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To Pay or Not to Pay: Medicare and the Preventable Adverse Event: A Rational Decision of Dangerous Philosophical Change

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TO PAY OR NOT TO PAY: MEDICARE AND THE
PREVENTABLE ADVERSE EVENT: A RATIONAL DECISION
OR DANGEROUS PHILOSOPHICAL CHANGE?

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I. INTRODUCTION

These are turbulent times for health care in America. Health care costs are spiraling out of control,¹ quality evaluations reveal a plethora of errors affecting delivery and outcome of care,² and a growing number of citizens find themselves without the ability to afford services or obtain access to care.³ A three-way battle wages among government regulators, health care providers,⁴ and patients.⁵ Government regulation is employed to improve quality and cost, hospitals and providers fight to stay economically viable while providing accessible and efficient care, and individual citizens are in desperate need of dependable and affordable medical services.⁶ The reasons for this battle are as varied as the proposed solutions.

Congress now enters this fray through a proposed Medicare payment scheme that introduces a new philosophy of self-protective cost containment that masquerades as a method of quality improvement.⁷ This new plan seeks to shift costs further onto hospitals and providers by the government's refusal to pay for certain services rendered for emergent, in-hospital care.⁸ Congress proposes to employ a hindsight review technique that denies payment for medical care when that care is deemed to have been preventable, adverse, and with resultant serious effect as defined by Medicare officials.⁹

¹ Brief Summaries of Medicare and Medicaid 16, November 1, 2006, available at <http://www.cms.hhs.gov/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2006.pdf>.

² Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson, *To Err is Human: Building a Safer Health System*, NAT'L ACAD. PRESS (Nov. 1, 1999), available at <http://www.iom.edu/CMS/8089/5575.aspx>.

³ DONALD L. BARLETT & JAMES B. STEELE, *CRITICAL CONDITION: HOW HEALTH CARE IN AMERICA BECAME BIG BUSINESS – AND BAD MEDICINE* 2-3 (2004); KATHLEEN HOGUE ET AL., *THE COMPLETE GUIDE TO HEALTH INSURANCE: HOW TO BEAT THE HIGH COST OF BEING SICK* 181 (1988).

⁴ Provider is defined for the purposes of this note as any entity that provides medical services to a patient. This would include hospitals (the main focus of this note), physicians and associated entities such as nurse practitioners, physician assistants, etc.

⁵ "Patient" generally refers to a beneficiary of Medicare throughout this note. There are many other entities that are involved in this triangle of care such as employers of beneficiaries, employees of providers, other health insurance entities, and share holders of for profit organizations. See generally ROBERT D. MILLER, *PROBLEMS IN HEALTH CARE LAW* (9th ed. 2006) for a discussion of the myriad interactions.

⁶ Leah Snyder Batchis, *Can Lawsuits Help the Uninsured Access Affordable Hospital Care? Potential Theories for Uninsured Patient Plaintiffs*, 78 TEMP. L. REV. 493, 494 (2005).

⁷ 42 U.S.C. § 1395ww(d)(4)(D) (2007).

⁸ *Id.*

⁹ *Id.*

Medicare officials have identified ten events that they believe to be the result of preventable provider actions.¹⁰ These events result in serious “injury” to the patient and are considered to be both costly and frequent.¹¹ Therefore, Medicare officials have determined that denial of payment for the necessary medical care that results from these events is permissible as quality and cost control measures.¹² However, contrary to the espoused intent of quality improvement, this scheme will likely endanger access to care and ultimately increase cost by further penalizing financially struggling hospitals and by shifting patients into the ranks of the under-insured.¹³

Furthermore, if, as expected, other insurance entities throughout the nation follow suit and deny payment for necessary medical care because of unilaterally defined “serious preventable events,”¹⁴ then foreseeable consequences include an extension of the philosophical precedent where preventability equates with non-payment.¹⁵ This precedent is a reflection of the inherent spending power of third-party payors that may be extended to influence non-criminal personal behavior through financial penalty.¹⁶ Refusal of payment for needed services conditioned upon the occurrence of unavoidable events represents an unjust punishment of hospitals and providers.¹⁷

¹⁰ CMS, Hospital Acquired Conditions, *available at* http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp (last visited Sept. 10, 2008).

¹¹ *Id.*

¹² *Id.*

¹³ *See, e.g.,* Batchis, *supra* note 6; Mary Crossley, *Discrimination Against the Unhealthy in Health Insurance*, 54 U. KAN. L. REV. 73, 76 (2005) (noting that unhealthy individuals suffer insurance discrimination and are consequently “exposed to many of the same harms that uninsured persons face”).

¹⁴ *See e.g.,* Kevin O’Reilly, *No Pay for “Never Event” Errors Becoming Standard*, AM. MED. NEWS, Jan. 7, 2008, *available at* <http://www.ama-assn.org/amednews/2008/07/07/prsc0107.htm> (last visited Sept. 9, 2008); Carol Ann Campbell, *Medicare Ends Coverage of Hospital Errors: New Incentive for better Care*, STAR LEDGER, August 12, 2007, *available at* Westlaw, 2007 WLNR 15589174.

¹⁵ *See, e.g. Crossley, supra* note 13, at 135.

¹⁶ To some extent this is the current situation. Many third-party payers are already penalizing otherwise healthy individuals by charging higher premiums for those who smoke or are over weight. Smokers may prevent the increased risk of pulmonary disease by not smoking and over weight individuals may decrease their weight and thereby prevent increased risks of health problems by diet and exercise. This phenomenon is generally known as “risk selection,” “adverse selection,” or “underwriting.” *See generally* Crossley, *supra* note 13, at 135; MIB Group, Inc., *A Few Words About Insurance and Underwriting* *available at* http://www.mib.com/html/insurance_underwriting.html (last visited March 14, 2008); Linda J. Blumberg, Ph.D., *Addressing Adverse Selection in Private Health Insurance Markets* (September 22, 2004) (addressing the Congress of the United States Joint Economic Committee) *available at* <http://www.urban.org/publications/900752.html>.

¹⁷ *See* Russell L. Christopher, *Deterring Retributivism: The Injustice of “Just” Punishment*, 96 Nw. U. L. REV. 843 (2002). Unjust punishment may occur when a defendant who is factually and legally guilty of committing an act which has been unjustly defined to be a crime. *Id.* at 885. It may be argued that an unavoidable adverse event or one not caused by the hospital is not a crime that requires punishment because the hospital is innocent of the act.

Moreover, denial of payment because a patient engages in actions which purportedly cause illness represents an invasion into the fundamental freedom of lifestyle choice that individual Americans enjoy.¹⁸

The government's plan to utilize non-standardized and unexplained data compiled by providers as a means to track these identified serious preventable events available for public review is also concerning.¹⁹ This data is published prior to appeals by providers and is intended to be used as a public quality measure of the provider.²⁰ Publication of this data has been strongly opposed by the medical community who claim that undeserved adverse publicity and increased litigation based upon the unexplained data will result.²¹

This note proposes that Congress avoid this change in fundamental philosophy and continue to provide reasonable payment for services rendered, regardless of cause for the needed care. Instead, Medicare's vast constitutionally authorized spending power should be utilized to encourage quality improvements through extensive data compilation and cooperative analysis that focuses on quality improvement and cost balancing.²² Through legislative power, Congress may play a central role that guides improvements,²³ while focus remains placed squarely upon the original intent of the Medicare program to enable vulnerable elderly, poor and disabled citizens to obtain health care.²⁴

This note begins with a brief review of the history, purpose, governance and funding of the Medicare program. Next will be a review of the program's impact upon the medical industry. An evaluation of the need for cost and quality improvements that leads to the proposed non-payment scheme follows. Subsequent sections analyze the authority and rationality of the proposed spending scheme

¹⁸ See *supra* note 16. Today, adult American citizens generally believe in civil freedoms that allow individuals to voluntarily engage in actions that involve health risk such as smoking, drinking, eating any food source in any amount, or participating in sports and activities that endanger their health, such as rock climbing or motorcycle racing, without extra cost for medical insurance. *Id. generally.*

¹⁹ Kohn, *supra* note 2, at 98, 181-82; CMS mandates compilation and submission of information regarding any of the identified serious adverse events and defined as "quality" data as a condition of participation in Medicare. Deficit Reduction Act § 5001(c) (2005); see also CMS, *Reporting [of Hospital Acquired Conditions]*, available at http://www.cms.hhs.gov/HospitalAcqCond/04_Reporting.asp#TopOfPage, (last visited March 14, 2008).

²⁰ *Id.*

²¹ Maxine M. Harrington, *Revisiting Medical Error: Five Years after the IOM Report, Have Reporting Systems made a Measurable Difference?*, 15 HEALTH MATRIX 329, 352-53 (2005); See also Kohn, *supra* note 2, at 109-111; Brian A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health Care and Legal Systems*, 29 J.L. MED. & ETHICS 346,359 (2001); See, e.g. Robert Pear, *Experts Cast Doubt on Medical Reporting Plan*, N.Y. TIMES, FEBRUARY 23, 2000), at A12, available at Westlaw 2000 WLNR 2999216.

²² See *infra* Part XI.

²³ *Id.*

²⁴ 42 U.S.C.A. § 1395c (West 2008).

followed by an evaluation of consequences. The problematic publication of data compiled for proposed quality control is then briefly reviewed. Finally, this note will suggest that Congress reconsider this change in payment philosophy and instead accept a leadership role that encourages cooperative resolution to the quality improvement and cost efficiency issues that face the health care industry today.

II. THE HISTORY OF MEDICARE

A. Funding and Governance

Medicare was established by Congress and President Johnson as part of Social Security in 1965 in response to a medical care crisis.²⁵ Retired American citizens were without affordable health care when they needed medical care most.²⁶ This crisis is strikingly similar to today's medical scenario. Today, the medical care crisis affects Americans younger than 65 years who are faced with exorbitant medical care costs and lack a third-party payor.²⁷ Today, as in 1965, adequate medical care in America is too expensive for the average American without help from employers or the government.²⁸

Medicare and associated entities²⁹ represent the only national health insurance programs. These programs are guaranteed by federal law to all citizens over the age of 65, the disabled and the poor.³⁰ Medicare is generally funded by the current work force through income tax and employer contributions.³¹ Payment is disbursed through an established trust fund.³² Medicare is an insurance program because it provides comprehensive care for a baseline fee by spreading the risk over the entire

²⁵ See HOGUE, *supra* note 3, at 181; Peter A. Corning, *The Evolution of Medicare ... from idea to law*, Social Sec. Admin. Office of Research & Statistics, 1969, available at <http://www.ssa.gov/history/corning.html>.

²⁶ Corning, *supra* note 25, at Ch. 4, ¶¶ 4-5 (noting the high cost of medical care as the "greatest single cause of economic dependency in old age" where two thirds of elderly citizens had annual incomes less than \$1000 and only one out of eight had health insurance).

²⁷ Batchis, *supra* note 6, at 494-95 (noting that in the year 2003 to 2004 forty-five million people were uninsured and 85.2 million were without insurance for some period of that year).

²⁸ See BARLETT, *supra* note 3, at 2-3.

²⁹ The Medicare associated entities include Medicaid, and the State Children's Health Insurance Program (SCHIP). See <http://www.cms.hhs.gov>. Other associated federally funded insurance programs include Civilian Health and Medical Program for the Uniformed Services (CHAMPUS), Federal Employee Health Benefits Program (FEHBP), and the Veteran's Administration. MILLER, *supra* note 5, at 499.

³⁰ 42 U.S.C.A. § 1395c (West 2008).

³¹ See Federal Hospital Ins. Trust Fund, 42 U.S.C. § 1395i (2008), see also Social Security & Medicare Boards of Trustees, Status of the Social Security & Medicare Programs: A Summary of the 2007 Annual Reports: A Message to the Public, <http://www.ssa.gov/OACT/TRSUM/trsummary.html> (April 23, 2007); Medicare Rights Center, *The History of Medicare and The Current Debate*, available at <http://www.medicarerights.org/maincontenthistory.html>.

³² Federal Hospital Ins. Trust Fund, 42 U.S.C.A. § 1395i(a) (West 2008).

covered population.³³ In this manner it functions as any private insurance company and beneficiaries may receive care anywhere within the United States because the insurance is provided at a national level.³⁴ Moreover, patient choice is safeguarded because services are paid without regard for how the injury or illness developed.³⁵

Medicare consists of four parts labeled as A, B, C, and D. Part A is basic Medicare,³⁶ Part B is supplemental Medicare,³⁷ Part C encompasses the Medicare choice plans³⁸ and Part D includes prescription coverage.³⁹ Medicaid is an adjunctive yet separate entity created to provide health assistance for individuals who qualify for benefits based upon financial determinations rather than age.⁴⁰ Medigap

³³ Crossley, *supra* note 13, at 77-78.

³⁴ This is true because even if a provider does not have a contract with Medicare, payment for care may still be provided especially for emergent services. MILLER, *supra* note 5, at 505. Medicare need not pay the provider directly. *Id.* Payment may be forwarded to the patient who then remits payment to the provider. *Id.* Medicare requires that the provider accept the payment even if the amount provided is less than what Medicare would pay to a provider who is officially contracted with Medicare. *Id.* Medicare also forbids further claims against the patient for any difference in cost for covered services. *Id.*

³⁵ 42 U.S.C.A. 1395a (West 2008). The current prospective payment system utilized by Medicare for payment calculations does not preclude any serious adverse events although there are defined diagnosis and therapies that are not covered such as most cosmetic surgeries or care provided outside of the United States. *See* CMS, *Your Medicare Benefits* (2006) available at <http://www.medicare.gov/Publications/Pubs/pdf/10116.pdf>.

³⁶ This is a compulsory program available to all qualifying citizens designed to cover aged and disabled beneficiaries for certain hospital, post-hospital, home health and hospice services. Eligible individuals include individuals who are older than 65 years and eligible for retirement benefits, <65 years old and eligible through Social Security or Railroad benefits, or individuals who have end-stage renal disease. *See* MILLER, *supra* note 5, at 500-01; *see generally* CMS available at <http://www.cms.hhs.gov>.

³⁷ This is a non-compulsory service paid for electively by qualifying citizens and is designed to cover costs not covered by Part A such as physician services. The program is funded through monthly premiums and matching federal contributions. *Id.*

³⁸ Eligible citizens may choose to implement coverage through private health plans. Beneficiaries must be eligible for Parts A and/or B. Part C was established by the Balanced Budget Act of 1997 codified in 42 U.S.C. section 1395w-21 and was implemented in Jan. 1999. This entity has largely been replaced by the Medicare Advantage plans established with Part D. *Id.*; *see* Introduction to Medicare & Medicaid, 5 West's Fed. Admin. Practice § 6301 (4th ed. 2007).

³⁹ Part D was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, 42 U.S.C.A. section 1395w-101. Currently, only beneficiaries who are enrolled in Part A and Part B, Medicare Advantage Plans or Medicare Savings Account plans are eligible. Coverage began Jan. 1, 2006 and is currently being considered for revision and greater inclusion. *Id.*

⁴⁰ Medicaid is implemented through state authority and is jointly financed through state and federal funds. This program is also called the Kerr-Mills Act and is found under Title XIX of the Social Security Act. It is a voluntary program. *See* MILLER, *supra* note 5, at 511-12; Introduction to Medicare & Medicaid, *supra* note 38.

policies are provided by private insurance companies as supplemental insurance that covers care not reimbursed by Medicare, such as deductibles and co-payments.⁴¹

Medicare is managed by the Centers for Medicare and Medicaid Services (CMS).⁴² CMS is an agency created by the Department of Health and Human Services (DHHS).⁴³ These agencies are administrative entities that act under the delegated authority of Congress and the President respectively.⁴⁴ Specifically, CMS has been granted the authority to oversee Medicare and its associated programs.⁴⁵ To that end, CMS has the authority to create regulations that affect its programs and beneficiaries.⁴⁶

B. Function and Purpose

The recognized purpose of the Medicare programs is to provide health care to citizens who are elderly, disabled or are in financial need.⁴⁷ Through this entity, societal cost is dispersed across all working citizens.⁴⁸ Traditionally, Medicare has reimbursed necessary medical care regardless of the cause or the preventability of the injury or illness that necessitated the care.⁴⁹

Moreover, the beneficiary is afforded a degree of choice between qualified providers and hospitals.⁵⁰ Beneficiaries are allowed to travel throughout the United

⁴¹ HOGUE, *supra* note 3, at 182.

⁴² See CMS, Office of the Administrator, http://www.cms.hhs.gov/CMSLeadership/08_Office_OA.asp#TopOfPage. CMS was called Health Care Financing Administration (HCFA) prior to 2001.

⁴³ See Dept. of Health & Human Serv. (DHHS), *available at* <http://www.hhs.gov/about/index.html#agencies>.

⁴⁴ DHHS is led by a Secretary who is appointed as a member of the president's cabinet. See <http://www.hhs.gov>.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ 42 U.S.C.A. § 1395c (West 2008); *see also* Corning, *supra* note 25; Judith Stein & Alfred J. Chiplin, Jr., *A Practical Guide to Medicare Hearings and Appeals*, 34 REAL PROP., PROB. & TRUST J. 403, 405-08 (1999); Social Security Administration, Social Security History, *available at* <http://www.ssa.gov/history/history.html>. Since inception, Medicare has now expanded to cover in some way all citizens over the age of 65, the disabled and those receiving end-stage renal care. *Id.*

⁴⁸ *Id.*

⁴⁹ 42 U.S.C.A. 1395a (West 2008). Consider the patient who never saw a doctor, didn't take medications, smoke, drank, used illicit drugs, or fell at home. All of these problems are considered to be preventable yet they are paid for because of need regardless of financial status. See MILLER, *supra* note 5, at 500; *see also* Crossley, *supra* note 13, at 77-79 (describing the communal pool as a social risk-sharing device).

⁵⁰ 42 U.S.C.A. 1395a (West 2008); *see* Alpha Center, *A Special Report: Risk Adjustment: A Key to Changing Incentives in the Health Insurance Market* 5, produced for The Robert Wood Johnson Foundation's Changes in Health Care Financing & Org. Program (HCFO) (1997) (identifying patient choice as a powerful desirable factor that drives insurance

States knowing that a facility that provides Medicare coverage will be available.⁵¹ The program has traditionally recognized that modern health care in America is not considered to be a right but rather a luxury afforded to those who can pay or who have work benefits.⁵² Therefore, by providing payment for services based on need for citizens with financial burdens and complex medical problems, Medicare has eliminated some capitalistic restraint upon access to care and choice, because all qualifying citizens have a guarantee of payment for medical services when they are needed.⁵³

II. MEDICARE'S IMPACT ON THE MEDICAL PROFESSION, INSURANCE INDUSTRY AND THE GENERAL POPULATION

Medicare has had a significant impact upon the medical industry by defining and controlling reimbursement through use of its congressionally granted spending power.⁵⁴ Medicare has become the leader in the field of medical reimbursement and its negotiated prices have become the baseline by which other medical insurance agencies determine fair reimbursement for specific types of care and services.⁵⁵ By determining covered services and the corresponding pay rates for those services, Medicare has been – appropriately – accused of practicing Medicine.⁵⁶

The advent of Medicare brought a significant change to the medical profession in the United States.⁵⁷ Although Medicare was intended to be only a payment method, it

decisions); *see also* Medicare: The Official U.S. Gov't Site for People with Medicare, available at <http://www.medicare.gov/Choices/Overview.asp>.

⁵¹ *Id.* Traditional Medicare has no limitations upon national travel while Medicare Advantage plans may have different reimbursement plans for out of network facilities and providers.

⁵² *See, e.g.,* BARLETT, *supra* note 3, at 2-3.

⁵³ *Id.* at 25; *see also* Stanley B. Jones, *Medicare Influence on Private Insurance: Good or Ill?* 18 HEALTH CARE FIN. REV. 153, 159 (1996) available at <http://www.ssa.gov/history/pdf/MedicareInfluencePrivateInsurance.pdf>.

⁵⁴ 42 U.S.C.A. 1395b-1(a)(1)(A) (2008) (describing “incentives for economy while maintaining or improving quality in provision of health services”); *see also* 42 U.S.C.A. 1395kk-1 (West 2008).

⁵⁵ *See* Stanley B. Jones, *Medicare Influence on Private Insurance: Good or Ill?*, 18 HEALTH CARE FIN. REV. 157 (1996) (likening Medicare to a “700 pound gorilla” such that “[w]hen it rolls over, providers who share the bed have no choice but to go along”).

⁵⁶ *See, e.g.,* Richard Dolinar & S. Luke Leininger, *Pay for Performance or Compliance? A Second Opinion on Medicare Reimbursement*, 3 IND. HEALTH L. REV. 397, 419 (2006); Lawrence R. Huntoon, M.D., Ph.D., President Assoc. of Am. Physicians and Surgeons, *Fraud, Abuse, and the Medicare Industrial Complex: A Practicing Physician's View*, Address Before the Heritage Foundation (March 1, 2000), in Pamphlet No. 1073, Assoc. of Am. Physicians and Surgeons, Inc., May 2000, at 2, available at <http://www.aapsonline.org/brochures/lhherita.htm>.

⁵⁷ *See, e.g.,* Batchis, *supra* note 6, at 501 (noting Medicare's impact upon hospital charges).

has become a vehicle for government control of medical care.⁵⁸ Through its spending power, the federal government has sought, gained control over, and now dictates reimbursement schedules for most medical treatments.⁵⁹ Originally, Medicare paid the full reasonable cost of services provided to beneficiaries.⁶⁰ However, through unilateral incremental pay reductions, Medicare has progressed to payment of only a percentage of the actual cost of care and has unilaterally determined compensation rates for physicians and hospital care.⁶¹ Many private insurance companies have followed suit and now pay or negotiate for the Medicare determined rates.⁶² Insurance officials argue that if the providers can afford these rates for governmental insurance, then their private insurance should enjoy the same payment scheme.⁶³

Inflationary prices result, especially for uninsured patients because the price claimed by providers for a given service is elevated to offset the lower amount paid by insurances.⁶⁴ For this reason, the billed medical cost is significantly higher than the amount actually paid and accepted.⁶⁵ Medicare and health insurance companies in general have inflated the cost of medicine by encouraging underpayment.⁶⁶ This cost inflation is reflected in the exorbitant charges of hospital care to the uninsured.⁶⁷ In short, persons without insurance are forced to pay inflated rates for medical care because those payments are needed to subsidize the insufficient Medicare and private insurance reimbursements.⁶⁸ However, over time Medicare has become more than an insurance entity.

⁵⁸ See *supra* note 56.

⁵⁹ Mark V. Pauly, *Symposium: The Future of Medicare, Post Great Society and Post Plus-Choice: Legal and Policy Issues: What if Technology Never Stops Improving? Medicare's Future Under Continuous Cost Increases*, 60 Wash & Lee L. Rev. 1233, 1236 (2003).

⁶⁰ Jones, *supra* note 55, at 156.

⁶¹ Batchis, *supra* note 6, at 501-02 (noting that Medicare and other third-party payers negotiate "steep discounts" that do not reimburse the actual cost of care); see also Raymond G. Davis, *Health Care Reform and the Probabilities of Change*, 3-WTR KAN. J. L. & PUB. POL'Y 25, 28-29 (1993/1994).

⁶² *Id.*; Margaret Cross, *Confronting the Medicare Cost Shift*, MANAGED CARE *3, Dec. 2006, available at <http://www.managedcaremag.com/archives/0612/0612.costshift.html>.

⁶³ Cross, *supra* note 62.

⁶⁴ Leah Snyder Batchis, *Can Lawsuits Help the Uninsured Access Affordable Hospital Care? Potential Theories for Uninsured Patient Plaintiffs*, 78 TEMP. L. REV. 493, 501 (2005); R. Brent Rawlings & Hugh E. Aaron, *The Effect of Hospital Charges on Outlier Payments under Medicare's Inpatient Prospective Payment System: Prudent Financial Management or Illegal Conduct?*, 14 ANNALS HEALTH L. 267, 294-297 (2005).

⁶⁵ Batchis, *supra* note 6, at 501-04 (identifies the "chargemaster price" as the inflated price computed by hospitals as a means to negotiate for a better percentage of reimbursement from insurances and to shift the cost of the discount onto the uninsured).

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

Through this control of price and payment, Medicare officials have progressively intruded into the practice of medicine.⁶⁹ The Medicare Act clearly declares that Medicare is “not to be construed as practicing medicine.”⁷⁰ Yet, initially through control of payment, and now through the threat of non-payment for identified serious adverse events, the government is, in effect, practicing medicine.⁷¹ Far beyond merely paying for services, Medicare officials have created a complex reimbursement code system whereby medical care may be completely controlled and tracked.⁷² This code determines what medical diagnoses are covered, which services are reimbursable to treat the diagnosis, what the length of recovery should be, and what follow-up care is required.⁷³ These codes generalize medical illness and create a “cook-book” approach to like-defined diseases at the expense of more complicated illnesses or more compromised patients.⁷⁴

Moreover, hospitals and providers that receive federal funding through the Medicare program are increasingly obligated to comply with incrementally invasive regulations.⁷⁵ A large portion of hospitals depend upon Medicare payments because the majority of their patient base is comprised of Medicare beneficiaries.⁷⁶ Federal

⁶⁹ See *infra* notes 70-76.

⁷⁰ Prohibition against any Federal Interference, 42 U.S.C. 1395 (1965).

⁷¹ The practice of medicine may be defined broadly as the diagnosing and treating of human ailments. 16 A.L.R. 4th 58 § 3[a] (defining chiropractics as a practice of medicine). CMS has established and imposed treatment protocols that create a one-size-fits-all method for diagnosing and treating some common emergent illnesses such as pneumonia, myocardial infarction, and surgical infection prevention. See Quality Improvement Organization (QIO), QIO Efforts to Reduce Healthcare Disparities 2002-2005: Final Report of Progress, Findings, and Results of QIO Projects 5-6 (2005) available at http://www.ahqa.org/pub/uploads/QIOs_Reduce_Disparities_Final_Report_w_Cover.pdf. Adherence to these protocols is tied to reimbursement and is used as a measure of quality. *Id.* In effect, the government instead of medical professionals, has determined diagnosis, treatment and expected outcomes for specific disease processes. This exemplifies the practice of medicine.

⁷² Dolinar, *supra* note 56, at 398, 403.

⁷³ *Id.* at 398, 403.

⁷⁴ *Id.* at 398, 403; see also QIO, *supra* note 71.

⁷⁵ See Dolinar, *supra* note 56, at 398, 403; QIO, *supra* note 71; see also 42 U.S.C.A. § 2000d-1; CMS, *Conditions for Coverage & Conditions of Participation*, available at <http://www.cms.hhs.gov/CFCsAndCoPs/>; Title 42, Ch. IV, Part 482 (2008) available at http://www.access.gpo.gov/nara/cfr/waisidx_04/42cfr482_04.html. These regulations are incremental because they begin with only coding or grouping of related diagnoses but increasingly impose time-restraints on care, types of drugs to be used, and types of therapies to be employed for the diagnosis. See QIO, *supra* note 71. New conditions of participation in Medicare involve regulation of the composition of the governing boards of participating hospitals. See Michael O. Leavitt, Sec’y of Health & Human Serv., *Report to Congress: Improving the Medicare Quality Improvement Organization Program – Response to the Inst. Of Med. Study* 33-34 (2006), available at http://www.cms.hhs.gov/QualityImprovementOrgs/downloads/QIO_Improvement_RTC_fnl.pdf.

⁷⁶ Dolinar, *supra* note 56, at 406; The Am. Hosp. Assoc., *Underpayment by Medicare and Medicaid: Fact Sheet *1* (2007) (noting that 55 percent of all care provided by hospitals is

law has mandated that no patient, regardless of ability to pay, may be turned away from any hospital facility when emergency care is needed.⁷⁷ Although this altruistic measure ensures emergency care to all citizens, it also forces all hospitals to accept Medicare or provide coverage for free or below cost.⁷⁸ Also, through retrospective review of patient beneficiary admissions, Medicare officials may unilaterally determine that certain provided services are included in a prorated global fee⁷⁹ and are therefore non-payable by either Medicare or the beneficiary.⁸⁰ The increasing number of services provided for free or only partially reimbursed, because of the lack of available personal funds or insurance, has resulted in the closing or consolidation of hospitals all over the United States.⁸¹ The federal government currently provides support to some facilities by funding “non-recoverable services” known as “bad debt” which prevents some closures.⁸²

Through this spending control, and by specifically denying recovery of funds from the patient for medical treatments that Medicare officials deem in hindsight to be unnecessary or globally inclusive, Medicare officials may now dictate the specific care a patient should receive, how long the care should take, how long the patient should be hospitalized, and what medications they should receive.⁸³ Changes effective October 2008 will increase Medicare’s power to determine what complications a patient should or should not develop, and who is liable for the cost of those complications.⁸⁴

funded by Medicare and Medicaid), available at <http://www.aha.org/aha/content/2007/pdf/07-medicare-shortfall.pdf>; see also Am. Hosp. Assoc., *Hospital Facts to Know*, available at <http://www.aha.org/aha/content/2007/pdf/07-am-hospital-facts.pdf>, (2007).

⁷⁷ Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. 1395dd(a) (2003).

⁷⁸ 42 U.S.C.A. 1395dd(b)(1) (West 2003).

⁷⁹ The Prospective Payment System imposed by Medicare for most services represents a global fee that includes all services and therapies utilized to treat the diagnosis. MILLER, *supra* note 5, at 502. For example, the Medicare fee paid to the hospital for pyelonephritis (kidney infection) will be the same regardless of which antibiotics must be used for treatment. One patient may only need a generic, affordable antibiotic while another may require an expensive alternative because of allergies. The pro-rated global fee places the loss of added expense of the medication upon the hospital provider. Pub. L. No. 98-21, 97 Stat.65 (1983), as amended by Pub. L. No. 98-369, 98 Stat. 1073 (1984).

⁸⁰ HOGUE, *supra* note 3, at 205.

⁸¹ See, e.g. Svetlana Lebedinski, *EMTALA: Treatment of Undocumented Aliens and the Financial Burden it Places on Hospitals*, 7 J.L. SOC’Y 146, 155 (2005); see also Am. Hospital Assoc., *Protecting the Promise* 13 (2004), available at <http://www.aha.org/aha/content/2004/pdf/ProtectingThePromise.pdf> (last visited March 16, 2008) (noting 900 hospital closings from 1980 to 2004).

⁸² *Id.*

⁸³ See *supra* note 75.

⁸⁴ *Id.*; but see Am. Med. Assoc. v. Matthews, 429 F. Supp. 1179 (N.D. Ill. 1977)(finding that regulations to control cost do not constitute supervision or control of medicine); Coll. Of Am. Pathologists v. Heckler, 717 F.2d 587 (D.C. Cir. 1984)(finding regulation prohibiting physician to seek compensation outside of Medicare did not constitute interference).

IV. THE NEED FOR COST CONTROLS IN HEALTHCARE AND FOR THE MEDICARE PROGRAM

Medicare and its associated entities are insurances that function under the auspices of the federal government.⁸⁵ All workers are required to pay tax into the Medicare system.⁸⁶ These individuals fund the current system and the health needs of the dependent elder population.⁸⁷ Medicare spent about \$336.4 billion on health care in 2005.⁸⁸ This number has risen from \$27.6 billion for the national total cost of health care at Medicare's inception in 1965 and is projected to increase to \$4 trillion by the year 2015.⁸⁹ President Bush highlighted this impending insolvency of the Medicare programs when he presented his budget calculations for 2009.⁹⁰

No one can dispute that the cost of medical care in America has skyrocketed beyond the pocket books of most United States citizens.⁹¹ Multiple factors contribute to this increase.⁹² Obvious reasons for the increase include advanced and expensive technology, greater availability of functional drugs, general inflation, and costs of medical liability.⁹³ The most obvious reason is that people are living longer, albeit with more illness.⁹⁴

Another problem that complicates cost control efforts is that unrestrained payment has led to a system of entitlement.⁹⁵ Prior to the advent of adequate medications that effectively treated infection⁹⁶ and permitted significant pain

⁸⁵ See *supra* notes 42-46.

⁸⁶ Federal Insurance Contributions Act (FICA), 26 U.S.C. § 3101 (2004).

⁸⁷ See Crossley, *supra* note 13, at 77-78.

⁸⁸ See *supra* note 1, at 16.

⁸⁹ *Id.* at 4-5.

⁹⁰ Proposed 2009 National Budget: Economic Assumptions and Analyses: Health Spending 188, available at <http://www.whitehouse.gov/omb/budget/fy2009/pdf/apers/assumptions.pdf>.

⁹¹ HOGUE, *supra* note 3, at 304-05; BARLETT, *supra* note 3, at 306.

⁹² *Id.* at 311-315.

⁹³ *Id.*

⁹⁴ John V. Jacoby, *Consumer-Directed Health Care and the Chronically Ill*, U. MICH. J. L. REFORM 531, 563 (2005) ("Providing health care services to people with chronic illnesses consumes about 75 percent of direct health care costs."); see also Maria Cheng, *Living Longer, Healthy Cost More*, THE PLAIN DEALER, February 5, 2008 at A3.

⁹⁵ HOGUE, *supra* note 3, at 304; Theodore Marmor et al., *The Future of Medicare, Post Great Society & Plus-Choice: Legal & Policy Issues: Medicare & P Political Analysis: Omissions, Understandings, & Misunderstandings* 60, WASH. & LEE L. REV. 1137, 1145-48 (2003).

⁹⁶ Antibiotics such as Penicillin became popular in the 1940's. Mary Bellis, *The History of Penicillin*, available at About.com: Inventors, <http://inventors.about.com/od/pstartinventions/a/Penicillin.htm?p=1>.

control,⁹⁷ people sought medical aid only when they were truly sick and local remedies would not suffice.⁹⁸ Hospitals were places for the homeless or the terminally ill to die in relative comfort.⁹⁹ Over the past century, society has embraced the need for preventive care.¹⁰⁰ People are now encouraged to see a medical provider to screen for illness because treatment of any illness prior to its physical manifestation allows for greater survival and comfort.¹⁰¹ However, this practice also encourages use of medical resources and thereby increases expenses.¹⁰² The increase of individuals diagnosed with chronic diseases has led to long-term dependence on medical resources for continued treatment to improve survival and, hence, become a long-term cost burden.¹⁰³

In general, the lack of personal affordability has generated the risk-based insurance industry, including the Medicare entities.¹⁰⁴ However, even the cost of insurance premiums has become unaffordable for some Americans.¹⁰⁵ Employers once offered to cover all the cost of health insurance for employees as a benefit.¹⁰⁶ Federal law has since mandated that health insurance be subsidized by certain employers.¹⁰⁷ This health care includes separate entities: one for on-the-job injuries in the form of workers compensation,¹⁰⁸ and another for general health coverage for

⁹⁷ Anesthesia medications such as Morphine which became popular in the 1800's. *See generally* BARBARA HODGSON, *IN THE ARMS OF MORPHEUS: THE TRAGIC HISTORY OF LAUDANUM, MORPHINE AND PATENT MEDICINES* (Firefly Books 2001) (presenting an interesting history of Morphine).

⁹⁸ *See, e.g.* History of Hospitals, http://web.bryant.edu/~ehu/h364proj/fall_97/prier/index.htm.

⁹⁹ *Id.*; HOGUE, *supra* note 3, at 182.

¹⁰⁰ Nat'l Ctr. For Policy Analysis, *Is Preventive Medical Care Cost-Effective?* *1, (1995), available at <http://www.ncpa.org/ba/ba188.html>.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Jacoby, *supra* note 94, at 564 (describing the high cost of diabetic patients and progressive disease prevention). Also, consider patients with HIV, prior cancer, or pregnancy prevention.

¹⁰⁴ HOGUE, *supra* note 3, at 304-05.

¹⁰⁵ BARLETT, *supra* note 3, at 16.

¹⁰⁶ *Id.* at 309.

¹⁰⁷ Health Insurance Portability and Accountability Act (HIPAA), 29 U.S.C. § 1182 (1996); *see also* Employment Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 (1984).

¹⁰⁸ Worker's Compensation is provided through state statutes and is intended to provide strict liability for employers toward injured employees during the course of employment. MILLER, *supra* note 5, at 202; Norman Singer, 3B Sutherland Statutory Const. § 75:3 (6th ed. 2007).

the workers and their families.¹⁰⁹ The development and maintenance of pension funds is highly contentious in labor negotiations involving large companies, because projected costs of medical coverage for retired employees are beginning to outweigh the costs for the current work force.¹¹⁰ Companies are essentially paying non-workers a benefit without the return benefit of labor. These costs are limiting the types of health insurance and other benefits that companies can offer to current employees.¹¹¹

Traditionally, both private and public health insurance entities have been able to defray cost by spreading it over many individuals.¹¹² Premiums paid for by all covered individuals, many of whom are healthy, offset the payouts for those who become ill.¹¹³ In general, the insurance industry is a risk-based entity because there is theoretically a risk that the insurance may need to pay more than it charges.¹¹⁴ Most insurers try to recoup the losses and maintain profits by minimizing this risk.¹¹⁵

Insurers may minimize risk by “increasing premiums, [by] lowballing claims, or [by] cherry-picking their customers to void those who pose the greatest threat to their bottom lines.”¹¹⁶ Another way for insurers to control costs is to pay less for care of their customers.¹¹⁷ This is done by negotiating with medical providers to obtain across-the-board discounts on fees charged.¹¹⁸ This practice shifts the differential burden of cost onto the uninsured or other insurances.¹¹⁹ Insurers also create monetary incentives for customers to be seen only by a limited number of preferred

¹⁰⁹ In the form of private insurance companies or through self-funded health care insurance. MILLER, *supra* note 5, at 521-27.

¹¹⁰ HOGUE, *supra* note 3, at 309; *see, e.g.* Anne P. Birge, *The Pending Crisis in Employer-Provided Health Benefits for Retirees: Are Tax Breaks for Employers the Answer?*, 19 N.Y.U. REV. L. & SOC. CHANGE 797, 798 (1992/1993).

¹¹¹ *See*, Lori Myers, *Employers Cutting Back on Health Benefits for Retirees*, 22 CENT. PENN BUS. J. 7 (July 14, 2006) (*available at Westlaw* 2006 WLNR 13835511) (noting that many employers are freezing or terminating retiree benefits because of a desire to protect active employee benefits. The employers observe that retirees have access to federally mandated Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), 26 U.S.C.A. § 4980(b) (West 2006), or Medicare benefits.)

¹¹² HOGUE, *supra* note 3, at 305; Crossley, *supra* note 13, at 77-79.

¹¹³ *Id.*; *see also* David D. Griner, *Paying the Piper: Third-Party Payor Liability for Medical Treatment Decisions*, 25 GA. L. REV. 861, 869-70 (1991).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ David Lazarus, *Insurers Taking Risk Out of the Equation*, L.A. TIMES, October 26, 2007, *available at* <http://www.latimes.com/features/health/la-fi-lazarus26oct26,1,6704461.column?coll=la-headlines-health&ctrack=1&cset=true>.

¹¹⁷ BARLETT, *supra* note 3, at 15 (noting that private health insurances and Medicare entities negotiate for large volume discounted rates that pay only a fraction of the cost).

¹¹⁸ *Id.*; Griner, *supra* note 113, at 871-74.

¹¹⁹ *See also* Griner, *supra* note 113, at 871-74.

providers who are specifically chosen because of their billing practices or acceptance of lower fees.¹²⁰

However, even a cursory review of relevant statistics¹²¹ reveals that the proportion of workers available to fund Medicare, compared to the number of ever increasing number of beneficiaries, will result in the Medicare fund's insolvency by 2019.¹²² Therefore, costs must be contained and/or other sources of revenue identified to preserve the system.¹²³ Despite this reality, beneficiaries continue to demand and expect expansion of the program.¹²⁴ The federal government appears eager to comply with these desires as noted by the recent passage of the pharmaceutical provisions in Medicare Part D despite readily acknowledged funding shortfalls.¹²⁵

Government officials have considered a variety of cost containment options for the Medicare program.¹²⁶ Currently, the program employs target cost containment by decreasing payment for services to hospitals and providers, by shifting some costs onto private insurances, and by collecting variable premiums from insureds who can afford to pay them.¹²⁷ Medicare also controls payments by closely reviewing medical records and verifying that only covered services are reimbursed.¹²⁸ CMS has an extensive waste and abuse department that constantly evaluates possible fraudulent schemes to obtain illegal payment and vigorously prosecutes and imposes heavy fines on wrongdoers through its administrative procedures.¹²⁹ Medicare has been

¹²⁰ *Id.*

¹²¹ The IOM authors have used a form of "extrapolated reality". Extrapolated means "inferred (unknown information) from known information." The American Heritage Dictionary of the English Language 254 (Paperback Ed. 1976). "Extrapolated reality" occurs when data is inferred from a known source and then treated as true data. *See, e.g., supra* note 100.

¹²² Social Security & Medicare Boards of Trustees, *supra* note 31, at *1.

¹²³ *Id.*

¹²⁴ *Id.*; *see also* Joseph R. Antos, Ph.D., *Fixing the New Medicare Law #2: How to Promote Real Medicare Cost Containment*, 1752 Backgrounder (The Heritage Foundation April 26, 2004), *available at* <http://www.heritage.org/Research/HealthCare/bg1751.cfm> (noting a premium increase for Part B where the amount is calculated based upon a beneficiaries personal income as a method of cost containment); *see generally* Marmor, *supra* note 69.

¹²⁵ *Id.*

¹²⁶ *See, e.g.,* Gail R. Wilensky, *The Balanced Budget Act: A Current Look at its Impact on Patients & Providers*, Medicare Payment Advisory Commission (MPAC) Testimony (July 19, 2000), *available at* http://www.medpac.gov/publications/congressional_testimony/071900.pdf.

¹²⁷ *Id.*

¹²⁸ Kevin Freking, *Audits Sting Hospitals, Physicians*, AOL NEWS (March 1, 2008) *available at* http://news.aol.com/story/_a/audits-sting-hospitals-physicians/n20080301035209990015.

¹²⁹ *See generally* HHS Office of the Inspector General, *available at* <http://www.oig.hhs.gov/fraud.html>.

accused of overly vigorous prosecution of innocent errors which government officials recognize as common occurrences due to the extremely complicated coding systems Medicare employs.¹³⁰ Nonetheless, "cost savings" from payment refusal and fines have been generally well received.¹³¹

Another cost saving measure is refusal to pay for certain services. Generally, Medicare will not pay for services that it deems to be "unnecessary."¹³² Recently Medicare officials have refused to pay for services that they identify as medical error in the form of a preventable adverse event.¹³³ By self-defining the problem, Medicare officials are able to control hospitals and providers by refusal of payment. Medicare officials expect to save about \$30,000 on average per hospital stay for each preventable adverse event, and estimate a savings of twenty million dollars in the first year.¹³⁴

V. THE ADVENT OF THE PREVENTABLE ADVERSE EVENT

Over the past two decades, political attention has been focused upon the escalating cost of medical care, and the recognition of preventable adverse events as a contributing factor of this cost.¹³⁵ CMS has defined seventeen adverse events that

¹³⁰ Jane Cys, *Bush on Health Fraud: Physicians Hope for Lighter Touch*, AM. MED. NEWS, Feb. 26, 2001, available at <http://www.ama-assn.org/amednews/2001/02/26/gvsb0226.htm> (describing angry physician groups' response to heavy-handed tactics that punish unintentional mistakes resulting in a criminalization of the practice of medicine); see also *Fraud & Waste in Medicare*, N.Y. TIMES, at A30, Aug. 1, 1997 ("The truth is that [CMS] has neither the financial nor the ability to tightly supervise the numbingly complex system.").

¹³¹ *Id.* (describing a cost savings of \$1.5 billion, \$840 million from civil actions in 2001). However, punishment for over-billing has not always been the norm. Historically, Medicare would not reimburse for mistakes made for under-billing due to erroneous coding. Rather, if an under-billed mistake was found, Medicare refused payment if the request for payment had passed the 90 day time limit for submissions. Therefore, to prevent under-billing, many providers over-billed Medicare because of uncertainty in the billing codes, claiming similar codes assuming that Medicare officials would choose the appropriate code and disallow the duplicates without penalty.

¹³² Medicare does not cover: acupuncture, dental care, care outside of the US, most chiropractic services, cosmetic surgery, custodial care (unless skilled nursing), eyeglasses (except after cataract surgery), hearing aids (except certain implants), long-term care, personal care, and private duty nursing. Medicare Rights Center, <http://www.medicarerights.org/medicareanswersonline.html> (last visited December 2, 2007).

¹³³ CMS Quarterly Provider Updates, CMS-1533-P § F, 72 Fed. Register 85 May 3, 2007, available at <http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1533p.pdf>. The range of expected savings is \$24,962 for surgery on the wrong body part, wrong patient or wrong surgery to \$88,781 for ventilator assisted pneumonias as average costs associated per hospital stay.

¹³⁴ *Id.*; See John H. Ferman, *Payments Will be Based on Quality not Quantity* *1, 23/2 HEALTHCARE EXECUTIVE 52 (March 1, 2008), available at Westlaw, 2008 WLNR 5128153.

¹³⁵ The increased attention toward serious adverse events may be traced to the IOM study of 1995. See Kohn, *supra* note 2.

are candidates for non-payment when they occur in the hospital setting.¹³⁶ Ten of these events are slated for non-payment beginning October 2008 and include catheter-associated urinary tract infections, stage III and IV pressure ulcers, vascular catheter-associated infections, certain surgical site infections (such as mediastinitis after coronary artery bypass graft, bariatric and orthopedic surgeries), falls or trauma resulting in serious injury, blood incompatibility, air embolism, manifestations of poor glycemic control (such as ketoacidosis and diabetic coma), deep vein thrombosis and pulmonary embolism and foreign objects left during surgery.¹³⁷ Another seven conditions are under consideration for future non-payment and include *Staphylococcus Aureus* septicemia, ventilator-associated pneumonia, *Clostridium Difficile*-associated disease, Legionnaires' disease, iatrogenic pneumothorax, delirium, and surgical site infections after knee or varicose vein surgeries.¹³⁸

These events were first catalogued in 1995 when the Institute of Medicine (IOM)¹³⁹ published an article entitled "To Err is Human: Building a Better Health System."¹⁴⁰ The article was the first in a series of congressionally commissioned reports regarding the quality of health care in America.¹⁴¹ By reviewing data collected and published from two separate case review studies that considered adverse events in four hospitals,¹⁴² published statistical data from the American Hospital Association and a conglomerate of adverse drug event collectives,¹⁴³ IOM convincingly proposed that the analyzed data revealed an unacceptable quality of care at hospitals.¹⁴⁴ IOM calculated that if the data from these hospital and drug

¹³⁶ See CMS, Hospital Acquired Conditions, available at http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp (last visited Sept. 10, 2008); see also Doug Trapp, *AMA Meeting: Delegates Decry CMS No-Pay List as Unrealistic and Call for Revision*, AM. MED. NEWS, July 7, 2008, available at <http://www.ama-assn.org/amednews/2008/07/07/prl20707.htm> (last visited Sept. 9, 2008).

¹³⁷ *Id.*

¹³⁸ See Trapp, *supra* note 136.

¹³⁹ The IOM is an entity established by the government to perform "independent" research upon medical issues as directed by the government. It is indirectly funded by the government. Its purpose is to gather information regarding a chosen topic then present the findings to Congress which it publicizes. See The Nat'l Acad., *History of the Nat'l Acad.*, available at <http://www.nationalacademies.org/about/history.html>.

¹⁴⁰ Kohn, *supra* note 2.

¹⁴¹ *Id.* at xi.

¹⁴² Troyen A. Brennan et al., *Incidence of Adverse Events & Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 N. ENG. J. MED. 370-76, 1991; see also Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II*, 324 N. ENG. J. MED. 377-84, 1991; Eric J. Thomas et al., *Incidence & Types of Adverse Events & Negligent Care in Utah & Colorado*, 38(3) MED. CARE 261-71, 2000.

¹⁴³ Kohn, *supra* note 2, at 15-16.

¹⁴⁴ *Id.* at 1, 26. This maneuver demonstrates the term "extrapolated reality" such that data from three studies in three states amounting to only 45,000 admissions have been extrapolated

studies were extrapolated to include the thousands of hospital admissions throughout the United States, then between 44,000 and 98,000 the patients die each year from medical errors in health care.¹⁴⁵

As is often the case with data analysis, the report contained several critical errors. It failed to define a “mistake,” and included all unexpected or complicating conditions as identifiable errors, regardless of whether the events were caused by negligence or were merely a common side effect of adequate care.¹⁴⁶ The study also included patient controlled errors, such as injuries that occurred when a competent patient refused to follow direct medical advice.¹⁴⁷ In addition, the study evaluators admitted that the data is biased and limited, but despite this the evaluators urged congressional involvement and immediate action.¹⁴⁸

Although the conclusions were admittedly ambiguous,¹⁴⁹ ill-defined,¹⁵⁰ non-scientific and non-reproducible,¹⁵¹ the staggering numbers of allegedly avoidable adverse incidents reported in this article gained the attention of Congress and the Clinton administration, resulting in a call to action based upon these results.¹⁵² The IOM article coined a variety of ambiguous terms, such as “preventable adverse event,” which it defined as a medical error that results in injury.¹⁵³ The article also redefined common terms such as “safety” to mean “freedom from accidental injury.”¹⁵⁴ By creating and redefining key terms and then interpreting data utilizing these new definitions, IOM’s conclusions were severely skewed.¹⁵⁵

to apply to 33.6 million admissions to the entire U.S. population over a period of a single year, 1997. See Harrington, *supra* note 21, at 334; see also *supra* note 121.

¹⁴⁵ *Id.*

¹⁴⁶ Kohn, *supra* note 2, at 35-36; see also Harrington, *supra* note 21, at 331-33, 334-35, 343-45.

¹⁴⁷ *Id.*

¹⁴⁸ Kohn, *supra* note 2, at 53.

¹⁴⁹ *Id.* at 28; see also Harrington, *supra* note 21, at 331-33, 335, 344.

¹⁵⁰ See Kohn, *supra* note 2, at 28.

¹⁵¹ Harrington, *supra* note 21, at 333, 340-45, 363 (noting that the reporting systems’ data reveal substantially fewer numbers at only “slightly more than one percent” of the IOM projected adverse event rate).

¹⁵² *Id.* at 349-50; see also The President’s Health Security Plan: The Complete Draft and Final Reports of the White House Domestic Policy Council, TIMES BOOKS (1993).

¹⁵³ Kohn, *supra* note 2, at 4; Adverse event has multiple definitions. See, e.g., Children’s Mercy Hospitals and Clinics, *What is an adverse event?*, available at <http://www.childrens-mercy.org/stats/definitions/AdverseEvent.htm>. In medicine, examples of an adverse event include such entities as medical errors, unexpected injuries, additional diagnosis, or aggravation of existing conditions. See Harrington, *supra* note 21, at 341-45.

¹⁵⁴ Kohn, *supra* note 2, at 4; safety is commonly defined as “freedom from danger or injury.” THE AM. HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 620, PAPERBACK ED. (1981).

¹⁵⁵ Harrington, *supra* note 21, at 334-35.

Unfortunately, this IOM article has become the basis for the identification and management of the current quality control “crisis.”¹⁵⁶ Consumer groups and other national offices have been established specifically to address “preventable adverse events.”¹⁵⁷ The term has been received with incremental name changes that gradually have come to signify medical error as their sole cause.¹⁵⁸ These same events have been renamed “serious adverse events,” which signifies any event where a patient suffers death or bodily injury while interned in a hospital, and ultimately “never happen events,” which are defined as events that should never happen in the hospital setting.¹⁵⁹ Over time, these adverse events have been collectively redefined as medical error.¹⁶⁰

The Deficit Reduction Act of 2006 established several methods intended to lower the federal deficit and reduce federal spending.¹⁶¹ One of those methods relies on the concept of “preventable adverse events” to redefine the payment system for Medicare and related entities.¹⁶² The Secretary of Health and Human Services is required to select at least two common medical “events” that meet three criteria.¹⁶³ The chosen event must be high cost or high volume, result in assignment of a higher payment for the associated diagnosis-related code (DRG),¹⁶⁴ and represent a

¹⁵⁶ The article is repetitively cited by successive reviews of quality measures and news articles.

¹⁵⁷ Such as The Nat’l Quality Forum (NQF), the Quality Improvement Professional Research Organization, and The Leapfrog Group to name a few.

¹⁵⁸ Harrington, *supra* note 21, at 338-39, 341-42 (addressing hindsight bias where retrospective review of outcome tends to impute presumptive knowledge of causation and exclaiming “Yet, the IOM could not have been naïve as to its choice of the term error, with its pejorative connotation and its potential for misuse by those with a political or economic agenda. Despite the IOM’s focus on system failures, the term error suggests blame.”). *Id.* at 344.

¹⁵⁹ *Id.* at 347-50. Discussion of the progression from simple adverse events to medical errors is a separate topic for later review but reading the successive IOM quality reports and studies that cite these reports is illuminating if not time consuming.

¹⁶⁰ *Id.* at 338-39; *see, e.g.*, Robert Pear, *Clinton to Order Steps to Reduce Medical Mistakes*, N.Y. TIMES, Feb. 22, 2000, at A1 (replacing “adverse events” with the terms “mistakes” and “medical errors”); *see also* Am. Med. Assoc. (AMA) Opinion, *Medicare’s No-Pay Conditions: Not Always Preventable*, AM. MED. NEWS, July 14, 2008, *available at* <http://www.ama-assn.org/amednews/2008/07/14/edsa0714.htm> (last visited Sept. 9, 2008) (recognizing “never events” as a “misnomer that ... creat[e] an unrealistic standard of perfection”).

¹⁶¹ Deficit Reduction Act Pub. L. No. 109-171(s1932), 120 Stat. 4 (2006).

¹⁶² 42 U.S.C.A. § 1395ww(d)(4)(D) (West 2007). Other methods in the Deficit Reduction Act involved direct decrease of payment to hospitals and providers for services.

¹⁶³ *Id.*; The Secretary not only met but also exceeded the Congressional mandate by choosing ten events.

¹⁶⁴ *Id.* The DRG is a coded number assigned to a specific diagnosis ostensibly for billing purposes. MILLER, *supra* note 5, at 506-07. It may be modified by additional codes describing

condition that “could reasonably have been prevented through the application of evidence based guidelines.”¹⁶⁵

Arguably, certain specific events are presumed preventable, such as an unintended foreign body retained after surgery or blood type incompatibility during transfusion.¹⁶⁶ However, most of the listed events are not always reasonably preventable by any measurable standard, and causation is indeterminable or compounded by complexity of existing disease and surrounding circumstances.¹⁶⁷ Thus, physicians and hospitals have decried that the proposed non-payment scheme is fundamentally flawed because eight of the ten triggering events are not preventable by following evidence-based procedures and are intended to hold providers to an unrealistic level of perfection.¹⁶⁸

VI. THE PROPOSED SPENDING SCHEME

The proposed payment schedule that CMS will impose upon the health care system represents a new condition with which hospitals must comply to maintain funding from Medicare programs.¹⁶⁹ This new condition includes denial of payment for medical services if these services are generated by the occurrence of any of the defined preventable adverse events.¹⁷⁰ CMS officials have concluded that refusal of payment is appropriate because these events are considered by Medicare and others to be events that should “never happen” in health care.¹⁷¹

associated circumstances such as adverse events. *Id.* It defines a prospective payment system where payment is determined prior to services rendered. *Id.*

¹⁶⁵ 42 U.S.C. §1395ww(d)(4)(1)(D)(iv). It should be noted that the guidelines require that the event only be “reasonably” preventable which is a subjective and ambiguous term when applied to medical science. Dolinar, *supra* note 56, at 406-07. Nonetheless, the events would be 100% non-payable thus acknowledging by design that the hospital will be denied payment for non-preventable occurrences.

¹⁶⁶ Only in the most emergent of cases where careful preparation is not possible would these events be understandable.

¹⁶⁷ Trapp, *supra* note 136; J. James Rohack, MD, *AMA Disappointed in HHS Decision to Add New Conditions to Hospital No-Pay List*, Statement on Am. Med. Assoc. website, July 31, 2008, available at <http://www.ama-assn.org/ama/pub/category/print/18817.html> (last visited Sept. 9, 2008) (“To be reasonably preventable, there should be solid evidence that by following guidelines, the occurrence of an event can be reduced to zero or near zero”).

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* This condition is imposed along with proposed direct cuts in both hospital and provider reimbursement.

¹⁷⁰ *Id.*

¹⁷¹ *Id.* The implications of naming any event as an “error” or a “never happen” entity are obvious. It is uncertain how these names and views of “preventable” errors will impact the medical malpractice arena. It is probably safe to assume that increased blame followed by increased litigation is inevitable. See Harrington, *supra* note 21, at 343-346, 353-355 (noting the relationship of perceived error to increased litigation and fear of expected litigation as a barrier to reporting). The scheme is likely based upon a theory of contract where a party is not obligated to pay for services that are erroneously performed. Uniform Commercial Code (UCC) §§ 2-314, 2-315 (West 2004) (warranties of merchantability and fitness). However,

The stated purpose for the imposed fee non-payment is two-fold. Medicare officials first claim that the non-payment for identified “never happen” events (hereafter preventable adverse events) will promote accountability and quality.¹⁷² Second, Medicare officials claim that the non-payment measure is a means to improve cost control by not paying for unexpected and preventable medical care.¹⁷³ While this reasoning makes sense in the abstract, its application to real world medical settings raises a number of troublesome issues.

One major issue is whether this new payment scheme is rationally related to the existing goals of quality improvement through increased accountability and cost containment. It has long been established that the federal government, through its designated administrative agencies,¹⁷⁴ has constitutional authority to utilize its spending power to regulate entities of national interest.¹⁷⁵ Health care involves every United States resident regardless of location, age, or nationality. Specifically, care for the elderly, disabled and poor is provided through the actions of the national Social Security programs such as Medicare.¹⁷⁶ Thus, the proposed non-payments may be directly authorized through use of constitutional spending power, but there are certain limits.¹⁷⁷

VII. CONGRESSIONAL POWER TO IMPOSE THE SPENDING SCHEME:

A. Authority

Congress has the authority to officially delegate power to CMS as an administrative agency.¹⁷⁸ CMS exists under the auspices of the Department of Health and Human Services.¹⁷⁹ This department is headed by the Secretary of Health and Human Services, who is appointed by the President and approved by the Senate per Constitutional protocol.¹⁸⁰ Therefore, the power of CMS to enact law is derived directly through the legislature. Congress has authorized the existence of CMS

patient beneficiaries are not merchandise, and needed health care services are not always predictable or preventable.

¹⁷² 42 U.S.C.A. § 1395ww (West 2007) which was entitled *Quality Adjustment in DRG Payments for Certain Hospital Acquired Infections* when it was amended by Pub. L. No. 109-171(s1932), 120 Stat. 4 (West 2006).

¹⁷³ *Id.*

¹⁷⁴ DHHS and CMS.

¹⁷⁵ This power is generally obtained through authority granted in the commerce and spending clauses of the constitution. *See* U.S. Const. art. I, §8, cl. 1 & 3; *see, e.g.*, ERISA, 29 U.S.C. § 1001 (1984) (declaring that benefit plans affect interstate commerce and involve the Federal taxing power).

¹⁷⁶ 42 U.S.C.A. § 1395c (West 2008).

¹⁷⁷ *See infra* notes 178-83.

¹⁷⁸ 42 U.S.C.A. 1395kk (West 2008); *see Am. Med. Assoc.*, 429 F. Supp. at 1193.

¹⁷⁹ *See supra* note 42.

¹⁸⁰ *See supra* note 43.

through its regulation of commerce.¹⁸¹ Through application of the spending power and associated conditions for promised payment, CMS has established the power to regulate and control hospitals within the United States.¹⁸²

B. Restraints

1. Intrinsic

One intrinsic restraint on the authority of CMS to regulate medical care is found in the text of the Medicare Act.¹⁸³ Specifically, the first paragraph of the Act declares that actions of CMS are “not to be construed as practicing medicine.”¹⁸⁴ Nonetheless, the degree of involvement in medical decision-making, as discussed in Section II of this note, strongly suggests that CMS has violated this restraint.¹⁸⁵ The practice of medicine is generally defined by state licensing boards, which determine the scope of permissible practice and discipline for violators.¹⁸⁶ Challenges to this federal restraint have been rejected on the grounds that federal forays into the practice of medicine are justified by the police power to protect the general health and welfare.¹⁸⁷ This makes sense, of course, when federal authority is taking action that in fact protects the public.¹⁸⁸ But as explained throughout this note, the Secretary’s exertion of power in declaring nonpayment for certain adverse effects may severely undermine the public’s interests related to the availability and quality of health care in this country.

2. Extrinsic: Tenth and Fourteenth Amendments; Punishment and Coercion

Federal power to regulate hospitals and the health care system has been challenged through claims of extrinsic restraints such as the Tenth and Fourteenth

¹⁸¹ *Id.*

¹⁸² See Leavitt, *supra* note 75, at 5 (noting CMS’ aim to “[p]lay in a way that expresses our commitment to supporting providers and practitioners for doing the right thing,” and to “become an active partner in driving the creation and use of evidence about the effectiveness of healthcare technologies ... to help doctors and patients use the treatments we pay for more effectively”).

¹⁸³ 42 U.S.C. § 1395 (1965).

¹⁸⁴ *Id.*

¹⁸⁵ See *supra* notes 75, 182.

¹⁸⁶ *Collins v. State of Texas*, 223 U.S. 288, 288 (1912) (finding osteopathic physicians subject to licensing provisions).

¹⁸⁷ See, e.g., *Gonzales v. Oregon*, 546 U.S. 243 (2006) (finding that physicians who medically assist terminally ill patients to suicide is unlawful even though state act authorized the process).

¹⁸⁸ Obvious examples would include traffic regulations, and the prevention of crime or fire.

Amendments.¹⁸⁹ These challenges have sought to retain the sovereignty of the state police power¹⁹⁰ and suggest private individual resistance to increased taxation.¹⁹¹

In general, challenges to CMS decisions based on Fourteenth Amendment Procedural Due Process violations have proven unsuccessful because notice and hearing opportunities are preserved.¹⁹² However, the fairness and objectivity of these processes has been questioned.¹⁹³

Other extrinsic restraints on the power of the federal government to regulate hospitals involve limiting Congressional power when it reaches the level of coercion or punishment.¹⁹⁴ The Supreme Court has held that government agencies may not use constitutional authority to coerce implementation of programs when those programs are purely punitive¹⁹⁵ or do not have a rational relationship to the specified governmental interest.¹⁹⁶ However, the line between coercion and induced cooperation is vague.¹⁹⁷ Although the Court specifically held in *United States v.*

¹⁸⁹ See *infra* notes 190, 193.

¹⁹⁰ In one such Tenth Amendment challenge, *West Virginia v. United States Dept. of Health & Human Serv.*, 289 F.3d 281 (2002) (rejecting a Tenth amendment challenge to a condition of participation that required states to use their police power to recover Medicaid funds from estates of deceased individuals).

¹⁹¹ *Helvering v. Davis*, 301 U.S. 619, 645 (1937) (ruling against a Tenth amendment challenge to the Social Security Act that was brought by a company share holder in an attempt to invalidate the imposed tax on employers to help fund the program. The Court held that Congress could utilize its spending power to favor the general welfare at the expense of states and citizens).

¹⁹² Administrative Procedure Act, 5 U.S.C.A. § 702 (West 2008). In general, administrative law applies where the “rules themselves provide adequate notice of regulatory requirements.” Charles H. Koch, Jr., *Procedural Due Process*, 1 ADMIN. L. & PRAC. § 2.20, [3] ¶ 3 (2007).

¹⁹³ See, e.g., *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 101, 104 (1994) (finding that the Secretary for DHHS could impose conditions of participation that require hospitals to apply generally accepted accounting principles but the DHHS need not apply these same principles when calculating hospital loss).

¹⁹⁴ *United States v. Butler*, 297 U.S. 1, 68-71 (1935). The Supreme Court has held that the spending power of Congress may not be used solely for coercive or punitive purposes but must be rationally related to promotion of the general welfare. Even the dissent, written by Justice Stone agreed that “the threat of loss, not hope of gain, is the essence of coercion.” *Id.* at 81. Therefore, in view of the strong need for cost controls, and the unequal distribution of power in negotiation (government v. Hospital or provider) this condition truly represents a form of coercion. Coercion is defined as “[c]ompulsion by force” or “[c]onduct that constitutes the improper use of economic power to compel another to submit to the wishes of one who wields it. BLACK’S LAW DICTIONARY 110 (3d POCKET ED. 1996).

¹⁹⁵ *Butler*, 297 U.S. at 72.

¹⁹⁶ *Id.* at 73. Justice Roberts states that “[t]he power to confer or withhold unlimited benefits is the power to coerce or destroy. [Thus, for] coercion by economic pressure [t]he asserted choice is illusory.” *Id.* at 71.

¹⁹⁷ See *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (upholding a federal condition to funding for state roads only if states cooperated by imposing alcohol restrictions upon minor

Butler that a choice between cooperation and survival represents coercion, subsequent Court decisions have not uniformly reached that conclusion.¹⁹⁸

This dilemma is most evident in the realm of education. The dependence of educational institutions upon federal financial aid is proven by the paucity of independent institutions that are able to survive without it.¹⁹⁹ However, acceptance of federal financial aid necessarily includes acceptance of a wide range of federal regulations that tend to make the federal government an active manager in school operations.²⁰⁰

The analogy between private institutions of higher education and America's hospital system is clear, because the majority of hospitals are dependent upon federal funds for survival, as are the majority of institutions of higher learning.²⁰¹ Federal regulation of both private and public schools has led to federal control of education through conditioned acceptance of necessary funds.²⁰² Similarly, federal regulation of hospitals leads to federal control over health care through conditioned funds.²⁰³ As the Court in *Fullilove v. Klutznick* declared, "[t]his court has repeatedly upheld against constitutional challenge the use of [conditioned funds] technique to induce [local and state] governments and private parties to cooperate voluntarily with federal policy."²⁰⁴ Nonetheless, the Court has subsequently mandated that conditions attached by Congress to receipt of federal funds must bear some relationship to the purpose of federal spending as a minimum scrutiny review.²⁰⁵ Therefore, the Congressional power of regulation as presented through CMS must have some

and adult individuals under the age of twenty-one whether they used the roads or not). This case highlights the power of the federal government to directly evade the voting power of the adult citizenry by subverting state power through financial inducement. The Court did apply a three part test to determine whether the federal government could impose this condition upon a state but it did not give the same test to the individual citizen who would ultimately be affected by the condition. *Id.*

¹⁹⁸ *United States v. Butler*, 297 U.S. 1, 68-71 (1935); *see, e.g., Fullilove v. Klutznick*, 448 U.S. 448 (1980) (finding constitutional use of Congressional spending power as a means to uphold The Public Works Employment Act of 1977 that required a percentage of minority workers).

¹⁹⁹ *See, e.g., Nat'l Ass'n of Indep. Sch. (NAIS), School Facts at a Glance* (2001-2007), http://www.nais.org/files/PDFs/NAIS_Facts_at_a_Glance_2001-2002.pdf (noting only 990-1145 schools nationwide).

²⁰⁰ *See, e.g., Regents of the Univ. of Cal. v. Bakke*, 438 U.S. 265 (1978); *Runyon v. McCrary*, 427 U.S. 160 (1976).

²⁰¹ Dolinar, *supra* note 56, at 406.

²⁰² Eugene Hickok, Ph.D. & Matthew Ladner, No. 2074 Backgrounder (Heritage Found. Wash., D.C.), June 27, 2007, at 2 (*citing* Barry Goldwater, *Conscience of a Conservative: Some Notes on Education*, 77-81 (1960)).

²⁰³ Dolinar, *supra* note 56, at 398, 403.

²⁰⁴ *Fullilove*, 448 U.S. at 474.

²⁰⁵ *See, e.g., New York v. United States* 505 U.S. 144, 166 (1992); *Nevada v. Skinner*, 884 F.2d 445, 447 (9th Cir. 1989).

rational relationship to the purpose of CMS, which is to provide medical coverage to the beneficiaries of the program.²⁰⁶

VIII. RATIONAL RELATIONSHIP OF NON-PAYMENT AS A MEANS TO QUALITY AND COST GOALS

A. *Is the Payment Scheme Rationally Related to Quality Promotion?*

It is highly speculative whether a scheme that denies payment of specific frequent and costly adverse events is rationally related to the stated goals of quality improvement and cost control. At first blush, the payment scheme appears to be related to quality control because only adverse events that reduce quality are affected.²⁰⁷ The refusal of payment for these events also appears to be rational because punishment for wrongful events represents a well-recognized method of inducing behavioral change.²⁰⁸ Thus, by punishing a hospital for undesirable adverse events, Medicare will arguably induce the hospital to avoid the occurrence of these events.²⁰⁹

Upon further reflection, however, the proposed non-payment is not rationally related to the goal of quality control for at least five reasons. First, the health system, including hospitals, has been radically changing its response to preventable adverse events since the IOM study brought the issue to light in 1995.²¹⁰ Many changes regarding compilation of data and reporting of events have resulted in on-going improvements.²¹¹ However, these improvements are limited by the costs of some procedures, such as increased number and training of staff, or costly investments in

²⁰⁶ *Guernsey*, 514 U.S. at 112-13 (finding that the “purpose of Medicare reimbursement [is] to provide payment of the necessary costs of efficient delivery of covered services to Medicare beneficiaries.”); *but see* *Bowen v. Am. Hosp. Assoc.*, 476 U.S. 610, 626-27 (1986) (finding that administrative agencies enjoy a “presumptive regularity” where that is not equivalent to minimum rationality under due process analysis).

²⁰⁷ 42 U.S.C.A. § 1395ww (West 2008).

²⁰⁸ *See* William M. Sage, *The Role of Medicare in Medical Malpractice Reform*, 9 J. HEALTH CARE L. & POL’Y 217, 224 (2007) (describing the impact of conditional spending penalties as a means to promote quality in healthcare); *see also* Christopher, *supra* note 17 (describing punishment theories of consequentialism and retributivism as avenues to induce change).

²⁰⁹ Sage, *supra* note 208, at 224.

²¹⁰ *See, e.g.*, Kevin O’Reilly, *Medicare’s No-Pay Events: Coping with the Complications*, AM. MED. NEWS (July 14, 2008), available at http://www.ama-assn.org/amednews/2008/07/14/prsa_0714.htm (noting the costly measures employed to successfully decrease pressure sore incidence including special mattress purchases, increased nursing protocols) (last visited Sept. 9, 2008); *see generally* American Hospital Association, www.aha.org. (detailing the American Hospital Association’s quality reform initiatives) (last visited Sept 9, 2008).

²¹¹ *See generally* Inst. of Med. (IOM), at <http://www.iom.edu/> (last visited Jan. 1, 2007); *see also* Nat’l Quality Forum (NQF), <http://www.qualityforum.org/> (providing examples of quality data and reports) (last visited Jan. 1, 2007).

modern computerized reporting systems.²¹² Therefore, punishing an entity, such as a hospital that is already striving to improve quality within real limits of cost and personnel, is not rational because the punishment will not cause the improvements to occur faster and may compound the difficulty in improving quality, especially for those institutions that are already struggling financially.

Second, the measures that are cited as adverse preventable events are neither well defined nor entirely preventable, as discussed above.²¹³ It is difficult to imagine how 100% punishment for prevention of events that are less than 100% preventable will improve quality.²¹⁴

Third, punitive measures already exist for preventable adverse events and they provide strong incentives for health care providers to monitor quality of care.²¹⁵ These measures include the court system.²¹⁶ Medical malpractice is well-established in the United States as a deterrent to wrongful actions and has produced significant economic compensation for many wrongly injured patients.²¹⁷ The malpractice

²¹² Samantha Chao, *Advancing Quality Improvement Research: Challenges & Opportunities-Workshop*, 27-36 (2007), available at <http://www.iom.edu/CMS/3809/38607/43175.aspx>; see also Inst. of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) available at <http://www.iom.edu/CMS/8089/5432.aspx> (describing the need for changes throughout the hospital system in order to improve quality).

²¹³ See *supra* notes 148-50. For example, surgical site infections are never completely avoidable even when performed in an ultra-clean operating room because complete sterility of the room is impossible. See Ronald K. Woods, M.D., Ph.D. & E. Patchen Dellinger, M.D., *Current Guidelines for Antibiotic Prophylaxis of Surgical Wounds*, 57/11 Am. Family Physician 2731, 2733 (1998), available at <http://www.aafp.org/afp/980600ap/woods.html> (noting wound cleanliness classifications). Also, many surgeries are performed on contaminated organs such as bowel or vagina. *Id.* at 2735-36. No matter how much disinfectant or antibiotics are used, these areas are rarely able to be sterilized and, therefore, a certain number of infections are normally anticipated. *Id.*

²¹⁴ Especially because hospital and providers have both noted that fears of punishment for unfavorable results has been a constant barrier to compilation of quality reports. See Chao, *supra* note 212, at 27-36.

²¹⁵ See Janet Rae Brooks, *US Legislatures Drive Accountability Measures*, 178(6) CMAJ 671, 671-72 (2008), available at <http://www.cmaj.ca/cgi/content/full/178/6/671?ck=nck> (noting that state legislatures through state medical boards and malpractice litigation are powerful accountability agents).

²¹⁶ *Id.*

²¹⁷ Many would argue that the Malpractice system is broken because it does not provide adequate legal redress for many injured beneficiaries. See Kohn, *supra* note 2, at 110 (“Liability is part of the system of accountability and serves a legitimate role in holding people responsible for their actions.”). However, this non-payment scheme would harm the beneficiary in two ways. First, the scheme is designed to ensure that Medicare receives damage payment before the injured beneficiary by simply refusing to pay for services rendered. 42 U.S.C.A. § 1395ww (West 2008). Second, this scheme effectively places the beneficiary in an even more vulnerable legal position by removing the powerful insurance company as a possible third-party to malpractice claims and placing the full cost of litigation upon the single injured individual. The Malpractice system may be broken but reforms are in progress and it is the best system available to the beneficiary. See generally David A. Hyman

system functions so well for this purpose that fear of litigation has been declared a primary cause of increased costs associated with health care and malpractice insurance.²¹⁸ Further economic punishment for events that were in fact avoidable further drains the limited economic resources available to hospitals to improve health care for all patients and is, therefore, not rational.

Fourth, the plan to refuse payment for services already rendered for unspecified lengths of time would ultimately be deleterious to the health system. The ubiquitous and often crushing financial burden that hospitals bear for providing uncompensated services has resulted in hospital closings, consolidations, and limitations of offered services.²¹⁹ As the number of non-paying patients and inadequately compensated services increases, this burden will only worsen.²²⁰ Therefore, creating another category of uncompensated service that is recognized as being both frequent and costly, will only add to this burden. Thus, further burdening the health care system by refusing payment for needed services at a time when the financial costs are critical and out of control is not rational.

Lastly, the plan to refuse payment for needed services that are required because of specified preventable adverse events is ultimately deleterious to the primary beneficiaries. By refusing to pay for needed medical services, Medicare has recreated the conditions that spurred implementation of the Medicare programs.²²¹ The beneficiary becomes an indigent, non-funded patient who requires free care.²²² Therefore, because the hospital is responsible for providing care at its own expense, it is likely that it will choose the least costly method that accomplishes the needed service. Thus, the patient beneficiary loses choice of treatment options and is not

& Charles Silver, *Medical Malpractice Litigation & Tort Reform: It's the Incentives, Stupid*, 59 VAND. L. REV. 1085, 1086 (2006).

The proposed non-payment scheme reveals self-interest for recovery of money damages at the expense of the beneficiary.

²¹⁸ Chao, *supra* note 212, at 27-36; *see also* Harrington, *supra* note 21, at 353-54.

²¹⁹ *See, e.g.*, Lebedinski, *supra* note 81, at 155; DHHS, Health Res. & Serv. Admin., *The Office of Rural Health Policy Celebrates 20 Years: A Look Back at the History of the Office & its Cont. Mission to Improve Health Care in Rural Am.*, (2007) (noting 400 hospital closings from 1983-87), available at <http://ruralhealth.hrsa.gov/pub/historyofORHP.htm>; Tim Bonfield, *Ohio Hospitals Face Stress: Closings Raise Fears about Quality*, THE CINCINNATI ENQUIRER, 01A, August 20, 2000, available at http://www.enquirer.com/editions/2000/08/20/loc_ohio_hospitals_face.html.

²²⁰ Hospitals are prohibited from refusing care to patients based on their ability to pay. *See* Rawlings, *supra* note 64, at 295.

²²¹ 42 U.S.C. § 1395 (1965).

²²² Moreover, Medicare specifically prevents the hospital from billing the patient beneficiary for services rendered when those services are related to the preventable adverse event. 42 U.S.C.A. § 1395cc(a)(1)(A) (West 2008). The hospital then is effectively providing these services for free. However, it is not clear how long this free service must be provided and whether other related entities such as providers, laboratories, other ancillary services and follow-up care are also affected. Furthermore, resulting issues of reimbursement for follow-up care needed at other facilities is in question such as other hospitals, providers or even rehabilitation or long term care facilities.

even permitted to offer to negotiate or pay for upgraded services.²²³ The payment scheme is not rational because it will ultimately harm the beneficiary and subvert the primary purpose of Medicare.

B. Is the Payment Scheme Rationally Related to Cost Savings?

Medicare officials' determination to tie non-payment with outcome by refusing to pay for certain adverse events appears to be rationally related to its goal of cost control because the retained funds theoretically become available to cover other services. However, this non-payment scheme is ultimately not rational because it will inevitably result in increased cost. Like the issues related to the purported increase in quality of health care, there are many reasons to doubt that the nonpayment system will realize actual savings.

First, the proposed plan will induce increased diagnostic tests.²²⁴ One of the criteria for inclusion in the non-payment scheme is that the adverse event is preventable.²²⁵ Therefore, if the diagnosis, such as an infection, is present upon admission, the resultant event of infection may be considered to be pre-existing and hence reimbursable.²²⁶ If not identified upon admission, however, the treatment necessitated by an infection discovered subsequent to admission may be construed by Medicare officials as a preventable adverse event, and hence not reimbursable.²²⁷ Hospital officials have already declared that they will be screening each admission for pre-existing conditions, and will then be able to appropriately expect reimbursement for the condition if it worsens during the hospital stay.²²⁸ These screening tests frequently involve invasive procedures such as blood tests or swabs of painful wounds or personal body parts.²²⁹ Hospital officials will, of course, appropriately bill Medicare for this admission testing.²³⁰ Therefore, the decision to

²²³ See 42 U.S.C.A. § 1395a (West 2008); *United Seniors Assoc. v. Shalala*, 2 F. Supp. 2d 39, 41-43 (1998) (finding that Medicare beneficiaries had no free choice of providers and upholding § 4507 of the 1997 Balanced Budget Act that prohibited any physician who participates in negotiation with a beneficiary outside of Medicare, agrees to forego receiving Medicare reimbursement for two years).

²²⁴ The practice of defensive medicine where additional tests are performed is recognized as a means to defend or prevent malpractice claims. HOGUE, *supra* note 3, at 313.

²²⁵ See *supra* note 167.

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ See *supra* note 165; see also O'Reilly, *supra* note 210, at *3 (noting that many hospitals are increasing energy and cost to obtain documentation for pre-existing conditions as a protective measure against the payment scheme).

²²⁹ Blood tests are invasive because they necessarily require needle sticks while swabs of wounds are generally painful or require cavity invasion. Urine production is not always possible on admission therefore catheterization to obtain the specimen is not only invasive but also another risk for infection.

²³⁰ 42 C.F.R. § 412.2(c)(5) (1994); see, e.g., Victoria Stagg Elliott, *Rapid MRSA test gets FDA OK*, AM. MED. NEWS (Jan. 28, 2008), available at <http://www.ama-assn.org/amed/news/2008/01/28/hlsb0128.htm> (noting the anticipated approval for new technology that will

refuse to pay based on outcomes is not rational because it will increase preventative and diagnostic costs and unnecessary procedures for its beneficiaries.

Second, Medicare will directly increase administrative costs to implement the refusal of payment for rendered services.²³¹ The scheme will require increased review of discharge records and increased defense of payment refusals. Certainly, the increased revision of records will require greater time and effort. Also, hospitals will challenge these non-payments frequently, especially when there is ambiguity regarding cause or pre-existence of the event.²³² Therefore, Medicare is actually increasing its administrative costs, as well as that of hospital administrators, by refusing payment thus representing an irrational cost control measure.

Third, an increase in civil liability based on refused payment for recognized needed and many times emergent services may result.²³³ In recent years, the courts have permitted litigation against insurance companies and found civil liability when the companies wrongfully refuse to pay for medically indicated services.²³⁴ By refusing to pay for these services, patient care may be compromised because of cost, patient choice of therapy will be decreased because of cost and further injury may result thereby costing even more. Therefore, the proposed payment plan is not rational because Medicare will be increasing its liability to providers and patients, such that defense and litigation resulting from this liability will ultimately increase costs.²³⁵

quickly and accurately test for infection upon admission). It not hard to see that this test would be easily applied to every likely patient upon admission as a way to detect pre-existing carrier status.

²³¹ This result is completely expected because no program of this nature may be enforced without review for compliance and associated costs. One need only note the creation and funding of the QIO which exists to “encourage” quality improvements. *See* Leavitt, *supra* note 75, at 4. The government also funds reviews of the QIO that evaluate whether the program is accomplishing its mission. *Id.*

²³² Hospitals have recently been awarded \$666 million in settlement for wrongful reimbursement policies. *See* Heather Won Tesoriero, *Hospitals Get \$666 Million from Medicare Settlement*, WALL STREET JOURNAL, March 13, 2008, at B7. Medicare claims an exposure cost of \$2.8 billion. *Id.* The hospitals had to sue twice over nearly 30 years in order to receive payments legally due them. *Id.*; *see* *In re. Medicare Reimbursement Litigation*, 414 F.3d 7 (D.C. Cir. 2005), *cert. denied* 547 U.S. 1054 (2006); *see also* *Cabell Huntington Hosp., Inc. v. Shalala*, 101 F.3d 984 (4th Cir. 1996).

²³³ Judicial review of Medicare prospective pay determinations is prohibited by statute. 42 U.S.C. § 1395ww(d)(7) (West 2007). CMS also isolates its decisions from review by requiring that administrative remedies be exhausted prior to court appeal. MILLER, *supra* note 5, at 510. However, the Supreme Court refuses to review Medicare cost report validity. *See* *Your Home Visiting Nurse Serv., Inc. v. Shalala*, 525 U.S. 449 (1999).

²³⁴ Griner, *supra* note 113, at 896; *but see* MILLER, *supra* note 5, at 583-85 (discussing current debate and variable decisions regarding liability of third-party payers).

²³⁵ *See supra* notes 233-34. This is also because civil rights groups have utilized the legal system as a means to force governmental change. *See generally* Batchis, *supra* note 6. Therefore, it is not unforeseeable that beneficiaries may seek to sue providers as a means to facilitate a change in CMS policies. *Id.* More likely, the federal government will immunize itself from civil lawsuits that result from its Medicare reimbursement decisions thereby

Fourth, CMS officials contend that the proposed non-payment is required because of an emergent need for cost control within the national Medicare system that specifically chooses adverse events that represent significant cost.²³⁶ CMS officials cite the amount it spent on these occurrences, implying that this amount would be the savings to Medicare when the non-payment measures are employed.²³⁷ However, CMS officials neglect to mention that subrogation of funds for some serious adverse negligent events is accomplished through malpractice awards.²³⁸ Therefore, the actual loss to Medicare for these litigated events in terms of billing and legal expenses is unknown and possibly small. Furthermore, if no liability is found the hospital should conceivably be permitted to receive payment for its services. Theoretically, the only events that would not involve entitled reimbursement through litigation would be those that are not negligent and therefore not malpractice.²³⁹ The problem with the proposed non-payment scheme arises because Medicare chooses to bypass litigation and constitutionally guaranteed rights of Due Process by unilaterally subjecting the health care party to punishment for ambiguous adverse events that Medicare defines to be *per se* medical errors.²⁴⁰ Therefore, claiming a cost savings for reimbursed expenses is not rational.

Fifth, the federal government already is required to provide emergency grants and tax relief to hospitals that are financially burdened to offset debt created by under-payments and required provision of uncompensated services to community indigent patients as charity care.²⁴¹ By refusing to pay for more services, Medicare has contributed to this crisis.²⁴² Therefore, costs will ultimately be increased indirectly because this uncompensated care will fall within the reported hospital

creating a program that is unaccountable to those it affects: providers and beneficiaries. Restatement (Second) of Torts § 895D(2) (1979).

²³⁶ 42 U.S.C.A. § 1395ww(d)(4)(D) (West 2008).

²³⁷ See O'Reilly, *supra* note 210, at *4 (anticipating a savings of \$22 billion in 2007 for non-payment of eight adverse events); see also *supra* note 133.

²³⁸ Guillermo Gabriel Zorogastua, *Improperly Divorced from Its Roots: The Rationales of the Collateral Source Rule and Their Implications for Medicare and Medicaid Write-Offs*, 55 U. OF KAN. L. REV. 463, 469-70 (2007).

²³⁹ This theory is derived from the recognized purpose for medical malpractice litigation where punishment is imposed for wrongful, negligent actions by providers but avoided for reasonable care. See generally Hyman, *supra* note 217.

²⁴⁰ See Harrington, *supra* note 21, at 343, 351 (noting that the adverse event occurrence would be classified as an error despite lack of determination of causation). Logically, this scheme would encourage beneficiary litigation against providers even though the risk (e.g. a surgical infection) was explained before surgery and is a common complication that is not always avoidable simply because Medicare has informed the patient that a medical "error" with monetary value has occurred.

²⁴¹ See, e.g., Cecilia M. Jardon McGregor, *The Community Benefit Standard for Non-Profit Hospitals: Which Community, and for Whose Benefit?* 23 J. CONTEMP. HEALTH L. & POL'Y 302, 312, 325-26 (2007) (discussing the favorable tax exemptions for charity write-offs and Medicare reimbursement for bad debt deductibles)

²⁴² *Id.*

charity or bad debt claims and will increase the federal subsidy requirement.²⁴³ In short, the government may just be shifting the cost of this care from one federal account to another, rather than avoiding it altogether.

Sixth, cost will be incurred because beneficiaries who are faced with a designated adverse event would effectively join the ranks of the underinsured, facing non-payment for pre-existing conditions.²⁴⁴ This problem is exacerbated because hospitals are not allowed to bill patients for needed services related to this allegedly preventable condition, and thus the hospital will not even realize partial recovery of the imposed loss.²⁴⁵ This possibility greatly weakens the patient and empowers the hospital.²⁴⁶ Involved health care entities could dictate care based upon minimal affordability for an acceptable outcome whereby patients would lose all power to negotiate for alternative care options.²⁴⁷ Because the health care provider knows that Medicare will not reimburse for the care of a person suffering from the allegedly preventable condition, the beneficiary will effectively revert to the pre-Medicare insurance status.²⁴⁸ The patient may be shuffled between facilities in an effort to share the burden, be given only minimal care, or simply choose to avoid care to avoid the resultant confusion.²⁴⁹ Therefore, the proposed payment scheme is irrational because it defeats the primary purpose of Medicare by placing the beneficiary in the same or worse position than had Medicare never come into existence.²⁵⁰

IX. CONSEQUENCES: SETTING A NEW PRECEDENT?

It is well-recognized that federal legislation causes many unintended consequences for hospitals and providers, beneficiaries, and for third-party payors.²⁵¹

²⁴³ *Id.*

²⁴⁴ *See, e.g.,* Crossley, *supra* note 13, at 76.

²⁴⁵ *See supra* note 79.

²⁴⁶ Ironically this is one rationale for creating Medicare originally. *See* Brief Summaries of Medicare and Medicaid, *supra* note 1.

²⁴⁷ Furthermore, because Medicare has not defined its payment policies regarding care for these events as provided by other hospitals, nor for how long this non-payment penalty will be imposed if chronicity develops. The patient beneficiary and future hospitals will remain with uncertainty as to which services will be paid such as for a later presenting adverse event that is only recognized when the patient is admitted to another facility. Which facility will Medicare not pay, the hospital where the event occurred or the one who is billing and treating? Would one hospital be forced to repay the other? Would the hospital where the adverse event occurred be forced to sustain losses for subsequent admissions? Outpatient care? Home health care? How long? How much? How many?

²⁴⁸ *See, e.g.,* Crossley, *supra* note 13, at 76.

²⁴⁹ *Id.* at 146 (noting cost conscious care decisions would likely pre-empt cost effective ones).

²⁵⁰ *See supra* Part II.B.

²⁵¹ *See, e.g.,* Clark C. Havighurst, *Am. Health Care & the Law-We Need to Talk!*, 19(4) HEALTH AFFAIRS 84-106 (2000), available at http://www.medscape.com/viewarticle/409824_print.

The consequences of refusal to pay for services rendered based upon a hindsight determination of cause will likely be considerable.²⁵²

Consider the elderly beneficiary who falls at a hospital and suffers a hip fracture. The fall may be due to any number of reasons including hospital negligence, such a liquid spill on the floor, well intended but ultimately disastrous efforts by a friend or relative to “help” the patient, or patient noncompliance with a doctor’s order to remain in bed who willfully neglects to call for assistance. Regardless of the cause, this injury requires additional medical intervention.²⁵³

According to the proposed CMS payment scheme, the additional medical care required will be non-reimbursable.²⁵⁴ Therefore, despite the serious injury, this needed medical care is provided free of charge at the hospital’s expense.²⁵⁵

The care would be free because hospitals generally provide needed care to an injured patient regardless of whether they are paid for these services.²⁵⁶ That is what hospitals and doctors do for a living; they provide care to injured people whom they call patients.²⁵⁷ Aside from the recognized professional duty to care for a patient regardless of pay status,²⁵⁸ hospitals as business entities are statutorily prevented from refusing care to patients once they are admitted to the hospital.²⁵⁹ Therefore, the patient beneficiary will receive medical care for the injury regardless of cause or pay status.

Problems arise when these needed services are refused payment. CMS officials admit that the never happen events were chosen as events worthy of non-payment because of their high frequency of occurrence and large cost.²⁶⁰ These events, including patient falls, may improve with preventative measures but they will not cease because preventative measures do not prevent 100% of falls.²⁶¹ That is why many falls are also sometimes considered to be unavoidable accidents.²⁶² Therefore,

²⁵² See Harrington, *supra* note 21, at 338-39.

²⁵³ Medical intervention may include procedures, such as imaging x-rays, MRI or CAT scans, physician orthopedic consultation, possible surgical correction, increased nursing care, additional medications, and a prolonged hospital stay with physical therapy after admission, and so on.

²⁵⁴ 42 U.S.C.A. § 1395ww(d)(4)(D) (West 2008).

²⁵⁵ See *supra* note 222.

²⁵⁶ *Id.*; Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. 1395dd(a) (2003).

²⁵⁷ See James Gaulte, *Retired Doc’s Thoughts: Physician Fiduciary Duty – A Thing of the Past?*, <http://mdredux.blogspot.com/2007/06/physician-fiduciary-duty-thing-of-past.html> (August 8, 2007) (describing the widely recognized fiduciary duty to treat).

²⁵⁸ See MILLER, *supra* note 5, at 280-302.

²⁵⁹ EMTALA, 42 U.S.C. 1395dd(a) (2003).

²⁶⁰ 42 U.S.C.A. § 1395ww(d)(4)(D) (West 2007).

²⁶¹ See, e.g. Richard W. Sattin et al., *The Incidence of Fall Injury Events Among the Elderly in a Defined Population*, 131-6 AM. J. EPIDEMIOLOGY 1028 (1990).

²⁶² *Id.*

patient falls will occur. Study of these events, including their root cause,²⁶³ is currently under way.²⁶⁴ However, the data of quality assessments throughout the United States has barely begun to be systematically gathered, much less comprehensively and competently analyzed.²⁶⁵ Therefore, CMS officials are categorically refusing to pay for events that include some unavoidable accidents, preferring to shift this financial burden to hospitals.²⁶⁶

The consequences of this cost shift could be enormous. Hospitals, especially those that provide indigent care or rely upon minimally-reimbursed public insurances such as Medicare and Medicaid, are already struggling to survive.²⁶⁷ In the broken hip scenario described previously, the cost of expensive surgery and prolonged rehabilitative care may well exceed any reimbursable expense related to the initial cause for admission.²⁶⁸ The hospital will in effect be providing free services to the patient at its own expense.²⁶⁹ Therefore, the proposed non-payment scheme will only further jeopardize the financial stability of these institutions.²⁷⁰

The anticipated consequences to the beneficiary are likewise considerable. The beneficiary is effectively reduced to an indigent status.²⁷¹ The greatest impact of this reduction in status to the beneficiary will be upon choice.²⁷² The hospital is required to provide adequate services at its expense, but it is not obligated to provide a choice

²⁶³ “A root cause of a consequence is any basic underlying cause that was not in turn caused by more important underlying causes.” SIX SIGMA DICTIONARY (2005), available at http://www.isixsigma.com/dictionary/Root_Cause-61.htm.

²⁶⁴ See, e.g. The Nat’l Quality Forum (NQF), available at <http://www.qualityforum.org/>, and The Leapfrog Group, available at <http://www.leapfroggroup.org/>, which are both performing health care quality data compilation and analysis.

²⁶⁵ See QIO, *supra* note 71, at 10 (noting that standardization of reported data is still problematic); Harrington, *supra* note 21, at 366 (noting that data collected via state reporting systems is “plagued by inconsistent, vague and cumbersome reporting formats).

²⁶⁶ See generally, Trapp, *supra* note 136.

²⁶⁷ Lebedinski, *supra* note 81, at 154-55.

²⁶⁸ See *supra* Part IX.

²⁶⁹ This is especially true because the hospital is specifically prevented from charging the beneficiary as a condition of acceptance. 42 U.S.C.A. § 1395ww(d)(4)(D) (West 2008). Furthermore, hospitals may claim the cost incurred as bad debt and reclaim some funds through tax abatement. See Lebedinski, *supra* note 81, at 155. Therefore, it can be argued that the cost may simply be shifted to a different federal agency or extra Medigap insurance once debt is acknowledged.

Consider also the fate of the physicians involved. They may also not be paid for their services and expenses. To control these events, hospital privileges may be tied to occurrences or litigation may ensue such that a provider found to be at fault will pay the hospital. Staff discipline may be weighted upon incidence of these events and so on. See generally MILLER, *supra* note 5, at 237-64.

²⁷⁰ See also *supra* Part II.B.

²⁷¹ See *supra* notes 222, 250.

²⁷² See *supra* Part II.B.

among adequate services.²⁷³ Therefore, questions arise regarding whether the patient, who now is classified as a non-payer, will be given any meaningful choice on critical issues such as conservative therapy versus surgery, type or style of medical device used, or length of stay after the unexpected procedure.²⁷⁴ Moreover, the patient beneficiary may also lose the choice of facility. Consider the confusion that would arise if the patient chooses to leave the hospital that caused the injury and decides to seek care at a different facility. Would the new facility then be paid for the services or would it be forced to provide services at its expense? Could the new facility seek payment from the facility charged with the event? If these services are reimbursed at a different facility, then offending hospitals will be encouraged to shift patients to other facilities for prolonged care.²⁷⁵ If the care is not reimbursed, then the patient becomes an undesirable non-paying entity and may be shuffled between facilities to avoid the cost of care.²⁷⁶ Either way, the patient is caught in the middle without the power to choose or to control his or her medical destiny.

CMS officials anticipate that one of the consequences of enacting this non-payment scheme is that other insurance companies will adopt similar non-reimbursement practices for events the companies deem preventable.²⁷⁷ This anticipated consequence is based upon historical evidence that other insurance entities follow Medicare's lead regarding reimbursement methods.²⁷⁸ However, refusal to pay for recognized medically indicated services is not a new theory in the private insurance world.²⁷⁹ Private insurances have long established that costs incurred by pre-existing conditions are not reimbursable by the insurance if they were specifically denied coverage pursuant to the terms of the insurance contract or if the insured did not fully disclose the pre-existing condition.²⁸⁰

²⁷³ Patients in general are due only a standard of care that is reasonable to the patient's condition as defined by malpractice law. See MILLER, *supra* note 5, at 591-92; see e.g., Goodman v. Sullivan, 712 F. Supp. 2d 334 (S.D. N.Y. 1989) (denying payment for an MRI).

²⁷⁴ *Id.*

²⁷⁵ This is akin to patient dumping which EMTALA was designed to prevent, EMTALA, 42 U.S.C. 1395 (2003).

²⁷⁶ *Id.*

²⁷⁷ See Campbell, *supra* note 14.

²⁷⁸ *Id.*

²⁷⁹ See generally Crossley, *supra* note 13 (discussing the effects of risk selection and underwriting as well-recognized and accepted insurance policies to decrease cost).

²⁸⁰ *Id.*; see, e.g., Aetna Small Group Sales, North Central Region, *What You Need to Know About HIPAA & Its Impact on the Availability & Portability of Health Coverage*, Aetna Broker Briefing, (2002), available at http://www.aetna.com/producer/data/Federal_HIPAA_and_Aetna_October_2002_FINAL_DRAFT.pdf (defining preexisting condition as "[a]n illness or injury for which medical advice, diagnosis, care, or treatment was recommended or received during the six-month period immediately prior to the date the member first becomes covered by the plan (i.e., the lookback period), or the six-month period immediately prior to the first day of a required employee waiting period, if any.").

Indeed, refusal to pay for costs incurred by pre-existing medical conditions is a recognized cost control measure well known to the insurance industry.²⁸¹ This measure has resulted in a new class of “under-insured” beneficiaries in the United States as some individuals with serious or chronic diagnoses such as cancer, epilepsy, asthma, or diabetes find themselves with no medical coverage for complications from these serious medical ailments.²⁸² Therefore, if private insurers adopt the CMS non-payment scheme for preventable occurrences, even persons with otherwise comprehensive health coverage will find themselves in the ranks of the uninsured related to treatment of the excluded event.²⁸³

Historically, beneficiaries contract with an insurance entity to obtain medical care for needed unforeseen injuries.²⁸⁴ Beneficiaries do not contract with insurance entities to become an indigent-like patient merely because the insurance decides that the specific injury is an adverse preventable event.²⁸⁵ After all, the beneficiary is the entity most affected, not only by the injury itself but also by the refusal to reimburse. The beneficiary did not contract to become injured or to lose choice of treatments and coverage of that treatment.²⁸⁶ This scenario effectively leaves the vulnerable, privately-insured beneficiary in the middle of provider and payor disagreements.²⁸⁷ Therefore, should the private insurance companies follow Medicare’s lead, which appears quite likely, contractual obligations will likely be challenged or changed to reflect this non-payment scheme.²⁸⁸

Furthermore, Medicare may well be setting a dangerous medical insurance precedent.²⁸⁹ This precedent will allow third-party payors to refuse payment for needed medical services when they deem that injuries have been caused by some preventable event.²⁹⁰ The basic issue then is converted to the need for a clear definition as to what level of prevention is required before an adverse event becomes

²⁸¹ See EMERIC FISHER ET AL., PRINCIPLES OF INSURANCE LAW 839 (Rev. 3d ed. 2006).

²⁸² *Id.* at 148-49.

²⁸³ This would set a new government approved precedent whereby private insurances may refuse to pay for contracted services because of the preventable component of any disease. This practice has been described as discriminatory especially when applied to factors of race, age, sex, genetics, mental illness, and victims of domestic violence. Crossley, *supra* note 13, at 85-107.

²⁸⁴ See Crossley, *supra* note 13, at 78-80 (citing insurance as a risk reduction entity purchased to protect against unpredictable medical risk).

²⁸⁵ HOGUE *supra* note 3, at 305. This is the risk based rationale for insurance in general.

²⁸⁶ *Id.*

²⁸⁷ *Id.* at 122-23 (describing cost-shifting mechanisms to insured employees such that the beneficiary bears a greater responsibility to pay for services).

²⁸⁸ See O’Reilly, *supra* note 14 (noting that the BlueCross BlueShield Assn. is currently phasing in new coding and claims processes to reflect a no-payment regimen for “never events”).

²⁸⁹ See *supra* note 285.

²⁹⁰ See Crossley, *supra* note 13, at 134.

non-reimbursable. Consider the current societal emphasis upon preventive care and lifestyle change.²⁹¹ By refusing to pay for preventable injuries, a medical insurance provider or employer may begin to examine the beneficiary's lifestyle.²⁹² The beneficiary may prevent lung cancer if he or she stops smoking.²⁹³ A beneficiary may prevent incurable breast cancer if she undergoes an annual mammogram.²⁹⁴ Diabetes may be prevented by losing weight,²⁹⁵ and heart disease may be prevented by regular exercise.²⁹⁶ It has been well-recognized that general definitions may be expanded and redefined over time.²⁹⁷ The evolution of the definition of serious adverse events is only one example.

Therefore, it is not inconceivable that refusal to pay for preventable injuries or illnesses of any kind may become common insurance risk-avoidance practice once the precedent is set. Also, this refusal to pay for lifestyle choices may soon be reflected, if not already employed, by large employers who refuse to hire people who smoke or are obese as a means to decrease their medical insurance premiums.²⁹⁸ These actions would effectively shift the high cost of medical care onto the beneficiary, if he or she does not comply with lifestyle requirements that prevent

²⁹¹ See Nat'l Ctr. For Policy Analysis, *supra* note 100.

²⁹² See Crossley, *supra* note 13, at 134 (noting that one rationale for cost-sharing is to "giv[e] Americans incentives ... to take greater personal responsibility for the consequences of their health-related behavior").

²⁹³ DHHS, CENTERS FOR DISEASE CONTROL AND PREVENTION, TARGETING TOBACCO USE: THE NATION'S LEADING CAUSE OF PREVENTABLE DEATH (2008), available at <http://www.cdc.gov/nccdphp/publications/aag/osh.htm>.

²⁹⁴ DHHS, CENTERS FOR DISEASE CONTROL AND PREVENTION, PREVENTING AND CONTROLLING CANCER: THE NATION'S SECOND LEADING CAUSE OF DEATH (2008), available at <http://www.cdc.gov/nccdphp/publications/aag/dcpc.htm>.

²⁹⁵ DHHS, CENTERS FOR DISEASE CONTROL AND PREVENTION, DIABETES: DISABLING DISEASE TO DOUBLE BY 2050 (2008), available at <http://www.cdc.gov/nccdphp/publications/aag/ddt.htm>.

²⁹⁶ DHHS, CENTERS FOR DISEASE CONTROL AND PREVENTION, DIVISION FOR HEART DISEASE AND STROKE PREVENTION: ADDRESSING THE NATION'S LEADING KILLERS (2008), available at <http://www.cdc.gov/nccdphp/publications/AAG/dhdsp.htm>.

²⁹⁷ See, e.g., Shimon Edelman & Bo Pederson, *Linguistic Evolution through Language Acquisition* (2002) (book review), available at <http://www3.isrl.uiuc.edu/~junwang4/langev/localcopy/pdf/edelman04bookreview.pdf>.

²⁹⁸ Employers are already refusing to hire individuals who engage in lifestyle choices that adversely affect their health. Three large employers, The Cleveland Clinic, Scotts Miracle-Gro Company, and Medical Mutual have already proclaimed that they will not hire smokers. *Cleveland Clinic Bans Hiring of Smokers*, COLUMBUS DISPATCH: OHIO'S GREATEST ONLINE NEWSPAPER, June 28, 2007, available at http://www.dispatch.com/live/content/local_news/stories/2007/06/28/clinic_smokers.html?print=yes (last visited Sept. 10, 2008); see also Michael Siegel, *Smokers Deemed Unsuitable for Employment at the Cleveland Clinic*, THE REST OF THE STORY: TOBACCO NEWS ANALYSIS AND COMMENTARY, July 3, 2007, available at <http://tobaccoanalysis.blogspot.com/2007/07/smokers-deemed-unsuitable-for.html> (last visited Sept. 10, 2008).

disease.²⁹⁹ Those costs would eventually be re-shifted to health care providers and possibly back to the federal government.³⁰⁰

The unintended and far reaching consequences of Medicare's new non-payment scheme could negatively affect all citizens of the United States. Not only could the non-payment scheme alter the fundamental nature of medical care reimbursement but also affect lifestyle and fundamental freedom of choice.³⁰¹ The proposed spending scheme may encourage third-party payers to coerce beneficiaries into performance of specified personal actions that are determined to be preventative of disease by way of financial pressure.³⁰² In this manner, the spending power of Congress may influence and be echoed by the spending power of the health insurance industry in general. And all of the issues previously discussed will become even more exaggerated if Medicare officials determine in the future to expand the list of uncovered "avoidable" events.³⁰³

X. THE PUBLICATION DILEMMA: INCREASED QUALITY OR INCREASED COST?

The IOM article has appropriately focused legislators, insurances, hospitals, providers, and beneficiaries upon the issue of quality care in America.³⁰⁴ This focus has spurred efforts by all stakeholders to find improved methods of health care delivery.³⁰⁵ Studies are currently under way that evaluate and quantify the effects of various quality measures such as hand washing, electronic charting, and improved communication between care givers.³⁰⁶ These efforts should identify common areas and cooperative methods of improvement so that serious adverse events are minimized.

Current legislation has mandated that all hospitals and providers submit specific data, including root cause reasons for the occurrence of the preventable adverse events in question, to the newly created Agency for Healthcare Research and Quality (AHRQ).³⁰⁷ Also, various private groups are collecting data and analyzing the

²⁹⁹ See *supra* note 292.

³⁰⁰ This circular theory would be accomplished through charity or bad debt subsidies. See Lebedinski, *supra* note 81, at 155.

³⁰¹ See *supra* note 292.

³⁰² *Id.*

³⁰³ Medicare officials are already considering adding the remaining nine categories noted in Part V. See Part V.; see also Trapp, *supra* note 136.

³⁰⁴ See *supra* Part IV.

³⁰⁵ *Id.*

³⁰⁶ See, e.g., National Quality Forum: Projects, <http://www.qualityforum.org/projects/> (last visited October 30, 2008) (presenting current ongoing projects); see also National Quality Forum, *Safe Practices for Better Healthcare 2006 Update*, (2006), available at http://www.qualityforum.org/publications/reports/safe_practices_2006.asp.

³⁰⁷ See Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001, 120 Stat. 4 (2006); CMS, Nat'l Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8 (July 12,2006); AHRQ, From the Field, Sharing Experience and

results.³⁰⁸ However, to be valid, the data must be uniform and thus comparable.³⁰⁹ So far, difficulty has arisen regarding different methods of reporting, different definitions of reported information, and different methods of analysis.³¹⁰ Despite these inconsistencies, publication of this data is intended and expected.³¹¹

A. How to Use Publicized Quality Data?

One of the most contentious recommendations of the original IOM report regarding serious adverse events is that of mandatory reporting and publication of hospital quality data.³¹² This contention is grounded in the malpractice debate.³¹³ Payors, such as Medicare and private insurance companies, contend that publication of this data will provide valuable insight and tools to improve care of beneficiaries.³¹⁴ Providers, especially physicians, contend that publication of this data will fuel litigation and malpractice claims by spotlighting possible errors.³¹⁵ Both appear to be theoretically correct. The contentious issue is not about how the data is used in the medical community for improved patient care but rather about how the data is used in various legal forums, especially civil courts.³¹⁶

In theory, publication of quality data especially regarding the root cause of serious adverse events should allow better analysis of causation.³¹⁷ This analysis

Findings From AHRQ-Funded Projects, <http://healthit.ahrq.gov/portal/server.pt?open=512&objID=650&PageID=0&parentname=ObjMgr&parentid=106&mode=2&dummy=/index.html> (last visited Nov. 30, 2007).

³⁰⁸ Such as the Leap Frog and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). See Harrington, *supra* note 21, at 355-66 (reviewing various reporting systems).

³⁰⁹ *Id.*; see DAVID LEBLANC, STATISTICS: CONCEPTS AND APPLICATIONS FOR SCIENCE 4-8 (2004) (discussing what constitutes valid data), available at <http://books.google.com/books?id=gtawVU0oZFMc&printsec=frontcover&dq=what+is+valid+data+in+scientific+study#PPR3,M1>.

³¹⁰ See *supra* notes 308-09.

³¹¹ See Leavitt, *supra* note 75, at 14 (noting the QIO's "focus on making publicly available measures of provider performance on its Compare website").

³¹² Kohn, *supra* note 2, at 87-88. The report recommends mandatory reporting for data regarding serious adverse events and voluntary reporting for near miss events.

³¹³ Harrington, *supra* note 21, at 353.

³¹⁴ Kohn, *supra* note 2, at 98; see also Harrington, *supra* note 21, at 351.

³¹⁵ Harrington, *supra* note 21, at 353-54; see, e.g., also Robert Pear, *Experts Cast Doubt on Medical Reporting Plan*, N.Y. TIMES, February 23, 2000, at A12, available at 2006 WLNR 16593293.

³¹⁶ Physicians are also concerned about publication because of reputation damage and threatened job security after adverse publicity. Harrington, *supra* note 21, at 352-55 (noting that even a minor error can jeopardize a physician's career).

³¹⁷ Kohn, *supra* note 2, at 98; see also Joanne Stow, *Using Medical-Error Reporting to Drive Patient Safety Efforts*, 84 ASS'N. OPERATING ROOM NURSES J. 406 (2006), available at 2006 WLNR 16593293.

should suggest ways to improve and further prevent these devastating and tragic events.³¹⁸ Publication would also facilitate discussion between facilities that would permit hospitals to learn from one another's mistakes in a peer review fashion.³¹⁹ However, this altruistic vision would be more believable if access to care and reimbursement were not adversely affected by the cost savings goals associated with the data.³²⁰ Using this public information specifically for cost savings goals allows the data to be used as a weapon in the malpractice arena as a method for third-party payors to claim repayment for treatment associated with possible medical errors.³²¹ This increase in repayment represents a decrease in risk and a one-sided cost savings because the third-party payor would be able to more efficiently avoid loss for payment of unexpected services rendered.³²² In this way, the cost burden of an adverse event is shifted to the provider (or beneficiary) and away from the third-party payor.³²³ Therefore, cost savings by the payor represents cost increase to the provider and is justified by public review of publicized data.³²⁴

An additional cost amplifier is the anticipated increase in litigation expected from review of unqualified data.³²⁵ This increase would likely come from both third-party payors and patients.³²⁶ Publication of unqualified material that suggests the occurrence of a medical error or malpractice will inevitably become fodder for personal injury claims, perhaps even class actions.³²⁷ These cases would only be strengthened by Medicare or other third-party payors' refusal to pay for care that is deemed erroneous in a *per se* fashion and then informing the patient beneficiary of this decision through billing information or quality reporting prior to protest by the hospital.³²⁸ Therefore, wide spread publication of quality data will likely lead to a cost shift where payors further shift the cost burden onto hospitals and providers.

³¹⁸ Kohn, *supra* note 2, at 98; *see also* Stow, *supra* note 317.

³¹⁹ Kohn, *supra* note 2, at 181-82; *see also* AHRQ, *From the Field: Sharing Experience and Findings from AHRQ-Funded Projects*, <http://healthit.ahrq.gov/portal/server.pt?open=512&objID=650&PageID=0&parentname=ObjMgr&parentid=106&mode=2&dummy=/index.html> (last visited Feb. 10, 2008).

³²⁰ *See generally* Crossley, *supra* note 13.

³²¹ Harrington, *supra* note 21, at 353-55. The information is also available for increased risk selection and underwriting practices. *See generally* Crossley, *supra* note 13.

³²² *See* Crossley, *supra* note 13, 75-77.

³²³ *Id.*

³²⁴ *Id.*

³²⁵ Harrington, *supra* note 21, at 343-44; *see also* Pear, *supra* note 316.

³²⁶ *See supra* note 325.

³²⁷ *See supra* note 326; *see generally* Batchis, *supra* note 6 (noting that lawsuits are an acceptable and effective way to change legislative policy and to obtain damages for patients).

³²⁸ *See supra* note 240.

B. Increased Cost with Increased Quality?

Furthermore, improved quality does not necessarily lead to decreased cost.³²⁹ In actuality, improved quality may demand increased cost.³³⁰ The current debate about mandated electronic records is an example.³³¹ CMS officials and private quality groups have all recognized that electronic records would allow faster and more efficient exchange of medical information between hospitals, providers and third-party payors.³³² However, this technology is expensive to implement and confusing to learn, especially when different systems are unable to communicate.³³³ The cost of implementing a nationwide system that functions as a cohesive unit is astronomical.³³⁴

Furthermore, many serious adverse events are determined to be the result of local factors related to poor funding. Understaffed nursing personnel, outdated machinery in the laboratory or imaging departments, and other factors contribute to substandard care.³³⁵ No hospital system desires to be understaffed or outdated.³³⁶ Nonetheless, cost concerns must be addressed and contained if the hospital is to survive.³³⁷ Mandated conditions for reimbursement that require expensive upgrades would burden the struggling hospital on a limited budget and commandeer funding

³²⁹ See, e.g., AHRQ, *Conference on Health Care Data Collection and Reporting: Collecting and Reporting* (2007), available at http://www.amia.org/inside/initiatives/health_data/2007/ahrq_datareport.pdf.

³³⁰ *Id.*

³³¹ President Bush has established a Health Information Technology (HIT) initiative whereby electronic medical records are mandated to be available by 2014. The HIT initiatives are to be administered through DHHS. See United States Dept. of Health and Human Services: Federal Health Architecture (FHA), <http://www.hhs.gov/fedhealtharch/background.html>; see also Cathy Tokarski, *Medical Error-Prevention Strategies Face Barriers to Acceptance*, MEDSCAPE MONEY & MED. (2000), <http://www.ahrq.gov/news/medscap2.htm>.

³³² See generally PAUL SHEKELLE ET AL., COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY: EVIDENCE REPORT/TECHNOLOGY ASSESSMENT NO. 132 (prepared by the Southern California Evidence-based Practice Center under Contract No. 290-02-0003) (2006), available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/hitsyscosts/hitsys.pdf>.

³³³ *Id.* at 57 (listing six challenges of data collection and measurement). Consider the software communication problems between extensive program systems such as Microsoft and MacIntosh.

³³⁴ *Id.* Also consider the many systems already in place that would need to be changed to become compatible with a national system. In general, hospitals and providers are expected to support the cost of implementing these changes.

³³⁵ See, e.g., THE 2007 STATE OF AMERICA'S HOSPITALS-TAKING THE PULSE: FINDINGS FROM THE 2007 AHA SURVEY OF HOSPITAL LEADERS (American Hospital Ass'n 2007), <http://www.aha.org/aha/content/2007/PowerPoint/StateofHospitalsChartPack2007.ppt#404,1>, Slide 1.

³³⁶ See generally *Protecting the Promise* (American Hospital Ass'n 2004), *supra* note 81.

³³⁷ *Id.* at 14.

priorities such as staffing issues.³³⁸ Therefore, if the quality data is used to impose conditional expenditures for technological advancement and conformity, the cost increase may exceed the value of the quality improvement because CMS, as a third-party payor, would likely prioritize hospital budgets.³³⁹

C. Patient Choice Based on Quality Data

Another stated intent of publication of quality data is to allow the patient beneficiary, as a health care consumer, to make informed decisions when choosing between health care facilities.³⁴⁰ However, this stated intention ignores the obvious: health care delivery and consumption are not completely akin to merchandise sales. Health care generally begins with the doctor-patient relationship, not a hospital-patient relationship.³⁴¹ The patient may have no choice as to which facility his or her physician admits patients.³⁴² Therefore, once a disease is identified that requires hospitalization, the patient necessarily attends the hospital where the physician has privileges or the patient must choose another physician and establish another doctor-patient relationship on short notice.³⁴³ It is well-established that the trusted doctor-patient relationship is a powerful entity that drives patient satisfaction, compliance and response to care.³⁴⁴ Therefore, patient choice of facility will truly only be a choice factor if the doctor-patient relationship is voided or physicians are able to admit and service several facilities.³⁴⁵

Patient beneficiaries are further deprived of meaningful health care choices because some insurance companies determine which hospitals they prefer and will maximally reimburse through preferred provider determinations.³⁴⁶ Thus, the

³³⁸ *Id.* at 11 (noting the nursing shortage with 110,000 vacant registered nurse (RN) positions in 2004 and a projected shortage of 800,000 RN's in 1012).

³³⁹ *Id.* at 14 (noting that capital budgeting is necessary in order to balance staffing shortfalls and technical modernization needs required by HIT).

³⁴⁰ See Leavitt, *supra* note 75, at 14 (noting the intent to publicize quality measures to allow "greater transparency of information on quality and cost for consumers...").

³⁴¹ See MILLER, *supra* note 5, at 280-83. Patients such as the uninsured who generally seek medical care through hospital emergency rooms or clinics would form a hospital-patient relationship first.

³⁴² *Id.* at 226 (noting that physicians must apply for and be appointed to a medical staff of hospital).

³⁴³ A patient may obtain a physician through the hospital emergency room where a physician "on call" will be assigned. MILLER, *supra* note 5, at 284-85.

³⁴⁴ See Scott Forehand, *Helping the Medicine Go Down: How a Spoonful of Mediation can Alleviate the Problems of Medical Malpractice Litigation*, 14 OHIO ST. J. ON DISP. RESOL. 907, 920 (1999).

³⁴⁵ If the doctor-patient relationship is valueless, then it would not matter to which hospital a patient is admitted because any suitably knowledgeable physician will suffice. However, the obvious difficulty of physicians who have privileges in multiple hospitals is the limited ability to be physically present at more than one place at a time.

³⁴⁶ See Griner, *supra* note 113, at 872-73.

publicized data may serve the needs of the insurance company as to which hospital organizations to reimburse as “in network” facilities more than it would aid patients who may prefer an “out of network” facility.³⁴⁷

Furthermore, many health emergencies depend upon speed of care as obviated by the existence and use of the ambulance as an emergency vehicle. Ambulance services are generally required by statute to transport patients to the closest facility capable of dealing with the emergent situation.³⁴⁸ These services generally do not show preference based on quality data.³⁴⁹ Therefore, the theory that patient beneficiaries will choose hospital admissions based upon this publicized quality data is not well supported. Rather, this data may encourage physicians and insurance companies to decide for the patient.³⁵⁰ The debate remains as to whether publication of data obtained ostensibly for quality improvement is a useful tool for prevention of adverse events or a weapon destined to be used as a cost shifting measure in the malpractice forum.³⁵¹

XI. GOAL ACCOMPLISHMENT THROUGH COOPERATION, REGULATION AND INFORMATION

Congress should not utilize its spending power through CMS to punish and coerce the hospital system based on non-uniform and poorly defined quality data. Rather, it should encourage cooperation to identify and find a solution to quality and cost issues.³⁵²

Quality improvement and cost control are shared goals of Congress, CMS, and health care providers. However, CMS and hospitals seek to accomplish these goals through different means. CMS tries to force improvement through legislation and resultant regulation while hospitals are focused upon direct interaction with

³⁴⁷ A hospital facility is “in network” if it has signed a reimbursement agreement with an insurance plan such that patient beneficiaries are encouraged to utilize the facility by providing increased coverage or lower fees for service. MILLER, *supra* note 5, at 527.

³⁴⁸ See Robert Steinbuch, *Preventing Under-Equipped Medical Facilities from Killing Heart Attack Patients: Correcting Inefficiencies in the Current Regulatory Paradigm for Providing Critical Health Care Services to Patients with Acute Coronary Syndrome*, 17 HEALTH MATRIX 17 (2007) (noting the current debate between regulations that mandate ambulance transport to the closest facility versus to the most capable facility).

³⁴⁹ *Id.*

³⁵⁰ Batchis, *supra* note 64, at 502. “In reality, patients cannot shop around for the best deal on medical care.” *Id.*

³⁵¹ See, e.g., *id.* at 501.

³⁵² See, e.g., Janet M. Corrigan et al, *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality*, NAT’L ACAD. PRESS 6 (2002), available at http://www.nap.edu/catalog.php?record_id=10537, (recommending that government health care programs establish consistent quality expectations, promote and encourage excellence through reward systems, actively collaborate with each other and the private sector, encourage and enable the consumer, and seek collaborative innovation).

patients.³⁵³ While CMS is able to view the healthcare industry from a vantage that should allow a global understanding, hospitals and providers are understandably enmeshed in the problems of day to day business.³⁵⁴ It is no secret that health care in this country is piecemeal and provides non-uniform care to similarly situated individuals.³⁵⁵ This lack of uniformity persists even though national hospital accreditation and physician certification agencies impose conformity at the cost of facility and practitioner survival.³⁵⁶

Nonetheless, an opportunity now exists where motivation to prevent serious adverse events, however defined, drives compilation of extensive quality related data which heretofore has been carefully guarded.³⁵⁷ Congress, through CMS and the spending power, may provide for focused quality review by encouraging report of quality issues.³⁵⁸ This reporting should not only be biased toward serious adverse events, but also to all adverse events because near miss events may illuminate ways to avoid disastrous outcomes.³⁵⁹

Also, Congress should protect this data from abuse and misuse. This deceptively difficult task must balance the need for open evaluation of the data with the fundamental rights of patient and provider privacy.³⁶⁰ Nonetheless, improved sharing of quality data should be encouraged among the various hospitals and providers to stimulate discussion about complex patient care and unforeseen problems of clinical advancement.

Congress may encourage innovation of new methods of care that improve quality and balance cost. Who better than the people most responsible for these adverse events, such as hospitals, physicians, and their staff, to discover and formulate working solutions to the quality and cost dilemma?³⁶¹

³⁵³ This distinction is notable in the IOM recommendations for QIO where the QIO program is placed in a guidance position for providers who perform the services. *See* Leavitt, *supra* note 75, at 3, 5.

³⁵⁴ *See* Huntoon, *supra* note 56, at *2-3. These arguments correspond to the colloquial “big picture” views where sometimes one is so enmeshed in detail that he “cannot see the forest for the trees.” *Id.* at *3.

³⁵⁵ This is especially true for the under or un-insured who face discriminatory pricing for hospital services. Batchis, *supra* note 6, at 500-03.

³⁵⁶ Hospitals and physicians must conform to the nationally set guidelines in order to receive payment for services from Medicare and many private insurers. *See* MILLER, *supra* note 5, at 65-74.

³⁵⁷ *See, e.g.*, Health Insurance Portability & Accountability Act (HIPAA), 42 U.S.C. § 1320d-2 (1996); Patient confidentiality of records is a response to a fundamental need for privacy and avoidance of misuse of data for employment or insurance discrimination. MILLER, *supra* note 5, at 428.

³⁵⁸ Kohn, *supra* note 2, at 88-90.

³⁵⁹ *Id.*

³⁶⁰ *See* Harrington, *supra* note 21, at 353-55.

³⁶¹ It is long recognized that people who develop their own methods of change better adjust and respond to change. *See generally*, Eric Brown et al., *Multilevel Analysis of Community Prevention Collaboration*, 41 AM. J. COMMUNITY PSYCHOL. 115 (2008); Lynne

With the spending power, Congress may encourage aid to hospitals and providers who are financially struggling and help them to catch-up to their more affluent counterparts.³⁶² This encouragement may be in the form of actual financial aid, such as costs of increased technological updates, or may include relief of existing costs such as taxes.³⁶³

Finally, Congress may utilize its power to further aid the beneficiary who has been injured by negligence and truly avoidable errors to seek justified damage awards through the court system.³⁶⁴ In this way, Congress may help vulnerable beneficiaries instead of forsaking them when serious adverse events occur yet still recuperate legitimate costs of unexpected care. In short, Congress, through CMS, may employ its constitutionally granted spending power to spur cooperative and innovative solutions to health care's emergent quality problems. Congress can aid providers to "heal themselves" by rational utilization of quality data.

XII. CONCLUSION

The proposed Medicare reimbursement schedule intended to become effective in October 2008 represents a drastic change to the traditional policy of payment for needed services.³⁶⁵ The proposal mandates that certain preventable adverse events should not be reimbursed.³⁶⁶ This spending scheme is intended to improve quality while decreasing cost to the Medicare system.³⁶⁷

The goals of the spending scheme are laudable. Quality improvement, when used to improve the health, safety and general welfare of the intended patient beneficiary of the Medicare program, is a rational and compelling government interest that warrants coercive use of authorized spending power.³⁶⁸ This beneficial interest may also rationally justify regulation of the health care industry through conditional

Baillie et al., *Community Health, Community Involvement, and Community Empowerment: Too Much to Expect?*, 32 J. COMMUNITY PSYCHOL. 217 (2004).

³⁶² The Value Based Purchasing Program (VBP) is an interesting spending incentive tool that allows for monetary rewards for hospitals that do well on quality reviews. *See Ferman, supra* note 134, at *1. However, the benefit of the program is ironic because the program also decreases hospital payments such that the bonuses merely replace the missing funds. *Id.* Therefore, the hospital is punished then offered redemption as a coercive method of behavioral change.

³⁶³ Congress may also encourage state participation in cost adjustments or offer financial aid to struggling hospitals on the condition they conform to HIT electronic record requirements. *See supra* note 331.

³⁶⁴ The beneficiary could be made aware of or even involved in the investigation of serious adverse events. If the investigation reveals a possible negligence action then CMS could facilitate the patient's litigation or mediation with the involved parties. In this way, Medicare would recover its loss through improved subrogation while providing a needed service to its beneficiaries.

³⁶⁵ *See supra* Part VI.

³⁶⁶ *Id.*

³⁶⁷ *Id.*

³⁶⁸ 42 U.S.C.A. § 1395c (West 2008).

acceptance agreements.³⁶⁹ However, the spending power and imposed regulations must bear a rational relationship to the intended goals and purpose of Medicare.³⁷⁰ Unintended consequences that will likely result from a refusal to pay for necessary medical care because of hindsight review will likely decrease the quality and increase the cost of the Medicare program.³⁷¹

Furthermore, other foreseen consequences involve the establishment of new precedent for health reimbursement that would likely worsen the number and status of un-insured and under-insured individuals in America by encouraging other third-party payors to follow suit.³⁷²

Nonetheless, the focus on serious adverse events provides a means to achieve both quality improvement and cost control goals.³⁷³ The focus has also spurred compilation and analysis of data from hospitals throughout the nation.³⁷⁴ This data, even in its raw and non-uniform state, may document scope of the problem and spur innovative discussion among legislators, health care providers, and facilities regarding necessary improvements.³⁷⁵ Discussion may be focused such that balance of quality improvement and cost savings may be achieved.³⁷⁶

However, care must be taken to avoid abuse of this data. Fear of abuse is the main obstacle to data compilation and open discussion.³⁷⁷ This data may be abused by third-party payors as a means to shift the cost burden upon the health care providers and facilities through use of the court system and malpractice claims.³⁷⁸ Further abuse may occur if third-party payors' use their inherent spending power to impose life style values upon covered individuals as a condition of coverage thereby severely hampering fundamental freedom of choice.³⁷⁹

Therefore, rather than impose the proposed spending scheme of non-payment for serious adverse events Congress, through CMS, should utilize its vast resources to encourage valid compilation of quality data throughout America's hospital and health care system.³⁸⁰ It should provide a means to obtain a non-biased and objective analysis of the data and identify methods which improve quality while balancing cost

³⁶⁹ See *supra* note 75.

³⁷⁰ See *supra* Part VII.

³⁷¹ See *supra* Part IX.

³⁷² *Id.*

³⁷³ See *supra* note 172.

³⁷⁴ See *supra* Part X.

³⁷⁵ *Id.*

³⁷⁶ See Rohack, *supra* note 167 (suggesting that "[a] more effective patient safety approach would be to encourage compliance with evidence-based guidelines by health care professionals.").

³⁷⁷ See, e.g., Kohn, *supra* note 2, at 110; Pear, *supra* note 315.

³⁷⁸ See *supra* note 235.

³⁷⁹ See Crossley, *supra* note 13, at 135.

³⁸⁰ See *supra* Part XI.

efficiency and avoiding undue punishment.³⁸¹ Publication should not occur until valid and open discussion has brought concurrence about realistic goals and methods of accomplishment.³⁸²

Congress and CMS should facilitate cooperation between the regulatory force of government and the functions of hospitals and providers because, in the end, both the government and health care facilities have the same goals. Both desire improved quality of health care through avoidance of serious adverse events and both desire improved cost efficiency. Congress has the power to identify goals and direct change while hospitals and providers have the means to effectuate change at the level of the beneficiary. Mutual cooperation while avoiding coercion and punishment will ultimately identify ways to improve quality and balance cost.

³⁸¹ *Id.*

³⁸² Even IOM maintains confidential all discussions and data analysis that were utilized in preparation of its publications to “protect the integrity of deliberative process.” Kohn, *supra* note 2, at vii.