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Alexander D. Eremia
Georgetown University Hospital

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When Self-Regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care

*Alexander D. Eremia, J.D., L.L.M.**

I. INTRODUCTION

Despite having the most technologically advanced and costly healthcare system in the world, both physicians and American healthcare consumers have increasingly perceived a decline in the quality of services provided by the medical community.¹ While no nationally accepted and uniform standards exist which succinctly define “quality of care,” consumers expect and deserve at least the minimally prescribed or professionally accepted standards for the treatment of their ailments. Historically, consumers have relied on self-regulation and the professionalism of their physicians and health care providers to ensure appropriate quality of care. Under the fee-for-service regime, it is alleged that over-utilization led to excessive services

* Alexander D. Eremia received his Bachelor of Science from the University of California, Santa Barbara, his Juris Doctor from DePaul College of Law where he was a Staff Writer on the *DePaul Journal of Health Care Law*, and his Master of Laws in Health Law from Loyola University Chicago School of Law where he was the Senior Editor of the *Annals of Health Law*. Mr. Eremia is Assistant General Counsel of Georgetown University Hospital and was formerly Associate Counsel for the Office of the Inspector General, Office of Counsel to the Inspector General of the Department of Health and Human Services (“OIG”) in Washington, D.C. and has represented the OIG in quality of care cases. The thoughts and ideas expressed herein are the author’s personal opinions and do not necessarily reflect the views of MedStar Health, Inc., Georgetown University Hospital, the OIG, the Department of Health and Human Services, or the United States Government.

1. See, e.g., Press Release, Harvard School of Public Health, Doctors in Five Countries See Decline in Quality of Care: New International Survey Reveals Physician Concerns with Medical Errors, a Shortage of Nurses, and Inadequate Facilities (Oct. 12, 2000), at <http://www.hsph.harvard.edu/press/releases/press10122000.html>; see also Marilyn Denny, *This is Who I Am, Don't Let Them Move Me: Autonomy in Nursing Homes*, 2 QUINNIPIAC HEALTH L.J. 203, 208 (1999) (claiming that “physical and psychological decline of residents, largely as a result of the treatment received in such institutions, has led to the perception of nursing homes as ‘houses of death.’”).

and “quality.”² Today, some financial incentives which may encourage underutilization, and a number of prominent failure of care incidents³ suggest a need to focus on quality and make it clear that self-regulation alone cannot be the sole mechanism for ensuring quality of care.⁴

Instead, consumers of health care services must rely on several mechanisms to assure minimum levels of quality. In democratic, capitalist and free societies, social and economic norms dictate that consumers purchase products and services primarily on the basis of favorable quality and price.⁵ Under such conditions, providers of poor quality or excessive cost are forced from the market because consumers refuse to utilize their services. Although these economic norms are effective in many non-health care markets, health care consumers do not always have the requisite information or market freedom necessary to make optimal quality and cost of care decisions. Even when appropriate information and market choices are available, variables including declining reimbursement or geographic limitations may impede a consumer’s ability to obtain quality health care.

In some instances, patients or residents have resorted to legal action in an effort to redress actual harms. Seen by some health care providers as a sufficient deterrent to prevent poor quality practices, malpractice and wrongful death actions are often compensatory in nature.⁶ In addition, individuals are frequently unsuccessful in such actions, which are reactive rather than proactive mechanisms for promoting quality of care. Moreover,

2. See Deborah A. Stone, *The Doctor as Businessman: The Changing Politics of a Cultural Icon*, 22 J. HEALTH POL. POL’Y & L. 533, 553 (1997) (arguing that under the fee-for-service system, doctors exploited generous health insurance policies to provide unnecessary and excessive “Cadillac-quality” services while lining their own pockets).

3. See, e.g., *United States v. Chester Care Ctr.*, No. 98 CV-139 (E.D. Pa. 1998) (alleging various inadequacies in the care provided to residents); *United States v. GMS Mgmt.-Tucker, Inc.*, No. 96-1271 (E.D. Pa. 1996) (charging that claims were submitted for care that was not rendered in compliance with federal regulations).

4. But see George E. Newton II, *Maintaining the Balance: Reconciling the Social and Judicial Costs of Medical Peer Review Protection*, 52 ALA. L. REV. 723, 724-25 (2001) (discussing the virtues of peer review and quality improvement).

5. Andrew Ruskin, *Empowering Patients to Act Like Consumers: A Proposal Creating Price and Quality Choice Within Health Care*, 73 ST. JOHN’S L. REV. 651, 652-53 (1999); see also Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 941-42 (1963) (distinguishing normative economics from the economics of the health care industry).

6. David F. Bragg, *Dealing with Nursing Home Neglect: The Need For Private Litigation*, 39 S. TEX. L. REV. 1, 4 (1997) (arguing that “the only effective restraint on those who allow their residents to be neglected is a serious threat to profits.”).

awards in these cases may have the unintended effect of limiting the level of services and quality of care available to the rest of the patient population. Finally, most providers carry ample liability insurance to cover such claims. As a result, the threat of a negligence action alone may not be a sufficient deterrent to prevent certain providers from furnishing substandard care.

As the largest purchaser of health care services in the world, the United States Government has a vested interest in the promotion of quality and the financial integrity of the healthcare delivery system.⁷ In particular, it must ensure that beneficiaries of Federal health care programs receive professionally acceptable levels of care.⁸ Among the nation's most important health care segments, the nation's nursing home industry has long been criticized for providing poor quality of care to its residents.⁹ In response to multiple and recurring quality problems at long-term care facilities, the federal and state governments have sought to tighten, enhance or propose additional regulations and licensing requirements to improve quality of care.¹⁰ Today, the health care industry, and particularly the long-term care segment, are among the most heavily regulated businesses in the nation.

Such enhanced regulation, oversight, and enforcement initiatives have often been criticized as being draconian, overly burdensome,¹¹ and the cause of unnecessary financial hardships that

7. See Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 319 (1999).

8. CMS Standards and Certification, 42 C.F.R. § 483.25 (2001) (stating that in long term care facilities, "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.").

9. See John F. Schnelle et al., *Policy Without Technology: A Barrier to Improving Nursing Home Care*, GERONTOLOGIST, Aug. 1, 1997, available at 1997 WL 27954312 (citing multiple articles in the medical and lay literature that document poor quality of care provided in this country's nursing homes).

10. See, e.g., The Omnibus Reconciliation Act of 1987, 42 U.S.C. §§ 1395i-3(a)-(h), 1396r(a)-(h) (West Supp. 1999); see also Sen. Charles Grassley, *The Resurrection of Nursing Home Reform: A Historical Account of the Recent Revival of the Quality of Care Standards for Long-Term Care Facilities Established in the Omnibus Reconciliation Act of 1987*, 7 ELDER L.J. 267, 281-82 (1999) (explaining that additional legislative initiatives may be necessary to ensure that the Congressional intent of COBRA is maintained); Press Release, HHS, Clinton Administration Announces New Initiatives to Improve the Quality of Care in Nursing Homes (July 21, 1998), at <http://www.hhs.gov/news/press/1998pres/980721a.html> (unveiling multiple new approaches to improve nursing home care).

11. See generally Mark S. Williams, *Are Federal Health Care Fraud Investigations Harming the Practice of Medicine?*, 4 HEALTH CARE FRAUD & ABUSE NEWSL. 4, May

actually contribute to diminishing levels of care. Some commentators have also argued that such micro-regulation without an emphasis on measuring clinical outcomes is not an effective means for improving quality of care.¹²

This paper examines why market forces, self-regulation, and private litigation, individually and collectively, have generally not been successful paradigms for ensuring quality health care. This paper also explores the federal government's role in promoting quality, deterring substandard care, and overseeing the healthcare industry. Particular attention will be paid to the regulatory and oversight framework in the long-term care industry. Finally, some of the federal government's regulatory inadequacies are examined, but ultimately, this paper concludes that consistent, appropriate, and meaningful government regulation and oversight are currently necessary to confront identified serious systemic deficiencies in the delivery of long-term health care services.

II. SELF-REGULATION, MARKET FORCES AND PRIVATE TORT ACTIONS

Traditionally, Federal health care programs and third-party payor reimbursement systems reimbursed providers of health care services with minimal regard for the cost of care.¹³ Instead, providers focused on providing efficacious services that were reimbursable. As reimbursement mechanisms have shifted to managed care and the prospective payment system ("PPS"), financial incentives to limit the level of services provided have given consumers the perception that overall quality has diminished.¹⁴ In fact, limiting the level of services by cutting staff, limiting stays, or otherwise curtailing the type and quantity of

2001 (contending that formal programs to ensure compliance with federal health care laws and regulations represent another example of "vague and onerous government oversight in an already heavily regulated service industry.").

12. See Marshall B. Kapp, *Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Got to Do With It?*, 31 McGEORGE L. REV. 707, 714 (2000) (claiming "there is a strong argument for concentrating regulatory activities on assuring that satisfactory outcomes are achieved.").

13. See Stone, *supra* note 2, at 533 (noting that until the late 1970s, doctors and policy makers believed that clinical decisionmaking should not be colored by the financial interests of those providing the care).

14. See Ruskin, *supra* note 5, at 651-52 (citing widespread accounts of consumer dissatisfaction with managed care); *but see* Stone, *supra* note 2, at 533 (noting that under managed care, "a good doctor takes financial considerations into account in making clinical decisions.").

services does potentially contribute to quality of care deficiencies.¹⁵ Mechanisms historically and currently employed to promote minimum quality of care standards while limiting cost have not always proven to be effective, and one single paradigm may not be adequate for every segment of the health care industry.¹⁶

A. *Self-Regulatory Measures*

Because clinical decisions affect the level and quality of care provided to patients throughout the health care continuum, it is logical that self-evaluative measures should be among the most efficient mechanisms for promoting consistent quality. However, with the emergence of various cost containment measures, physicians have been forced to consider cost when making clinical decisions. Some physicians complain in particular that managed care has caused them to lose their autonomy in the medical decision making process.¹⁷ Under this cost containment mechanism, managed care organizations purport to regulate the level and quality of care, yet many consumers disfavor managed care because of its perceived limitations on care and choice.¹⁸ In some cases, managed care participating physicians may be financially rewarded for limiting care, adding to the perception that managed care contributes to diminished quality.¹⁹ While this financial reward is often nominal, there is the appearance and possibility that professional judgment may be compromised, thereby

15. See HEALTH CARE FIN. ADMIN., REPORT TO CONGRESS: APPROPRIATENESS OF MINIMUM NURSE STAFFING RATIOS IN NURSING HOMES 7 (2000), available at <http://www.hcfa.gov/medicaid/reports/rp700hmp.htm> (concluding that there may be a critical ratio of nurses to residents, under which nursing home residents are substantially at risk for quality of care problems); see also J. Scott Andresen, Comment, *Is Utilization Review the Practice of Medicine? Implications for Managed Care Administrators*, 19 J. LEGAL MED. 431, 432 (1998) (commenting that because “[utilization review] may severely limit or ration the amount of health care available, it has an inherent potential to deprive individuals of the quality of care to which they have become accustomed.”).

16. See Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 343-44 (2001) (acknowledging that professional self-regulation has been blamed for the escalation in health care spending and is widely viewed as ineffective).

17. See Stone, *supra* note 2, at 552-54.

18. See Humphrey Taylor, *Hostility to Managed Care Continues to Grow; But It Is Far From Overwhelming*, THE HARRIS POLL, July 29, 1998, at http://harrisinteractive.com/harris_poll/index.asp?PID=170 (finding that a 47%-40% plurality of the public believes that the increasing presence of managed care is a bad thing and that a 58%-31% majority believe this increasing presence will harm the quality of patient care currently provided).

19. See Stone, *supra* note 2, at 548.

weakening the argument in favor of physician self-regulation.²⁰ Although designed to be a cost containment strategy and quality control strategy, pre-authorization and prospective utilization review by non-clinical decision-makers may actually diminish quality of care if non-clinical judgments are substituted for the physician's judgments.²¹

Some commentators have suggested that improved quality assurance practices, enhanced practice guidelines,²² or other self-regulatory measures such as improved peer-review processes²³ can restore consumer confidence in the health care delivery system and ensure that minimum standards of quality of care are met.²⁴ Others suggest that outcome-oriented credentialing of physicians, with an increased focus on ways to measure quality of care, will have a significant impact on professional and institutional practices,²⁵ or that professional standards are an overlooked determinant of physician conduct that may be preferable to market forces or government oversight to ensure quality of care.²⁶ While acknowledging that self-regulatory activities need not be entirely voluntary and may be encouraged, sanctioned, or mandated by government action, it is argued that physicians are the constant force in health care and are arguably responsible for allocating most healthcare resources.²⁷ Therefore, it is suggested that cooperative self-regulation can better facilitate voluntary conduct when deviant conduct goes undetected by market forces and government regulation.²⁸

20. *But see* JEFFERY STODDARD et al, CTR. FOR STUDYING HEALTH SYS. CHANGE, ISSUE BRIEF: PHYSICIANS MORE LIKELY TO FACE QUALITY INCENTIVES THAN INCENTIVES THAT MAY RESTRAIN CARE 1 (Jan. 2002), available at <http://www.hschange.org/CONTENT396/index.html>.

21. Andresen, *supra* note 15, at 435 (noting that the likely consequence of managed care denials of coverage is that the patient will forgo the procedure).

22. *See* Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J.L. MED. & ETHICS 323, 329 (2001) (supporting the use of practice guidelines to improve quality of care).

23. *See* Newton, *supra* note 4, at 724-27 (indicating that peer review is based on the logical premise that only a physician's peers have the requisite expertise to evaluate a physician's work and that the peer review process is currently flawed because confidentiality problems undermine its effectiveness).

24. *See* Agrawal, *supra* note 16, at 27 (arguing that standards of professional conduct are an overlooked determinant of physician conduct which "can be used to achieve results that evade both market forces and command-and-control legislation.").

25. *See* Michael F. Anthony, NAT. HEALTH LAW. ASS'N., ENHANCED MEDICAL STAFF CREDENTIALING, 3 Health L. Prac. Guide § 32:8 (2001).

26. *See generally* Agrawal, *supra* note 16.

27. *Id.* at 344-45.

28. *See id.* at 377-404.

However, many of the existing self-regulatory mechanisms are aimed primarily at physician conduct, and even then, some question the value of such measures. Designed to encourage physicians to participate in peer review activities, Congress enacted the Health Care Quality Improvement Act of 1986 ("HCQIA")²⁹ to promote self-policing. Under the HCQIA, peer-review boards may take limited disciplinary action against physicians for misconduct.³⁰ Depending on the seriousness of the misconduct, a physician may be questioned, counseled, disciplined, suspended, or even terminated.³¹ In conjunction with the HCQIA, Congress established the National Practitioner Data Bank ("NPDB") to gather and provide information regarding disciplinary actions against physicians.³² However, the general public cannot obtain information contained in the NPDB, nor can they directly report information to the NPDB.³³ Even after physicians are disciplined for providing inadequate care, they may be allowed to continue practicing. As a result, some have complained that they can find out more about their plumbers than their physicians.³⁴

Although self-regulation, professional standards, and disciplinary mechanisms may have roles in promoting physician conduct, a lack of knowledge about the peer-review process and resultant disciplinary actions may lead to the perception that self-regulation is inadequate. In addition, such self-regulatory measures may not sufficiently incentivize other health care professionals and health care entities, or aid in promoting quality within the corporate environment.

In the long-term care industry, for instance, it is often nurse's aides and other attendants, not the physician, who provide much of the day-to-day care to residents. Therefore, enhanced self-regulatory measures and physicians' professional standards may not have a significant impact on the level or quality of care provided to nursing home residents. In addition, since many long-term care providers are motivated, at least in part, by profit, it

29. 42 U.S.C. §§ 11101 (providing limited immunity for physicians that participate in peer-review activities).

30. *See id.*

31. *See id.*

32. Kara M. McCarthy, Note, *Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care*, 28 SETON HALL L. REV. 569, 593-94 (1997).

33. *Id.* at 597-98.

34. *Id.* at 598-99.

can be argued that professional standards, guidelines, and self-regulation will not adequately ensure that patients and residents receive quality care, without some level of oversight. While in some industry segments, self-regulation coupled with private accreditation standards and utilization review may be sufficient to ensure appropriate care, in the long-term care industry, self-regulation has not yet proven to be entirely successful in ensuring quality care. Because it may be in the long-term care provider's financial interest to limit services, resulting in potential quality deficiencies, competitive pressures suggest that provider self-regulation alone may not be sufficient to ensure minimum standards of quality.

B. Market Choice

Since the healthcare industry is financially influenced, other commentators have suggested that market-place forces are sufficient to maximize quality of care.³⁵ However, unlike consumers of other markets, health care consumers often do not have freedom to choose their health care services on the basis of quality and price. In many instances, consumers do not have a choice of providers due to geographic limitations or lack of competition among providers. In addition, recent health care consolidations and mergers have minimized competition in many markets and as a result of such mergers, or simply due to the size of the market, many consumers have limited access to only a handful of health care providers.³⁶

Similarly, many health care consumers are constrained by employer selected insurance carriers and managed care providers.³⁷ Such constraints affect not only the price consumers pay for healthcare services, but also affect the level and quality of care

35. See Ruskin, *supra* note 5, at 652-53 (noting that in most other markets, consumers chose their preferences based upon cost and quality in order to maximize satisfaction).

36. See Karen Davis, *Can the Market Ensure Quality Work Without Government?*, 24 J. HEALTH POL. POL'Y & L. 1127, 1131 (1999) (noting that between 1987 and 1997 there were 162 mergers or acquisitions involving HMOs and that by 1998 the ten largest managed care companies were accounting for almost two-thirds of the nation's HMO enrollment); see also AM. HOSP. ASS'N, TREND WATCH: MEDICARE'S POST-ACUTE CARE CHALLENGE 3 (June 1999), available at <http://www.ahapolicyforum.org/trendwatch/twjune1999.asp> (noting that the availability of post-acute care services varies widely from region to region).

37. See Davis, *supra* note 36, at 1130 (noting that only 40 percent of America's workforce is given a choice of two or more plans by their employer); see also Ruskin, *supra* note 5, at 656.

provided to the individual. In fact, there is some evidence that only the largest employers consider quality of care when selecting managed care options for their employees.³⁸ And when consumers do have choices among providers, many are unable to meaningfully compare or reconcile the cost of health care services with quality received. Even when costs are comparable between health plans, consumers often lack the ability to compare providers, understand disparities in the services offered, or consider the quality of care provided among providers.³⁹

Furthermore, health care consumers are often uninformed about the education, experience, and qualifications of their caretakers and do not understand how their caretaker's compensation arrangements may affect the delivery of care.⁴⁰ Additionally, consumers are often unaware of their health care provider's history of isolated or systemic quality of care deficiencies. As a result, many people are not selecting their health care providers based upon independent or objective knowledge of the provider's history. Instead, they may select their health care provider because of their geographic convenience, religious affiliation, or referrals from friends, neighbors, and co-workers. They may even base their choices on appealing marketing campaigns or other subjective factors.

Long-term care residents in particular are vulnerable to the limitations of market-place regulation and often have limited choices when selecting long-term care facilities. In many cases, long-term care residents desire proximity to their families and medical professionals. They may not have access to the best facilities, which often maintain high occupancy levels or are too expensive. Similarly, long-term care residents are often too weak, immobile, or infirm to be able to freely leave a facility. As a result, market-forces alone cannot be the only mechanism for ensuring quality of care in the long-term care environment. Economic, geographic and informational disparities may limit

38. See Davis, *supra* note 36, at 1130 (indicating that only certain large employers like General Motors, Ford, Xerox, GTE, and IBM, consult reports on plan quality when making a plan selection. In addition, only 9 percent of employers with two hundred or more employees require NCQA accreditation, and only 6 percent use Health Plan Employer Data and Information Set ("HEDIS") data in selecting managed care plans); see also Ruskin, *supra* note 5, at 669.

39. But see CTR. FOR MEDICARE & MEDICAID SERV., NURSING HOME COMPARE, at <http://www.medicare.gov/Nhcompare/Home.asp> (data last updated Mar. 21, 2002) (providing a public forum to compare long-term care facilities on-line).

40. See generally Stone, *supra* note 2 (discussing how managed care financial incentives that limit services may inhibit the quality of care provided).

the efficacy of the traditional market driven model that promotes quality services at competitive costs in non-healthcare markets.

C. *Private Legal Actions*

Under existing laws in most states, private individuals can bring tort actions against their caregivers for assault, battery, negligence, false imprisonment, medical malpractice, or other causes of action in order to redress inadequate or sub-standard care.⁴¹ Each of these remedies may lead to compensatory damages for successful plaintiffs and may serve as a deterrent for principled health care providers. However, there are several reasons why private legal actions alone do not adequately prevent sub-standard care.

First, in order to establish a prima facie case of an intentional tort to a person, the plaintiff must generally prove intent, causation and damages. If proven, the plaintiff would usually be entitled to compensatory damages, but because most intentional torts are considered outside of the scope of employment, the employer is generally not liable for such intentional actions and most insurance coverage does not include intentional acts. As a result, the plaintiff's recourse is usually against the individual employee and, even if proven, it is often difficult for plaintiffs to collect on such actions. Further, usually only in the most egregious cases are punitive damages or government intervention warranted. Consequently, absent statutory or regulatory oversight, there may be no direct incentive for the facility to adopt significant corrective measures. Often a provider may perceive such incidents as isolated events that are more indicative of a human resources issue than a quality of care problem requiring facility-wide attention.

Alternatively, plaintiffs may attempt to pursue any number of negligence theories against long-term care providers for actual injuries sustained that are caused by the provider or their agents. Again, although such actions may result in compensatory awards, liability coverage is often sufficient to cover the damages and there may be little direct financial impact on the provider that necessarily mandates corrective action. In addition, many incidents rising to the level of negligence may truly

41. *But see* McCarthy, *supra* note 32, at 571, 601-07 (noting that in egregious instances of medical error, criminal prosecution by state or local prosecutors may also be appropriate for assault, battery, reckless endangerment, neglect, or other crimes).

be isolated incidents rather than an indication of systemic failure, and appropriate corrective action may not involve any significant change in internal practices. Moreover, private tort actions are reactive to actual incidences or failures to take action. As a result, tort actions only promote quality through the deterrent effect they have on reputable providers. Unless required as a condition of settlement, such actions generally will not directly force providers to take corrective action in order to prevent the recurrence of similar wrongdoing.

To redress some of these deficiencies, many states have enacted specific statutes which permit private causes of action against owners and operators of nursing facilities for various quality of care violations. In California, for instance, individuals may pursue owners and operators of facilities under the Elder Abuse and Dependant Adult Civil Protection Act for physical abuse, neglect, or breach of fiduciary duty.⁴² Similarly, Illinois enacted the Illinois Nursing Home Care Act to provide residents with a private cause of action for violation of residents' rights.⁴³ States such as New York,⁴⁴ Missouri,⁴⁵ Louisiana,⁴⁶ and others have adopted similar legislation to afford individuals with a private right of action to enforce various regulatory violations.

Although laudable, many of these statutes may not serve their purported intent and may have little effect on the promotion of quality or the deterrence of sub-standard care. In New York, for instance, at least one court has refused to impose strict liability on a provider by reasoning that the statute was not intended to change the normal negligence burden of proof.⁴⁷ Similarly, in Missouri, individuals must first file their complaint with the state attorney general and only if the attorney general fails to initiate a legal action may the individual proceed.⁴⁸ Even when success-

42. See CAL. WELF. & INST. CODE §§ 15600-15763 (West Supp. 2002).

43. See 210 ILCS 45/3-602 (2002); see also Stephen M. Levin, et al., Protecting the Rights of Nursing Home Residents Through Litigation, 84 Ill. B. J. 36 (1996) (discussing the private right of action nursing home residents have in Illinois).

44. See N.Y. PUB. HEALTH LAW § 2801-d(1)-(10) (McKinney 1993).

45. See MO. ANN. STAT. § 198.093(1)-(6) (WEST 1996).

46. LA. REV. STAT. ANN. § 40:2010.9 (2001).

47. See Jeffrey Spitzer-Resnick & Maya Krajcinovic, *Protecting the Rights of Nursing Home Residents: How Tort Liability Interacts with Statutory Protections*, 19 NOVA L. REV. 629, 633-34 (1995) (citing the holding in *Begandy v. Richardson*, 510 N.Y.S.2d. 984 (Sup. Ct. 1987)).

48. Angela Snellenberger Quin, *Imposing Federal Criminal Liability on Nursing Homes: A Way of Deterring Inadequate Health Care and Improving the Quality of Care Delivered?*, 43 ST. LOUIS U. L.J. 653, 674-75 (1999) (describing Missouri's Omnibus Nursing Home Act).

ful, damages are often limited.⁴⁹ In fact, because of the limitation on damages, statutory affirmative defenses, or other exclusions from liability, there is little evidence that such actions by nursing home residents are meaningful methods of promoting quality.⁵⁰ Accordingly, appropriate governmental intervention remains necessary to promote quality of care and prevent the provision of substandard services.

III. GOVERNMENT REGULATION AND OVERSIGHT OVER QUALITY OF CARE

While self-regulation, market forces, and private tort actions all serve important roles in the promotion of quality and deterrence of sub-standard care, long-term care providers have had trouble sustaining quality standards, absent some level of government intervention. Even under the government's existing regulatory and enforcement safety net, some long-term care providers have been unable to achieve even minimal levels of quality.⁵¹ As a result, the question is not whether the government should have regulatory and oversight authority over long-term care providers, but how much?⁵²

The nursing home industry contends that existing regulations are burdensome and complex, that they contribute to the financial instability of the industry, and that regulatory enforcement

49. See *id.* at 677; see also 735 ILCS 5/2-1115 (1994) (where Illinois' General Assembly disallowed all punitive or vindictive damages in any case involving damages for malpractice or in any healing art claim).

50. See Quin, *supra* note 48, at 677.

51. See, e.g., *California Nursing Homes: Federal and State Oversight Inadequate to Protect Residents in Homes With Serious Care Violations: Hearing Before the S. Spec. Comm. on Aging*, 105th Cong. 2 (1998) (statement of William J. Scanlon, Dir., Health Financing and Pub. Health Issues, Health, Educ., and Human Serv. Div., U.S. Gen. Accounting Office) (noting that between July 1995 and February 1998, California surveyors cited nearly one third of all California nursing homes for serious care violations, and that the GAO believes this number is understated); see also GEN. ACCOUNTING OFFICE, *NURSING HOMES: SUSTAINED EFFORTS ARE ESSENTIAL TO REALIZE POTENTIAL OF THE QUALITY INITIATIVES 5* (2000) (noting the GAO's findings—fifteen percent of the nation's 17,000 nursing homes (an unacceptably high number) repeatedly had serious care problems that caused actual harm to residents or placed them a risk of death or serious injury (immediate jeopardy)).

52. See William T. Gormley, Jr. & Cristina Boccuti, *HCFA and the States: Politics and Intergovernmental Leverage*, 26 J. HEALTH POL. POL'Y & L. 557, 565 (2001) (explaining that nursing home regulation is a "zero-sum game" because regulations that benefit nursing home residents usually come at the expense of the nursing home industry, which opposes more stringent standards and more stringent enforcement).

is overzealous.⁵³ In support of these arguments, industry advocates cite examples of alleged inappropriate sanctions.⁵⁴ For example, the industry has complained that pre-existing conditions like pressure sores should not be the basis for deficiency citations.⁵⁵ In addition, longstanding practices that have not previously resulted in serious harm, such as making hot coffee available to residents or providing heaters, have been alleged to be an insufficient basis for citation.⁵⁶ The industry further complains that the system does not distinguish between minor infractions and major problems.⁵⁷

Nevertheless, a review of the existing regulatory framework reveals that the sanctions are intended to respond specifically to, and in proportion to, the scope and severity of the conditions causing actual harm or having the potential to cause harm. Moreover, recent federal studies of nursing home care demonstrate that many long-term care providers actually do have difficulty attending to quality issues.⁵⁸ The current oversight mechanisms for the long-term care industry have largely been established as a safeguard in response to perceived and actual deficiencies in the health care delivery system.⁵⁹ Though not

53. See *HHS Announces Task Force to Reduce Regulatory Burden*, CAL. HEALTH L. MONITOR, July 2, 2001, WL 13 SMCAHTHLM 7 (quoting HHS Secretary Tommy Thompson, “[h]ealth care providers have been telling HCFA for years that many of our regulations are overly burdensome.”); see also AM. HOSP. ASS’N, PATIENTS OR PAPERWORK? THE REGULATORY BURDEN FACING AMERICA’S HOSPITALS, 2 (2002), available at <http://www.aha.org/ar/Advocacy/paperworkreport.asp> (finding that for every hour of patient care, thirty minutes of paperwork is required, much of that associated with regulatory compliance); see also GEN. ACCOUNTING OFFICE, NURSING HOME OVERSIGHT: INDUSTRY EXAMPLES DO NOT DEMONSTRATE THAT REGULATORY ACTIONS WERE UNREASONABLE, 4-9 (1999) (noting industry advocates’ objections to the current regulatory process) [hereinafter *Nursing Home Oversight*].

54. See *Nursing Home Oversight*, *supra* note 53, at 1.

55. *Id.* at 4.

56. *Id.*

57. *Id.* at 1.

58. See e.g., OFFICE OF EVALUATION & INSPECTIONS, OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH AND HUMAN SERV., NURSING HOME SURVEY AND CERTIFICATION: DEFICIENCY TRENDS, 2 (1999), available at <http://www.oig.hhs.gov/oei/oei.html>; OFFICE OF EVALUATION & INSPECTIONS, OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH AND HUMAN SERV., LONG TERM CARE OMBUDSMAN PROGRAM: COMPLAINT TRENDS 1-3 (1999), available at <http://www.oig.hhs.gov/oei/oei.html>; OFFICE OF EVALUATION & INSPECTIONS, OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH AND HUMAN SERV., ABUSE COMPLAINTS OF NURSING HOME PATIENTS, 8-12 (1999), available at <http://www.oig.hhs.gov/oei/oei.html>. See generally OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH AND HUMAN SERV., SAFEGUARDING LONG-TERM CARE RESIDENTS (1998), available at <http://www.oig.hhs.gov/oei/oei.html>.

59. See, e.g., Margaret M. Flint, *Nursing Homes*, NEW YORK ELDER LAW 274 (noting that in the early 1970’s, New York State was rocked by extensive media cover-

perfect,⁶⁰ many of the government's oversight initiatives are intended to redress industry-wide deficiencies.

A. Legislative Standards

Federal oversight over long-term quality of care is essentially a multi-tiered process that includes minimum statutory and regulatory requirements, intermediate administrative remedies with due process rights for violators, and civil, criminal, or other administrative enforcement measures for egregious offenders.⁶¹ In addition to state licensing requirements, existing federal quality oversight measures impose pressure on providers to adhere to minimum statutory and regulatory requirements through the threat of denial of payment, civil monetary penalties, enhanced monitoring, directed training, termination of the provider agreement, or even expulsion from the Federal health care programs.⁶²

Quality of care at participating Federal health care program long-term providers is governed by a variety of federal statutes including the Nursing Home Reform Law of 1987 ("NHRL"),⁶³ among several others.⁶⁴ Long-term care providers must also generally comply with a number of associated regulations,⁶⁵ the State Operations Manual ("SOM"),⁶⁶ and other informal gui-

age of deplorable conditions in nursing homes, and claiming that residents were neglected and abused, and that government agencies charged with overseeing the industry were unable or unwilling to protect residents). *See also* Denny, *supra* note 1, at 206 (indicating that in 1974, one study showed that over 50 percent of skilled facilities were approved for the Medicaid program despite life threatening safety violations).

60. *See* Williams, *supra* note 11 (noting that not infrequently, regulations and intermediary and carrier interpretations are conflicting).

61. Quality of care in long-term care facilities is not limited to the Federal government. Many state agencies, including state departments of social services, state attorney general offices, Medicaid Fraud Control Units ("MFCUs"), and various protection and advocacy agencies, may also become involved in certain quality of care cases.

62. *See* 42 U.S.C. § 1396r(h)(2)(A)(i)-(iv).

63. *See* The Omnibus Budget Reconciliation Act of 1987 ("OBRA-87"), Pub. L. No. 100-203, § 4201, codified at 42 U.S.C. § 1395i-3(a)-(h) and 42 U.S.C. § 1396r (a)-(h).

64. *See e.g.* U.S.C. § 1395cc (Agreements with providers of service); *see also* 42 U.S.C. § 1396a (State plans for medical assistance); *see also* 42 U.S.C. § 1395c-5 (Obligations of health care practitioners and providers of health care services; sanctions and penalties; hearings and review).

65. *See e.g.* 42 C.F.R. §§ 483.10 et seq., and 488.3.

66. The State Operations Manual provides state survey agencies with the CMS official guidance on survey tasks, procedures, and interpretations of law and regulations.

dance or written directives from the Centers for Medicare & Medicaid Services (“CMS”) (formerly the Health Care Financing Administration or “HCFA”). In addition, long-term care providers must comply with a number of similar state statutes and regulations, including state licensing requirements.⁶⁷ Among the federal requirements, long-term care providers must abide by regulations pertaining to quality of care, quality of life, resident rights, physical environment, infection control, dietary requirements, medical care, staffing, and others.⁶⁸ The regulations that specifically address quality of care further require providers to approach specific resident issues associated with activities of daily living, vision and hearing, pressure sores, urinary incontinence, range of motion, mental and psychosocial functioning, naso-gastric tubes, accidents, nutrition, hydration, as well as a number of other special needs that a resident may have.⁶⁹

B. *The Survey Process*

CMS monitors compliance with long-term care requirements through a survey and certification process administered by various state regulatory agencies.⁷⁰ State survey agencies conduct unannounced surveys of nursing homes at least every 15 months⁷¹ or in response to complaints or allegations of resident neglect or abuse⁷² and issue citations when providers are found to be in substantial non-compliance with their conditions of participation.⁷³ In addition, CMS conducts validation surveys of a representative sample of facilities within two months of the state survey to determine whether the state surveys are adequate.⁷⁴ CMS will also initiate a survey when it has reason to question the compliance of a facility with its requirements for participation.⁷⁵

67. See e.g. N.Y. COMP. CODES R. & REGS. 10 § 415 *et seq.*; see also 210 I.L.C.S. 45/1-101 *et seq.*, see also 77 ILL. ADMIN. CODE PART 300.

68. See 42 C.F.R. § 483.1 *et seq.*

69. See 42 C.F.R. § 483.25 *et seq.*

70. See 42 U.S.C. §§ 1395i-3(g) and 1396r; see also 42 C.F.R. §§ 488.300 *et seq.* and 488.110 (noting that the purpose of the surveys is to “assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes”).

71. 42 U.S.C. § 1395i-3(g)(2)(a); 42 C.F.R. §§ 488.305, 488.308.

72. 42 U.S.C. § 1395i-3(g)(4); 42 C.F.R. § 488.332; see also 42 U.S.C. §§ 1395i-3(g)(1)(C).

73. 42 U.S.C. § 1395i-3(g)(2)(a); 42 C.F.R. §§ 488.305, 488.308.

74. 42 U.S.C. § 1395i-3(g)(3)(A).

75. 42 U.S.C. § 1395i-3(g)(3)(D).

In addition, surveys may be performed as frequently as necessary to determine compliance, to confirm that corrective action has been taken,⁷⁶ or to measure whether certain changes, such as change of ownership, have caused a decline in quality of care.⁷⁷ When sub-standard quality of care has been determined, the survey agency must also perform an extended survey to further investigate the cause of the deficiencies.⁷⁸

Whenever a provider is found in substantial non-compliance, the surveying agency has a number of potential administrative sanctions to address the deficiency, including potential termination of the provider agreement.⁷⁹ In determining the appropriate remedy, CMS and the participating state survey agency must conduct an initial assessment to establish the seriousness of the deficiency and must also consider whether the facility's deficiencies constitute: (i) no actual harm with a potential for minimum harm; (ii) no actual harm with a potential for more than minimal harm; (iii) actual harm that is not immediate jeopardy; or (iv) actual harm that is an immediate jeopardy to resident health or safety.⁸⁰ In addition, the assessment must consider whether the deficiencies are (i) isolated; (ii) constitute a pattern; or (iii) are widespread.⁸¹ Following the initial assessment, CMS and the state surveyors may consider other factors including, but not limited to (i) the relationship of one deficiency to others; or (ii) the facility's history of non-compliance.⁸²

By definition, a long-term care facility has provided sub-standard quality of care when it receives one or more survey deficiencies related to [their] participation requirements under 42 C.F.R. § 483.13 (Resident behavior and facility practices), § 483.15 (Quality of life), or § 483.25 (Quality of care), which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a wide-spread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.⁸³

76. 42 C.F.R. § 488.308(c).

77. 42 C.F.R. § 488.308(e).

78. 42 C.F.R. § 488.310.

79. *See* 42 C.F.R. § 488.406.

80. 42 C.F.R. § 488.404(a)-(b)(1).

81. 42 C.F.R. § 488.404(b)(2).

82. 42 C.F.R. § 488.404(c).

83. 42 C.F.R. § 488.301.

C. *Intermediate Administrative Sanctions*

CMS uses scope and severity data collected in the survey process to determine whether termination of the facility's provider agreement is appropriate or whether some lesser sanction is suitable.⁸⁴ To avoid terminating the provider agreement in less serious cases, CMS may impose intermediate administrative remedies that include denial of payment, denial of payment for new admissions, civil monetary penalties, state monitoring, a directed corrective action plan, directed in-service training, transfer of residents, closure of the facility, appointment of temporary management, or other remedies approved by CMS.⁸⁵

For instance, when the deficiencies are isolated and constitute no actual harm, CMS or the state must impose one or more "Category 1" remedies including: (i) directed corrective action; (ii) state monitoring; or (iii) directed in-service training.⁸⁶ Where the deficiencies are more widespread, do not constitute actual harm, but have the potential for more than minimal harm, or if there are deficiencies constituting actual harm, CMS or the state must impose one or more "Category 2" remedies including (i) denial of payment for new admissions, (ii) denial of payment for all individuals (imposed by CMS only), or (iii) civil monetary penalties.⁸⁷ If the deficiencies are serious constituting immediate jeopardy to health and safety, CMS or the state must impose "Category 3" remedies including either (i) temporary management, or (ii) termination of the provider agreement, and may also impose (iii) enhanced civil monetary penalties.⁸⁸

When there are widespread deficiencies constituting actual harm that is not immediate jeopardy, CMS and the state may impose temporary management of the facility, in addition to Category 2 remedies.⁸⁹ Additional mandatory remedies exist for repeat offenders or for those providers that are unable to achieve substantial compliance within certain prescribed time

84. 42 C.F.R. § 488.406; *see also* Lake County Rehab. Ctr., Inc. v. Shalala, 854 F.Supp. 1329, 1340 (N.D. Ind. 1994) (finding that the Secretary of Health and Human Services has the authority to terminate a provider agreement even without a finding of immediate jeopardy).

85. 42 C.F.R. § 488.406(a).

86. 42 C.F.R. § 488.408(c)(i-iii).

87. 42 C.F.R. § 488.408(d).

88. 42 C.F.R. § 488.408(e); *see also* 42 C.F.R. § 488.410 (mandating termination of the provider agreement or appointment of a temporary manager to remove the immediate threat).

89. 42 C.F.R. § 488.408(e)(3).

periods.⁹⁰ However, even when such sanctions are imposed, providers have due process procedures for challenging such penalties and may be able to eliminate, reduce, or forego actual penalties for some period of time.⁹¹ As a result, though long-term care providers complain about burdensome regulations, inconsistent compliance monitoring, and punitive sanctions, they do have the ability to contest the imposition of sanctions and can force the government to prove alleged violations.

D. *Problems in Measuring and Enforcing Quality of Care*

Despite efforts to legislate, monitor compliance and enforce quality of care requirements, the survey and certification process has been criticized as being an ineffective apparatus for measuring quality of care at long-term care facilities. At least one commentator has argued that the state surveys emphasize medical record documentation and are, therefore, not indicative of a resident's actual condition.⁹² Others have argued that the survey process is flawed because "those with the most clinical training are often forced to preoccupy themselves with administrative responsibilities."⁹³ Likewise, because the surveys are not centrally administered, the issuance of deficiency citations between states may be inconsistent because of variance in individual interpretations of program rules.⁹⁴

In addition, others have argued that CMS has significantly eroded the legislative intent of Congress and the NHRL through administrative dilution of the survey enforcement mechanism.⁹⁵ It has been maintained that CMS used its informal guidance to undermine the states' and federal government's ability to sanction providers.⁹⁶ Specifically, it is claimed that the survey regu-

90. See, e.g. 42 C.F.R. § 488.414.

91. See, e.g. 42 C.F.R. § 488.408(g); see also 42 C.F.R. § 498; *First-Ever Decision Reverses Nursing Home's Termination from Medicare Program*, ANDREWS NURSING HOME LITIG. REP., Feb. 9, 2001, WL 9 ANNHLTGR 3 (summarizing *Carehouse Convalescent Hosp. v. HCFA*, No. C-00-006 (H.H.S. Jan. 16, 2001), an unprecedented decision dismissing most deficiencies and overturning a termination decision against a facility).

92. See Schnelle et al., *supra* note 9, at 5.

93. Kapp, *supra* note 12, at 720.

94. See *Quality of Care Sanctions Haphazardly Imposed*, PA. Auditor Says, 8 No. 5 ANDREWS HEALTH L. LITIG. REP. 13 (Dec. 2000).

95. See TOBY S. EDELMAN, WHAT HAPPENED TO ENFORCEMENT? A STUDY OF ENFORCEMENT UNDER THE NURSING HOME REFORM LAW 9 (Nat'l. Senior Citizens Law Ctr. ed., 1999), available at <http://www.nslc.org>.

96. See *id.* at 3.

lations did not achieve the goals or purposes of the NHRL⁹⁷ because CMS ceded to providers due process demands⁹⁸ and significantly relaxed its enforcement mandate.⁹⁹ For instance, even when serious conditions may be present, there is evidence of inadequate investigation and corrective action, as well as evidence that providers have been able to avoid sanctions by temporarily correcting deficiencies.¹⁰⁰ There is also evidence that CMS has in the past not adequately monitored state survey agencies and has not appropriately evaluated the effectiveness of state survey processes.¹⁰¹ Supporting these contentions, Senator Grassley, a Republican from Iowa, recently suggested that enforcement reform may be necessary.¹⁰²

Despite recent efforts by CMS to design an objective outcome-based Quality Indicator (“QI”) system to evaluate facilities,¹⁰³ quality of care in the long-term care industry remains exceedingly difficult to measure.¹⁰⁴ The QI system identifies 24 indicators of quality, derived from the Minimum Data Set (“MDS”), and groups them into eleven domains associated with quality of care.¹⁰⁵ Those domains include accidents, behavior/emotional patterns, clinical management, cognitive patterns, infection control, nutrition/eating, physical functioning, psycho-

97. *Id.* at 9.

98. *Id.* at 4.

99. *See id.* at 5-6.

100. *See generally* *Nursing Homes: Stronger Complaint and Enforcement Practices Needed to Better Ensure Adequate Care: Testimony Before the Senate Special Comm. on Aging*, 106th Cong. (1999) (statement of William J. Scanlon, Director, Health Financing and Pub. Health Issues, Health, Educ., and Human Serv. Div., U.S. Gen. Accounting Office).

101. *See generally* *Nursing Homes: Enhanced HCFA Oversight of State Programs Would Better Ensure Quality of Care: Testimony Before the Senate Special Comm. on Aging*, 106th Cong. (1999) (statement of William J. Scanlon, Director, Health Financing and Pub. Health Issues, Health, Educ., and Human Serv. Div., U.S. Gen. Accounting Office).

102. *See generally* Grassley, *supra* note 10 (noting existing enforcement measures have not been consistent with OBRA’s Congressional intent); *see also* Press Release, University of California-San Francisco, Federal Enforcement of Nursing Homes may be Inadequate, Say UCSF Researchers (Dec. 6, 1999), *available at* <http://media.ucsf.edu/>.

103. *See generally* Richard L. Butler & Steven B. Littlehale, Can HCFA’s QIs Really Identify Poor Care? Legal Implications for Defense Strategies, AM. HEALTH LAW. ASS’N, LONG TERM CARE AND THE LAW SYMPOSIUM PAPERS, Feb. 5-7 (2001) (on file with the author).

104. *See id.* at 6 (noting that prevalence-based measures are not necessarily indicative of a provider’s outcomes).

105. *See id.* at 2.

tropic drug use, quality of life, and skin care.¹⁰⁶ Unfortunately, the QI system may have its own inadequacies because, like the survey process, the QI data represents a “snapshot” of resident conditions at a point in time.¹⁰⁷ It is argued that “prevalence based” QIs do not distinguish between pre-existing conditions and those caused by a provider. At least one commentator has argued that “incidence-based” indicators are a fairer means for measuring quality of care because they better identify the negative outcomes that are caused by the facility.¹⁰⁸

Long-term care providers may also argue that the government’s enforcement efforts do not further the goal of promoting quality of care. Specifically, it can be argued that punitive measures such as denial of payment and civil monetary penalties for quality deficiencies divert monetary resources away from direct patient care activities. Because such financial penalties may impede quality improvement measures including staffing levels, training, and facility improvements, the value of such financial penalties may be questioned. Of course, the government’s argument is that had those resources been “voluntarily” devoted to quality improvement measures prior to the survey, the deficiencies may never have existed. Nonetheless, if providers are devoting resources to pay for, appeal, defend, or “prevent” survey deficiency citations, rather than allocating such resources toward overall quality improvement, the imposition of financial penalties may arguably encumber the government’s objectives.

As a result, the question remains: are existing regulatory and oversight mechanisms too much, too little, or just right? Although regulatory oversight does fill some of the voids left after market-place and self-regulation, by deterring and penalizing sub-standard quality of care, governmental regulation has not eliminated quality of care concerns. Providers complain that the requirements are too burdensome and that measuring compliance with these standards may be too difficult. Similarly, long-term care providers argue that the penalties are so onerous that they impede quality. Conversely, repeated incidents of poor care, complaints, and a number of federal studies suggest that

106. *Id.*

107. *See id.* at 5.

108. *Id.* at 6. *But see* MDS Quality Indicator Report, available at http://www.hcfa.gov/projects/mdsreports/qi/qi_start.asp (noting that QI reports exclude those residents who were recently admitted to the nursing home or those recently admitted after a stay in a hospital. In addition some QIs are “risk adjusted” to account for residents who are frailer and sicker).

quality is not improving and that enforcement actions alone have not been effective in deterring or preventing inadequate quality

Because of these perceived deficiencies in governmental oversight mechanisms, as well as ongoing quality of care concerns, the federal government has explored other enforcement mechanisms for use against inadequate providers. In addition to potential sanctions from CMS through the survey process, egregious quality of care violations may subject long-term care providers to Federal civil prosecution and/or other administrative sanctions for violating Federal health care program requirements.

IV. THE FALSE CLAIMS ACT AND QUALITY OF CARE

In conjunction with the United States Department of Justice (“DOJ”), the United States Department of Health and Human Services Office of Inspector General (“OIG”) has begun to focus on the delivery of care (independent of or in connection with financial fraud, waste, or abuse) when resolving False Claims Act (“FCA”)¹⁰⁹ cases against nursing facilities. Though somewhat controversial, the government has declared the FCA to be a viable tool for pursuing inadequate care,¹¹⁰ and the government has generally taken the position that claims and submissions for reimbursement under Federal health care programs are false if the services rendered do not meet minimum standards of care.¹¹¹

Under this theory, the government must overcome several significant hurdles to prove its case. First, the prevailing view in several circuits¹¹² is that the provider must either expressly or

109. 31 U.S.C. § 3729.

110. See David R. Hoffman, *The Role of the Government in Ensuring Quality of Health Care in Long-Term Care Facilities*, 6 ANNALS HEALTH L. 147, 155 (1997); but see Michael M. Mustokoff et al., *The Government’s Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Ingenuity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANNALS HEALTH L. 137 (1997); see also John T. Boese, *Can Substandard Medical Care Become Fraud? Understanding an Unfortunate Expansion of Liability Under the Civil False Claims Act*, 29-SUM BRIEF 30 (2000).

111. See e.g. *United States v. GMS Management-Tucker, Inc.*, No. 96-1271 (E.D. Pa. 1996) (where the government alleged that claims were submitted for care that was not rendered in compliance with federal regulations); *United States v. Chester Care Center*, No. 98-CV-139 (E.D. Pa. 1998) (where the government alleged various inadequacies in the care provided to residents).

112. See e.g. *United States ex rel. Siewick v. Jamieson Sci. & Eng’g. Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir. 1999); *United States ex rel. Thompson v. Columbia/HCA Healthcare*

implicitly certify compliance with applicable statutes, regulations, or other compulsory rules requiring the provision of some identifiable standard of care in order to obtain reimbursement.¹¹³ In the most recent case supporting this view, *United States ex rel. Mikes v. Straus*, the court stated that the FCA is a restitutionary statute, and therefore, “it would be anomalous to find liability when the alleged non-compliance would not have influenced the government’s decision not to pay.”¹¹⁴ The court went on to find that the Medicare forms do not include an express certification of quality and that statutes requiring compliance with professionally recognized standards of health care were conditions of participation, not conditions of reimbursement.¹¹⁵ Therefore, the court found the defendants not liable under the FCA.¹¹⁶

However, other courts have deemed the FCA applicable under the theory that providers implicitly certify compliance with conditions of participation which generally require the provision of professionally accepted quality of care. For instance, in *United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.*, the court noted that “statutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider’s failure to meet those standards is a ground for exclusion from the program” under 42 U.S.C. § 1320a-7(b)(6)(B).¹¹⁷ Without specifically addressing standards of care that may have been violated, the court denied the defendant’s motion to dismiss and noted that:

It may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its services meet ‘professionally recognized standards for health care.’ . . . [But] a problem of measurement

Corp., 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996).

113. See *United States ex rel. Mikes v. Straus, et al.*, 274 F.3d 687 (Dec’d Dec. 19, 2001) (holding that implied certification theory is appropriately applied only when the statutes or regulations expressly state that they must be complied with as a precondition to payment).

114. See *id.* at 697.

115. See *id.* at 697-702.

116. See *id.*

117. *United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.*, 945 F.Supp. 1485, 1487 (Oct. 1, 1996) (where the government argued that defendant “implicitly certifi[ed] that it was abiding by applicable statutes, rules and regulations” requiring provision to patients of “appropriate quality of care and a safe and secure environment”).

should not pose a bar to pursuing an FCA claim against a provider of substandard health care services under appropriate circumstances.¹¹⁸

In practice, although the outcomes of these cases were very different, there may be little distinction between them because the OIG's authority to exclude providers from participation in the Federal health care programs for egregious violations of the conditions of participation may limit the viability of not settling such FCA actions.

In addition to the above theories of liability, the provision of "unnecessary" or worthless services may also be grounds for an FCA action if services are indicative of such a gross deviation from the standard of care that the services provided, if any, are of no value.¹¹⁹ Under this theory, the government has the burden of establishing the value, or lack of value, of services provided.

In any instance, however, the government must also establish that when the claim was submitted, the provider either knowingly, with deliberate ignorance of the truth or falsity, or with reckless disregard, billed the Federal health care program for services. Finally, it seems that the government must prove that the provider has actually deviated from an identifiable and applicable standard of care, by either providing inadequate, excessive, unnecessary, or otherwise inappropriate services, thus causing damages. Whether such deviation is from the standard of care required for reimbursement or the standard of care required as a condition of participation, the government must factually show that such a deviation occurred and caused a bad outcome.¹²⁰

Consequently, although some may argue that the FCA is an inappropriate enforcement mechanism in quality of care cases,¹²¹ it is clear that the government has a significant burden to establish liability, and therefore, the government is unlikely to pursue such cases unless the government believes that the

118. See *id.* at 1488.

119. See Boese, *supra* note 110, at 36 (noting that the provision of unnecessary services may be peripherally linked to the substandard care theory of liability); *Accord Mikes*, *supra* note 113, at 702-3.

120. See Joan H. Krause, *Medical Errors as False Claims*, 27 AM. J.L. & MED. 181, 194 (2001) (noting that substantial medical literature describes variations in medical practice that do not always correspond to bad outcomes).

121. See generally Robert Fabrikant and Glenn Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105 (1999); See also Boese, *supra* note 110.

facts undeniably support such an action. However, when the government asserts FCA liability for the provision of substandard care, it is also clear that the provider may be subject to a number of undesirable sanctions, including potential treble damages under the FCA or administrative actions affecting their participation in Federal healthcare programs.

A. *Exclusion from Participation*

Specifically, the OIG has authority to impose administrative sanctions including civil monetary penalties (“CMPs”)¹²² or exclusion¹²³ from participation in Federal health care programs for a number of program related offenses. Although the OIG’s enforcement efforts against nursing homes have historically been focused on financial crimes, fraud, waste, and abuse of HHS programs,¹²⁴ the OIG does have authority to exclude providers “for quality which fails to meet professionally recognized standards of healthcare.”¹²⁵ Nonetheless, except when individuals or facilities have been convicted of criminal offenses relating to the neglect or abuse of patients, the OIG traditionally has not pursued exclusion of individuals or nursing facilities for quality of care issues.¹²⁶

Over the past several years, however, the OIG has increasingly become interested in long-term care quality matters and has begun to undertake certain oversight responsibilities.¹²⁷ In 1999, the OIG’s Office of Evaluations and Inspections (“OEI”)

122. 42 U.S.C. § 1320a-7a.

123. 42 U.S.C. § 1320a-7.

124. See e.g. Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities, OIG Special Fraud Alert, Issued Aug. 1995, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/081095.html> (identifying several fraudulent billing schemes by nursing facilities including schemes involving falsification of bills and medical records as well as misrepresentation of services provided); see also Fraud and Abuse in Nursing Home Arrangements with Hospices, OIG Special Fraud Alert, Issued March 1998, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>.

125. 42 U.S.C. § 1320a-7(b)(6); see also Morris and Thompson, *supra* note 7, at 325 (noting that the National Medical Enterprises case (1994) highlighted the government’s focus on quality of care as a fraud issue).

126. But see Lorraine McCarthy, *Substandard Care at Nursing Homes Results in Sanctions Against Owner*, 5 BNA HEALTH CARE FRAUD REP. 549 (2001), citing *United States v. Chester Care Center* No. 98-CV-139 (E.D. Pa. 1998) (one of the first cases where the OIG excluded an individual for quality of care lapses).

127. See Elaine C. Zacharakis, *Increased Federal Enforcement of Nursing Homes Expected*, 11 HEALTH LAW. 12 (1999) (noting that HCFA recently entered into a Memorandum of Understanding with DOJ and OIG to better communicate and refer egregious nursing home violations to the OIG and DOJ).

conducted a series of studies on nursing homes, demonstrating the OIG's interest in nursing home care.¹²⁸ In March 2000, the OIG issued a final voluntary compliance program guidance for the nursing home industry which identifies several risk areas, including quality of care and resident rights, and describes the "seven elements" that it feels are essential to have an "effective" compliance program.¹²⁹ Since then, representatives from the OIG have developed expertise in both nursing home reimbursement and quality of care regulations and have fostered a number of relationships with industry sources to assist in evaluating nursing home quality of care.

B. *Quality of Care Monitoring*

In order to avoid exclusion,¹³⁰ providers that are subject to potential FCA liability for providing substandard care may be required to adopt enhanced intermediate sanctions as a condition of settlement. As part of FCA settlements involving quality of care allegations, certain quality monitoring obligations may be required in addition to the "traditional" Corporate Integrity Agreement ("CIA").¹³¹ Like the traditional CIA, it is anti-

128. See generally OFF. OF INSPECTOR GEN., NURSING HOME SURVEY AND CERTIFICATION: DEFICIENCY TRENDS (1999), available at <http://oig.hhs.gov/oei/reports/oei-02-98-00331.pdf>; OFF. OF INSPECTOR GEN., NURSING HOME SURVEY AND CERTIFICATION: OVERALL CAPACITY (1999), available at <http://oig.hhs.gov/oei/reports/oei-02-98-00330.pdf>; OFF. OF INSPECTOR GEN., LONG TERM CARE OMBUDSMAN PROGRAM: COMPLAINTS TRENDS (1999), available at <http://oig.hhs.gov/oei/reports/oei-02-98-00350.pdf>; OFF. OF INSPECTOR GEN., LONG TERM CARE OMBUDSMAN PROGRAM: OVERALL CAPACITY, available at <http://oig.hhs.gov/oei/reports/oei-02-98-00351.pdf>; OFF. OF INSPECTOR GEN., PUBLIC ACCESS TO NURSING HOME SURVEY AND CERTIFICATION RESULTS (1999), available at <http://oig.hhs.gov/oei/reports/oei-06-98-00280.pdf>; OFF. OF INSPECTOR GEN., SAFEGUARDING LONG TERM CARE RESIDENTS (1999), available at <http://oig.hhs.gov/oas/reports/aoa/d9700003.pdf>.

129. OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14289 (Mar. 16, 2000). The seven areas include (1) the use of written policies, procedures, and standards of conduct, (2) designating a compliance officer and committee, (3) effective training and education, (4) effective communication, (5) enforcement of standards by well-established guidelines, (6) internal monitoring for compliance, and (7) prompt corrective response to perceived deficiency. *Id.*

130. 42 U.S.C. § 1320a-7(b).

131. See Morris and Thompson, *supra* note 7, at 341-43 (describing the OIG's CIAs and noting that traditionally, the CIAs have required that provider implement a compliance program that includes: the Appointment of a Compliance Officer and Compliance Committee, implementation of written standards including a Code of Conduct, Policies and Procedures as well as the establishment of a Training and Education program. In addition, such CIAs typically require the engagement of an Independent Review Organization ("IRO") to perform financial reviews of the provider's claim submission process.

pated that the quality monitoring period will generally last three to five years.

While there are several different quality monitoring models that may be employed when systemic deficiencies are found, the Quality Monitor's role should be to promote quality services through the development of adequate internal systems. Viewed as a collaborative and proactive effort rather than a punitive measure, the OIG's quality monitoring seeks to promote quality through systemic and outcome-based evaluations of the provider's practices.¹³² However, the quality monitor also enjoys the freedom to use its discretion and evaluate subjective variables that may contribute to quality deficiencies.¹³³ Rather than reacting to quantifiable declines in care, the OIG's quality monitoring methodology attempts to promote quality through operational evaluations and best practice recommendations. When corrective actions are necessary, the Quality Monitor may make recommendations or assist in implementing facility-wide policies, programs, or protocols. However, since each facility has its own unique strengths and weaknesses, the Quality Monitor may focus on promoting quality practices in the provider's most deficient areas.

Under its terms of engagement, the Quality Monitor generally performs a series of quality related evaluations aimed at identifying a facility's actual or potential systemic problems.¹³⁴ Under the OIG's model, the Quality Monitor is generally allowed unrestricted access to facilities, as well as access to current or former employees, residents, and their families. The Quality Monitor may also perform site visits, conduct interviews, make assessments of staff qualifications, compile and analyze staffing ratios or staffing data (such as turnover rates), review survey and incident reports, and evaluate corrective action mechanisms, in addition to other objective and subjective factors potentially affecting quality. Among the objective data, the Quality Monitor may also evaluate certain quality indicators to determine the facility's performance in comparison with other nursing facilities.

132. See Roy Snell, *OIG and Vencor Outline Concerns About Monitoring Quality of Care, New CIA Linking Financial and Quality Issues is a Challenge*, J. OF HEALTH CARE COMPLIANCE, 20, 21 (2001).

133. *Id.* at 23.

134. It should be noted, however, that a series of seemingly isolated incidents may be construed as systemic failure depending on the nature and timing of the events.

Though potentially intrusive, it is not intended that the Quality Monitor will undertake operational control over the provider. Instead, the Quality Monitor is supposed to work with the provider to identify risk areas, recommend corrective actions, recommend modification to operational practices if necessary, measure resident outcomes, and make reports to the provider and the OIG as to the facility's progress in implementing sound quality practices. Among the monitoring methods used, providers may hire outside consultants or engage qualified internal specialists, or the government may oversee the quality monitoring functions. In some cases, a combination of the above may serve as the Quality Monitor.

Quality monitoring, however, is not without cost. Clearly, providers who are required to engage quality monitors must pay for such functions. Arguably, if the monitor is successful in promoting quality practices, the provider may ultimately save money in improved efficiencies, reductions in denials of payment, reduced civil monetary penalties, and reduced civil litigation. Nonetheless, providers will undoubtedly argue that quality monitoring requirements represent an additional layer of unnecessary and burdensome oversight. However, providers should recognize that any quality monitoring required as part of FCA settlements is in exchange for continued participation in Federal health care programs. And it is unlikely that such comprehensive quality monitoring requirements would be imposed unless there is a clear indication of systemic quality of care deficiencies.

C. *Evaluation Sources*

Though FCA quality of care cases are often predicated upon specific failure incidents, in order to determine whether a Quality Monitor will be a condition of settlement, the OIG may evaluate information from a number of sources to determine whether the provider has a more fundamental, systemic problem. In a FCA case, the *qui tam* Relator may be the best source of information regarding quality of care deficiencies. In long-term care facilities, *qui tam* relators may include present or former managers, administrators, nursing directors, individual nurses, physicians, billing agents, or possibly even residents of the facility. Such sources may provide the OIG with evidence including photographs, billing records, internal written memos/reports, equipment maintenance records, or other evidence sup-

porting claims of substandard care and violations of a provider's conditions of participation.

In addition, the OIG may examine the CMS Online Survey Certification and Reporting ("OSCAR") data to determine whether a Quality Monitor is warranted. With assistance from consultants, the OIG may try to demographically compare facilities to their peers. The OIG may also consult with state survey agencies or attorneys general to determine whether a history of problems with the facility or chain exists. In addition, the OIG may consult with state ombudsmen¹³⁵ to obtain incident reports and assessments. Similarly, the OIG may consult with resident advocacy groups to obtain complaint information or any reports of substandard care. Finally, the OIG may also review news reports, court dockets, and other publicly available sources in its assessment of the providers. Upon a review of the totality of the circumstances, and a determination of systemic quality problems, a Quality Monitor may become a required element of the CIA and condition of settlement.

D. OIG Focus Areas

In addition to compliance with the statutory and regulatory requirements pertaining to quality of care,¹³⁶ the OIG has identified the following issues as potential contributors to quality of care deficiencies. Should a Quality Monitor be required as a condition of settlement, a review of available integrity agreements suggests that a focus of the monitor's attention may include the following operational functions, among others:

Operational Infrastructure Issues

- Compliance Officer & Committee with Quality Oversight Responsibilities;
- Facility Level Individuals Charged with Quality Oversight Responsibilities:
 - Who Do Not Report Directly to CFO; and
 - Have Direct Access to Compliance Staff.

Traditional "Voluntary" Compliance Mechanisms

- Written Compliance Plan Emphasizing Quality Measures;
- Confidential Disclosure Mechanism;
- Training and Education Program Focused on Quality;
- Written Policies and Procedures Relating to Quality.

135. The state long-term care ombudsman program was established under the Older Americans Act of 1965. 42 U.S.C. § 3001 *et seq.*

136. See 42 U.S.C. § 1395r; see also 42 C.F.R. § 483 *et seq.*

Internal Quality Review Functions

- Facility-Wide Quality Promotion Programs;
 - Quality Data Collection/Assessment Mechanisms?
 - Resident Satisfaction Surveys?
 - Appropriate Data Assessment Methods?
 - Identification/Knowledge of Specific Deficiencies/Quality Indicators?
 - Frequency & Quality of Internal Assessments?
 - Quality Incentive Mechanisms?
- Effective Corrective Action Mechanisms
 - Centralized Incident Reporting Mechanisms?
 - Effective Communication Mechanisms?
 - Appropriate/Timely Response to Incidents?
 - Information Conveyed to Persons in Authority Positions?
- Disaster Preparation/Readiness
 - Utility & Weather Contingencies?
- Appropriate Resources Devoted to Regular Internal Reviews?

Employee/Staffing Issues

- Employee Background Checks?
- Promotion of Quality of Care
 - Appropriate Training Program?
 - Quality = Positive Factor in Determining Compensation?
 - Staffing Ratio Per Resident and Per Shift?
 - Level of Temporary Staff Utilization?
 - Mechanism to Track Staff Turnover?

V. CONCLUSION

A review of the federal government's regulatory and oversight framework in the long-term care industry reveals that it is intended to be a multi-level systemically-oriented mechanism for remedying quality of care deficiencies. Though there are a number of requirements for participation in Federal health care programs, the objective of the government's regulatory and enforcement framework is to target those conditions that have led to, or will likely lead to, resident harm. In response to perceived and actual deficiencies, the legislative and regulatory framework provides guidance as to the minimally acceptable levels of care required for participation in, and reimbursement from, Federal health care programs. In support of these requirements, the government certifies long-term care providers through a survey process aimed at identifying and correcting deficiencies and im-

poses financial and/or more severe penalties when deficiencies exceed prescribed levels of care. Isolated incidents and incidents not causing actual harm are clearly handled differently from widespread instances of actual harm. When deficiencies are serious or place residents in immediate jeopardy of harm, the facility may be subject to enhanced oversight or even termination of their provider agreement.¹³⁷ In extreme cases, new management may be appointed, providers may be shut down, or providers may be excluded from participation in Federal health care programs.

When long-term care providers bill Federal health care programs for inadequate, unnecessary, or substandard services, the government may attempt to pursue a FCA action to recover the funds paid for such services. In connection with settlements in such cases, when systemic quality of care deficiencies are present, providers may be subject to enhanced proactive quality monitoring obligations. Unlike punitive measures such as denial of payment, civil monetary penalties, or denial of new admissions, quality monitoring serves several important goals. Instead of excluding providers from participation, long-term care providers are permitted to continue operations. As a result, the government is not forced to relocate residents or take over the provider's operations. In addition, the Quality Monitor may work collaboratively with the long-term care provider in order to establish "best practices" and promote organizational efficiencies that improve care.

Nonetheless, long-term care providers continue to argue that that the federal government's oversight and enforcement is excessive, despite the fact that self-regulation and market-place regulation have been inadequate controls over quality of care. As a result, government intervention aimed at pressuring long-term care providers into compliance has been adopted. Such multi-level oversight and enforcement mechanisms that allow due process opportunities should theoretically serve to fill the gaps inherent in the market-place, self-regulatory, and private litigation oversight mechanisms described above.

Unfortunately, while some level of government oversight is probably necessary to redress limitations of the market-place, the existing framework may not entirely achieve the govern-

137. In egregious cases, providers may also be subject to potential tort liability and state liability, but those remedies are afforded by the states in which the provider operates and those remedies are generally aimed at redressing specific harms.

ment's goals. In order to further promote quality and discourage sub-standard care, the government should consider refinements to the existing mechanisms and should contemplate the promotion of alternative quality incentives. In theory, minimally intrusive oversight mechanisms that reward exceptional providers and constructively penalize or eliminate sub-standard providers may better optimize quality and cost.

Through either direct or indirect financial incentives, including direct reimbursement or reduced monitoring for exceptional providers, the government may more rapidly further its goals of promoting quality and discouraging sub-standard care.¹³⁸ Rewarding exemplary providers with quality promotion incentives may help distinguish providers in competitive markets. However, in markets where there is no competition, other oversight measures, including termination or exclusion of individual operators, may still be necessary. Such incentives and/or penalties, however, must be balanced against the need to ensure appropriate access to long-term care. Use of such financial incentives may be tied to direct quality enhancement initiatives, including enhanced training, increased staffing, or potentially even limited facility improvements. Since staffing, in particular, has been identified as an important determinant in quality of care, long-term care providers and the government should determine what levels of staffing are minimally acceptable.¹³⁹ In addition, both the state and federal governments should further determine or refine appropriate reimbursement rates for resident conditions. Such measures coupled with enhanced information dissemination may assist in closing the informational disparities that limit the efficacy of market-place competition. Specifically, the federal government may be able to improve the propagation of deficiency data and provide it to consumers so they will have the ability to make informed choices. Furthermore, enhanced public recognition of exceptional long-term care providers may improve consumer awareness. In addition, when providers have a demonstrated history of substantial non-compliance, the govern-

138. *But see* John E. Wennberg et al., *Geography and the Debate Over Medicare Reform*, HEALTH AFFAIRS, (Feb. 13, 2002) (suggesting that higher spending may not result in more effective care or better outcomes), available at http://www.healthaffairs.org/WebExclusives/Wennberg_Web_Excl_021302.htm.

139. *But see Study: Nation's Nursing Homes Understaffed*, CNN, Feb. 18, 2002, (indicating that 91 percent of nursing homes do not have enough staff to provide routine care in five areas, but suggesting that it may cost too much to mandate minimum staffing levels), at <http://www.cnn.com/2002/HEALTH/02/18/nursing.homes.understaffed/index.html>.

ment should more rapidly respond to such deficiencies with heightened oversight remedies. Finally, the government should exercise its termination and exclusion powers more frequently when appropriate to eliminate habitual sub-standard facilities and their operators from the marketplace.

The long-term care industry should also consider serious self-regulatory improvements and standards to demonstrate their commitment to quality. Until the industry is able to improve its image by improving the care provided, regulatory oversight and enforcement will probably be necessary. However, for the oversight and enforcement to be effective, appropriate, and meaningful, the oversight mechanisms should supplement, but not necessarily surmount, market-place competition and self-regulatory oversight.