DANCES WITH ELEPHANTS: ADMINISTRATIVE RESOLUTION OF MEDICAL INJURY CLAIMS BY MEDICARE BENEFICIARIES

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TABLE OF CONTENTS

I. INTRODUCTION

The stated purpose of Hoffmann and Rowthorn's excellent analysis of the statutory mechanism for addressing quality of care problems in the Medicare program is to "add to the debate about the most appropriate home for the [program's] beneficiary complaint process."[1] In the process of doing so, they catalog persistent inadequacies in this process that date from its inception and that have not been remedied by its current placement within Medicare's Quality Improvement Organizations ("QIOs").[2]

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1. Diane E. Hoffmann & Virginia Rowthorn, *Achieving Quality and Responding to Consumers The Medicare Beneficiary Complaint Process: Who Should Respond?* 5 IND. HEALTH L. REV. 9, 9 (2008).

2. The seeds of the current QIO process were planted in the Peer Review Improvement Act of 1982, Pub. L. No. 97-248, § 143, §§ 1151-1163, 96 Stat. 324 (1982). Handling beneficiary complaints has been a QIO responsibility since 1995, when Congress specifically required it. 42 U.S.C. § 1320c-3(a) (2000). The function became a more prominent aspect of QIOs' contractual scope of work following a 2001 report by the Office of Inspector General of the US Department of Health and Human Services. DHHS Office of Inspector Gen., Pub'n No. OEI-01-00-00060, THE MEDICARE BENEFICIARY COMPLAINT PROCESS: A RUSTY SAFETY VALVE (2001), *available at* http://oig.hhs.gov/oei/reports/oei-01-00-00060.pdf [hereinafter 2001 OIG Report].

Hoffman and Rowthorn review reports from the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG")[3] and the Institute of Medicine ("IOM")[4] finding QIOs' management of beneficiary complaints to be severely lacking. The IOM recommended that the Centers for Medicare and Medicaid Services ("CMS") consolidate the beneficiary complaint and review functions into a few regional or national organizations awarded competitive contracts or locate these functions in state health departments and/or licensing bodies.[5]

Echoing the IOM, Hoffmann and Rowthorn's preferred alternative is to outsource resolution of Medicare beneficiaries' complaints to state boards of medicine and institutional survey and certification authorities, who perform similar functions on a larger scale. Tellingly, many state disciplinary officers Hoffmann and Rowthorn interviewed were unaware that Medicare QIOs even processed patient complaints, and one state regulator who contacted the QIO in his area regarded that organization's low self-reported caseload as "somewhat comical."[6]

In our judgment, Hoffmann and Rowthorn's research clearly demonstrates that the QIO-based complaint review process does not provide genuine relief to beneficiaries. People who complain typically want an explanation of their bad experience, compensation for harm they may have suffered, and assurance that future experiences will be better for themselves and for others. Medicare beneficiaries, however, receive minimal information about the resolution of their complaints and no substantive relief whatsoever.

As Hoffmann and Rowthorn point out, several reform proposals are now before Congress, including moving the beneficiary complaint function from QIOs to new "Medicare Provider Review Organizations."[7] It is not clear from the authors' analysis what is motivating bipartisan interest in reform, but it seems to involve potentially conflicting concerns about lack of consumer responsiveness, on one hand, and wasteful bureaucracy, on the other.

II. MEDICARE'S PRESUMPTION OF EXPERTISE

We believe that one cannot suggest meaningful improvements to a process hardly anyone uses, because it is more or less useless without trying to under-

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3. *See* DHHS OFFICE OF INSPECTOR GEN., PUBL'N NO. OEI-01-93-00250, THE BENEFICIARY COMPLAINT PROCESS OF THE MEDICARE PEER REVIEW ORGANIZATIONS (1995), *available at* http://oig.hhs.gov/oei/reports/oei-01-93-00250.pdf; 2001 OIG Report, *supra* note 2.

4. INST. OF MED., MEDICARE'S QUALITY IMPROVEMENT ORGANIZATION PROGRAM: MAXIMIZING POTENTIAL (National Academic Press 2006) [hereinafter 2006 IOM REPORT].

5. 2006 IOM REPORT, *supra* note 4, at 112-15.

6. Hoffmann & Rowthorn, *supra* note 1, at 42.

7. *See* Continuing the Advancement of Quality Improvement Act of 2007, S. 1947, 110th Cong. (2007); The Medicare Quality Improvement Organization Modernization Act of 2007, S. 2396; 110th Cong. (2007); Medicare Quality Improvement Organization Modernization Act of 2007, H.R. 1046, 110th Cong. (2007).

stand how things got that way. Imagine a ballroom dance. Nicer invitations won't draw guests to a party with no music, bad food, and a dance floor the size of a postage stamp. There is an elephant in Medicare's ballroom that frightens the musicians, devours the refreshments, and crowds the dancers. Call it the presumption of expertise.[8]

Medicare was enacted in 1965 with the grudging support of American physicians,[9] who persuaded the program's architects to accept two assertions as fact and draft legislation accordingly.[10] One was that physicians were financially incorruptible; the other was that physicians were clinically competent. Few observers believed even at the time that the medical profession would be immune to monetary temptation, but the robustness of its appetite for resources was nonetheless surprising.[11] As Wilber Cohen, then Secretary of the Health, Education and Welfare, said: "[T]he ideological and political issues between 1960 and 1965 were so dominating that they precluded consideration of issues such as reimbursement alternatives and efficiency options."[12] Consequently, Medicare has spent the last thirty years, through payment policy and criminal enforcement as well as professional peer review, trying to distinguish patient advocacy from moral hazard and fraud as sources of clinical cost-ineffectiveness.[13]

Medicare's presumption of expertise manifests itself in three ways with respect to the beneficiary complaint process. First, the complaint process was designed to focus on individual physicians, ignoring the organizational struc-

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8. Less charitable characterizations might focus on such matters as the political power of organized medicine, the trench warfare between business and the trial bar over tort reform, and the behind-the-scenes influence of Medicare contractors, including QIOs themselves.

9. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. 18 §§ 1395-1396). *See* JUDITH M. FEDER, MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE (1977); SYLVIA LAW, BLUE CROSS C WHAT WENT WRONG? (2d ed. 1976); THEODORE MARMOR, THE POLITICS OF MEDICARE (1973); ROBERT J. MYERS, MEDICARE (1970).

10. Indeed, the opening section of the Social Security Amendments of 1965 so reflects these assertions:

> Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services . . . or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

42 U.S.C. 18 § 1395(a).

11. *See* William D. Fullerton, *Politics of Federal Health Policy, 1960-1975: A Perspective*, HEALTH CARE FIN. REV., Winter 1996, at 169; Marian Gornick et al., *Twenty Years of Medicare and Medicaid; Covered Populations, Use of Benefits, and Program Expenditures*, HEALTH CARE FIN. REV., 13, 35-45 (Supp. 1985). *See also* STAFF OF SENATE COMM. ON FIN., MEDICARE AND MEDICAID: PROBLEMS, ISSUES, AND ALTERNATIVES, 91st Cong., 1st Sess. 53, 140-43 (Comm. Print 1970).

12. Wilber Cohen, *Reflections on the Enactment of Medicare and Medicaid*, 7 HEALTH CARE FIN. REV. 3, 5 (Supp. 1985).

13. *See* David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and "the Trust Reposed in the Workmen,"* 30 J. LEGAL STUD. 531, 531 (2001).

tures used to deliver health care. Second, the process assumes that most laypersons' complaints involve issues tangential to "true" quality. Third, the process regards malpractice litigation as an illegitimate quality improvement device and therefore considers serving plaintiffs' interests to be a perversion of its core purpose. An additional premise underlying peer review is that medical quality can only be judged by the medical profession itself.

These premises turned out to be wrong. Two decades of health services research have revealed unexpected deficiencies in the modal quality of American medical care. Population health indicators in the U.S. substantially trail most European countries and other English-speaking countries, the burden of preventable chronic disease is high and rising, adherence to clinical best practices is distressingly low, and avoidable medical errors are widespread.[14]

Delivery systems matter. It is increasingly understood by patient safety experts that institutional practices drive error rates more than individual failings,[15] and by medical quality experts that care coordination is essential to successful health outcomes. So does patient involvement. Patient-centeredness has become a core characteristic of good medical care,[16] with many commentators emphasizing the importance of reliable information about the cost and quality of health care services and providers. Moreover, physicians' propensity to generate complaints seems to be a marker for clinically significant quality lapses in hospitals.[17] And while few would defend the medical malpractice system as a cost-effective method of either compensation or quality improvement, it has become clear from empirical research that unprevented, uncompensated injuries are a more troubling problem that frivolous lawsuits.[18]

A major problem Hoffman and Rowthorn identify is Medicare's longstanding preoccupation with protecting the reputation of individual physicians by assuring strict confidentiality during, and even after, complaint review.[19] In an era increasingly (and properly) concerned about keeping *patients'* personal health information private and secure from others, denying beneficiaries information about the disposition of their *own* complaints seems bizarre unless one understands its history. As Hoffman and Rowthorn note, recent reforms pro-

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14. *See* WORLD HEALTH ORG., THE WORLD HEALTH REP. 2000, HEALTH SYSTEMS: IMPROVING PERFORMANCE (2000), *available at* http://www.who.int/entity/whr/2000/en/whr00_en.pdf (last visited May 5, 2008); Org. Econ. & Cultural Dev., *Health Care Quality Indicators Project*, http://www.oecd.org/documentprint/0,3455,en_2649_34631_2484127_1_1_1_1,00.html (last visited May 5, 2008); KAREN DAVIS ET AL., THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: LOOKING AT THE QUALITY OF AMERICAN HEALTH CARE THROUGH THE PATIENT'S LENS (2004).

15. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

16. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001).

17. Gerald B. Hickson et al., *Patient Complaints and Malpractice Risk* 287 JAMA 2951, 2951 (2002).

18. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 N. ENG. J. MED. 2024, 2024 (2006).

19. Hoffmann & Rowthorn, *supra* note 1, at 12.

posed by CMS seem half-hearted, as much concerned with restricting access to information by malpractice lawyers as with liberalizing information access for beneficiaries.[20] They report, for example, that QIOs systematically exclude from mediation any case involving actual quality of care problems, even though CMS introduced mediation in 2003 to provide a less constrained environment than case review for resolving beneficiaries' complaints.[21]

Concealing provider error from affected patients runs counter to current thinking among patient safety experts about the transparency of adverse events,[22] and to emerging professional norms regarding candor.[23] Although early formulations of the patient safety problem recommended shielding professional process reengineering from external scrutiny in order to promote event reporting and frank analysis, excruciatingly slow progress has convinced both individual pioneers in the field (e.g., Donald Berwick, Lucian Leape) and leading quality improvement organizations (e.g., the Joint Commission, the Institute of Medicine) that errors causing harm should be openly acknowledged and reasonable compensation for injury promptly offered.[24] Early mediation is increasingly recognized as an effective vehicle for these conversations.[25]

A related problem with the QIO process is that few corrective actions are taken against providers even when complaints are found to be valid. The QIO process is disconnected from other carrots and sticks Medicare possesses to promote quality, such as payment policy. Nor do QIOs share information with other regulatory bodies that have greater enforcement capabilities with respect to physicians or hospitals, notwithstanding their supposedly similar consumer protection missions. Consequently, "accountability" through QIO review offers

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20. *Id.* at 17.

21. *Id.* at 15.

22. See JOINT COMM'N ON THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS, SETTING THE STANDARD: THE JOINT COMMISSION AND HEALTHCARE SAFETY AND QUALITY 12 (2005), *available at* http://www.jcaho.org/accredited+organizations/patient+safety/setting_the_standard.pdf (on file with the authors). *See generally* INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001); INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

23. Editorial, *Medical Error and Ethics: A Call for Candor Without Fear*, 46 AM. MED. NEWS 14, (July 21, 2005), *available at* http://www.ama-assn.org/amednews/2003/07/21/edsa0721.htm (last visited May 3, 2008).

24. Robert Galvan, *"A Deficiency of Will and Ambition": A Conversation With Donald Berwick*, 10 HEALTH AFF. w5-1, w5-1 (Jan. 12, 2005), http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.1v2.pdf (last visited May 5, 2008); Lucian L. Leape, *Full Disclosure and Apology: An idea Whose Time has Come*, PHYSICIAN EXECUTIVE (Mar.-Apr. 2006), http://findarticles.com/p/articles/mi_m0843/is_2_32/ai_n16123939/pg_3 (last visited May 5, 2008); INST. OF MED., FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS (2002); JOINT COMM'N ON ACCREDITATION OF HEALTH CARE ORGANIZATIONS, HEALTH CARE AT THE CROSSROADS: STRATEGIES FOR IMPROVING THE MEDICAL LIABILITY SYSTEM AND PREVENTING PATIENT INJURY 12 (2005), http://www.jcaho.org/news+room/press+kits/tort+reform/medical_liability_exec_summary.pdf (on file with the authors).

25. Carol B. Liebman & Chris Stern Hyman, *A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients*, 23 HEALTH AFF. 22, 22 (2004).

little opportunity to assess problems with the institutional processes by which care is delivered. The only exception to this pattern was the development in the 1990s of a parallel set of procedures for handling complaints involving Medicare managed care,[26] but even those changes reflected a general desire to maintain beneficiary trust in an unfamiliar administrative environment rather than specific concern with the quality of reconfigured medical care.

III. REINVENTING COMPLAINT REVIEW AS ADMINISTRATIVE COMPENSATION FOR INJURY

A radical reinvention of Medicare's beneficiary complaint review process would give QIOs both the authority and the responsibility not only to review complaints, but also to provide beneficiaries with complete information and appropriate compensation for medical injury. Conventional malpractice litigation serves Medicare beneficiaries poorly, with aged or previously disabled individuals being far less likely than other negligently injured patients to obtain compensation through the courts.[27] The Medicare program has shaped national health policy and molded the politics of health care since the 1960s, but (as Hoffmann and Rowthorn's article illustrates) has walled itself off from liability determinations in part for fear of alienating physicians. Bringing injury compensation for beneficiaries within Medicare's scope therefore could have a salutary effect on the malpractice system as well as on the weak system of complaint review that Medicare currently supports.

In previous scholarship,[28] we argued that the Medicare program has the requisite infrastructure in place today to adjudicate the medical malpractice claims of Medicare beneficiaries. That infrastructure at present includes the QIOs and their Medicare beneficiary complaint function,[29] as well as the grievance and administrative review functions available for disputes about Medicare coverage and other disputes that Medicare beneficiaries have with the Medicare program.[30] Information derived from the detection and disclosure of adverse events by QIOs in connection with the disposition of medical injury claims would feed into the overall QIO process and other quality-oriented Medicare

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26. ELEANOR D. KINNEY, PROTECTING AMERICAN HEALTH CARE CONSUMERS 136-38 (2002).

27. *See* GOV'T ACCOUNTABILITY OFFICE, LEAFLET NO. GAO-93-126, MEDICAL MALPRACTICE: MEDICARE/MEDICAID BENEFICIARIES ACCOUNT FOR A RELATIVELY SMALL PERCENTAGE OF MALPRACTICE LOSSES 2-3 (1993).

28. *See* William M. Sage & Eleanor D. Kinney, *A Malpractice System for Medicare, in* MEDICAL MALPRACTICE REFORM IN THE UNITED STATES: NEW CENTURY, DIFFERENT ISSUES (William M. Sage & Rogan Kersh eds. 2006); Eleanor D. Kinney & William M. Sage, *Resolving Medical Malpractice Claims in the Medicare Program: Can it be Done?*, 12 CONN. INS. L.J. 77, 77 (2005-2006).

29. *Id.* at 88-92.

30. *Id.* at 92-97.

initiatives. Over time, this comprehensive data resource would facilitate greater understanding about the epidemiology of medical injuries.[31]

We have specified in detail elsewhere how the Medicare quality assurance infrastructure might be modified in a formal demonstration project that would adjudicate medical injury claims for providers and beneficiaries who elected to participate. We suggested offering federal stop-loss protection and other incentives to providers with the structural capacity to monitor and improve quality and safety.[32] This condition would focus the demonstration on hospitals, multispecialty physician practices, and similar models of health care delivery that have developed organized systems for identifying, redressing, and preventing unanticipated outcomes of care. For beneficiaries, we emphasized speed, ease, and fairness of the adjudication and compensation process as enticements to participate.[33]

IV. THE NEED FOR "DISRUPTIVE REGULATION" IN MEDICARE

It is currently fashionable to describe bottom-up changes in the marketplace that challenge and eventually overturn longstanding top-down structures as "disruptive innovations."[34] Public programs of Medicare's scale and scope may require an analogous process of "disruptive regulation" at key contact points between the government and its citizens to dislodge entrenched but fundamentally misguided biases that diminish those programs' effectiveness.

A demonstration program that charged the QIO process with hearing and resolving cases of patient injury, with mediated discussions, reasonable awards of compensation, and feedback to participating institutional providers regarding the safety and quality of their care could productively disrupt current practices in both Medicare and conventional malpractice litigation. Put differently, testing the QIO process on cases of real medical injury would move the elephant off the dance floor, leaving room for collaborative quality improvement. Closing the loop between patient experience and system response would change the beneficiary complaint process from one that is relatively impotent to one that produced real results for Medicare beneficiaries while enabling providers to identify, rectify, and learn from medical errors in an expeditious fashion.

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31. *Id.* at 107.

32. *Id.* at 99-103.

33. *Id.* at 103-04.

34. *See* Christensen, Clayton M., Bohmer, Richard, & John Kenagy, *Will Disruptive Innovations Cure Health Care?*,78 HARV. BUS. REV. 102, 102 (Sept. 2000). *See also* Clayton M. Christensen, THE INNOVATOR'S DILEMMA, HARV. BUS. SCH. PRESS. (1997); Bower, Joseph L. & Christensen, Clayton M., *Disruptive Technologies: Catching the Wave,* 73 HARV. BUS. REV. 43 (Jan.-Feb. 1995).