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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?

AMY J. CHAHO, MD

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I. INTRODUCTION

These are turbulent times for health care in America. Health care costs are spiraling out of control, quality evaluations reveal a plethora of errors affecting delivery and outcome of care, and a growing number of citizens find themselves without the ability to afford services or obtain access to care. A three-way battle wages among government regulators, health care providers, and patients. 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. 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. 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. 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.

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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.
8 Id.
9 Id.
Medicare officials have identified ten events that they believe to be the result of preventable provider actions. These events result in serious “injury” to the patient and are considered to be both costly and frequent. 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. 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.

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,” then foreseeable consequences include an extension of the philosophical precedent where preventability equates with non-payment. 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. Refusal of payment for needed services conditioned upon the occurrence of unavoidable events represents an unjust punishment of hospitals and providers.
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.\textsuperscript{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.\textsuperscript{19} This data is published prior to appeals by providers and is intended to be used as a public quality measure of the provider.\textsuperscript{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.\textsuperscript{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.\textsuperscript{22} Through legislative power, Congress may play a central role that guides improvements,\textsuperscript{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.\textsuperscript{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

\textsuperscript{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. \textit{Id. generally}.

\textsuperscript{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, \textit{last visited} March 14, 2008.

\textsuperscript{20} \textit{Id}.


\textsuperscript{22} See \textit{infra} Part XI.

\textsuperscript{23} \textit{Id}.

\textsuperscript{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. Retired American citizens were without affordable health care when they needed medical care most. 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. Today, as in 1965, adequate medical care in America is too expensive for the average American without help from employers or the government.

Medicare and associated entities 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. Medicare is generally funded by the current work force through income tax and employer contributions. Payment is disbursed through an established trust fund. Medicare is an insurance program because it provides comprehensive care for a baseline fee by spreading the risk over the entire population.

See 

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).

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).

See Barlett, supra note 3, at 2-3.

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.


covered population. 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. Moreover, patient choice is safeguarded because services are paid without regard for how the injury or illness developed.

Medicare consists of four parts labeled as A, B, C, and D. Part A is basic Medicare. Part B is supplemental Medicare, Part C encompasses the Medicare choice plans and Part D includes prescription coverage. 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. 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.\footnote{41} Medicare is managed by the Centers for Medicare and Medicaid Services (CMS).\footnote{42} CMS is an agency created by the Department of Health and Human Services (DHHS).\footnote{43} These agencies are administrative entities that act under the delegated authority of Congress and the President respectively.\footnote{44} Specifically, CMS has been granted the authority to oversee Medicare and its associated programs.\footnote{45} To that end, CMS has the authority to create regulations that affect its programs and beneficiaries.\footnote{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.\footnote{47} Through this entity, societal cost is dispersed across all working citizens.\footnote{48} Traditionally, Medicare has reimbursed necessary medical care regardless of the cause or the preventability of the injury or illness that necessitated the care.\footnote{49}

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

\footnote{41} HOGUE, supra note 3, at 182. 

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

\footnote{43} See Dept. of Health & Human Serv. (DHHS), available at http://www.hhs.gov/about/index.html#agencies. 

\footnote{44} DDHS is led by a Secretary who is appointed as a member of the president’s cabinet. See http://www.hhs.gov. 

\footnote{45} Id. 

\footnote{46} Id. 

\footnote{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. 

\footnote{48} Id. 

\footnote{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). 

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

\(^{51}\) 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.


\(^{55}\) 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”).


\(^{57}\) 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. Through its spending power, the federal government has sought, gained control over, and now dictates reimbursement schedules for most medical treatments. Originally, Medicare paid the full reasonable cost of services provided to beneficiaries. 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. Many private insurance companies have followed suit and now pay or negotiate for the Medicare determined rates. Insurance officials argue that if the providers can afford these rates for governmental insurance, then their private insurance should enjoy the same payment scheme.

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. For this reason, the billed medical cost is significantly higher than the amount actually paid and accepted. Medicare and health insurance companies in general have inflated the cost of medicine by encouraging underpayment. This cost inflation is reflected in the exorbitant charges of hospital care to the uninsured. 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. However, over time Medicare has become more than an insurance entity.

58 See supra note 56.


60 Jones, supra note 55, at 156.


63 Cross, supra note 62.


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.\textsuperscript{69} The Medicare Act clearly declares that Medicare is “not to be construed as practicing medicine.”\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{74}

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

\textsuperscript{69} See infra notes 70-76.


\textsuperscript{71} The practice of medicine may be defined broadly as the diagnosing and treating of human ailments. 16 A.L.R. 4th 4th § 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) \textit{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. \textit{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.

\textsuperscript{72} Dolinar, \textit{supra} note 56, at 398, 403.

\textsuperscript{73} \textit{Id.} at 398, 403.

\textsuperscript{74} \textit{Id.} at 398, 403; see also QIO, \textit{supra} note 71.


\textsuperscript{76} Dolinar, \textit{supra} note 56, at 406; The Am. Hosp. Assoc., \textit{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. 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. Also, through retrospective review of patient beneficiary admissions, Medicare officials may unilaterally determine that certain provided services are included in a prorated global fee and are therefore non-payable by either Medicare or the beneficiary. 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. The federal government currently provides support to some facilities by funding “non-recoverable services” known as “bad debt” which prevents some closures.

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. 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.


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.


82 Id.

83 See supra note 75.

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.
87 See Crossley, supra note 13, at 77-78.
88 See supra note 1, at 16.
89 Id. at 4-5.
91 HOGUE, supra note 3, at 304-05; BARLETT, supra note 3, at 306.
92 Id. at 311-315.
93 Id.
control, people sought medical aid only when they were truly sick and local remedies would not suffice. Hospitals were places for the homeless or the terminally ill to die in relative comfort. Over the past century, society has embraced the need for preventive care. 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. However, this practice also encourages use of medical resources and thereby increases expenses. The increase of individuals diagnosed with chronic diseases has lead to long-term dependence on medical resources for continued treatment to improve survival and, hence, become a long-term cost burden.

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


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


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.


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. 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. 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.

Traditionally, both private and public health insurance entities have been able to defray cost by spreading it over many individuals. Premiums paid for by all covered individuals, many of whom are healthy, offset the payouts for those who become ill. 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. Most insurers try to recoup the losses and maintain profits by minimizing this risk.

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.” Another way for insurers to control costs is to pay less for care of their customers. This is done by negotiating with medical providers to obtain across-the-board discounts on fees charged. This practice shifts the differential burden of cost onto the uninsured or other insurances. Insurers also create monetary incentives for customers to be seen only by a limited number of preferred

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


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.


114 Id.

115 Id.


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.\textsuperscript{120}

However, even a cursory review of relevant statistics \textsuperscript{121} 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.\textsuperscript{122} Therefore, costs must be contained and/or other sources of revenue identified to preserve the system.\textsuperscript{123} Despite this reality, beneficiaries continue to demand and expect expansion of the program.\textsuperscript{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.\textsuperscript{125}

Government officials have considered a variety of cost containment options for the Medicare program.\textsuperscript{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.\textsuperscript{127} Medicare also controls payments by closely reviewing medical records and verifying that only covered services are reimbursed.\textsuperscript{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.\textsuperscript{129} Medicare has been

\begin{itemize}
  \item \textsuperscript{120} Id.
  \item \textsuperscript{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.
  \item \textsuperscript{122} Social Security & Medicare Boards of Trustees, supra note 31, at *1.
  \item \textsuperscript{123} Id.
  \item \textsuperscript{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.
  \item \textsuperscript{125} Id.
  \item \textsuperscript{127} Id.
  \item \textsuperscript{128} Kevin Freking, Audits Sting Hospitals, Physicians, AOL NEWS (March 1, 2008) available at http://news.aol.com/story/_a/audits-sting-hospitals-physicians/n2008030103520 9990015.
\end{itemize}
accused of overly vigorous prosecution of innocent errors which government officials recognize as common occurrences due to the extremely complicated coding systems Medicare employs. Nonetheless, “cost savings” from payment refusal and fines have been generally well received.

Another cost saving measure is refusal to pay for certain services. Generally, Medicare will not pay for services that it deems to be “unnecessary.” Recently Medicare officials have refused to pay for services that they identify as medical error in the form of a preventable adverse event. 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.

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. CMS has defined seventeen adverse events that

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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.


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. 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. 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.

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

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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.


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.\textsuperscript{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.\textsuperscript{146} The study also included patient controlled errors, such as injuries that occurred when a competent patient refused to follow direct medical advice.\textsuperscript{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.\textsuperscript{148}

Although the conclusions were admittedly ambiguous,\textsuperscript{149} ill-defined,\textsuperscript{150} non-scientific and non-reproducible,\textsuperscript{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.\textsuperscript{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.\textsuperscript{153} The article also redefined common terms such as “safety” to mean “freedom from accidental injury.”\textsuperscript{154} By creating and redefining key terms and then interpreting data utilizing these new definitions, IOM’s conclusions were severely skewed.\textsuperscript{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.”\textsuperscript{156} Consumer groups and other national offices have been established specifically to address “preventable adverse events.”\textsuperscript{157} The term has been received with incremental name changes that gradually have come to signify medical error as their sole cause.\textsuperscript{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.\textsuperscript{159} Over time, these adverse events have been collectively redefined as medical error.\textsuperscript{160}

The Deficit Reduction Act of 2006 established several methods intended to lower the federal deficit and reduce federal spending.\textsuperscript{161} One of those methods relies on the concept of “preventable adverse events” to redefine the payment system for Medicare and related entities.\textsuperscript{162} The Secretary of Health and Human Services is required to select at least two common medical “events” that meet three criteria.\textsuperscript{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),\textsuperscript{164} and represent a...
condition that “could reasonably have been prevented through the application of evidence based guidelines.”

Arguably, certain specific events are presumed preventable, such as an unintended foreign body retained after surgery or blood type incompatibility during transfusion. 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. 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.

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. 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. 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.

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

42 U.S.C. §1395ww(d)(4)(I)(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.

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

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”).

Id.

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

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. 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. 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, has constitutional authority to utilize its spending power to regulate entities of national interest. 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. Thus, the proposed non-payments may be directly authorized through use of constitutional spending power, but there are certain limits.

VII. CONGRESSIONAL POWER TO IMPOSE THE SPENDING SCHEME:

A. Authority

Congress has the authority to officially delegate power to CMS as an administrative agency. CMS exists under the auspices of the Department of Health and Human Services. 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. 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).


177 See infra notes 178-83.


179 See supra note 42.

180 See supra note 43.
through its regulation of commerce. 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.

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. Specifically, the first paragraph of the Act declares that actions of CMS are “not to be construed as practicing medicine.” 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. The practice of medicine is generally defined by state licensing boards, which determine the scope of permissible practice and discipline for violators. 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. This makes sense, of course, when federal authority is taking action that in fact protects the public. 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

\[\text{References}\]

\[181\] Id.

\[182\] See Leavitt, supra note 75, at 5 (noting CMS’ aim to “[p]ay 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”).


\[184\] Id.

\[185\] See supra notes 75, 182.


\[187\] 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. These challenges have sought to retain the sovereignty of the state police power and suggest private individual resistance to increased taxation.

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

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. The Supreme Court has held that government agencies may not use constitutional authority to coerce implementation of programs when those programs are purely punitive or do not have a rational relationship to the specified governmental interest. However, the line between coercion and induced cooperation is vague. Although the Court specifically held in United States v.

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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).


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.*


201 Dolinar, *supra* note 56, at 406.


204 Fullilove, 448 U.S at 474.

rational relationship to the purpose of CMS, which is to provide medical coverage to the beneficiaries of the program.\textsuperscript{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.\textsuperscript{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.\textsuperscript{208} Thus, by punishing a hospital for undesirable adverse events, Medicare will arguably induce the hospital to avoid the occurrence of these events.\textsuperscript{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.\textsuperscript{210} Many changes regarding compilation of data and reporting of events have resulted in on-going improvements.\textsuperscript{211} However, these improvements are limited by the costs of some procedures, such as increased number and training of staff, or costly investments in

\textsuperscript{206} \textit{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.”); \textit{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).

\textsuperscript{207} 42 U.S.C.A. § 1395ww (West 2008).

\textsuperscript{208} \textit{See} William M. Sage, \textit{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); \textit{see also} Christopher, \textit{supra} note 17 (describing punishment theories of consequentialism and retributivism as avenues to induce change).

\textsuperscript{209} Sage, \textit{supra} note 208, at 224.

\textsuperscript{210} \textit{See}, e.g., Kevin O’Reilly, \textit{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/prsa0714.htm (noting the costly measures employed to successfully decrease pressure sore incidence including special mattress purchases, increased nursing protocols) (last visited Sept. 9, 2008); \textit{see generally} American Hospital Association, www.aha.org. (detailing the American Hospital Association’s quality reform initiatives) (last visited Sept 9, 2008).

\textsuperscript{211} \textit{See generally} Inst. of Med. (IOM), at http://www.iom.edu/ (last visited Jan. 1, 2007); \textit{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.\footnote{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).} 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.\footnote{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.} It is difficult to imagine how 100% punishment for prevention of events that are less than 100% preventable will improve quality.\footnote{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.}

Third, punitive measures already exist for preventable adverse events and they provide strong incentives for health care providers to monitor quality of care.\footnote{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).} These measures include the court system.\footnote{Id.} 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.\footnote{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


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.


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

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. 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. One of the criteria for inclusion in the non-payment scheme is that the adverse event is preventable. 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. 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. 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. These screening tests frequently involve invasive procedures such as blood tests or swabs of painful wounds or personal body parts. Hospital officials will, of course, appropriately bill Medicare for this admission testing. Therefore, the decision to


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/amednews/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. 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. 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. 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. 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.

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.

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.

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).

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).

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).

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. \(^{240}\)

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

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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.


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.


242 Id.
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 uninsured, facing non-payment for pre-existing conditions. 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. This possibility greatly weakens the patient and empowers the hospital. 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. 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. 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. 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.

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.

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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.
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.


\(^{255}\) See supra note 222.

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


\(^{258}\) See MILLER, supra note 5, at 280-302.


\(^{261}\) 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, is currently under way. However, the data of quality assessments throughout the United States has barely begun to be systematically gathered, much less comprehensively and competently analyzed. Therefore, CMS officials are categorically refusing to pay for events that include some unavoidable accidents, preferring to shift this financial burden to hospitals.

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. 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. The hospital will in effect be providing free services to the patient at its own expense. Therefore, the proposed non-payment scheme will only further jeopardize the financial stability of these institutions.

The anticipated consequences to the beneficiary are likewise considerable. The beneficiary is effectively reduced to an indigent status. The greatest impact of this reduction in status to the beneficiary will be upon choice. 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.


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. 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. 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. 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. 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. This anticipated consequence is based upon historical evidence that other insurance entities follow Medicare’s lead regarding reimbursement methods. However, refusal to pay for recognized medically indicated services is not a new theory in the private insurance world. 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.

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Indeed, refusal to pay for costs incurred by pre-existing medical conditions is a recognized cost control measure well known to the insurance industry. 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. 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.

Historically, beneficiaries contract with an insurance entity to obtain medical care for needed unforeseen injuries. 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. 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. This scenario effectively leaves the vulnerable, privately-insured beneficiary in the middle of provider and payor disagreements.

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.

Furthermore, Medicare may well be setting a dangerous medical insurance precedent. 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. 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

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. By refusing to pay for preventable injuries, a medical insurance provider or employer may begin to examine the beneficiary’s lifestyle. The beneficiary may prevent lung cancer if he or she stops smoking. A beneficiary may prevent incurable breast cancer if she undergoes an annual mammogram. Diabetes may be prevented by losing weight, and heart disease may be prevented by regular exercise. It has been well-recognized that general definitions may be expanded and redefined over time. 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. 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 “give[s] Americans incentives … to take greater personal responsibility for the consequences of their health-related behavior”).
disease. Those costs would eventually be re-shifted to health care providers and possibly back to the federal government.

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. 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. 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.

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. This focus has spurred efforts by all stakeholders to find improved methods of health care delivery. 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. 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). Also, various private groups are collecting data and analyzing the

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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.


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

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. This contention is grounded in the malpractice debate. 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. Providers, especially physicians, contend that publication of this data will fuel litigation and malpractice claims by spotlighting possible errors. 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.

In theory, publication of quality data especially regarding the root cause of serious adverse events should allow better analysis of causation. This analysis
should suggest ways to improve and further prevent these devastating and tragic events.\textsuperscript{318} Publication would also facilitate discussion between facilities that would permit hospitals to learn from one another’s mistakes in a peer review fashion.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{323} Therefore, cost savings by the payor represents cost increase to the provider and is justified by public review of publicized data.\textsuperscript{324}

An additional cost amplifier is the anticipated increase in litigation expected from review of unqualified data.\textsuperscript{325} This increase would likely come from both third-party payors and patients.\textsuperscript{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.\textsuperscript{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 \textit{per se} fashion and then informing the patient beneficiary of this decision through billing information or quality reporting prior to protest by the hospital.\textsuperscript{328} Therefore, widespread publication of quality data will likely lead to a cost shift where payors further shift the cost burden onto hospitals and providers.

\textsuperscript{318} Kohn, supra note 2, at 98; see also Stow, supra note 317.


\textsuperscript{320} \textit{See generally} Crossley, supra note 13.

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

\textsuperscript{322} \textit{Id.}

\textsuperscript{323} \textit{Id.}

\textsuperscript{324} \textit{Id.}

\textsuperscript{325} Harrington, supra note 21, at 343-44; see also Pear, supra note 316.

\textsuperscript{326} \textit{See supra} note 325.

\textsuperscript{327} \textit{See supra} note 326; \textit{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).

\textsuperscript{328} \textit{See supra} note 240.
B. Increased Cost with Increased Quality?

Furthermore, improved quality does not necessarily lead to decreased cost. In actuality, improved quality may demand increased cost. The current debate about mandated electronic records is an example. 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. However, this technology is expensive to implement and confusing to learn, especially when different systems are unable to communicate. The cost of implementing a nationwide system that functions as a cohesive unit is astronomical.

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. No hospital system desires to be understaffed or outdated. Nonetheless, cost concerns must be addressed and contained if the hospital is to survive. Mandated conditions for reimbursement that require expensive upgrades would burden the struggling hospital on a limited budget and commandeer funding.


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.


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.


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

337 Id. at 14.
priorities such as staffing issues. 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.

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. 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. The patient may have no choice as to which facility his or her physician admits patients. 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. It is well-established that the trusted doctor-patient relationship is a powerful entity that drives patient satisfaction, compliance and response to care. 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.

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. 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 2012).

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.


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.

patients.\textsuperscript{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.\textsuperscript{354} It is no secret that health care in this country is piecemeal and provides non-uniform care to similarly situated individuals.\textsuperscript{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.\textsuperscript{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.\textsuperscript{357} Congress, through CMS and the spending power, may provide for focused quality review by encouraging report of quality issues.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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?\textsuperscript{361}

\textsuperscript{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.

\textsuperscript{354} See Huntion, 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.

\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{358} Kohn, supra note 2, at 88-90.

\textsuperscript{359} Id.

\textsuperscript{360} See Harrington, supra note 21, at 353-55.

\textsuperscript{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.\footnote{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.\footnote{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.\footnote{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.

\section*{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.\footnote{365} The proposal mandates that certain preventable adverse events should not be reimbursed.\footnote{366} This spending scheme is intended to improve quality while decreasing cost to the Medicare system.\footnote{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.\footnote{368} This beneficial interest may also rationally justify regulation of the health care industry through conditional

\begin{footnotes}

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, \textit{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. \textit{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. \textit{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 \textit{See supra} Part VI.

366 \textit{Id.}

367 \textit{Id.}


\end{footnotes}
acceptance agreements. However, the spending power and imposed regulations must bear a rational relationship to the intended goals and purpose of Medicare. 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.

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.

Nonetheless, the focus on serious adverse events provides a means to achieve both quality improvement and cost control goals. The focus has also spurred compilation and analysis of data from hospitals throughout the nation. 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. Discussion may be focused such that balance of quality improvement and cost savings may be achieved.

However, care must be taken to avoid abuse of this data. Fear of abuse is the main obstacle to data compilation and open discussion. 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. Further abuse may occur if third-party payors’ use their inherent spending power to impose lifestyle values upon covered individuals as a condition of coverage thereby severely hampering fundamental freedom of choice.

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. 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

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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.\textsuperscript{381} Publication should not occur until valid and open discussion has brought concurrence about realistic goals and methods of accomplishment.\textsuperscript{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.

\textsuperscript{381} \textit{Id.}

\textsuperscript{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, \textit{supra} note 2, at vii.