Health Courts and Malpractice Claims Adjudication through Medicare: Some Questions

Timothy Stoltzfus Jost

Follow this and additional works at: http://digitalcommons.law.umaryland.edu/jhclp
Part of the Courts Commons, and the Health Law Commons

Recommended Citation
Available at: http://digitalcommons.law.umaryland.edu/jhclp/vol9/iss2/5
HEALTH COURTS AND MALPRACTICE CLAIMS
ADJUDICATION THROUGH MEDICARE:
SOME QUESTIONS

TIMOTHY STOLTZFUS JOST*

It is difficult not to be cynical about the current malpractice reform debate. On the side of "reform," which almost always means limiting the rights of malpractice victims by curtailing remedies or erecting procedural barriers to litigation, is organized medicine, a whole coterie of business and manufacturing groups that would like also to limit their exposure to tort litigation, the public interest advocacy groups they fund, and the Republican lawmakers whom they generously support. In the fight to maintain the status quo are the plaintiffs’ bar, consumer groups (some of which are funded by the plaintiffs’ bar), and Democratic lawmakers whom they also generously support. Both sides fight for their narrow financial interest but make a lot of noise about the public’s interest. At the national level these groups have fought to a standstill, a situation that is, incidentally, to the benefit of both Democrats and Republicans, since continued donations are always needed to carry on the battle. At the state level, advocates of limiting the rights of malpractice plaintiffs have achieved more victories, though they tend to be more successful in the legislature than in state supreme courts.

Most of us who do not have a dog in this fight, that is to say, independent researchers and organizations, agree that our current situation is far from ideal. First, medical injury is common. Some argue whether the Institute of Medicine (IOM) estimate of 44,000 to 98,000 deaths from medical errors per year is accurate, but most commentators agree that the number of iatrogenic deaths and

---

* Robert L. Willett Family Professor of Law, Washington and Lee University School of Law.
2. COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (Linda T. Kohn et al. eds., 2000). Compare Lucian L. Leape, Institute of Medicine Medical Error Figures Are Not Exaggerated, 284 JAMA 95, 97 (2000) (explaining three reasons why “the IOM report did not exaggerate the extent of medical injury and death”), with Troyen A. Brennan, The Institute of Medicine Report on Medical Errors – Could It Do Harm?, 342 NEW ENG. J. MED. 1123, 1123 (2000) (“The combination of the strikingly large numbers of errors cited by the report and the connotations of the word ‘error’ create an impression that is not warranted by the scientific work underlying the IOM report.”), and Clement J. McDonald et al., Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report, 284 JAMA 93, 93-94 (2000) (arguing that conclusions drawn about the preventability of medical errors should be limited by the failure to factor out baseline death risks in observed patients), and Andrew R. Robinson et al., Physician and Public Opinions on Quality of Health Care and the Problem of Medical Errors, 162 ARCHIVES OF INTERNAL MED. 2186, 2189 (2002) (“Most physicians (73%) in our survey indicated that
injuries is very high. Many of these injuries are preventable, and a significant number are caused by negligence.\(^3\) Second, the vast majority of victims of medical error are never compensated for their losses, and many more are not adequately compensated.\(^4\) Moreover, even when victims are compensated, compensation is long delayed as cases wend their way through the court system.\(^5\) Third, the administrative costs of the current medical malpractice system are very high. Much of the money in the system ends up with plaintiffs’ and defendants’ lawyers and with malpractice insurance companies.\(^6\) Fourth, doctors find the current system very frustrating,\(^7\) and some specialists in some regions of the country find premiums untenably high.\(^8\) Fifth, there is some evidence, though not as much as organized medicine would have us believe, that malpractice encourages

\(^3\) See Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients – Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370, 373 (1991) (“Even more disturbing was the number of adverse events caused by negligence.”); INST. OF MED., supra note 2, at 26 (“Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).”).


\(^7\) See Michelle M. Mello et al., *Caring for Patients In a Malpractice Crisis: Physician Satisfaction and Quality of Care*, 23 HEALTH AFF. 42, 44, 51 (2004) (reporting findings that “suggest that the malpractice crisis in Pennsylvania is decreasing specialist physicians’ satisfaction with medical practice in ways that may affect the quality of care”).

\(^8\) See U.S. GEN. ACCOUNTING OFFICE, *MEDICAL MALPRACTICE INSURANCE: MULTIPLE FACTORS HAVE CONTRIBUTED TO INCREASED PREMIUM RATES 10-14 (2003) (reporting increases in malpractice premium rates by as high as 165% in some regions); see also David Dranove & Anne Gron, *Effects of the Malpractice Crisis on Access to and Incidence of High-Risk Procedures: Evidence From Florida*, 24 HEALTH AFF. 802, 802 (2005) (reporting that surgeons have been performing fewer procedures in response to increased insurance premiums); Pamela Robinson et al., *The Impact of Medical Legal Risk on Obstetrician-Gynecologist Supply*, 105 OBSTETRICS & GYNECOLOGY 1296, 1296 (2005) (reporting that “liability insurance for obstetrician-gynecologists (ob-gyns) has become prohibitively expensive and is forcing ob-gyns to restrict or abandon their obstetrical practices.”).
dysfunctional behavior on the part of doctors, including abandoning high risk geographic and specialty areas of practice and performing unnecessary procedures to insulate themselves against liability.9

Damage caps, the most frequently proposed solution to the malpractice problem, address some of these problems, but aggravate others. They limit the amount of the biggest judgments and probably limit the frequency of judgments and the rapidity of the rise of malpractice premiums.10 Caps also, however, discriminate against those who are most seriously injured by medical malpractice, as well as against women, who are more likely to suffer forms of non-economic loss, such as loss of fertility.11 Caps alone do nothing to promote patient safety and certainly do not expand access to justice for malpractice victims who now go uncompensated.

The proposals posed by Mr. Barringer and Professor Sage at this conference, "Beyond the New Medical Legislation: New Opportunities, Creative Solutions, and Best Practices for Patient Safety, Tort Reform and Patient Compensation," are both welcome in taking us beyond the debate on caps.12 Both are also wise in suggesting demonstration projects rather than immediate implementation of revolutionary changes.13 Both involve taking malpractice disputes away from the civil courts and placing them with administrative tribunals.14 But, both must be evaluated by how they would be superior to the present situation. In what respects do they improve patient safety, expand access to compensation, assure adequate compensation, reduce administrative costs, rein in increases in malpractice premiums, and reduce inefficient adaptive behavior on the part of health care practitioners and providers? This article will address these questions.

The health courts proposal discussed by Barringer is based in the end on an exceedingly narrow diagnosis of the basic problem with our current system. The


13. Barringer, supra note 6, at 249-50 (suggesting that there has been support from the IOM, consumer groups, and the media to implement demonstration projects designed to test the health courts concept).

14. Id. at 236 (describing the role of trained judges with health care expertise as the decisionmakers in the health court system).
fundamental problem it identifies is jury irrationality, which results in findings of negligence when none is present, irrational inconsistencies in judgment amounts, unreasonably large judgments, and the absence of consistent standards of liability that physicians accept as legitimate.\footnote{15}{Id. at 246-47 (citing inconsistencies in jury decision-making as a source of physician confusion in delivery of care); see also NANCY UDELL & DAVID B. KENDALL, PROGRESSIVE POLICY INST., HEALTH COURTS: FAIR AND RELIABLE JUSTICE FOR INJURED PATIENTS 6 (2005) (concluding that “the judicial system offers only irrational signals to doctors”), available at http://www.ppionline.org/documents/healthcourts_0217.pdf.}

It is certainly the case that juries sometimes make bad decisions, just as all decisionmakers do. I am not convinced that juries are at the root of our malpractice problem, however. In fact, academic research tends to show that juries reach pretty much the same conclusions experts do with respect to whether negligence is present or not, and if anything are more willing to allow defendant doctors to have the benefit of the doubt than are experts.\footnote{16}{See CATHERINE T. STRUVE, PEO PROJECT ON MEDICAL LIABILITY, EXPERTISE IN MEDICAL MALPRACTICE LITIGATION: SPECIAL COURTS, SCREENING PANELS, AND OTHER OPTIONS 37-44 (2003) (citing Henry S. Farber & Michelle J. White, A Comparison of Formal and Informal Dispute Resolution in Medical Malpractice, 23 J. LEGAL STUD. 777, 802 (1994) (finding a “statistically significant relationship” between quality of care and trial outcome); Bryan A. Liang, Assessing Medical Malpractice Jury Verdicts: A Case Study of an Anesthesiology Department, 7 CORNELL J.L. & PUB. POL’Y 121, 129 (1997) (reporting that jury verdicts concurred with physician assessments in 56-58% of cases, and that cases of non-concurrence occurred most often in cases where physician experts would have found physician defendants liable); Frank A. Sloan et al., The Dispute Resolution Process, in SUING FOR MEDICAL MALPRACTICE 153, 166-68 (Frank A. Sloan et al. eds., 1993) (finding physician reviewers twice as likely to find practitioner liability than jurors).}

Juries undoubtedly find negligence in cases where experts would find none, but experts also find negligence in cases where other experts find none—interrater reliability is just not that high when complex judgments like this need to be made.\footnote{17}{One of the more common criticisms of the Harvard Medical Practice Study, for example, is that the level of interrater reliability among the experts who identified medical errors was low. See, e.g., Richard E. Anderson, Harvard Study Continues to Distort Malpractice Debate, THE DOCTORS COMPANY (2005), http://www.thedoctors.com/reference/1996-2002/distortquality.asp (noting that two sets of reviewers failed to identify the same group of adverse events, although they did find the same incidence of adverse and negligent events); Tom Baker, Reconsidering the Harvard Medical Practice Study Conclusions about the Validity of Medical Malpractice Claims, 33 LAW, MED. & ETHICS 501, 504 (2005) (noting strong disagreement between study researchers as to individual incidence of negligence).}

Also, while it is true that doctors distrust juries, doctors distrust anyone—particularly any layperson—who second-guesses their judgments. They have continually fought managed care over on the issue of oversight of medical judgments and have resisted medical discipline and hospital peer review quite successfully as well. Doctors might be more willing to accept a judgment on their practice from an expert health court, but I am doubtful.

The important question, however, is how the health court proposal fares in terms of improving on our current system. The proposal purports to expand the number of compensated claims, which would be an improvement. I am not confident, however, that it would in fact do this. Both proposals do provide for liberalizing the standard of compensability from negligence to a preventable or avoidable medical mistake standard. This should expand compensation awards, though experience from other countries shows that application of standards like this is difficult and leaves open serious and controversial causation questions.

The key factors with respect to access expansion, however, would be the nature and role of the local review boards created by the proposal to screen out unmeritorious or trivial claims. Who would constitute these boards, who would appoint them, what standards would they apply, and what evidence would they consider? These boards are to make their decisions based on reviewing medical charts and interviewing “patients, doctors, and nurses.” Would they also consult independent experts? Would they simply accept the story of the health care providers as to what happened, or would they conduct thorough investigations? They are to be located “in or near hospitals.” What would guarantee their independence? Further, more needs to be said in the health courts proposal about the obligation of health care providers to notify injured persons of the fact that a medical error has occurred. This requirement was missing in earlier proposals and needs to be fleshed out. If medical mistakes continue to be concealed, many of their victims will go without compensation.

The proposal also claims to increase the rationality of compensation by scheduling non-economic loss in lieu of leaving damages to the discretion of the jury. This sounds like a good idea, but everything will depend on how schedules are set, and who sets them. This could turn out to be simply damage caps at a micro rather than macro level. If the process of setting and updating these caps becomes a political process and is captured by health care providers, it could be more effective in limiting compensation for malpractice victims than MICRA caps have been. If, on the other hand, schedules are set through a truly fair and independent process, they could improve the rationality, perhaps even the level, of

---


21. See Barringer, supra note 6, at 245-48.

22. MICRA is an acronym for the Medical Injury Compensation Reform Act, a damage cap statute that has been enacted by California. Medical Injury Compensation Reform Act, ch.1, 1975 Cal. Stat. 3949 (codified as CAL. CIV. CODE § 3333.2(6) (West 2006)). California’s MICRA cap has been criticized because, although premiums for malpractice insurance have gone up, the MICRA cap on how much a plaintiff can recover has not changed since 1975. Martin Ramey, Comment, Putting the Cart Before the Horse: The Need to Re-Examine Damage Caps in California’s Elder Abuse Act, 39 SAN DIEGO L. REV. 599, 628-29 (2002).
compensation. It is also important to know what all is included in noneconomic loss, as far more than pain and suffering is at stake here.

The health courts proposal asserts that it would cut the administrative costs of litigation and speed it up. Reliance on independent experts could cut costs, as could the elimination of juries. Early investigation of claims by screening panels could cut discovery costs. On the other hand, the proposal still relies on an adversarial system, and now adds another layer to the process in local screening panels. The proposal does eliminate contingent fees. This should reduce the transactions costs of claims and get more money to malpractice victims. It is not clear, however, what incentive a lawyer would have to bring a claim for a victim whose case is going to be difficult to prove if there is only risk and no opportunity. Up-front payment of fees is never going to cover the costs of litigation in these cases, and attorneys fees can only be awarded to those who win.

It is also not clear that the health courts proposal would improve quality or protect safety. The hope is, apparently, that a process with greater professional integrity and legitimacy could be a more open process that would set clearer ground rules for defining adequate performance than does the current system, as well as greater exposure to adverse publicity and to disciplinary action for those who do not perform adequately. Perhaps, though I doubt that many health care providers are going to learn much from the avoidable events list that they do not already know. Most providers, for example, already know that it is inappropriate to leave foreign objects in surgical sites.

Health court advocates also join the chorus claiming that doctors currently hide their mistakes because they fear malpractice liability and that health courts would make doctors more forthcoming in admitting and dealing with their errors. I believe that the notion that doctors would freely discuss and address their mistakes if malpractice liability would just go away is nonsense. Doctors did not freely discuss their faults before malpractice became an issue and do not today in countries where it is not a problem. Law professors seldom get sued for making mistakes, yet they do not sit around the faculty lounge talking about how badly they screwed up in class. No one, under any circumstances, likes to admit to making mistakes, least of all physicians. I cannot imagine that they would be more

24. See id. at 251-53 (noting that juries would be replaced with review boards in clear cases and health court judges relying on court appointed experts in unclear cases).
25. Id. at 245, 248-49; see also David A. Hyman & Charles Silver, The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?, 90 CORNELL L. REV. 893, 909-14 (2005) (contesting the widely accepted belief that “malpractice liability impedes efforts to improve patient safety and health care quality by restricting the free flow of information about mistakes.”).
27. See id. at 928-30 (discussing the relevance of underreporting in the United Kingdom, a country in which malpractice suits are “relatively rare”).
likely to admit their mistakes if they faced being dragged in front of a health court rather than a jury. I am, in the end, not convinced that health courts would expand access to justice, reduce administrative costs, or improve patient safety. I am most of all, however, troubled with the question of whether they could truly be impartial. At the heart of the proposal is a call for "judges with expertise in health care." I am not sure, as I wrote earlier, how useful this expertise would be. Given the highly specialized nature of modern medicine, general "health care expertise" may not help in understanding what went wrong in particular cases. But if "judges with health care expertise" means doctors, I would be truly troubled by the proposal. I have known many doctors in my life and met few whom I would trust to judge a malpractice claim evenhandedly. We also need to know more about how "independent expert witnesses" would be chosen to avoid partiality.

We all know how easily administrative agencies can be captured. The current situation has many faults, but it does have the virtue of relatively unbiased decisionmakers. I am not confident that this proposal preserves that virtue.

Professor Sage's proposal to use Medicare's administrative structure to adjudicate malpractice disputes avoids some of these problems. First, it clearly attends to quality improvement and patient safety. Though it is not wholly clear on how malpractice adjudications under the program would contribute to patient safety, Professor Sage correctly notes that the Centers for Medicare and Medicaid Services (CMS) is seriously committed to using the Medicare program to improve quality and protect patients, and various components of this strategy, such as the Quality Improvement Organization (QIO) program, the Quality Assessment and Performance Improvement (QAPI) initiative, and a number of pay for performance projects, are in place or soon will be. One can easily imagine a number of ways in which medical error evaluations could be linked to these programs.

The Medicare proposal also seems more likely to expand access to compensation for victims of medical error who now do not receive compensation.

28. See Barringer, supra note 6, at 245.
29. Id. at 246 (describing how health courts would consult "neutral medical experts" to determine the standard of care); STRUVE, supra note 16, at 73-75.
As Professor Sage points out, Medicare beneficiaries and the elderly in particular often now do not receive compensation when they suffer injury from medical error. The proposal would attempt to ensure that these persons are told when they have been the victims of medical error. It would also help overcome one of the primary barriers to compensations now faced by the elderly: the unattractiveness of their cases to lawyers paid strictly on a contingent fee basis because of small recoveries. The availability of an administrative tribunal might make claiming less costly and thus more frequent. Finally, the charge to the Medicare beneficiary ombudsperson to assist beneficiaries in claiming could also increase the frequency of claiming and compensation. On the other hand, the proposal also contemplates a minimum threshold of injury before a claim could be brought, and where this threshold was set would go far toward determining the extent to which the proposal actually expanded access to justice for Medicare beneficiaries.

I agree with Professor Sage that Medicare could probably carry out at least a voluntary experiment under its demonstration authority, and that Congress could probably preempt common law state tort remedies for Medicare beneficiaries against Medicare providers under the spending power if it chose to do so. Though the Supreme Court has been rather ambivalent about the scope of the power of Congress under the Commerce Clause, it has until now been tolerant of expansive interpretations of the Spending Clause.

I do have real concerns about the proposal, however. First, I am not sure how successful Medicare would be in imposing this program on providers, especially physicians. The checkered history of the former Department of Health, Education, and Welfare’s (DHEW’s) attempts to enforce the civil rights laws through the Medicare program are here instructive. DHEW was successful in requiring hospitals to integrate as a condition of their participation in the nascent Medicare program. In the mid-1960s it faced down considerable resistance from segregated hospitals and ultimately almost all integrated. It did not attempt, however, to desegregate nursing homes, where greater resistance was expected. It did not even try to require doctors to comply with the civil rights laws. As

---

33. Sage, supra note 12, at 221-25.
34. Id. at 220.
35. See id. at 233.
37. See David Barton Smith, Health Care Divided: Race and Healing a Nation 125-26 (1999) (providing an overview of Title VI compliance enforcement through DHEW); Sidney D. Watson, Race, Ethnicity and Quality of Care: Inequalities and Incentives, 27 Am. J.L. & Med. 203, 213-16 (2001) (documenting the use of the Medicare system to desegregate medical care).
38. See Smith, supra note 37, at 137-41 (documenting federal persistence in enforcing integration under Title VI).
39. Id. at 159-61.
recently as 2002, the Department of Health and Human Services (HHS), the successor to DHEW, again reiterated its position that physicians who are receiving only Medicare Part B payments are not bound by Title VI. HHS still regards Part B as an indemnity insurance plan, through which beneficiaries pay doctors who are not government contractors.

I believe that the position of HHS on civil rights law compliance enforcement reflects a realistic appraisal of how much leverage it has with providers and professionals. Hospitals are so financially dependent on the Medicare program that CMS can do almost anything to them without driving them away, including, perhaps, requiring them to participate in a demonstration project dealing with medical error. Physicians, on the other hand, or at least physicians not located in a few Medicare-dependent specialties like ophthalmology, will leave Medicare if pushed too hard, as recent annual debates on Resource-Based Relative Value Scale (RBRVS) increases have made clear. This program would have to be made very attractive to doctors to get them to participate voluntarily.

A second concern is whether the Medicare claims review and appeals system can really be adapted to hear medical negligence cases. The Medicare administrative process is adapted to hear a particular kind of case-coverage determinations. This is what Medicare contractors, Qualified Independent Contractors (QICs) (which provide reconsiderations for Part A and B determinations), Medicare Advantage plans, and Maximus CHDR (which reviews Medicare Advantage appeals) do. These can be complex cases, but they are usually quite straightforward compared to medical negligence cases. They are usually guided by thousands of local coverage determinations and dozens of national coverage determinations. Administrative law judges (ALJs) play an increasingly routinized role in this process. Under recent regulations, virtually all ALJ hearings will be conducted by video conferencing. They are also moving increasingly toward exercising strictly a review, as opposed to a fact-finding, function. The Medicare Modernization Act prohibits ALJs from hearing new


41. Id. at 47313 n.4 (confirming that Title VI regulations do not apply to “[a]ny federal financial assistance by way of insurance or guaranty contracts . . .”).

42. See AM. MED. ASS’N, AMA MEMBER CONNECT SURVEY: MEDICARE PAYMENT CUTS WILL HURT ACCESS TO CARE (Apr. 5, 2005), http://ama-assn.org/ama/pub/category/14925.html (reporting that 38% of physicians will decrease the number of new Medicare patients they accept as a result of the payment cut).


44. See 42 C.F.R. § 405.1020(b) (2005).
evidence in cases brought by providers or suppliers unless good cause is shown.\textsuperscript{45} Moreover, as Professor Sage's article acknowledges, by the summer of 2005, HHS was forming its own ALJ corps, in place of using Social Security ALJs as it has in the past.\textsuperscript{46} Though Professor Sage's essay is correct that Social Security ALJs have a great deal of experience in evaluating disability, which could be applied toward assessing causation and damages, my impression is that few SSA ALJs are transferring to HHS and that HHS is by and large bringing in a new group of ALJs with very mixed experiences.\textsuperscript{47}

Most importantly, the Medicare appeals process is currently in crisis, incorporating new procedures and actors (including the QICs, who just began contracting with the program this year, and the new HHS ALJs), subject to very strict time limits for throughput imposed by BIPA and the MMA, and overwhelmed by impossible numbers of appeals.\textsuperscript{48} Imposing on this system a new, very different, and very complicated task is difficult to imagine and would meet stiff resistance.

A third concern is how liability would be assessed and damages imposed under the program. The proposal suggests again, like the health courts proposal, a no-fault system based on avoidable events and reliance on schedules for determining damages.\textsuperscript{49} The definition of avoidable events and the crafting of the damage schedules would unavoidably become the task of some administrative entity, presumably CMS (though an argument could be made that these decisions would better lie somewhere else within HHS, such as with the Agency for Healthcare Research and Quality or the Centers for Disease Control and Prevention). CMS is already burdened beyond capacity with rulemaking responsibilities, including annual revisions of a number of prospective payment system regulations that regularly run to hundreds of pages and dozens of new


\textsuperscript{46} Sage, \textit{supra} note 12, at 231.

\textsuperscript{47} See Letter from Leslie G. Aronovitz, Dir., Health Care Program of the U.S. Gov't Accountability Office, to Hon. Charles E. Grassley, Chairman, and Hon. Max Baucus, Ranking Minority Member, Committee on Finance (June 30, 2005), \textit{available at} http://www.gao.gov/new.items/d05703r.pdf (noting the "extremely ambitious" timetable of HHS in hiring and training sufficient numbers of ALJs); Kenneth E. Stewart, \textit{Medicare Appeals Before Administrative Law Judges} (Feb. 2005).


\textsuperscript{49} Sage, \textit{supra} note 12, at 229-32.
rulemaking requirements imposed by the MMA. In all likelihood, CMS would 
have to resort to informal processes for coming up with these standards, as it does 
not with coverage determinations. This process, however, is highly subject to 
interest group manipulation. It would be likely to prove intensely political, and 
quite messy.

Finally, I would raise an overall question for both proposals. Both basically 
propose to adapt the model that we have used in this country for almost a century 
for workers’ compensation to medical malpractice. It would seem to me, therefore, 
that we should take a long hard look at workers’ compensation to see how that 
program has worked out before we proceed down this path with malpractice 
adjudication. Has it broadened access to compensation, provided more rational 
compensation, improved safety, simplified administration, and brought down 
costs? Are both workers and employers satisfied with the system? Is it a just 
system? There must be a large volume of literature evaluating workers’ 
compensation. I am not familiar with it, and did not presume to familiarize myself 
with it for the purposes of this brief article. But it seems to me that an essential 
step in any argument for moving from our current malpractice system to an 
administrative adjudication model would be to come to terms with this literature. 
I, for one, would be very interested in finding out what this investigation would 
yield.

the “visible policy-making output” of Medicare regulations, illustrated by the fact that the 1997 Code of 
Federal Regulations contained two thick volumes of Medicare regulations).