Health Care Financing Administration Retreats from Regulatory Role

by Toby S. Edelman

In the summer of 1995 the director of the Health Standards and Quality Bureau, Barbara Gagel, announced the Health Care Quality Improvement Project (HCQIP), a collaborative approach between the Health Care Financing Administration (HCFA) and health care providers to address health care quality issues in a nonregulatory "quality-management program that emphasizes improving the processes by which care is delivered."¹

I. Health Care Financing Administration's Antiregulatory Attitude

HCFA's reorientation is more than a semantic revision. The shift contemplated by the HCQIP has been profound and pervasive within the agency as new rules, policies, meetings, and the health care agenda in general reflect both an embrace of the corporate language of quality improvement and an antiregulatory bent. The premise of HCFA's reorientation to its role, however, is questionable. While Gagel relies, in part, on nursing home experience to explain the shift in HCFA's approach to regulating health care, a more accurate reading of the history supports a far different perspective on health care regulation.

Gagel reports that HCFA's traditional quality assurance programs focus on external management programs, which identify poor care and then demand correction or expulsion from the federal payment program.² She contends that these programs are only marginally suc-

¹ Barbara Gagel, Health Care Quality Improvement Project: A New Approach, 16 HEALTH CARE FIN. REV. 15 (1995). The new orientation implements the Clinton Administration's approach to regulatory issues; this combines a call for a "more flexible, effective, and user-friendly approach to regulation" with a direct invocation of business management principles (60 Fed. Reg. 20621 (Apr. 26, 1995)). In an executive order issued early in his Administration the President established a program to reform the federal regulatory process (Exec. Order No. 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993)). In a variety of subsequent executive orders and memoranda and in the Vice President's Reinventing Government Initiative, the executive branch expanded on this theme and called for government to be like business (58 Fed. Reg. 48257(Sept. 14, 1993)) and, whenever possible, to waive civil penalties against regulated entities that correct their deficiencies. In response to these directives, the Health Care Financing Administration (HCFA) initiated a Plan for Periodic Review of Rules to make them "less burdensome, more effective, and in greater alignment with the President's priorities and regulatory principles" (69 Fed. Reg. 3040 (Jan. 20, 1994)). HCFA's manuals also reflect the Administration's approach to regulations.

² Id.
cessful. But while the Institute of Medicine found that public enforcement systems often fail to bring about high-quality care, the institute also found fault with state and federal enforcement systems that tolerate poor performance and that seek to "consult" providers into compliance. The institute, unlike Gagel, recommends strengthening public enforcement systems so that they are less permissive and imposing remedies when deficiencies are first identified.

Gagel's call for HCFA to act like a purchaser, rather than a regulator, is curious for other reasons. In an early nursing home case, Estate of Smith v. Heckler, the Tenth Circuit rejected the district court's holding that the Department of Health and Human Services had a passive role in handing out money to the states. Reviewing the statutory history of the Medicaid program, which reflects an increasingly active federal role in overseeing quality of care in nursing homes, the court ruled that the Secretary had a duty to determine whether facilities receiving federal funds satisfied requirements under federal regulations.

Likewise, the nursing home reform law, enacted three years after the Smith decision, expanded the federal responsibility to regulate and enforce nursing home standards. The law states it is the Secretary's duty to assure that the enforcement of requirements that govern the provision of care is adequate to protect the health, safety, welfare, and rights of residents. The law also provides sanctions against facilities providing deficient care. Gagel recites HCFA's "experience that a provider's own quality-management system is the key to good performance," but she does not report what the federal experience has been. Again, in the nursing home context, the experience with quality assurance has not been promising.

In March 1991 Beverly Enterprises, the largest nursing home corporation in the United States, settled a series of criminal and civil investigations with Missouri. Part of the settlement required Beverly to implement an intensified version of its Quality Assurance (QA) program throughout the state. The Food and Allied Services Trade Department of the AFL-CIO studied the quality of care provided in 35 Beverly facilities between April 1991 and December 1993 and looked at three quality factors: (1) the prevention and treatment of bedsores; (2) the presence of unnecessary physical or chemical restraints; and (3) the prevention and treatment of incontinence. It found that while the QA program successfully identified violations of care standards, the program did not prevent recurrence of care problems.

Advocates for Beverly's residents also recall that deregulatory initiatives in the early 1980s led the industry to promote quality assurance. Industry literature described the American Health Care Association's launch of a voluntary quality assurance program for long-term care facilities to quell the public outcry over

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3 Committee on Nursing Home Regulation, Inst. of Medicine, Improving the Quality of Care in Nursing Homes (Mar. 1986).
4 Estate of Smith v. Heckler, 747 F.2d 583, 589 (10th Cir. 1984).
5 Id.
7 42 U.S.C. §§ 1395i-3(d)(1), 1396r(d)(1).
8 Id. §§ 1395i-3(h)(1), 1396r(h)(1)-(2).
9 Gagel, supra note 1, at 16.
proposals to deregulate the industry.\textsuperscript{11} In other words, regulatory history shows that quality assurance and deregulation have been two sides of the same coin.

II. Total Quality Management

In vogue today is not the term “quality assurance” but rather “total quality management” and “continuous quality improvement”—two terms taken directly from the manufacturing and service industries.\textsuperscript{12} On the basis of data that compare the performances of providers, these “quality” management systems help health care providers develop plans to improve the care they provide. Provider-developed plans for improvement replace public accountability and an external standard of performance. The primary components of these management systems in health care are quality indicators and customer satisfaction.

HCFA’s new approach focuses on outcomes of care rather than on the structure and process of care.\textsuperscript{13} Avedis Donabedian, the author of the triad of structure, process, and outcome, has criticized the misunderstanding and abuse of his terms. Donabedian sees them as complementary, not alternative, ways of assessing quality.\textsuperscript{14} Moreover, the focus on outcome, which the \textit{Smith} plaintiffs originally sought, has been distorted into waiting for poor outcomes before taking regulatory action.

The appropriate preventive nature of a regulatory system is obscured by this wait-and-see approach. Structure and process standards are useful, in part, because they are expected to lead to better outcomes. For example, the requirement that a person be trained in surgery before performing surgery recognizes that this person will produce better outcomes for patients than one with no surgical training at all.

Gagel’s reference to the development of quality indicators is also misplaced. The primary author of quality indicators for nursing facilities, David Zimmerman, defines them as useful in internal and external quality assurance activities. Quality indicators can be used by facilities to evaluate their own performance, and they can help focus surveyor resources in the survey process, but Zimmerman does not offer them as a replacement for the survey process.\textsuperscript{15}

The new HCFA approach also looks to customer satisfaction surveys as a method of evaluating quality of care. The value of these surveys is often questionable. The Inspector General’s report on health maintenance organiza-


\textsuperscript{12} Nicholas G. Castle et al., \textit{Quality Improvement in Nursing Homes}, 3 \textit{Health Care Management: State of the Art Reviews} 1 (1996); Gagel, supra note 1, at 17. According to a newspaper article, “What’s good for General Motors is good for nursing home patients. That is what UCLA gerontologist John F. Schnelle learned when he applied quality control techniques from factory assembly lines to nursing homes” (\textit{Quality Control Moves into Nursing Homes}, \textit{L.A. Times}, Mar. 11, 1995).

\textsuperscript{13} Gagel, supra note 1, at 18.


tion (HMO) customer satisfaction surveys found that the instruments used by HMOs might mask problems and inflate satisfaction with managed care plans. The survey results are used as much for marketing as for quality improvement.

These findings undermine valid efforts to use surveys as a basis for oversight and public accountability.

In fact, customer surveys may yield little meaningful information. Nursing facility residents may overstate satisfaction because of fear of retaliation or they may be unable to express their feelings because of cognitive impairments. They may have such low expectations for care that their "satisfaction" has little significance. Satisfaction also assumes choice. If patients have no choice about their health care provider, they may "make do." But resignation to the unavoidable is not satisfaction in a real sense. Even supporters of satisfaction surveys see them as most useful in evaluating nontechnical aspects of health care such as a facility's environmental aesthetics, a physician's bedside manner, or a facility's amenities.

III. Nonregulatory Quality Initiatives

As discussed, the HCQIP approach to health care quality has many limitations, but HCFA is moving forward with nonregulatory quality initiatives in a variety of areas. The themes, taken from executive orders and Vice President Al Gore's "Reinventing Government" initiative, are common across a broad spectrum of providers. In a variety of health care settings HCFA identifies quality indicators, calls for collaboration with the industry, and supplies data to the industry and encourages it to use them. The result, however, is fewer surveys, less public oversight, and more self-regulation.

A. Nursing homes

The HCQIP is very evident in the nursing facility area. In July 1995 HCFA began requiring surveyors to determine whether a facility had a quality assurance committee along with a method to address quality care issues. Although the survey evaluates neither the adequacy nor the effectiveness of a facility's QA committee, the system gives considerable credibility to QA because it distinguishes between facilities with an effective quality assurance process in place that in fact leads to enhanced care and those facilities without.

Another example of how the nursing home industry has been focusing on quality is the June 1996 Nursing Facility Quality Assessment and Assurance Symposium at which the last panel of the day asked whether an enforcement mechanism was counterproductive in a Continuous Quality Improvement environment. The American Health Care Association drafted and promoted a § 1115 Medicaid waiver request, the South Dakota Quality Initiative, to replace the current long-term care survey process with a new system based on

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17 Castle, supra note 12, at 8.


20 Id., No. 273, § 7000 (July 1995).
describes the flexible survey as supporting Gore’s reform initiative and as rewarding laboratories with good performance by using a self-assessment format. He believes that the new procedure will maintain quality by focusing inspections and rewarding exceptional performance. He describes the self-survey forms as reflecting an outcome-oriented, quality improvement assessment. States will survey 5 percent of laboratories adopting the self-survey procedure.25

C. Medicare Ambulatory Surgical Centers

A July 1996 HCFA-sponsored town meeting on ambulatory surgical centers considered HCFA’s role as a monitor versus a management consultant. The meeting’s discussion paper described major revisions of conditions for ambulatory surgical centers and the shift from a focus on structure and process to outcomes and patient satisfaction.26 The paper identified HCFA’s strategic plan and Gore’s initiative as the source of the new approach, with the familiar language of quality improvement:

[T]he heart of the new conditions should be a new section (transforming the current Evaluation of Quality requirement) setting the expectation that the ASC [Ambulatory Surgical Center] will develop, implement and maintain a strong, data driven, quality assessment and performance improvement program (QA/PI), based on the use of a system of measures. By defini-

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22 17 Robert Streimer, Director, Office of Survey and Certification, Health Standards and Quality Bureau, HCFA, Presentation to Campaign for Quality Care (May 20, 1997). The South Dakota Quality Initiative may still be under consideration, however. HCFA has continued to meet with the American Health Care Association to discuss the waiver proposal.

23 Alternatives to the survey and enforcement processes are being discussed and tested in Kansas, Ohio, Vermont, and Virginia.


25 Id.

26 Health Care Fin. Admin., Transformation of the Ambulatory Surgical Center Conditions for Coverage (July 25, 1996) (draft discussion paper for HCFA’s Medicare town meeting: Ambulatory Surgical Centers).
tion, a QA/PI program is based on a continuous, proactive approach to both managing the facility and improving outcomes of care and satisfaction for patients. A QA/PI enables the organization to systematically view its operating systems and processes of care to identify and implement opportunities for improvement.27

The paper questioned whether process requirements would be needed if the rules stated the expected outcome and specifically asked whether HCFA should continue to regulate structure/process requirements in surgical services, medical staff, nursing services, laboratory and radiologic services, among others.28

D. End-Stage Renal Disease

An HCFA initiative involving facilities that furnish hemodialysis treatments will test a mechanism for tracking clinical indicators. Instead of on-site surveys to measure compliance with regulatory standards, the new system envisions the establishment of baseline measures of clinical indicators, use of national and regional data to set facility-specific quality improvement goals, and a mechanism for facilities to report their progress.29 The collaboration is intended to foster continuous improvement.30 HCFA says:

It is our belief that an outcome-oriented approach to quality can reduce the cost and improve the quality of the ESRD [end-stage renal disease] program and ultimately reduce regulatory burden. This project will take advantage of electronic communication technology through a system to track identified quality indicators.31

IV. Other Initiatives

While HCFA is moving forward on quality initiatives, two national studies are under way on many of the same issues. Last year’s federal budget bill called for HCFA to evaluate the nursing home enforcement system that went into effect in 1995.32 It also called for HCFA to evaluate the status of facilities meeting standards set by a private accrediting entity33 and nonregulatory quality initiatives.34 President Clinton’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry is considering quality assurance activities35 and appears intent on reviewing quality across a broader spectrum of health care providers.

27 Id. at 2.
28 Id. at 6.
30 Id. at 23252.
31 Id.
32 The nursing home reform law required that the federal government publish rules on enforcement by October 1, 1988, and that states enact enforcement systems, consistent with the federal rules, by October 1, 1989 (42 U.S.C. § 1396r(h)(2)(B)(i)). HCFA did not publish final rules until November 10, 1994, with a July 1, 1995, effective date (59 Fed. Reg. 56116 (Nov. 10, 1994)).
33 Deemed status is controversial. See Claudia Schlosberg & Shelley Jackson, Assuring Quality: The Debate over Private Accreditation and Public Certification of Health Care Facilities, 30 CLEARINGHOUSE REV. 699 (Nov. 1996). Deemed status has been particularly controversial in the nursing home area. Proposed rules—published in 1982—which would have granted deemed status to what was then called the Joint Commission on the Accreditation of Hospitals were opposed by Congress and the subject of two legislative moratoria prohibiting deregulation of the nursing home industry. They were the impetus for the Institute of Medicine’s review of nursing home law and enactment of the nursing home reform law in December 1987.
V. Conclusion
Advocates recognize that facility-based quality improvement activities have a role in health care and welcome the idea that providers take responsibility and not wait for state and federal agencies to tell them what the problems are and how to correct them. However, quality improvement is an internal process of getting good care; it is not the outcome of good care. Whether a health care facility is providing good care in compliance with public standards is the critical issue and is a decision that only a public agency can make. While it is fine to have a third-base coach, it is the umpire, and not the coach, who decides if the runner is safe at third base.36

36 Robert Kane, Symposium on Nursing Facility Quality Assessment and Assurance (June 1996). Dr. Robert Kane is the chair in Long-Term Care and Aging, Institute for Health Services Research, School of Public Health, University of Minnesota.