Resolving Medical Malpractice Claims in the Medicare Program: Can It Be Done?

Eleanor D. Kinney
William M. Sage

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RESOLVING MEDICAL MALPRACTICE CLAIMS IN THE MEDICARE PROGRAM: CAN IT BE DONE?

Eleanor D. Kinney, JD, MPH* & William M. Sage, MD, JD**

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* Hall Render Professor of Law and Co-Director, Center for Law and Health, Indiana University School of Law-Indianapolis; MPH, University of North Carolina at Chapel Hill; JD, Duke University School of Law. This article was supported by a grant from The Commonwealth Fund. Prof. Kinney thanks her research assistant, Jennifer Wallander, for assistance on this project.

** Professor, Columbia Law School; A.B., Harvard University; M.D., J.D., Stanford University.
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INTRODUCTION

There is increasing interest in an integrated approach to patient safety and medical liability among policymakers. We have proposed Medicare-led malpractice reform that would provide Medicare beneficiaries with better safety, improved communication in the event of error, preservation of therapeutic relationships, timely settlement, and fair compensation at a lower administrative cost. Disputes in the reformed system would be adjudicated by Medicare's existing administrative appeals system that would work together with Medicare's quality improvement regulation and payment policy to reduce errors and compensate injured patients.

Despite the laudable rationale for Medicare-led malpractice reform, important issues attend the constitutional and statutory authority for such reform. The first issue, assuming legal authority exists, is the feasibility of Medicare-led malpractice reform. Quite simply, does the Medicare program, with the primary purpose of providing acute care services to the elderly, severely disabled, and people with end stage renal disease, have the requisite infrastructure to launch such reform without compromising its central functions? Second, does the federal Congress and/or the Executive Branch, in our constitutional scheme, have the requisite authority to establish Medicare-led malpractice reform especially when states have and always have had the authority to adjudicate medical malpractice in the common law tort system?

This article explores these critical issues for Medicare-led malpractice reform. First, this article explores the infrastructure of the Medicare program and how it could accommodate Medicare-led malpractice reform without compromising its central mission. Second, the article briefly describes the elements of a Medicare malpractice adjudication and compensation system for Medicare beneficiaries. Third, the article explores the legal authority for a federal benefits program to supplant a function performed by state common law of torts in the civil judiciary and


generally with jury trials. Finally, the article concludes with an assessment of the legal and practical feasibility of Medicare-led malpractice reform.

I. RATIONALE FOR REFORM

There are two major reasons to support Medicare-led malpractice reform. First, such reform connects malpractice policy to health policy thus bringing new considerations and dimension to consideration of malpractice reform. Second, Medicare beneficiaries are poorly served by the common law tort system and deserve better.

Medical malpractice policy has been in suspended animation for decades. Non-academic proponents of reform have hardly budged in their recommendations since 1975, and opponents have countered those proposals without offering promising alternatives. The principal cause of stagnation is that medical malpractice policy has never been connected to overall health policy. In particular, the Medicare and Medicaid programs—which have shaped health policy and molded health politics since the 1960s—have never been engaged in malpractice reform. Because malpractice has not been connected to overall health policy, the politics of medical liability has been co-opted by the politics of general (non-medical) tort reform. Policy debates focus on how lawsuits destroy or preserve America’s economy and social fabric, and not on reasoned discussion of the effect of liability on the quality, cost and availability of medical care.

Having Medicare play a principal role could dramatically change the politics of medical malpractice. Framing liability reform around Medicare shifts power from legislative committees primarily concerned with the judicial system to committees primarily concerned with the health care system. Medicare-led malpractice reform also may recruit new political voices, such as the American Association of Retired Persons, that have a greater stake in health care generally and Medicare specifically than the general business and “consumer” lobbyists who currently control the debate. Finally, as occurred twenty years ago with respect to provider


payment reform, it is highly likely that a successful Medicare malpractice initiative can be leveraged into system-wide reform as private payers and health care providers—particularly hospitals—realize the advantages of a uniform approach to managing medical errors.

Second and perhaps more importantly, conventional medical malpractice law serves Medicare beneficiaries poorly. There is persuasive evidence that injured aged or disabled individuals are less likely than other patients to obtain compensation in the existing common law tort system.\(^5\) In its review of the literature to date as well as independent analysis of empirical data, the U.S. Government Accountability Office (GAO) found that hospital malpractice awards paid on behalf of Medicare and Medicaid patients account for a relatively small share of total hospital malpractice losses.\(^6\) Further, the GAO also found that Medicare and Medicaid patients received awards half as large as privately insured patients when they were successful.\(^7\)

More recent studies have confirmed these findings.\(^8\) Burstin and colleagues found that poor patients, uninsured patients and the elderly were significantly less likely to file malpractice claims. Similarly, in the study of claims in Utah and Colorado, Studdert and colleagues found that non-claimants with medical injuries were more likely to be Medicare recipients, Medicaid recipients and greater than seventy-five years of age. These investigators concluded that the elderly may be said to suffer a kind of "double jeopardy" because they also experience higher rates of medical injury.\(^9\)

II. WHY ADMINISTRATIVE REFORM THROUGH MEDICARE MAKES SENSE

An administrative alternative to medical malpractice litigation linked to quality oversight and improvement attracted widespread support in the late

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6. GAO, supra note 5, at 3.

7. Id. at 14 (citing GAO, LEAFLET NO. GAO-87-55, MEDICAL MALPRACTICE: CHARACTERISTICS OF CLAIMS CLOSED IN 1984 51 (1987)).


1980s. However, interest in comprehensive reform waned as malpractice insurance markets recovered and physicians' political attention turned to managed care. There remains interest in state-level systems of administrative compensation, perhaps connected to health care regulation, but little progress has been made to date.

We believe that administrative reform could be launched through the Medicare program at the federal level. Our proposed reform would use existing Medicare infrastructure to adjudicate claims involving Medicare beneficiaries in a manner that would both improve compensation for injury and encourage performance improvement.

Medicare has an extensive administrative structure in place that could be used to implement Medicare-led malpractice reform. Medicare has the authority to require health care institutions to implement quality improvement strategies. Medicare has a nationwide network of contractors that administer the Medicare program, which includes managing claims for coverage and payment and conducting medical and quality reviews of care for Medicare beneficiaries. Medicare operates various programs aimed at ensuring and improving the quality of health care for beneficiaries. Finally, Medicare has an independent administrative appeals system to adjudicate disputed cases.

This infrastructure gives Medicare the ability to proactively detect and disclose unanticipated events rather than waiting passively for lawsuits to be filed and pursued. Thus, a Medicare-based system could enable malpractice reform that identifies and resolves potential and actual claims earlier and in a more congenial and efficient manner from the perspective of beneficiaries, providers and malpractice carriers. These features enable

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11. See generally Thorpe, supra note 3.
13. Id.
14. See infra notes 25-30 and accompanying text.
15. See infra notes 37-45 and accompanying text.
16. See infra notes 53-69 and accompanying text.
17. See infra notes 70-104 and accompanying text.
a Medicare-led malpractice reform to connect the handling of individual injury claims to other initiatives currently under way within the Medicare program and to important health policy issues affecting that program.

III. PRACTICAL FEASIBILITY

The Medicare program's highly developed quality assurance infrastructure, which includes medical review in several contexts, as well as its administrative appeals system, makes the Medicare program an attractive venue for malpractice reform. One of the unique characteristics of the infrastructure of the Medicare program is that it is comprised primarily of different private organizations throughout the nation that contract with the Medicare program to perform specific functions. Thus, there is no monolithic federal bureaucracy that manages the program. Rather, the Centers for Medicare and Medicaid Services (CMS), the agency responsible for the Medicare and Medicaid programs within the Department of Health and Human Services (HHS), sets policy for the Medicare program and relies on its contractors to implement the policies at the state and local level. Thus, Medicare beneficiaries and providers are actually dealing primarily with contracts comprised of local and known personnel regarding the day-to-day operation of the Medicare program. These various contractual relationships that are the foundation of the Medicare infrastructure are described below.

A. MEDICARE CONTRACTS WITH SERVICE PROVIDERS

To participate in the Medicare program, institutional providers and prepaid health plans contract directly with the Medicare program and meet specific contractual requirements.\(^{19}\) Also, Medicare has a contractual relationship with the physicians and suppliers serving Medicare beneficiaries by virtue of an assignment arrangement described below.\(^{20}\) The contractual relationships with providers and practitioners described below are the foundation upon which any initiative to improve the quality of care for Medicare beneficiaries is predicated.

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19. See infra notes 21-27 and accompanying text.
20. See infra notes 31-35 and accompanying text.
1. Medicare Contracts with Institutional Providers

The Medicare statute defines the specific types of health care institutions that can provide services to Medicare beneficiaries and defines the conditions upon which these institutions can participate in the Medicare program. CMS and its predecessors have promulgated regulations setting forth the so-called “conditions of participation” for each type of health care institution. The major health care institutions covered are hospitals, extended care facilities and home health agencies, and ambulatory surgery centers.

Any institution that wants to serve Medicare beneficiaries and thereby “participate” in the Medicare program has to enter into a contract with the federal government. Contractual conditions include the specific conditions of participation that define the basic characteristics of the health care institutions needed to assure high quality care. An important issue discussed below is the latitude available to the federal government to impose conditions on health care institutions that voluntarily contract with the federal government to serve Medicare beneficiaries. The Medicare statute explicitly states that the Medicare program can impose conditions on participating hospitals: “The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.”

The Medicare program has historically taken this mandate quite literally and imposed important quality improvement measures on hospitals as part of the conditions of participation. Most recently, Medicare modified its conditions of participation for hospitals to require hospitals to institute a so-called Quality Assessment and Performance Improvement (QAPI) program. The new QAPI program provision focuses on “the

26. See infra notes 28-47 and accompanying text.
continuous improvement of the hospital as an organization requiring hospitals to track incidents, analyze their causes, and share and implement preventive actions and mechanisms of feedback and learning throughout the facility. Specifically, the rule states the following mandate for the QAPI program:

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

This program requires hospitals to systematically examine quality on an ongoing basis and implement some of the patient safety strategies that have developed in recent years.

2. Medicare's Relationship with Physicians

Medicare's relationship with physicians is quite different. Theoretically, the Medicare program does not contract directly with physicians for their services to Medicare beneficiaries. Rather, Medicare's relationship is with the beneficiary enrolled in Medicare's Part B Supplementary Medical Insurance program. Medicare only has a formal relationship if the physician actively accepts the assignment of the beneficiary's claim for payment under the Medicare program. If a

30. Id. at 3454, (to be codified at 42 C.F.R. pt. 482.21).
32. Id. § 1395cc (defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services).
physician accepts assignment, the physician must accept Medicare payment as full payment for the services in the claim.\textsuperscript{33}

However, over the years, mainly in an effort to gain control over the inflation in physician payment, the Medicare program has made it extremely difficult for physicians to serve Medicare beneficiaries and not accept assignment. In 1989, Congress established a new fee schedule for physician services. Specifically, the Omnibus Budget Reconciliation Act, implemented in 1992, introduced a Resource-Based Relative Value Scale (RBRVS) to reform Medicare physician payment and align it more closely with resources used by particular physician specialties for the care of Medicare patients with specific conditions.\textsuperscript{34} Further, the act required physicians to submit bills to Medicare on behalf of Medicare patients and greatly limited the degree to which physicians could charge beneficiaries for fees in excess of Medicare payment levels.\textsuperscript{35} These provisions made it highly advantageous for physicians to accept assignment for all Medicare claims. Thus, as a practical matter, Medicare does have a direct contractual relationship with most physicians through the mechanism of assignment.

3. Medicare Contracts with Carriers for Medicare Administration

The Medicare program was intentionally designed from its inception to relate to providers through private insurance carriers regarding coverage and, particularly, payment matters. Indeed, Medicare is organized like the Blue Cross and Blue Shield plans that were the predominant source of private hospital and medical insurance at the time of its inception.\textsuperscript{36} Part A (hospital insurance) is analogous to a traditional Blue Cross plan and Part B

\textsuperscript{33} Id. § 1395hh.
\textsuperscript{35} Id. § 5201 (codified as amended at 42 U.S.C. § 1395u(b)(4)(E)).
\textsuperscript{36} Peter Corning, The Evolution of Medicare: From Idea to Law (1969); Theodore R. Marmor, The Politics of Medicare (2d ed. 2000) (noting that the Medicare bill included two related insurance programs to finance substantial portions of the hospital and physician expenses incurred by Americans over the age of sixty-five); Robert J. Myers, Medicare (1970) (explaining that the enactment of Medicare provided extensive coverage against the costs of medical care for persons aged sixty-five or over); Herman Miles Somers & Anne Ramsay Somers, Medicare and the Hospitals: Issues and Prospects (1967).
(supplementary medical insurance) is analogous to a traditional Blue Shield plan.\textsuperscript{37}

Today, working with the Blue Cross and Blue Shield Association, the Medicare program contracts with Blue Cross plans to act as fiscal intermediaries between hospitals and the Medicare program for purposes of paying and otherwise managing claims for hospital and other services paid under Part A of the Medicare program.\textsuperscript{38} Medicare also contracts with Blue Shield plans and other insurance companies to operate as carriers to pay and otherwise manage claims for physicians and other outpatient services under Part B of the Medicare program.\textsuperscript{39} Fiscal intermediaries and carriers are expected to operate with providers just as private Blue Cross and other private insurance plans would operate.\textsuperscript{40}

4. Medicare Contracts with Medicare Advantage Health Plans

Medicare’s relationship with health maintenance organizations (HMOs) and other health plans that serve Medicare beneficiaries is entirely contractual and voluntary. Again, the Medicare statute and regulations impose a variety of conditions on HMOs and other health plans that they must meet to provide care to Medicare beneficiaries.\textsuperscript{41} In addition to payment terms, these contracts require health plans participating in the Medicare Advantage program (formerly called Medicare+Choice) to serve Medicare beneficiaries that choose to enroll in the health plan, as opposed to receiving their benefits and health care through the traditional fee-for-service Medicare program.\textsuperscript{42} Each Medicare Advantage organization that offers one or more Medicare plans must have an ongoing quality assessment and performance improvement (QAPI) program for each plan.\textsuperscript{43} Federal regulations establish the QAPI requirements that sponsoring organizations must meet.\textsuperscript{44}

Given the pressures of implementing the Medicare Modernization Act


\textsuperscript{39} Id. § 1395u.

\textsuperscript{40} \textit{Id.}


\textsuperscript{43} 42 C.F.R. § 422.152 to -.159 (2004).

\textsuperscript{44} \textit{Id.}
(MMA), CMS decided that Medicare Advantage organizations did not need to implement a national QAPI project in 2005. 45

B. MEDICARE REGULATION OF THE QUALITY OF HEALTH CARE SERVICES

Immediately after the inception of the Medicare program, Medicare expenditures began rising at an alarming rate. 46 In 1969, out of concern for escalating costs in the program, Congress required utilization review of hospital services, 47 and began Medicare’s express responsibilities regarding the volume and quality of care of Medicare beneficiaries.

1. The Professional Standards Review Organization Program

In 1972, finding utilization review by hospitals ineffective, 48 Congress inaugurated the Professional Standards Review Organization (PSRO) program. 49 This program required the Medicare program to contract with independent physician-dominated organizations to review the utilization of health care services for Medicare beneficiaries. Pursuant to statute, services to Medicare beneficiaries would be paid under the following circumstances:

(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and (2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized

45. Memorandum from Cynthia Moreno, Director, Health Plan Benefits Group, to Medicare+Choice/Medicare Advantage Organizations on Selection of 2005 QAPI project focus (March 3, 2004).
46. Marian Gornick et al., Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures, 6 HEALTH CARE FIN. REV. 13, 14 (1985); Margaret H. Davis & Sally T. Burner, Three Decades of Medicare: What the Numbers Tell Us, 14:4 HEALTH AFF. 231, 231-243 (1995) (showing data that Medicare spending had increased to forty-five percent of the nation’s total elderly health care bill by 1969).
health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.\textsuperscript{50} This program was extremely unpopular with the medical profession and health insurers as an improper interference into medical practice.\textsuperscript{51} In 1981, the Reagan Administration and Congress repealed the program apparently in response to concerns from the medical profession about the program’s intrusiveness into medical practice.\textsuperscript{52}

2. The Medical Utilization and Quality Control Program

In 1982, Congress, in preliminary legislation to support the move to prospective payment for hospitals, established the Medical Utilization and Quality Control program.\textsuperscript{53} This program established Peer Review Organizations (PROs) to review the utilization of services provided to Medicare beneficiaries to ensure that they were medically necessary and met professionally recognized standards of quality. Congress adopted this program in preparation for a new prospective payment system for hospitals to counter anticipated and undesirable incentives for excessive hospital

\textsuperscript{50} 42 U.S.C. § 1320c (2000).

\textsuperscript{51} See Social Security Amendments of 1972: Hearing on H.R. 1 Before the S. Comm. on Finance, 92d Cong. 2282 (1972) (statement of Richard M. Loughery, Administrator of the American Hospital Center on behalf of the American Hospital Association, acknowledging the intended goal of PSRO’s but warning that “it would be a great mistake to establish a programs of such magnitude on a nationwide basis without carefully organized demonstrations or experiments to ascertain the results of such a program, the administrative problems, and the effects on the delivery of quality medical care, as well as the cost involved”). See also id. at 2746 (statement of Bernard R. Tresnowski, Senior Vice President for Federal Programs, Blue Cross Association, expressing “reservations about any one form of peer review fitting the entire country”); id. at 2645 (statement of Thomas Dority, M.D., President of the Association of American Physicians and Surgeons, criticizing the federal government for failing to “heal its own sickness of uncontrolled spending, which is its responsibility, instead of interfering in medical care, where it is incompetent and has no proper responsibility”).


admissions for Medicare beneficiaries under the new system. In 2002, CMS, pursuant to regulation, changed the name of PROs to Quality Improvement Organizations (QIOs) to reflect the new responsibilities placed upon PROs in 2001 to provide comparative information on nursing homes and hospitals.54

The authority for CMS to contract with QIOs and implement this program is based on the section of the Medicare Act establishing coverage criteria for the Medicare program.55 Specifically, Section 1395y(g) provides that the Secretary, in making determinations of whether items or services meet coverage criteria and “for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services,” “shall” enter into contracts with utilization and quality control peer review organizations.56

The powers of QIOs are broad. QIOs can retrospectively deny Medicare payment for services not meeting their utilization or quality standards.57 The PRO can also initiate proceedings before the Office of the Inspector General (OIG) in HSS to fine or exclude a provider or practitioner from receiving payment under the Medicare program if they are found guilty of gross and flagrant violations of their obligation to provide care of acceptable quality, or are guilty of substantial violations in a substantial number of cases.58 In 1986, Congress also required PROs (now QIOs) to review all written complaints about the quality of services not meeting professionally recognized standards of health care.59 Today, a national network of fifty-three QIOs, located in each state, territory and the District of Columbia, review the provision of Medicare services in hospitals and other health care institutions.60

54. Office of Inspector General-Health Care; Medicare & Medicaid Programs; Peer Review Organizations: Name and Other Changes-Technical Amendments, 67 Fed. Reg. 36,539 (May 24, 2002) (to be codified at 42 C.F.R. ch. IV & V) (changing name to "quality improvement organizations").
56. Id. § 1395y(g).
57. Id. § 1320c-3(a)(2).
58. Id. §§ 1320c-5(b)(1) & (2)
3. Federal Quality Initiatives for the Health Care Sector

In recent years, CMS has launched specific quality initiatives for the major classes of providers, which involve the collection of data on quality measures and implementation of strategies to improve quality.\textsuperscript{61} Specifically, HHS has engaged in a number of initiatives to prevent medical injury and improve the safety of Medicare beneficiaries in hospitals, other institutional providers, and Medicare health plans.

The initiatives for hospitals and health plans are especially important to a proposal for Medicare-based malpractice reform. In CMS' Hospital Quality Initiative, CMS works with the Hospital Quality Alliance (HQA), which includes the American Hospital Association and other key stakeholders with the support of Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), among other organizations.\textsuperscript{52} Through this initiative, CMS has developed a standardized set of hospital quality measures for use in voluntary public reporting. As part of this initiative, CMS has launched the website Hospital Compare to provide information on the comparative performance of hospitals on health care quality.\textsuperscript{63}

Another important project in the Hospital Quality Initiative is the Premier Hospital Incentive Demonstration.\textsuperscript{64} This demonstration recognizes and provides financial rewards to hospitals that demonstrate high quality performance in a number of areas of acute care. The performance of participating hospitals will be posted at www.cms.hhs.gov for health care professionals. CMS selected Premier it is able to track and report data on quality measures for each of its hospitals.\textsuperscript{65}

Similar quality initiatives are underway for health plans participating in the Medicare program. As discussed above, each participating Medicare


\textsuperscript{62} CENTERS FOR MEDICARE & MEDICAID SERVICES, HOSPITAL QUALITY INITIATIVE OVERVIEW (2005), http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalOverview200512.pdf.


\textsuperscript{64} CENTERS FOR MEDICARE & MEDICAID SERVICES: REWARDING SUPERIOR QUALITY CARE: THE PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION (2005), http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalPremierFactSheet.pdf.

\textsuperscript{65} Id.
health plan organization must have a QAPI program in place. However, at this point in time, CMS is engaged in launching the Medicare Advantage program, which has diverted attention from quality initiatives. Also, as noted above, CMS has promulgated a rule instructing hospitals to develop and implement quality improvement programs to identify patient safety issues and reduce medical errors in hospitals.

Medicare also launched the National Health Information Infrastructure, a comprehensive knowledge-based network to enhance clinical decision making by providing health information when and where it is needed, with the ambitious goal of improving the efficiency, effectiveness and overall quality of health care in the United States. The Food and Drug Administration (FDA), also part of HHS, promulgated a rule to reduce medication errors by requiring bar coding of drugs used in hospitals and by instituting safety reporting requirements for drugs and biologics.

C. THE MEDICARE BENEFICIARY APPEALS SYSTEM

The Medicare program operates a national administrative appeals system to adjudicate disputes between Medicare beneficiaries and the program. As most beneficiary disputes involve coverage of Medicare benefits, all appeals processes have an independent medical review component that marshals medical expertise on disputed medical issues. These procedures could be adapted for use in resolving disputes over medical injury.

1. Appeal Proceedings before Medicare Contractors

There are separate systems in place for the preliminary management of appeals for each part of the Medicare program. Since 2000, the beneficiary appeals systems for Parts A and B, so-called "fee-for-service" Medicare, and Part C, Medicare’s longstanding HMO program (now called Medicare Advantage) all have grievance systems with independent medical review.

67. 42 C.F.R. § 482.21 (2005)
Part D, the new Medicare prescription drug benefit, also has a grievance system that is integrated into Part C’s system if the beneficiary’s appeal involves a Medicare Advantage plan’s action. For all parts, there is a common administrative appeals system within CMS and judicial review in federal district court.

In recent years, Congress and CMS have reformed the Medicare appeals process in important respects and in response to widespread criticism of the prior procedures. Several of the reforms facilitate the potential use of the Medicare appeals process in the adjudication of malpractice claims. First, the reformed process for fee-for-service Medicare has incorporated independent medical review at the state level and independent review for Medicare Advantage and Prescription Drug Plans on a national or regional level. Second, Congress has statutorily insulated the administrative review of all appeals from CMS policy makers who have historically sought to influence appeal outcomes in favor of saving funds. The only barrier is problems with the implementation of these reforms given the financial and resource constraints on CMS.

a. Fee-For-Service Medicare

Congress established the current appeals process for Part A and Part B beneficiary appeals in 2000. The appeal is based on a denied claim for coverage and/or payment submitted to a Medicare contractor—fiscal intermediaries in the case of Part A and carriers in the case of Part B. With respect to a claim, the contractor makes an initial determination on coverage and/or payment. If the beneficiary is dissatisfied with the initial determination, the beneficiary can seek a redetermination by the Medicare contractor.

Independent review is available for reconsideration of the contractor’s determination before a qualified independent contractor (QIC), independent organizations comprised of panels of physicians and other health care professionals. Professional panels for medical review must have the

73. See supra note 71 and accompanying text.
requisite expertise to judge the clinical experience and the medical, technical and scientific evidence associated with the appeal. The QIC’s written reconsideration decision must include a detailed explanation of the decision, a discussion of the pertinent facts and regulations, and, where the issue is reasonable and necessary services, an explanation of the scientific rationale. QIOs are also required to maintain a database on their decisions that will essentially permit analysis of the medical issues in the cases.

This process before Medicare contractors is important. Before there is even administrative review before an ALJ, the Medicare appeals system provides for independent medical review of any medical issues involved in an appeal. This infrastructure is invaluable for Medicare-led malpractice reform because it provides an informal medical review of medical issues before the initiation of more legalistic proceedings.

b. Medicare Advantage and Prescription Drug Plans

The appeals system for the Medicare Advantage program is the same as the Medicare+Choice program with some additions. All Medicare Advantage plans must have “meaningful grievance procedures” to adjudicate beneficiary complaints with the health plan. Because “claims” per se are not submitted in prepaid health plans, the precipitating event for an appeal can be any adverse action against a Medicare beneficiary—although most appeals involve denials of treatment on coverage grounds. The plan must also afford beneficiaries a hearing in its grievance process.

External review for reconsiderations of the plan’s final determination is available before an independent entity. These entities are required to have medical expertise available for their reviews involving medical issues.

The appeals process for the prescription drug benefit is the same as for Medicare Advantage plans because they administer the Medicare

78. Id. § 1935ff(c)(3)(E); 42 C.F.R. § 405.982 (2005).
80. Id. §§ 1395w-22(f), 1395w-22(g); 42 C.F.R. § 422.560 (2005).
prescription drug benefit for enrolled Medicare enrollees.\textsuperscript{85} Prescription drug plans must have a similar appeals process with comparable steps, timetables and other characteristics for their fee-for-service Medicare beneficiaries.\textsuperscript{86} To initiate an appeal, the beneficiary must request a coverage determination from the plan.\textsuperscript{87} As with fee-for-service Medicare, the Medicare Advantage program provides for independent medical review of medical issues in an informal process before more formal administrative review proceedings.

2. Administrative Review for all Medicare Beneficiary Appeals

All beneficiaries, regardless of the part of Medicare in which their appeal is generated, are entitled to administrative review before a corps of administrative law judges (ALJs) within CMS.\textsuperscript{88} In fee-for-service Medicare, the QIC becomes a party in the ALJ hearing and prepares information that is required for the appeal including, as necessary, an explanation of the issues and the relevant policies.\textsuperscript{89} The beneficiary may appeal an ALJ decision to the HHS Departmental Appeals Board (DAB).\textsuperscript{90} In the MMA, Congress redesigned the Medicare administrative appeals system, moving it from the Social Security Administration (SSA) to an independent office within HHS.\textsuperscript{91} MMA also specified with unusual detail what the transfer plan should address.\textsuperscript{92} The most important reform of the MMA is the required independence of ALJs from CMS and its contractors by locating Medicare ALJs in an office “organizationally and functionally separate” from CMS.\textsuperscript{93} The ALJ office reports to the Secretary but “shall


\textsuperscript{89} \textit{Id.} § 1395ff (b)(1)(a); 42 C.F.R. § 405 (2005).

\textsuperscript{90} 42 U.S.C. §§ 1395ff(b)(1)(a), 1395w-22(g)(5) (2000).


\textsuperscript{93} \textit{Id.}
not report to, or be subject to supervision by" any other officer within HHS. The Secretary must also provide for an appropriate geographic distribution of ALJs performing ALJ functions throughout the U.S. to ensure timely access for beneficiaries.

3. Judicial Review of Medicare Administrative Adjudications

Judicial review in federal district court is available for all claims under all parts of the Medicare program. The standards for judicial review are those for the Social Security program appeals under Title II of the Social Security Act. As to facts, the standard of review is whether the agency decision is supported by substantial evidence. The court can order the agency to take new evidence if there is good cause for its prior exclusion under limited conditions. In addition, there are limits on the court's review of national coverage determinations that might be relevant in a malpractice case. Specifically, the courts can invalidate CMS' coverage determinations, but must remand to the agency for revision rather than establishing a binding alternative as judicial precedent.

D. MEDICARE'S BENEFICIARY OMBUDSMAN PROGRAM

The MMA established within HHS a Medicare Beneficiary Ombudsman to assist Medicare beneficiaries with complaints, grievances and requests for information with respect to any aspect of the Medicare program including appeals from adverse determinations by Medicare contractors. The ombudsman does not serve as an advocate for any increases in payments or new coverage of services but may identify issues and problems in payment or coverage policies. Presumably, under a Medicare malpractice adjudication system, the ombudsman could play a key role in assisting beneficiaries in sorting out a claim for medical injury.

94. Id.
96. 42 U.S.C. §§ 1395ff(b)(1), 1395w-22(g)(5) (2000). See also id. § 405(g) (availability of judicial review under the Social Security Act referenced in § 1395ff(b)(1) and § 1395w-22(g)(5)).
98. Id.
99. Id. § 1395ff(b).
101. Id.
and putting beneficiaries in touch with the relevant personnel in a provider organization, health plan, and/or Medicare contractor that could assist with the resolution of the malpractice claim.

E. MEDICARE DEMONSTRATION AUTHORITY

Medicare frequently tests innovations through pilot programs and demonstration projects. Thus, HHS could, and probably should, launch Medicare-led malpractice reform initially in a demonstration before adopting it permanently. Specifically, CMS has general authority for demonstrations and studies regarding improvements in Medicare payment methodologies and other matters related to the operation of the Medicare program.\textsuperscript{102} CMS is currently using this authority, for example, to launch a demonstration of reinsurance payment for prescription drug plans and Medicare Advantage organizations participating in the prescription drug benefit.\textsuperscript{103} CMS also has specific authority under Section 646 of the MMA to offer “incentives to improve safety of care provided to beneficiaries” on a demonstration basis.\textsuperscript{104}

IV. A VISION OF A MEDICARE MALPRACTICE ADJUDICATION AND COMPENSATION SYSTEM FOR MEDICARE BENEFICIARIES

The overriding concept of Medicare–led malpractice reform is to incorporate the resolution of medical injury claims into the infrastructure that addresses concerns about the quality and safety of medical services rendered to Medicare beneficiaries. Medical injuries already are included among the problems in patient care that the Medicare quality and safety infrastructure addresses.

This section outlines the specific steps that would be needed to include the resolution of medical injury claims into the quality and safety infrastructure of institutional health care providers and health plans.\textsuperscript{105} Some components are substantive, including provider and beneficiary participation, triggering events, and safety and compensation outcomes.

\textsuperscript{102} 42 U.S.C. § 1395ll (2000).
\textsuperscript{103} CMS, Medicare Program; Part D Reinsurance Payment Demonstration, 70 Fed. Reg. 9360 (Feb. 25, 2005).
\textsuperscript{105} The material in this section has also been presented in Sage and Kinney, supra note 2.
Other components are procedural, involving presenting evidence, adjudicating liability and damages, and the effect of decisions.

It should be emphasized that what is proposed here is in line with other progressive thinking on malpractice reform today. Specifically, progressive thinking on reform includes linking the identification of medical injury through institutional quality assurance and patient safety promotion infrastructure with an associated early offer program to compensate injuries before litigation. 106 For example, perceiving that the current medical liability system thwarted its efforts to implement effective systems in health care organizations to improve patient safety, JCAHO has recommended fundamental reforms of the medical system. The proposed reform has three major strategies: (1) creation of alternative mechanisms for compensating injured patients such as through early settlement offers, (2) resolving disputes through a so-called “no-fault” administrative system or through health courts, and (3) shifting liability from individuals to organizations. 107

A. Substantive Components

The substantive components of a reform first must address how providers and beneficiaries would participate in the system and whether their participation would be mandatory or voluntary. If participation is mandatory, as discussed below, there are some important constitutional hurdles. If the program is voluntary, the design must be enticing to both beneficiaries and providers so that they will trust the system and participate in it throughout the resolution of the claim. In addition, there are lesser substantive issues such as the definition of triggering events for compensation, scheduling of damages and promoting patient safety. Any system must be seen as an attractive alternative to the common law tort system for both providers and, more importantly, beneficiaries. Even if it were possible to mandate participation, cooperation would be limited and


political pressure would mount for termination of the reform. Undeniably, the strong and imaginative trial bar in this country would challenge a mandatory regime that cut off access to the courts and tort system for medically injured individuals. Thus, we have conceptualized participation of providers as a voluntary incentive system in which providers would only be able to participate if they had achieved certain achievements with respect to quality and safety. For beneficiaries, we have sought to emphasize speed, ease and fairness of the resolution of the adjudication and compensation process as enticements to participate.

1. Criteria for Including Institutional and Professional Providers

Currently, all health care providers do not have equal capacity to deliver high-quality care. Single-threshold forms of professional qualification with pro forma renewal such as state licensing and specialty board certification of physicians, and multiple-year reviews with nearly universal passage such as JCAHO accreditation of hospitals convey a perception of uniformity. However, with greater availability of data on provider performance on quality measures, major differences among institutional providers and health plans have become evident. Further, such reporting is becoming standard practice. Reporting is already a

108. See Eric Nordman et al., Medical Malpractice Insurance Report: A Study of Market Conditions and Potential Solutions to the Recent Crisis 47 (2004), http://www.naic.org/models_papers/papers/MMP-OP-04-EL.pdf (draft report presented to the NAIC's Property and Casualty Committee on July 14, 2004 arguing that "[s]ince the costs of researching and arguing a medical malpractice case can be very large, awards available once caps are introduced may not, in some cases, cover even the costs associated with pursuing a claim."). See also Rachel Zimmerman, As Malpractice Caps Spread, Lawyers Turn Away Some Cases, WALL ST. J., Oct. 8, 2004, at A1.

109. See supra notes 60-68 and accompanying text.

110. See supra notes 69-74 and accompanying text.


requirement for hospital accreditation by JCAHO\textsuperscript{114} and health plan accreditation by the National Committee on Quality Assurance (NCQA).\textsuperscript{115}

Further, institutional providers and health plans are fast acquiring the requisite infrastructure to implement Medicare-led malpractice reform. CMS now requires hospitals to have Quality Assessment and Performance Improvement (QAPI) programs as a condition of participation in Medicare,\textsuperscript{116} and is promoting similar infrastructure to advance the quality and patient safety in Medicare Advantage plans.\textsuperscript{117} This quality assurance and safety promotion infrastructure required by the Medicare program for hospitals and health plans\textsuperscript{118} is described above.

In addition, JCAHO has refocused its accreditation standards on patient safety. Since 1996, JCAHO has operated a national voluntary adverse event reporting database,\textsuperscript{119} and has used this database to develop and incorporate into its accreditation process a series of concrete goals, specifically National Patient Safety Goals and Requirements.\textsuperscript{120} JCAHO accreditation standards advise health care organizations to disclose unexpected outcomes and adverse events to their patients through the responsible physician.\textsuperscript{121}

Certainly, criteria and standards must be developed and established to determine the eligibility of providers and also health plans to participate in Medicare-led malpractice reform. These criteria should address: (1) the adequacy of the institution’s quality assurance and patient safety promotion infrastructure to identify and respond to medical injuries; (2) the adequacy of medical liability insurance arrangements in terms of inclusion of relevant providers; and (3) the adequacy of past performance on quality and patient safety indicators. Eligibility criteria would favor integrated delivery systems, which are likely to include all of the relevant professionals under


\textsuperscript{115} NCQA, What is NCQA Accreditation?, \url{http://hprc.ncqa.org/aboutaccred.asp} (last visited Feb. 7, 2006).


\textsuperscript{117} See supra notes 42-44 and accompanying text.

\textsuperscript{118} See supra note 30 and accompanying text.

\textsuperscript{119} See supra note 107, at 5.


\textsuperscript{121} See infra note 141 and accompanying text.
their liability insurance and have well developed infrastructure for promoting and measuring quality of care and patient safety.

The criteria regarding participating physicians and other health professionals are important. For example, participation might be limited to hospitals that provide malpractice coverage for a set percentage such as fifty percent of their medical staffs. Participating providers should also follow identified clinical and informational "best practices" for safety and quality measured by such national data systems as HEDIS\textsuperscript{122} and CAHPS/consumer information,\textsuperscript{123} and other measures developed by organizations such as the National Quality Forum,\textsuperscript{124} National Patient Safety Foundation,\textsuperscript{125} and the Leapfrog group.\textsuperscript{126}

The real challenge is how to bring physicians into a Medicare-led malpractice reform. And historically, physicians have obtained liability insurance independently of the hospitals in which they practice.\textsuperscript{127} Indeed, responding to earlier crises in the affordability and availability of medical liability insurance, physicians even formed their own mutual insurance companies.\textsuperscript{128} In the current crisis, by contrast, physicians have sought assistance with liability coverage from hospitals that have greater capital and financial resources.\textsuperscript{129} There is no reason why these types of arrangements could not be used for Medicare-led malpractice reform.

Clearly, the circumstances must be carefully defined under which enterprises eligible for Medicare-led malpractice reform may bring independent physicians under their liability umbrella. In general terms, physicians would have to agree to participate fully in the quality assurance and patient safety promotion programs of the hospital or health plan. Specifically, physicians would have to agree to report, disclose and

\begin{footnotesize}
\begin{enumerate}
\item NCQA, The Health Plan Employer Data and Information Set (HEDIS), http://www.ncqa.org/Programs/HEDIS/ (last visited Feb. 6, 2006).
\item The Leapfrog Group, http://www.leapfroggroup.org (last visited Feb. 6, 2006).
\end{enumerate}
\end{footnotesize}
remediate specific medical errors to improve collective performance at the institutional level. A useful analogy is "clinical integration" in antitrust law, a concept newly endorsed by the federal antitrust enforcement agencies as indicating that otherwise independent providers are not merely engaged in financial collusion but are working to offer a better quality product to patients.130 Participating physicians caring for Medicare patients at participating hospitals also would be covered by a Medicare reform demonstration's malpractice rules with respect to outpatient services associated with the same episode of care.

An important question is how to make a reformed liability system sufficiently and immediately attractive to providers to encourage their voluntary participation. One important incentive would be a subsidy for medical liability insurance that would stabilize the cost of medical liability insurance for participating institutional and professional providers. Such a subsidy would be attractive because financial strains from rising liability premiums differ between physicians and hospitals. Specifically, physicians, at least in the most exposed specialties, struggle to maintain affordable primary coverage.131 On the other hand, hospitals can self-insure routine litigation costs but must purchase excess layers of insurance that protect against the occasional case that generates a $10 million or $20 million damage award.132 The cost of these layers is very volatile and may not be priced competitively.133

A federal subsidy in the form of direct federal reinsurance of hospital liability with appropriate corridors of shared risk for participating physicians (virtually impossible for individual physicians134) would be an excellent incentive to encourage participation. Federal reinsurance is already used in a variety of other contexts,135 and has done much to

131. See Alec Shelby Bayer, Looking Beyond the Easy Fix and Delving Into the Roots of the Real Medical Malpractice Crisis, 5 HOUS. J. HEALTH L. & POL'Y 111, 118 (2005).
133. Id.
stabilize the cost of liability insurance for participating insureds.\textsuperscript{136} Such reinsurance would be valuable in connection with Medicare-led malpractice reform because the reform will tend to surface more injuries eligible for compensation than the current tort system in addition to compensating those injuries more predictably.

2. Methods for Assuring Beneficiary Participation

Ideally, the Medicare demonstration would provide an exclusive administrative remedy for Medicare beneficiaries injured by medical care from participating providers and conventional state law tort claims would be preempted. However, for constitutional and practical reasons, making the reform truly mandatory for beneficiaries may be problematic. Specifically, there are constitutional questions about Congress’ authority to cut off rights to a common law tort case before a jury.\textsuperscript{137} Even if the Supreme Court were to uphold such a regime, there is enough doubt in current law\textsuperscript{138} that dissatisfied beneficiaries could challenge the reform judicially and severely limit full implementation of the reform. Consequently, it is best to consider from the outset that the reform is ultimately voluntary for beneficiaries. However, its design would be such that beneficiaries would recognize the advantages of participation in terms of its efficiency and fairness of adjudication and compensation.

The question of “voluntariness” is particularly difficult to factor into a Medicare demonstration that tests the concept of Medicare-led malpractice reform. The evaluation component of any demonstration is crucial and selection bias is a major threat to a good evaluation. Specifically, if decisions to participate are non-random and claims channeled into administrative resolution are representative of neither events nor disputants,\textsuperscript{139} the evaluation is compromised.


\textsuperscript{137} See infra notes 194-67 and accompanying text.

\textsuperscript{138} See infra notes 194-67 and accompanying text.

\textsuperscript{139} See THE SAGE ENCYCLOPEDIA OF SOCIAL SCIENCE RESEARCH METHODS (Michael S. Lewis-Beck, Alan E. Bryman & Tim Futing Liao eds., 2003).
There are several ways to structure voluntary participation in a demonstration of a Medicare-led malpractice reform. Specifically, Medicare beneficiaries living in the geographic area served by participating hospitals could be given notice of the demonstration rules and could make a one-time election to proceed with any claims that arise through the Medicare appeals system instead of the common law tort system with subsequent opportunities to opt out for medical care not yet received. Or hospitals and physicians participating in the demonstration could notify existing patients that they will be asked to consent to adjudication of claims through the Medicare appeals system, and new patients could be asked to consent upon the initiation of care. Patients incapable of election or consent such as those receiving emergency services would retain their existing legal rights but might be offered an opportunity to enter the reformed system for follow-up care. Similarly, the system might allow patients to retain the ability to litigate in exceptional circumstances such as willful misconduct.

Obtaining beneficiary participation should not be problematic as there is much about Medicare-led malpractice reform to entice elderly and disabled Medicare beneficiaries to participate. Further, existing data already suggests that Medicare patients file fewer tort claims than younger patients relative to the injuries they suffer, receive less in damages both in average terms and in likelihood of a very large payout, and experience similar delays in payment. Non-monetary benefits such as timely, honest disclosure of error and injury and a less adversarial process that permits therapeutic relationships with familiar physicians and hospitals to continue are also likely to be valued greatly by seniors and their families.

3. Medical Injury Event Detection and Disclosure

In a Medicare malpractice system, unlike the conventional tort system, patients would not be solely responsible for determining that they had a claim for medical injury. Rather, under Medicare-led reform participating providers would actively root out medical errors and facilitate compensation rather than assuming the reactive posture of conventional tort litigation. As discussed above, participating hospitals and health plans would have in place some constellation of adverse event detection systems as a condition of participating in the reformed system. These patient safety monitoring systems would be modified to connect those processes to the

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140. See supra note 9 and accompanying text.
141. See supra note 119 and accompanying text.
currently independent process for identifying medical injury, assessing
damages and compensating patients. Similarly, reporting systems for
medical errors such as those contemplated by recent federal legislation
modeled on the Aviation Safety Reporting System\textsuperscript{142} should be configured
to capture categories of events potentially eligible for compensation.

Reform would also aim to improve how patients and families learn
about medical errors. Participating providers would be required to notify
beneficiaries quickly and fully in the event of serious error or injury.
Although JCAHO merely urges but does not require notification of patients
regarding medical errors,\textsuperscript{143} the American Medical Association has stated
that disclosure is ethically required of physicians and a handful of states
mandate it for hospitals.\textsuperscript{144} Pennsylvania’s statute, which requires written
disclosure within seven days, is a good model.\textsuperscript{145} With disclosure
mandatory, participating hospitals and physicians would have a strong
interest in productive conversations that air concerns, relate information
valuable for patient safety, and reach settlements in as many cases as
possible.

Information derived from these activities would also feed into other
Medicare programs. Unlike tort litigation, both dispute-related data and
underlying clinical information would be available to quality regulators. If
data on medical malpractice claims collected in a closed Medicare system
were joined with data on Medicare beneficiaries collected in these other
programs, much could be learned about the epidemiology of medical
injuries.

4. Determining Liability and Designation of Compensable
Events

Eligibility for and amount of payment are the key questions for any
administration compensation system. It is generally accepted that the
negligence-based standard of care used in tort litigation functions poorly.
Conceptually, a finding of professional negligence denotes a departure

\textsuperscript{142} See Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-44,
\textsuperscript{143} JCAHO, supra note 107.
\textsuperscript{144} Editorial, Medical Error and Ethics: A Call for Candor without Fear, 46 AM.
MED. NEWS 14 (July 21, 2005).
\textsuperscript{145} Medical Care Availability and Reduction of Error (MCare) Act, 40 PA. CONS.
STAT. § 1303.308 (2002).
from customary and reasonable practice. Because physicians often practice medicine unscientifically, relying on habit rather than clinical evidence, this standard excuses substantial suboptimal care. At the same time, an accusation of negligence constitutes a personal affront and reputational threat that many physicians fiercely resist because it connotes egregious conduct that violates the norms of their professional community. Also, proof of negligence in traditional tort cases is offered through expensive expert testimony that adds cost and delay to claim resolution.

For these reasons, most advocates of administrative compensation favor a standard of “avoidability” or “preventability” judged by scientific experts. Under designated events schemes, certain events are automatically compensable on the theory that their occurrence is almost always avoidable. These “accelerated compensation events,” first developed by Bovbjerg and Tancredi, initially would be identified and updated by an expert process upon which a Medicare administrative review system would rely. More recently, a forum of stakeholders has established a consensus list of events that should “never” happen in the provision of care.

Medicare-led malpractice reform would use designated events schemes to determine liability without further consideration of fault. Early

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149. Id.


152. NATIONAL QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE: A NATIONAL QUALITY FORUM CONSENSUS REPORT (2002).
disclosure and settlement could be rewarded in a way that is similar to the incentives that O'Connell and colleagues have proposed to identify claims early and encourage payers to make early offers and injured patients to accept those offers. Upon the occurrence of a designated event, the provider would notify the patient of the event, report the event to the appropriate quality oversight bodies within Medicare and elsewhere, and offer compensation without contesting eligibility. There would be strict timetables for mediation and adjudication that would ensure prompt resolution. Where avoidability of the medical injury is contested, beneficiaries and providers could appeal to the relevant Medicare contractor for an initial determination and subsequently seek administrative review in the Medicare appeals system described above.

This approach to determining liability would have one major advantage over the current tort system. Information about the incidence of serious injuries would be captured immediately and used for quality improvement purposes and also for epidemiological research on the incidence and characteristics of medical injury. As a result, providers and researchers would force the health care system to deal appropriately with both avoidable and unavoidable but serious injuries—a phenomenon that does not now occur in the adjudication of malpractice claims in tort.

5. Determining Damages and Calculating Compensation Awards

A Medicare-led malpractice reform would use a uniform and predictable method of determining damages and presumably would use prospectively established schedules. With respect to non-economic damages, reformers have long suggested scheduling damages as a means of bringing rationality and consistency to injury compensation in medical malpractice. Medical injuries invoke the same issues as other statutory compensation schemes—the nature, severity and permanency of the injury.


154. See supra notes 70-79 and accompanying text.

Most public compensation programs administered by agencies award benefits pursuant to schedules that have already predetermined how much should be awarded for specific types and degrees of injury or illness.\textsuperscript{156} When an acknowledged preventable event has occurred but the parties cannot agree on an appropriate payment, beneficiaries or providers could appeal to the relevant Medicare contractor and on to Medicare's administrative review process described above.\textsuperscript{157}

The specifics of the elements of damages and their method of calculation are open to debate. Damages would likely include all provable economic damages such as lost wages (typically low for Medicare beneficiaries) and future medical expenses. Periodic payment of future medical expenses would be allowed. Compensation would also include lump-sum non-economic damages. The maximum amount of non-economic damages for the most severely and persistently injured could not exceed a preset figure. Also, any schedule would have to address the difficult issues of causation that often attend the evaluation of medical injuries in the elderly and disabled with their multiple medical conditions. Of note, the Medicare program could deal directly with medical costs by expanding benefits to injured patients and waiving subrogation rights against liable providers.

A final consideration is the threshold degree of injury that merits payment. An administrative compensation system could be swamped by small dollar claims. For this reason, proposals for “no-fault” compensation in medical malpractice typically include an injury threshold below which compensation is unavailable regardless of injury causation.\textsuperscript{158} Moreover, because a Medicare-led malpractice system is proactive rather than reactive with respect to event detection, it will capture a much larger number of small claims than occurs in tort and can convey that information to institutional and regulatory quality improvement efforts.

**B. PROCEDURAL FEATURES**

Medicare has two principal procedural advantages over generic "medical courts" for resolving malpractice claims. First, Medicare can be proactive with respect to error and injury reporting rather than simply reacting to filed claims. Second, Medicare already has in place a tested system for adjudicating beneficiary disputes with the Medicare program.


\textsuperscript{157} See \textit{supra} notes 70-79 and accompanying text.

\textsuperscript{158} Sage, Hastings & Brennan, \textit{supra} note 148.
onto which a malpractice adjudication system can be grafted. Still, critical procedural elements remain to be determined. These include (1) how a claim for medical malpractice as opposed to a claim for coverage or payment would be presented, (2) what parts of the current Medicare appeals system would be involved with adjudicating malpractice claims, and (3) how evaluating claims with respect to malpractice liability and damages would differ from evaluating benefits claims.

1. Initiation of Complaints through Grievance Resolution Process

As discussed above, in most cases Medicare beneficiaries or their families would receive information about unanticipated outcomes of medical care from participating providers. Or beneficiaries and/or family members could raise concerns with the provider or health plan directly. Ideally there should be an identifiable office within the institutional provider or plan, already required for Medicare Advantage plans, at which beneficiaries can lodge their grievances including perceptions of medical injury. In any event, discussions would ensue with or without formal mediation in hopes of reaching a consensual settlement. Specifically, the management of the provider or health plan would endeavor to resolve the matter through the following steps: (1) disclosure of the medical injury to the patient, (2) an apology, (3) an offer of compensation, and (4) amelioration of the injury. Each of these steps would be informed by published guidance that would be accessible to beneficiaries and their families as well as to physicians and other providers. If a beneficiary were dissatisfied with the determination of the provider or health plan, the beneficiary could appeal the decision to the Medicare carrier (for fee-for-service Medicare) or medical review contractor (for Medicare Advantage plans) designated to handle such events. These contractors are well positioned to handle medical injury claims as they already handle Medicare coverage disputes involving medical issues. If the beneficiary were not satisfied with the determination of the Medicare

159. See supra note 119 and accompanying text.
160. See supra notes 80-82 and accompanying text.
161. See supra notes 73-79 and accompanying text.
162. See supra notes 80-87 and accompanying text.
contractor, the beneficiary could appeal to the Medicare administrative appeals system and ultimately obtain limited judicial review through the Medicare appeals system described above.\textsuperscript{164}

To ensure expeditious resolution of medical injuries cases, participating providers might be required to offer patients mediation within sixty days of disclosure of a serious event with the goal of promoting voluntary settlement in the majority of cases. A non-adversarial process that convenes the parties as soon after the episode of care as possible enables the parties to resolve situations through explanation, apology, system improvement, or monetary compensation is useful for both technical lapses and failures of communication, with one often serving as a marker for another.\textsuperscript{165} Experience discussing both grievances and injuries with patients and families might lead providers and health plans to utilize similar mediation skills and mechanisms for both categories of dispute. Medicare is already introducing mediation at the QIC level for beneficiary complaints as an alternative to medical record review.\textsuperscript{166}

Finally, the decision of the ALJ should be \textit{de novo} as is the current practice for ALJs in Medicare appeals.\textsuperscript{167} Upon judicial review, the standard for review should be based on established administrative law rather than on civil procedure. Specifically, reversal is ordered only for an unreasonable interpretation of law for legal questions,\textsuperscript{168} or lack of substantial evidence for factual questions.\textsuperscript{169} Otherwise, incentives will exist for parties to look to courts inappropriately for ultimate relief and shortchange the administrative process.

2. Presentation of Expert Opinion Evidence

Medicare-led malpractice reform offers an opportunity to improve the quality of expert medical opinion brought to bear in resolving medical injury claims. In the current tort system, civil procedure relies on expert witnesses selected and paid by the litigants to present factual evidence to a lay jury. This convention has been criticized as both unreliable and

\textsuperscript{164} See \textit{supra} notes 88-99 and accompanying text.

\textsuperscript{165} See Gerald B. Hickson et al., \textit{Patient Complaints and Malpractice Risk}, 287 JAMA 2951 (2002).


\textsuperscript{169} Id.
expensive, and often requires the judge to exert greater control over expert testimony than he or she is comfortable with. Yet malpractice litigation commonly presents difficult issues regarding the standard of care, causation of injury, and extent of damages, all of which involve medical proof.

The proposed Medicare-led malpractice reform would move away from the adversarial methods of obtaining medical opinions in the adjudication of medical injury cases. For disputed medical issues that proceed to the Medicare contractor for resolution, the relevant Medicare contractor would have access to the QICs for medical review of disputed issues. Parties would be able to submit their versions of the medical facts informally as well as letters from outside experts (if desired) as part of the QIC medical review.

On appeal, the ALJ follows an inquisitorial style of legal proceeding in which the judge assumes the dominant role in developing the evidence and does not rely on the parties. The use of an inquisitorial model rather than an adversarial model for the ALJ proceeding should not be problematic; research in social psychology suggests that the adversarial model was not always perceived as the most just and fair model in a health care context. Specifically, Poythress and colleagues compared the conventional adversarial model in which the parties developed medical expert testimony with two hybrid models in which the judge took greater control over the development of expert testimony. In one hybrid model, the judge selected the expert, and in the other the judge arranged for an empirical survey of physicians in the relevant field and geographic area to determine breach of the standard of care. Both hybrid models were perceived to be more just and fair than the purely adversarial model in which the disputants arranged for their own expert testimony. Quasi-inquisitorial procedures of this sort differ from the common law tradition by emphasizing truth finding.

171. See supra notes 76-79 and accompanying text.
174. Id.
over political rights of litigants yet comport with traditional principles of equity courts.\textsuperscript{175}

Medicare-led malpractice reform, by making medical review available through QICs and administrative review in the Medicare appeals system, provides an excellent opportunity to marshal required medical expertise in a fair and expeditious manner. As described above,\textsuperscript{176} regulations listing designated compensatory events would conclusively establish liability for certain avoidable injuries. In less clear cases of medical injury, medical practice guidelines could be used to establish a standard of avoidability. At their best, medical practice guidelines are a "standardized specification for care developed by a formal process that incorporates the best scientific evidence of effectiveness with expert opinion"\textsuperscript{177} and constitute the theoretical foundation of evidence-based medicine.\textsuperscript{178} Indeed, CMS could encourage the development of medical practice guidelines and decision trees that would guide medical reviewers at QICs and Medicare ALJs in making liability determinations. Social Security Administration ALJs,\textsuperscript{179} who until recently handled Medicare appeals, currently use detailed medical-vocational guidelines for determinations of life expectancy, degree of injury, and forgone earnings.\textsuperscript{180} These are similar to the tools and tasks needed to resolve malpractice cases.

3. Requirements for and Effects of Decisions

As discussed above,\textsuperscript{181} creating an information-rich environment for patient safety, quality improvement and fairness of compensation is one of the major reasons for pursuing malpractice reform through Medicare. Unlike the common law of tort, participating providers in a Medicare-led malpractice reform would be obligated to disclose medical errors to patients or their families in order to foster systematic improvement as well as to vindicate individual rights. Similarly, the public interest in safe medical care and reasonably equal treatment of Medicare beneficiaries

\begin{itemize}
  \item 175. Kessler, \textit{supra} note 172.
  \item 176. See \textit{supra} notes 144-54 and accompanying text.
  \item 179. See \textit{supra} notes 91-95 and accompanying text.
  \item 181. See \textit{supra} notes 60-69 and accompanying text.
\end{itemize}
suggests that resolution of malpractice claims and the rational for resolutions, although not necessarily the identity of patients or providers, should be publicly available. Data on resolutions should include the initial decisions of the participating providers or plans, determinations by relevant Medicare contractors including decisions by any QICs that rendered medical reviews at the behest of Medicare contractors, and also decisions of the ALJ, the HHS Departmental Review Board, and the reviewing court.

Whether ALJ determinations should constitute precedent in subsequent cases presenting similar facts is an open question. Because clinical circumstances vary widely in cases of medical injury, and situations requiring administrative resolution often will not involve ACEs or treatment subject to guidelines, past decisions offer valuable guidance to hearing officers. Furthermore, all prior decisions will be readily available, as will information about settlements, thereby reducing the risk that precedents will be invoked selectively.

However, it seems prudent, at least for any demonstrations of malpractice reform, to use prior decisions to improve the regulatory infrastructure of Medicare’s malpractice system such as the identification of designated compensation events, scheduling of damages and referral of clinical questions for guideline development, rather than to constrain individual ALJs during periods in which experimentation and innovation are desirable. For example, HHS should review ALJ determinations annually to inform its best-practice reporting. A separate mechanism should be in place to monitor Medicare ALJ performance, which has been suggested by administrative law experts observing ALJs generally. Records of settlements and hearing outcomes may also be useful in any federal clearinghouse of patient safety information that is developed.

V. LEGAL AUTHORITY

The constitutional issue presented by a Medicare malpractice proposal is whether Congress can delegate authority to a federal administrative agency charged with implementing a federal health insurance program to

182. See supra notes 88-90 and accompanying text.
adjudicate state common tort claims as part of that federal program. In our constitutional scheme, administrative agencies have always had an uneasy role. In modern administrative law theory, which took shape with President Franklin Roosevelt's New Deal, administrative agencies must have legislative and judicial power as well as executive power to carry out their statutory assignments. In Medicare-driven malpractice reform, Congress would be delegating judicial powers to adjudicate state court claims to a federal administrative agency.

A. THE LEGAL NATURE OF MEDICARE AND STATE COMMON LAW OF TORT

To understand how Medicare-led malpractice reform could be enacted and implemented, it is necessary to examine how the legal regime for the Medicare program fits into the federal constitutional framework. It is also necessary to assess whether the federal administrative scheme complements or replaces the state tort law mechanism under which malpractice claims are currently adjudicated.

1. The Legal Basis of the Medicare Program

In 1966, Congress enacted the Social Security Amendments of 1965 that established the Medicare program and also the Medicaid programs as titles XVIII and XIX of Social Security Act.184 Both programs were established as part of the framework established in the Social Security Act of 1935 to provide public insurance and a welfare program to protect the economic security of Americans.185 The Social Security Act of 1935 also established income maintenance programs through social insurance and welfare for the elderly, disabled and blind. At the time of its enactment, the constitutionality of the Social Security Act of 1935, particularly with respect to its taxation provisions, was hotly debated.186 Of note, in Charles

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186. See Barbara Nachtrieb Armstrong, The Federal Social Security Act and Its Constitutional Aspects, 24 CAL. L. REV. 247 (1936); Charles Denby, Jr., The Case Against the Constitutionality of the Social Security Act, 3 LAW & CONTEMP. PROBS. 315 (1936); James D. Hayes, Some Legal Aspects of the Social Security Act, 13 NOTRE DAME L. REV.
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C. Steward Mach. Co. v. Davis,187 the United States Supreme Court ruled that the Social Security Act of 1935 did not violate the Fifth Amendment of the federal constitution and that the tax imposed to fund the program was constitutional.188

2. The State Common Law Tort System

The state common law tort system originated in the common law of England and was brought to the original thirteen colonies with the English colonists. The western part of the United States and Louisiana, being settled originally by countries with continental civil law, relied on civil law with respect to personal injury and property damage in non-consensual relationships. Nevertheless, the common law of torts dominates tort law in the United States today. The tort that defines medical malpractice is the tort of negligence, which, according to the Restatement (Third) of Torts, occurs when “a person does not exercise reasonable care under all the circumstances.”189

The Restatement continues with factors to consider in determining whether the person's conduct lacks reasonable care: “the foreseeable likelihood that the person's conduct will result in harm, the foreseeable severity of any harm that may ensue, and the burden of precautions to eliminate or reduce the risk of harm.”190 To establish a prima facia case of negligence, the plaintiff must present evidence that the defendant had a duty not to expose the plaintiff to a reasonably foreseeable risk of injury, that the defendant breached that duty as defined by the applicable standard of care, that the breach caused the damage, and that there was actual damage.191

After the American Revolution, most colonies, with much contentious debate, adopted constitutional provisions or enacted statutes to recognize English common law in some fashion as the law of the new state.192

188. Id. at 579.
190. Id.
Western states and Louisiana have comparable laws with respect to their former colonial masters. As the colonies were folded into the United States in 1787, the federal constitution established the states as sovereign powers ceding derivative powers to the federal government.

It is noteworthy that, over the years, states have established administrative systems to adjudicate tort matters when the legislature has concluded that the common law tort has been inadequate in assuring expeditious adjudication of tort claims. Specifically, in the early twentieth century, state legislatures sought to improve the adjudication and compensation of injuries on the job with administrative workers compensation schemes. In many states, there were challenges to these schemes on grounds that they inappropriately replaced common law tort remedies. When automobile accidents and insurance became problematic in the 1950s and 1960s, reformers looked to statutory no-fault compensation plans to adjudicate and compensate auto accident claims.

Of interest, scholars and stakeholders have long promoted administrative systems for malpractice reform at the state level. Many states have established quasi-administrative processes with such regimes as medical review prior to trial and patient compensation funds under the auspices of state agencies. While these reforms have been subject to state constitutional challenges, in more recent years, state courts have tended to uphold these administrative reforms.

193. Id at 148-56.
194. See supra note 130 and accompanying text.
198. See supra Part IB.
B. CONSTITUTIONAL CONSIDERATIONS

In American federalism, Article I of the U.S. Constitution limits federal legislative authority to enumerated powers,\textsuperscript{202} and, reinforced by the Tenth Amendment, reserves residual authority to state government.\textsuperscript{203} The federal constitution does provide for federal spending powers and regulatory powers over interstate commerce.\textsuperscript{204} The Constitution gives Congress the power to regulate interstate commerce stating, "To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."\textsuperscript{205} Also, the federal constitution provides explicitly for the preemption of state law that conflicts with federal law under the Supremacy Clause.\textsuperscript{206}

Specifically, there are two key constitutional issues: (1) would the power delegated to the Medicare program violate the requirements in Article III of the United States Constitution, which vest judicial authority in the Supreme Court and such inferior courts as Congress may establish, and (2) would the delegated power violate the Seventh Amendment’s preservation of the right to trial by jury in suits at common law. The question of delegation arises because the matter to be adjudicated is a conventional state common law tort claim that is generally adjudicated in state courts or, if federal diversity jurisdiction is invoked, by Article III courts applying state tort law.\textsuperscript{207}

1. Adjudication by Article III Judges

The Constitution vests federal judicial power in Article III judges; specifically in "one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish."\textsuperscript{208} The theory of the Article III requirements was to accord federal judges life tenure and other protections that insulate them from political and other employment pressures and thereby allowing them to make decisions without concern for these factors. However, it seems clear that Article III is not a bar to agency

\textsuperscript{202} See generally U.S. CONST. art. I.
\textsuperscript{203} Id. at amend. X.
\textsuperscript{204} Id. art. I, § 8, cl. 1-7.
\textsuperscript{205} Id. at cl. 3.
\textsuperscript{206} Id. at art. VI, cl. 2.
\textsuperscript{207} Erie R. Co. v. Tompkins, 304 U.S. 64, 80 (1938) (establishing that federal courts adjudicating state tort claims pursuant to diversity jurisdiction apply state tort law).
\textsuperscript{208} U.S. CONST. art. III, § 1.
adjudication in general or agency adjudication of matters affecting individuals.

Crowell v. Benson\textsuperscript{209} is the most important decision regarding delegation of the authority to adjudicate state tort causes of action to a federal administrative agency. \textit{Crowell} concerned a benefits program for seamen injured in the course of employment while working on “navigable waters” pursuant to the Longshoremen’s and Harbor Workers’ Compensation Act.\textsuperscript{210} The Court upheld the delegation. However, because so-called “private rights,” e.g., tort liability under common law, were implicated, the Court held that Article III judges must have independent power to decide all issues of law and “jurisdictional fact” upon review of the agency’s decision.\textsuperscript{211} Jurisdictional facts were those on which the agency’s jurisdiction depended—in \textit{Crowell}, whether an employment relationship existed and whether the injury occurred on navigable waters.\textsuperscript{212}

The important aspect of \textit{Crowell v. Benson} for purposes of Medicare-driven malpractice reform is that the Supreme Court sanctioned a federal regulatory scheme to supplant a common law tort schemes under federal maritime law but did not address the question whether Congress could supplant state tort law.\textsuperscript{213} Also, because \textit{Crowell v. Benson} concerned admiralty law, the issue of entitlement to a jury trial under the Seventh Amendment was not adjudicated.\textsuperscript{214}

The Supreme Court revisited delegation of judicial powers of Article III courts to other governmental bodies in \textit{Northern Pipeline Construction Co. v. Marathon Pipeline Co.}\textsuperscript{215} and, more recently, in \textit{Thomas v. Union Carbide Agricultural Products Co.}\textsuperscript{216} and \textit{Commodity Futures Trading Commission v. Schor.}\textsuperscript{217} In \textit{Northern Pipeline}, the Supreme Court invalidated a statute that assigned breach of contract issues in bankruptcy proceedings to bankruptcy judges not appointed pursuant to Article III.\textsuperscript{218} In a plurality opinion, Justice Brennan ruled that contract cases involved “private rights,” which could only be decided by Article III judges.\textsuperscript{219}

\begin{itemize}
\item \textsuperscript{209} Crowell v. Benson, 285 U.S. 22 (1932).
\item \textsuperscript{211} \textit{Crowell}, 285 U.S. at 92-93.
\item \textsuperscript{212} \textit{Id.} at 36-37.
\item \textsuperscript{213} \textit{Id.} at 39.
\item \textsuperscript{214} \textit{Id.} at 45.
\item \textsuperscript{215} \textit{Northern Pipeline Constr. Co. v. Marathon Pipeline Co.}, 458 U.S. 50, 84 (1982).
\item \textsuperscript{218} \textit{Northern Pipeline Constr. Co.}, 458 U.S. at 84.
\item \textsuperscript{219} \textit{Id.} at 70.
\end{itemize}
plurality defined "public rights" as those involving the government and "private rights" as involving liability among private parties. \textsuperscript{220}

Later, in \textit{Thomas v. Union Carbide Agricultural Products Co.},\textsuperscript{221} the Supreme Court upheld a statutory scheme under the Federal Insecticide, Fungicide, and Rodenticide Act to adjudicate compensation amounts for the use of data in determining whether to approve a competitor's similar pesticide.\textsuperscript{222} Specifically, if the competing pesticide manufacturers disputed the compensation amounts, arbitration with limited federal court review was available to adjudicate the dispute.\textsuperscript{223} Petitioners had argued that the adjudicated matters were state law claims adjudicated under state common law.\textsuperscript{224} The Court responded that: "Many matters that involve the application of legal standards to facts and affect private interests are routinely decided by agency action with limited or no review by Article III courts."\textsuperscript{225} The Supreme Court further argued that a manufacturer's right to compensation was not just a "private right" but that the use of data played "an integral part" in "a complex regulatory scheme" to protect public health.\textsuperscript{226}

The \textit{Thomas} court made observations about \textit{Crowell} and \textit{Northern Pipeline} that seem apposite to the issue of Medicare-led malpractice reform. The Court, in distinguishing the statutory scheme at issue in \textit{Thomas} from that in \textit{Crowell}, stated:

Most importantly, the statute in \textit{Crowell} displaced a traditional cause of action and affected a pre-existing relationship based on a common-law contract for hire. Thus it clearly fell within the range of matters reserved to Article III courts under the holding of \textit{Northern Pipeline}. See 458

\textsuperscript{220} \textit{Id.} at 69.
\textsuperscript{221} \textit{Thomas}, 473 U.S. at 594.
\textsuperscript{223} \textit{Thomas}, 473 U.S. at 573.
\textsuperscript{224} \textit{Id.} at 583.
\textsuperscript{226} \textit{Thomas}, 473 U.S. at 592 (internal citations omitted).
U.S., at 70-71, and n. 25 (plurality opinion) (noting that matters subject to a "suit at common law or in equity or admiralty" are at "protected core" of Article III judicial powers); id. at 90 (opinion concurring in judgment) (noting that state law contract actions are "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789"). 227

Further, the Court noted that the relevant statute "limits but does not preclude review of the arbitration proceeding by an Article III court" and thereby determined that, "in the circumstances," the review afforded preserves the "appropriate exercise of the judicial function" required in Crowell v. Benson. The Court stated that the statute "at a minimum allows private parties to secure Article III review of the arbitrator's 'findings and determination' for fraud, misconduct, or misrepresentation under the statute." 228 The Court concluded that the statutory scheme "therefore, does not obstruct whatever judicial review might be required by due process." 229 However, the Court specifically declined to reach the issue of whether due process would require judicial review and what would be the scope of that review. 230

The most recent case is Commodity Futures Trading Commission v. Schor 231 in which the Supreme Court ruled that state contract law counterclaims (by brokers against customers) in reparations proceedings initiated by the federal Commodities Futures Trading Commission (CFTC) 232 could be adjudicated by the CFTC. Schor delineated the degree to which Congress can delegate adjudication of traditionally common law matters to administrative agencies without violating the constitutional guarantees associated with Article III courts. Justice O'Connor, writing for the majority, stated:

Although our precedents in this area do not admit of easy synthesis, they do establish that the resolution of claims such

227. Id. at 557.
228. Id. at 593.
229. Id.
230. Id. at 593-94. The Court stated: "We need not identify the extent to which due process may require review of determinations by the arbitrator because the parties stipulated below to abandon any due process claims. [citations omitted] For purposes of our analysis, it is sufficient to note that FIFRA does provide for limited Article III review, including whatever review is independently required by due process considerations." Id.
as Schor’s cannot turn on conclusory reference to the language of Article III. Rather, the constitutionality of a given congressional delegation of adjudicative functions to a non-Article III body must be assessed by reference to the purposes underlying the requirements of Article III. This inquiry, in turn, is guided by the principle that “practical attention to substance rather than doctrinaire reliance on formal categories should inform application of Article III.”

The Court then laid out the guiding principles for when the Constitution requires adjudication of claims by an Article III court. The major concern is whether the delegation of adjudicative authority “impermissibly threatens the institutional integrity of the Judicial Branch.” In making this determination, the following factors are considered: (1) the extent the “essential attributes of judicial power” are reserved to Article III courts; (2) the extent to which the non-Article III forum exercises a “range of jurisdiction and powers normally vested only in Article III courts”; (3) the “origins and importance of the right to be adjudicated”; and (4) the “concerns that drove Congress to depart from the requirements of Article III.”

The Court also emphasized that the CFTC’s jurisdiction over the common law counterclaims under state law was necessary to the success of the regulatory scheme. Further, the Court was convinced that this “little single deviation from the agency model” was not fatal. Besides the authorization of counterclaim jurisdiction, the statute “left far more of the ‘essential attributes of judicial power’ to Article III courts than did that portion of the Bankruptcy Act found unconstitutional in Northern Pipeline,” which covered “all civil proceedings” arising under or related to

233. Schor, 478 U.S. at 847.
234. Id. at 851.
235. Id. at 834.
236. Id. at 835.
237. Id.
238. Id.
239. Id. at 856 (“It was only to ensure the effectiveness of [the reparations] scheme that Congress authorized the CFTC to assert jurisdiction over common law counterclaims. Indeed . . . absent the CFTC’s exercise of that authority, the purposes of the reparations procedure would have been confounded.”). See Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 2 Yale J. of Health Pol’y, Law & Ethics 587 (2005).
cases under a particular section of the act.\textsuperscript{240} The court concluded that the regime in \textit{Schor} more closely approximated the agency model approved by the Court in \textit{Crowell v. Benson}, which dealt only with a "particularized area of law."\textsuperscript{241}

The Court emphasized that the CFTC's orders, like those of the agency in \textit{Crowell v. Benson}, were only enforceable by order of the federal district court and were reviewed by the same "weight of the evidence" standard sustained in \textit{Crowell}, rather than the more deferential standard found lacking in \textit{Northern Pipeline}.\textsuperscript{242} Further, the CFTC's legal rulings, also like those in \textit{Crowell}, were subject to \textit{de novo} review. Finally, the commission in \textit{Schor}, unlike the bankruptcy courts in \textit{Northern Pipeline}, did not "exercise 'all ordinary powers of district courts,' and thus may not, for instance, preside over jury trials or issue writs of habeas corpus."\textsuperscript{243}

While acknowledging that the counterclaim was "a 'private' right for which state law provides the rule of decision," and thus was at the "core" of matters normally reserved to Article III courts,\textsuperscript{244} the Court approved the delegation to a federal administrative agency stating:

\begin{quote}
[W]e are persuaded that the congressional authorization of limited [the Commission's] jurisdiction over a narrow class of common law claims as an incident to the CFTC's primary, and unchallenged, adjudicative function does not create a substantial threat to the separation of powers . . . .\textsuperscript{245}
\end{quote}

According to the Court, the delegation was justified because Congress "intended to create an inexpensive and expeditious alternative forum through which customers could enforce the provisions of the Commodities Exchange Act against professional brokers."\textsuperscript{246} The Court, in making its point that Congress should have flexibility to craft remedies even though they originally lie in state common law, quoted \textit{Crowell's} conclusion that a contrary holding would "defeat the obvious purpose of the legislation to furnish a prompt, continuous, expert and inexpensive method for dealing with a class of questions of fact which are peculiarly suited to examination

\begin{flushleft}
\begin{itemize}
\item \textsuperscript{240} \textit{Schor}, 478 U.S. at 852.
\item \textsuperscript{241} \textit{Id}.
\item \textsuperscript{242} \textit{Id} at 853.
\item \textsuperscript{243} \textit{Id}.
\item \textsuperscript{244} \textit{Id}.
\item \textsuperscript{245} \textit{Id} at 854.
\item \textsuperscript{246} \textit{Id} at 855.
\end{itemize}
\end{flushleft}
and determination by an administrative agency specially assigned to that task.\textsuperscript{247}

One important factor of the administrative proceedings that the Court emphasized in both the \textit{Schor} and \textit{Thomas} decisions was that they were voluntary. In \textit{Thomas}, the Court mentioned in passing: "Congress has the power, under Article I, to authorize an agency administering a complex regulatory scheme to allocate costs and benefits among voluntary participants in the program without providing an Article III adjudication."\textsuperscript{248} Later in the opinion, the Court observed: "The danger of Congress or the Executive encroaching on the Article III judicial powers is at a minimum when no unwilling defendant is subjected to judicial enforcement power as a result of the agency 'adjudication.'"\textsuperscript{249} However, \textit{Schor}, even more than \textit{Thomas}, emphasized and indeed turned on the fact of consent to the non-Article III tribunal. As the Court emphasized:

Schor indisputably waived any right he may have possessed to the full trial of Conti's counterclaim before an Article III court. Schor expressly demanded that Conti proceed on its counterclaim in the reparations proceeding rather than before the District Court, and was content to have the entire dispute settled in the forum he had selected until the ALJ ruled against him on all counts; it was only after the ALJ rendered a decision to which he objected that Schor raised any challenge to the CFTC's consideration of Conti's counterclaim.\textsuperscript{250}

In a thorough and thoughtful analysis of the law in this area, Professor Catherine Struve concludes that the submission of the adjudication of private rights to a non-Article III tribunal does not "not offend \textit{structural} Article III concerns."\textsuperscript{251} However, since the litigant in \textit{Schor} had consented to submit the claim to the CFTC, \textit{Schor}'s holding "did not extend to cases in which no such waiver had occurred."\textsuperscript{252} This emphasis on the fact of consent has important implication for the design of any Medicare-led malpractice adjudication scheme.

\textsuperscript{247} \textit{Id.} at 856 (quoting Crowell v. Benson, 285 U.S. 22, 46 (1932)).
\textsuperscript{249} Thomas, 473 U.S. at 591.
\textsuperscript{250} Schor, 478 U.S. at 849 (citation omitted).
\textsuperscript{251} See Struve, \textit{supra} note 239, at 634-35.
\textsuperscript{252} \textit{Id.} at 635.
2. Seventh Amendment Guarantees of Trial by Jury

The remaining issue is the guarantee to a trial by jury in the Seventh Amendment of the federal constitution. The major modern case involving an action arguably comparable to a common law cause of action is *Atlas Roofing Co. v. Occupational Safety and Health Review Commission* in which petitioners challenged the authority of the enabling statute of the Occupational Safety and Health Administration (OSHA) to impose civil money penalties enforceable in federal court on employers for unsafe working conditions. The Supreme Court concluded that the Seventh Amendment had not been violated as the imposition of the penalty only sought to enforce a public rather than a private right. The Court concluded that:

> Congress is . . . not prevented from committing some new types of litigation to administrative agencies with special competence in the relevant field. This is the case even if the Seventh Amendment would have required a jury where the adjudication of those rights is assigned to a federal court of law instead of an administrative agency.

The Court also explained in a footnote that the agency’s decisions could be reviewed by the federal courts of appeals and thus the case did not present the question whether Congress could commit the adjudication of fines for the violation of public rights to the agency “without any sort of intervention by a court at any stage of the proceedings.”

In a later case, *Tull v. United States,* involving an award of injunctive relief and monetary penalties to the government in a suit under the Clean Water Act, the Court observed that an action for civil penalties under the Clean Water Act “is clearly analogous to the 18th-century action in debt, and federal courts have rightly assumed that the Seventh Amendment

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253. U.S. CONST. amend. VII.
255. *Id.*
256. *Id.* at 455.
257. *Id.*
258. *Id.* at 456 n.13.
required a jury trial." The Court ruled that the defendant had a right to a jury trial on the question of whether civil penalties should be imposed but not on the amount of the penalties to be imposed. Some have suggested that the right to a jury trial under the Seventh Amendment might depend on whether it is the agency that sets the penalty as in the case of Atlas Roofing rather than the court.

A subsequent decision, Granfinanciera, S.A. v. Nordberg raised the question of "whether a person who has not submitted a claim against a bankruptcy estate has a right to a jury trial when sued by the trustee in bankruptcy to recover an allegedly fraudulent monetary transfer." The Supreme Court held that the Seventh Amendment entitled one to a jury trial notwithstanding Congress' designation of fraudulent conveyance actions as "core proceedings" under the Bankruptcy Act.

In outlining its rationale for the right to the jury trial in this case, the Court observed that it had consistently interpreted the phrase "[s]uits at common law" in the Seventh Amendment to refer to "suits in which legal rights were to be ascertained and determined, in contradistinction to those where equitable rights alone were recognized, and equitable remedies were administered." Continuing, the court stated that, while the "thrust" of the Seventh Amendment "was to preserve the right to jury trial as it existed in 1791," the Seventh Amendment "also applies to actions brought to enforce statutory rights that are analogous to common-law causes of action ordinarily decided in English law courts in the late 18th century, as opposed to those customarily heard by courts of equity or admiralty.

The Court then proceeded to outline the analysis for determining the application of the Seventh amendment. The Court stated that the first step is comparing "the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity" and then examining "the remedy sought and determine whether it is legal or equitable in nature." The Court would conclude that, if "on balance, these two factors indicate that a party is entitled to a jury trial under the Seventh Amendment, we must decide whether Congress may assign and has assigned resolution of the relevant claim to a non-Article III

261. Tull, 481 U.S. at 420.
265. Id. at 41 (quoting Parsons v. Bedford, 3 Pet. 433, 447 (1830)).
266. Id. at 41-42.
267. Id. at 42 (citing Curtis v. Loether, 415 U.S. 189, 193 (1974)).
268. Id. (citing Tull v. United States, 481 U.S. 412, 417-18 (1987)).
adjudicative body that does not use a jury as factfinder.\textsuperscript{269} The court basically concluded that the claim involved was a private right and thus could not be assigned to a non-Article III tribunal and adjudicated without a jury.\textsuperscript{270}

\textit{Granfinanciera} has important implications for the flexibility of Congress to assign traditionally private law claims arising under common law to administrative tribunals to which adjudication of facts by a jury is not available. Professor Catherine Struve has concluded that: "in the absence of litigant consent, a private-rights claim of that that would carry a jury right if litigated in federal court is not assignable to a non-Article III tribunal for juryless adjudication" and that "the \textit{Granfinanciera} Court explicitly equated the scope of the Seventh Amendment constraint with that of the Article III constraint."\textsuperscript{271} Consequently, she concludes that, although "\textit{Schor} indicates that private-rights disputes may be assigned to non-Article III tribunals when the litigants consent, \textit{Granfinanciera} indicates that absent litigant consent, a case must fall within the public-rights category (or another traditional exception) in order to be validly assigned to a non-Article III tribunal."\textsuperscript{272}

3. Federal Preemption of State Tort Law

There have been numerous instances where Congress has enacted federal laws that have preempted state tort law both in terms of substantive issues in tort law and also in terms of tort remedies in state courts. The most notable example is the Employee Retirement Income Security Act of 1974 (ERISA), which established a federal scheme for the adjudication of claims against employer sponsored benefit plans.\textsuperscript{273} Furthermore, ERISA located regulation of employer-sponsored health insurance—the predominant source of health insurance for the non-elderly—in the federal government and removed it from state insurance regulation.

ERISA establishes requirements for employee benefit plans that are eligible for favorable federal tax treatment. ERISA establishes the plan’s administrator as a fiduciary with associated duties and liabilities to plan participants and beneficiaries (dependents of employees).\textsuperscript{274} ERISA

\textsuperscript{269} Id.
\textsuperscript{270} Struve, supra note 239, at 635.
\textsuperscript{271} Id.
\textsuperscript{272} Id.
RESOLVING MEDICAL MALPRACTICE CLAIMS

requires that plan fiduciaries act solely in the interest of plan participants and beneficiaries and imposes sanctions and limited liability for failure to do so. For qualified ERISA plans, ERISA preempts state laws that would otherwise relate to the plans. However, ERISA explicitly excludes state insurance codes from preemption but then provides that ERISA plans will not be deemed insurers for purposes of state insurance regulation.

ERISA has very specific enforcement provisions. All plans must maintain internal review procedures. ERISA authorizes civil actions against plan fiduciaries for any breaches of ERISA requirements including plan fiduciary determinations under ERISA's internal review procedures. ERISA also authorizes equitable relief as well as damages although damage awards are limited essentially to the recovery of lost benefits only. In Pilot Life Insurance v. Dedeaux, the Supreme Court ruled that ERISA's enforcement remedies preempted state remedies.

The jurisprudence on the ERISA preemption is convoluted. Courts have historically interpreted the ERISA preemption broadly. In Pilot Life Insurance Co. v. Dedeaux, the Supreme Court ruled that ERISA preempted state causes of action in tort for bad faith breach against employee welfare benefit plans and the commercial insurers that funded these plans. From time to time, the Court has re-evaluated the

276. Id. § 1144(a).
277. Id. § 1144(b).
278. Id.
281. Id. § 1132(a)(6).
boundaries of ERISA preemption more narrowly and precisely, but has never wavered as to its validity. Under current law, ERISA routinely extinguishes tort claims for medical injury that otherwise would be available in state court.

The issue of federal preemption of tort remedies has arisen in other contexts. With respect to the Federal Employees Health Benefit Plan, the federal government typically asserts that state law tort causes of action are preempted by federal law. However, courts are split as to whether such preemption exists. Some courts also have recognized that Medicare beneficiaries may bring state tort claims against Medicare HMOs, notwithstanding the regulatory scheme contained in the Medicare statute.

C. STATUTORY AUTHORITY

In addition to the constitutional issues, the question of statutory authority is also important. There are two dimensions to this question. First, does the current Medicare statute contain the requisite authority to launch Medicare-led malpractice reform or at least an initial demonstration testing the concept? Second, if not, what changes to the statute are required to launch Medicare-led malpractice reform, first as a demonstration project and then as a permanent reform?

Congress has extraordinary latitude to legislate for the Medicare program. First of all, the legality of the Social Security Act in which the Medicare program's enabling legislation resides is not in doubt. Congress has also exercised this latitude in the Medicare statute particularly with respect to initiatives to improve the quality of care accorded Medicare beneficiaries. Indeed, the statutory foundations for


289. Id.

290. See supra notes 106-15 and accompanying text.

291. See supra notes 37-45 and accompanying text.
the infrastructure for the Medicare program described above\textsuperscript{292} have rarely been challenged judicially.

Despite this expansive flexibility, it is important to point out the first section of the Medicare statute as it might pose a barrier to Medicare-led malpractice reform. Mindful of the ideological controversy over design and implementation of the Medicare program, particularly within the provider community,\textsuperscript{293} Congress opened Title XVIII of the Social Security Act with an admonition about federal interference in the practice of medicine or the management of health care institutions:


\begin{quote}
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 are provided, . . . or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.\textsuperscript{294}
\end{quote}

While this provision seems quaint today given the complex role of the Medicare program in the business of physicians and other providers, it could be a basis for challenge to Medicare-led malpractice reform from the provider community.


The Supreme Court and lower federal courts have been remarkably deferential to Congress, HHS, and the Medicare program in reviewing challenges to legislation, regulation and policy under the Medicare program. In a superb review of Supreme Court and lower court decisions on the Medicare program since its inception, Professor Tim Jost identifies three categories of Supreme Court decisions on challenges to the Medicare program’s enabling legislation and its implementation.\textsuperscript{295} The first category, which occurred early in the Medicare program, considered challenges to the constitutionality of specific provisions of the Medicare statute. With respect to these cases, Jost observes that the Supreme Court denied relief in two early cases and thus “set the tone for the lower courts,

\begin{itemize}
\item \textsuperscript{292} See \textit{supra} notes 19-105 and accompanying text.
\item \textsuperscript{294} 42 U.S.C. § 1395 (2000).
\item \textsuperscript{295} Jost, \textit{supra} note 288, at 46-54.
\end{itemize}
which soon lost their own early hospitality to constitutional claims in Medicare cases." 296

An early case in which the courts rejected constitutional challenges to the Medicare statute is Association of American Physicians and Surgeons v. Weinberger. 297 In this case, a medical organization challenged the PSRO program claiming that it violates rights guaranteed the plaintiff physicians and their patients by the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. The United States District Court for the Northern District of Illinois, affirmed by the Supreme Court six months later, 298 ruled that the PSRO program was constitutional.

Association of American Physicians and Surgeons is instructive because the court responded to the logical constitutional arguments that would likely be invoked in a legal challenge to any Medicare regime to regulate quality and certainly Medicare-led malpractice reform. The ease with which these constitutional claims were rejected suggests that, from a constitutional perspective, there exists wide latitude to establish quality improvement programs through the Medicare program as a condition of participation.

The district court ruled that the fact that the statute set forth conditions for being compensated by federal funds under the Medicare and Medicaid programs did "not bar physicians from practicing their profession" and further, that the statute was not so "patently arbitrary and totally lacking in rational justification" as to violate the due process clause of the Fifth Amendment. 299 The court also dismissed other specific constitutional claims. 300

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300. Specifically, the court rejected the argument that the law prohibited physicians from performing surgical operations deemed necessary in exercise of professional skill and judgment, pointing out that the statute provided only that a physician must comply with certain guidelines and procedures enumerated in statute if that physician wished to be compensated by federal government for services. Id. at 134. Thus, the legislation did not violate Fifth Amendment by unconstitutionally interfering with right to practice. The court also rejected the argument that the system of norms to be established under statute would violate the Fifth Amendment by unconstitutionally interfering with the physician-patient
In its rejection of the substantive due process claim, the court emphasized that the statute’s “primary purpose” was to “control rapidly rising cost of governmental health care delivery systems” and thus was “not arbitrary for lacking reasonable relationship to end within competency of government.” The court concluded that the intent of Congress to “achieve better cost control in the field of health care” was within the competency of the federal government and that this economic goal was neither “arbitrary and totally lacking in rationality” nor a violation of the Fifth Amendment as an “inefficient and unnecessary interference with right

relationship, in light of the legislative standards of reasonableness and statutory flexibility that take into account various methods of treatment. Id.

The court rejected the allegation that the statute infringed the right of privacy of doctors and their patients as guaranteed by First, Fourth, Fifth and Ninth Amendments, concluding that the statute sought information for legitimate government purpose, that the manner in which information was to be gathered and maintained was reasonable, and that proper confidentiality was assured. Id. at 135-36.

Claimants asserted that the statute was unconstitutionally vague in violation of the Fifth Amendment as members of medical profession would necessarily have to guess at meaning of phrases set forth in statute, such as "medically necessary," "professionally recognized health care standards," and "proper care." Id. at 138-39. The court concluded that, while such phrases were not highly specific, language of legislation was not impermissibly vague or uncertain. Id. at 138-39.

Claimants also asserted that the statute unconstitutionally expose plaintiffs to civil liability. Id. at 139. See also 42 U.S.C. § 1320c-6(c) (2000). The court reasoned that, where norms to be established for physicians under the program were “by definition, typical medical practices,” risk of civil liability would arise from common law standards of negligence and not from the statute. Weinberger, 395 F. Supp. at 139. Further, the court concluded that the possibility of exposure to civil liabilities sometime in the future due to compliance with norms would not amount to that type of real and immediate threat of injury giving rise to actual case or controversy under Article III of the constitution. See id.

The court also rejected the allegation that the statute, by “merely” requiring practitioners to furnish evidence of their services in order to be compensated, violated the Fifth Amendment by creating presumptions inconsistent with competence, good moral character and regularity of motive and conduct inherent in medical licensure. Id.

Further, the court rejected the allegation that the fact that PSROs were required to be nonprofit organizations paid by the Secretary for their expenses did not mean that PSROs would have a financial interest in retaining their contractual relationships with the government, and thus the legislation unconstitutionally empowered biased private organizations to exercise quasi-judicial authority in violation of Fifth Amendment. Id. at 140.

Finally, the statute did not violate procedural due process requirements as it apprised the practitioner or provider of adverse determinations and accorded an opportunity to be heard before the Secretary or by judicial review. Id. at 133.

301. Weinberger, 395 F. Supp. at 133.
to practice medicine." Of interest, the court justified its decision on the following finding of the Senate Finance Committee:

The Committee on Finance has, for several years, focused its attention on methods of assuring proper utilization of these services. That utilization controls are particularly important was extensively revealed in hearings conducted by the subcommittee on medicare and medicaid. Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, and the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of over-utilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care.

The second group of Supreme Court and lower court decisions regarding the Medicare program that Jost identifies involves challenges to the restrictive jurisdictional, ripeness and exhaustion requirements for appeals under the Social Security Act. Specifically, the Social Security Act expressly bars federal question jurisdiction for all challenges to claims that are not brought under grants of authority for judicial review under the Social Security Act. For both the Medicare program and all other programs under the Social Security Act, the Supreme Court has been relentless in its insistence that litigants proceed through the statutory procedures under the Act. Only in two quite extraordinary cases,

302. Id. at 140.
303. Id. at 128-29 (citing Sen. R. No. 92-1230, 92d Cong., 2d Sess. 254 (1972)).
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Bethesda Hospital Association v. Bowen and Michigan Academy of Family Physicians v. Blue Cross & Blue Shield of Michigan did the Supreme Court even consider deviating from the strict limits on judicial review under the Social Security Act as interpreted in its prior cases. More recently, in Shalala v. Illinois Council for Long Term Care, Inc., the Supreme Court got squarely back on track in sharply limiting Michigan Academy and reinstating the jurisdiction, exhaustion and ripeness requirements of the Social Security Act for all practical purposes.

This line of cases is important for Medicare-led malpractice reform for it represents a strong inclination on the part of courts to hold challengers to the jurisdiction, exhaustion and ripeness requirements of the Social Security Act. Such strict limits could be very useful in a Medicare system for malpractice adjudication, assuming Social Security Act § 405(b) applied to the regime. Specifically, claimants would have difficulty proceeding to court and leaving the reformed adjudication system. However, an important question in designing Medicare-led malpractice reform is determining whether and how this restriction in § 405(b) should apply to the reformed system.

A third group of decisions involves provider payment disputes in which the Supreme Court has been very deferential to the agency with respect to its regulations, interpretative policy statements and other practices regarding the payment of providers for the service to Medicare beneficiaries. This is probably due in part to the extreme complexity of the payment methodologies and their implementation. Of note, the Supreme Court has consistently denied that providers have a property interest in Medicare payment, which would entitle them to procedural due process as a matter of constitutional law in their dealings with the Medicare program. (In only one case, Fischer v. United States, and in dicta, did the Court even suggest otherwise.)

308. 485 U.S. 399 (1988) (permitting providers to pass over some administrative procedures before the fiscal intermediary where the intermediary had virtually no authority to rule on the validity of the challenged payment regulation).
309. 476 U.S. 667 (1986) (holding that federal question jurisdiction existed for review of the "method" under which Part B benefits were determined).
310. See Jost, supra note 288, at 47.
2. Judicial Review of Medicare Regulations and Program Guidance

Much of the Medicare program has been implemented through legislative rules, interpretative rules and policy statements. It is likely that any permanent Medicare-led malpractice reform will be implemented in the same matter. Another important theme in the judicial review of the Medicare program has been the legality of these regulations and other guidance, both in terms of their substance and the procedures by which they were promulgated. Because of the scope and complexity of the Medicare program, CMS and its predecessors have issued numerous legislative rules and even more program guidance.\footnote{316}

The Secretary of HHS has broad rulemaking authority to make rules for the Medicare program.\footnote{317} Further, because the programs under the Social Security Act are benefits programs, rulemaking for these programs is exempt from notice and comment rulemaking procedures under § 553(a)(2) of the Administrative Procedure Act.\footnote{318} Like many other agencies following recommendations from the Administrative Conference of the United States,\footnote{319} HHS has agreed to follow notice and comment rulemaking procedures when making legislative rules for its programs, including the Medicare and Medicaid programs.\footnote{320} In 1982, HHS tried to rescind this policy.\footnote{321} In 1986, however, Congress codified the requirement with respect to certain Medicare program regulations and also specified detailed procedures for Medicare rulemaking.\footnote{322}

The Supreme Court and lower federal courts have been relatively, but not universally, deferential in reviewing Medicare program legislative rules, interpretative rules, statements of policy and other program

\footnotesize{315. Fischer v. United States, 529 U.S. 667 (2000).}
\footnotesize{317. 42 U.S.C. § 1395hh(b) (2000).}
\footnotesize{318. 5 U.S.C. § 553(a)(2) (2000).}
\footnotesize{320. Public Participation in Rule Making, 36 Fed. Reg. 2532 (Feb. 5, 1971).}
\footnotesize{322. 42 U.S.C. § 1395hh(b) (2000).}
In that regard, with few exceptions, the Court has willingly followed the prescription of *Chevron Inc. v. Natural Resources Defense Council, Inc.* to defer to the agency’s reasonable interpretation of the statute in legislatives rules unless Congress has clearly indicated otherwise. In part, this willingness is probably due to the fact that most agency rules and guidance pertain to Medicare payment to providers, which is arcane, dense and boring. The lower federal courts have taken their cue from the Supreme Court regarding *Chevron* deference and have generally deferred to HHS rules and other guidance.

CONCLUSION

In a modern democratic state, it should be possible to implement a well-conceived and beneficial solution to a major societal problem. This principle has attended the interpretation of constitutional law when Congress has sought to address problems with the common law tort system in the past through federal statutory reforms. The principle should apply equally to Medicare-led malpractice reform—an innovative but pragmatic approach to addressing the inadequacies of conventional malpractice litigation.

The major impediment to mandatory Medicare-led malpractice reform is the guarantee to a jury trial in the Seventh Amendment of the federal constitution. As discussed above, the Supreme Court revisits this issue sporadically, and a well developed jurisprudence offering clear guidance does not exist. It is not clear, therefore, whether Congress has the authority to enact a mandatory malpractice adjudication system in a federal benefits program that is ancillary to the program’s mission but replaces the state common law tort system for malpractice claims.

323. Jost, supra note 288, at 54-55.
325. Jost, supra note 288, at 49-55. In Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988), the Court refused to give *Chevron* deference to a statutory interpretation that CMS’s predecessor, the Health Care Financing Administration, developed in the course of litigation to justify the promulgation of a payment policy as a legislative rule with retroactive effect.
326. Jost, supra note 288, at 54.
327. Id. at 55-65.
328. See supra notes 129-205 and accompanying text.
329. See supra notes 172-89 and accompanying text.
Consequently, we believe that Medicare-led malpractice reform should be voluntary, allowing beneficiaries to opt out if they so desire. This model has been used in special federal compensation schemes in the past.\textsuperscript{330} This voluntary character, however, puts the onus on the designers of Medicare-led malpractice reform to establish a system that will truly benefit the beneficiary and make it clear to beneficiaries that, when they sustain a medical injury, it is in their best interest to proceed through the Medicare malpractice resolution system rather than seek common law remedies in court.

It is essential to test any program of Medicare-led malpractice reform in demonstration projects in which various approaches to reform can be evaluated. These experiments will elucidate how health care providers can use their mandatory quality assurance and patient safety promotion programs to identify medical injuries early, and to facilitate their resolution and subsequent prevention.

Clearly, any malpractice reform of this magnitude and originality will generate legal challenges. A carefully designed, transparent demonstration project also can convince stakeholders that the proposed reform is indeed what it purports to be—a way to resolve medical claims of Medicare beneficiaries expeditiously and fairly while eliminating undue burdens on patients, health care providers, and medical liability insurers from costly, protracted tort litigation.

\textsuperscript{330} See supra note 158 and accompanying text.