson, *Nursing Home Receiverships: Design and Implementation*, 24 ST. LOUIS U.L.J. 681 (1981); Grad, *Upgrading Health Facilities: Medical Receiverships as an Alternative to License Revocation*, 42 U. COLO. L. REV. 419 (1971).

241. IOM STUDY, *supra* note 1, at 166-67.

pliance record. In certain cases, such as immediate closures, the state may have to be ready to assist with planning for transfer or continuation of care from another agency on a temporary basis. It may be useful for the state to have the authority to take possession of the patient records of a closing or seriously substandard agency to better provide notice and make provision for continuity of care for the patients. Thus, the temporary management remedy provided for in OBRA of 1987 for both home health agencies and nursing homes should look quite different in each context.<sup>242</sup> Temporary management for home health care should be quite limited while temporary management for nursing homes should replicate the nursing home receivership that has proved successful in that setting.

If a public regulatory system for home health care develops, intermediate sanctions will be important, as they have been in nursing home regulation. The intermediate sanctions for home health care, however, must reflect the distinctive characteristics of that context.

#### IV. CONCLUSION

"There's no place like home. There's no place like home."<sup>243</sup>

Dorothy may have been correct, but policymakers concerned with the well-being of the elderly should not be lulled into complacency by the image of home and hearth. They have a responsibility to take a hard look at the reality of the shifting of health care from hospitals and long-term care facilities to private residences. This task is challenging because the problems can easily remain hidden from view. The pictures of "warehoused," wheelchair-restrained elderly in nursing home lobbies or dayrooms, which periodically prompt nursing home reform, will not be available. Although home may seem safer than a hospital or nursing home, patients may avoid complaining about care for fear that the home care provider may retaliate.

The concept of quality of care and quality of life in forming the aspirations of home health care will be different from that of nursing home care. It may be that the concerns for the regulation of home health care may be more limited, for example, in relation

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242. OBRA of 1987, *supra* note 1, at § 4023 (codified as amended at 42 U.S.C.A. § 1395bb (West Supp. 1989)).

243. Dorothy, on her way back to Kansas in *THE WIZARD OF OZ* (Loew's 1939).

to the provider's responsibility for quality of life, because the patient is not living within an institution and depending on that institution. In particular, it would be inappropriate to adopt the "catastrophic" approach to quality of life used in nursing home regulation. This approach is viewed as "emphasiz[ing] physical well-being and safety at the expense of psychological and social well-being"<sup>244</sup> and is extremely risk averse. Even aside from arguments over the tolerable level of risk of physical injury in inverse relation to increased mobility and choice among nursing home patients, such risk aversion is simply unachievable in a home health care setting.

An acceptable measure of quality of care and quality of life for home health care, however, must also consider the quality of care and quality of life that the caregiver, who often is elderly herself, needs. Home care shifts financial, emotional, and physical costs to family members. Those costs, especially those that result in diminishing the health of the caregivers, must be identified and included in the cost of home health care even if the government ultimately decides not to support caregivers with additional resources such as increased reimbursement for home care services or respite care. Home care is not cheap, even though the amount paid to home health care agencies favorably compares to that paid to other health care providers.

At this point it is difficult to obtain a good sense of the quality of home care now provided, as anecdotal representations concerning the quality of home health care are contradictory. There should be far more disciplined and empirically valid study of the quality of care provided outside of institutions. Within the limits of the information currently available concerning quality-control regulation in home health care, this Article has made several proposals to improve enforcement.

Undoubtedly, private litigation has a significant role to play in quality control, but home health patients face substantial obstacles in their attempts to use the tort system.<sup>245</sup> For private litigation, this Article makes three recommendations.

First, states should enact statutes providing private rights of action for home health patients.<sup>246</sup> These statutes should provide

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244. Kane & Kane, *Long Term Care: Variations on a Quality Assurance Theme*, 25 INQUIRY 132, 135 (Spring 1988).

245. Refer to notes 33-60 *supra* and accompanying text.

246. Refer to notes 94-104 *supra* and accompanying text.

enhanced damages in the form of substantial minimum damage awards, causes of action that survive the death of the plaintiff, and attorney's fees for prevailing plaintiffs. Although these statutes may have small effect on the quality of care generally provided, their cost to the regulatory budget is minimal, if not nonexistent, and their unique capacity for compensating the victim recommends their enactment.

Second, the organizational structure of many home health agencies dilutes and blurs legal responsibility for breaches of standards of care.<sup>247</sup> At a minimum, for the compensation of patients injured by negligent care, state statutes should require the agency to carry adequate liability insurance and should define what is adequate.

Third, the liability of home health agencies for the negligence of persons providing care under the auspices of the agency but as independent contractors, and of persons provided under contract with other agencies, lacks clear definition and depends on an analysis of the facts of a particular case.<sup>248</sup> State statutes should specify that the home health agency with case management responsibility is liable to the patient for all services provided by the agency or by other agencies with which the agency contracts. Home health agencies may reallocate this liability in agreements with contractors. The injured patient would be compensated by the case-management home health agency, and the agency would then seek reimbursement from the contractor under the terms of their agreement. The patient could, of course, also sue the contracting organization that actually provided the direct care.

For enforcement of state licensure of home health agencies, this Article proposes three revisions to current practices and procedures. First, because enforcement costs more than nonenforcement, adequate funding for survey and inspection becomes critical. Second, state legislatures should provide the enforcement agencies with the intermediate sanctions of civil fines,<sup>249</sup> suspension of admissions,<sup>250</sup> and a form of temporary management<sup>251</sup> quite different from that required for nursing homes but with adequate authority to protect the patients of agencies at risk of closing.

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247. Refer to notes 51-60 *supra* and accompanying text.

248. Refer to notes 46-50 *supra* and accompanying text.

249. Refer to notes 227-29 *supra* and accompanying text.

250. Refer to notes 230-36 *supra* and accompanying text.

251. Refer to notes 238-42 *supra* and accompanying text.

Finally, the regulatory models<sup>252</sup> appropriate for home health care should be further explored. Between the self-regulation model of hospitals and the public regulation model of nursing homes, home health care, based on the characteristics of population and structure alone, should fit within the public regulation model. Efforts to substitute private accreditation for public regulation should be discouraged until there is more experience with quality control and more reliable information on the quality of home health care.

It appears, however, that home health care does not easily fit within regulatory systems designed for institutions. It is more akin to situations in which persons provide services outside of institutional settings than to situations in which persons provided services within an institution that can easily monitor performance and socialize service providers to the expectations of the institution. Regulatory methods focusing on the licensure, certification, or registration of individual direct-care providers are promising and warrant further investigation.

Regulatory programs alone do not guarantee quality of care. The individual patient always retains some responsibility for the selection and monitoring of his or her own care. The effectiveness of systems that encourage the production and dissemination of information should be investigated. Certificate-of-need requirements for home health agencies should be re-examined in the context of their potentially negative impact on consumer choice and thus on the quality of home health care.<sup>253</sup>

The development of home health care and its use by an increasing number of individuals indicate the preference of the majority of elderly persons to remain in their homes should they become ill. Because it also implicates shifts in the costs of health care, the visibility of that care, and the activity of agencies with the public responsibility for enforcing quality of care standards, home health care requires sophisticated quality-control regulation and enforcement.

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252. Refer to notes 110-54 *supra* and accompanying text.

253. Refer to notes 136-42 & 223 *supra* and accompanying text.