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Introduction

The recent changes to the core structure of modern American health care are nothing short of epic, rivaled in historic scale only by the introduction of Medicare in 1965. Although each decade over the past 50 years has in some way used government programs and incentives in an attempt to urge health care to undergo recalibration as a means to establish industry stability, by the end of the first decade of the 21st Century it had become evident that health care in the United States was fast becoming unsustainable as it existed.

Three years after the Federal Government passed the Affordable Care Act in an attempt to right the sinking ship, we the people are still waiting for the tide to turn. Having survived last summer's monumental challenge before the United States Supreme Court and a presidential election in November, the Affordable Care Act has not only emerged as the law of the land, it has cemented its place as health care's blueprint throughout America for decades to come.

The speed at which health care reform appears to move can at times be dizzying, and its demands are often draconian at first glance. However, history has shown that health care in the United States is resilient, and often finds ways to surprise even its toughest critics. Make no mistake, the Affordable Care Act is in many ways a trillion dollar gamble with a trifold agenda that attempts to improve the long-term health of Americans by promoting innovation in the delivery of medicine, placing stronger emphasis on the prevention of disease, and enhancing education in the adoption and maintenance of healthier lifestyles. Without such a nationwide commitment to change, our health care structure has no solid foundation on which to rest. Given the alternative, the epic solution may in this case be the only viable option.

The articles in this journal represent my most recent writings on the Affordable Care Act. Though it is too soon to predict the future of health care in the United States, the value of historical information pertaining to the evolution of our health care system should not be discounted. Only through the combination of historical perspective and modern-day analysis have I been able to understand the essence of the Affordable Care Act. It is my hope that the following articles will provide the reader with similar guidance.

--Craig B. Garner

Proceed With Caution: Matters to Consider for Business Lawyers Transitioning into Health Care

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When venturing into areas of law outside their usual practice, attorneys should be mindful of state-specific standards to which they are held. Rule 3-110 of the California Rules of Professional Conduct sets the standard on the west coast, just as Rule 1.1 of the New York Rules of Professional Conduct applies on the east. Absent the requisite skill to accommodate a client's needs, an attorney may still engage and adhere to the statutory definition of competence by "associating with or, where appropriate, professionally consulting another lawyer reasonably believed to be competent" or "by acquiring sufficient learning and skill before performance is required."[1] In 2003, a California Appellate Court explained: "Attorneys are expected 'to possess knowledge of those plain and elementary principles of law which are commonly known by well informed attorneys, and to discover those additional rules of law which, although not commonly known, may readily be found by standard research techniques.'"[2]

However, due to the sheer volume and complexity of information generated regularly in the wake of reform, modern health care law exists in a league of its own. To be sure, there is nothing otherworldly about health care law,[3] and a conscientious advocate can find the answers he seeks given enough time and resources. Yet even the savviest business lawyer should be mindful before accepting a new assignment involving health care concerns, as the fiduciary pathway can be treacherous and unforgiving. The ever-evolving body of laws governing today's health care industry bears at least partial blame for the inherent disconnect between traditional notions of business (referenced occasionally in a state's Corporations[4], Corporations and Associations[5] or General Business Code[6], for example) and the business of health care (found within a plethora of statutory domiciles in various states, including California[7], New York[8] and Texas[9], among others).[10] Regardless of where it is encountered, health care law should never be underestimated, even if its underlying logic exists outside the scope of case law and statutes frequented by a business lawyer on any given day.

The False Claims Act, 150 Years in the Making

To further confuse the issue, many of the core tenets central to health care law are inherently inconsistent with those meanings employed on a regular basis by the corporate attorney, such as "goods and services," "financial interests," "referrals," "discounts" and "rebates." The situation has not improved with the passage of the Patient Protection and Affordable Care Act[11], as amended by the Health Care and Education Reconciliation Act[12] (collectively referred to as the Affordable Care Act or health care reform) particularly in regard to matters of health care fraud and abuse. Dating back to the American Civil War, the False Claims Act (FCA) has over time become both the federal and state governments' "primary litigative tool for combating fraud."[13] At its core, the FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[14]

What began as a way to protect the Union Army from purchasing substandard horses, faulty weaponry, and inedible provisions has evolved considerably since Congress passed the FCA in 1863.[15] In its present incarnation under the Affordable Care Act, a health care provider must return any "overpayment" of federal funds within 60 days after identifying the error or risk liability under the FCA.[16] However, the meaning of the term "overpayment" extends beyond a simple miscalculation of price in response to which a refund or store credit will suffice.

Under federal law, overpayments can result from unintentional billing errors, overutilization or by working with an excluded vendor. They can also occur when a facility does not employ accurate procedures for billing and collecting in connection with hard work on behalf of real patients, unnecessary work with not-so-real patients, and necessary work for patients within 72 hours of a hospital inpatient admission or discharge.[17] An overpayment may include a duplicate payment to a hospital by a patient and her automobile insurer.[18] It may also apply in "the situation where a provider is given money by Medicare to pay for certain health care services, and the provider contracts with a third party who, in turn, provides those services, but the provider fails to liquidate the liability by paying the third party within a designated period of time.[19] There may exist both "anticipated" overpayments as well as "erroneous" overpayments,"[20] and a delay of as much as fourteen years in attempting to recover an overpayment should be considered reasonable.[21]

Exclusion From the Medicare Program

Yet another concept that has grown far more expansive under the Affordable Care Act is the

notion of what it means to be "excluded" from participation in a health care program funded at least in part by the Federal government, and the potential ramifications of such exclusion from a business standpoint.[22] As a general rule, the Federal government requires advanced approval of every entity that participates in the delivery of health care under a federal program such as Medicare. In the event that any one participant in a provider's delivery of health care is either unauthorized or excluded[23] from participation by the Federal government, everything related to the actual remuneration of these health care services by the Federal government may constitute an overpayment and/or false claim.[24] In essence, any items or services furnished by an excluded individual or entity are not reimbursable by any Federal health care program, including monies paid to another, third party provider or supplier that is an authorized participant, such as a doctor or hospital. This creates an implied indemnification of any health care provider who receives Federal funds in exchange for the delivery of medical services, yet fails to afford that same provider any viable remedy against a third party who bears technical culpability for the break in the chain, thereby rendering the entire reimbursement void *ab initio*. A single weak link effectively nullifies the entire chain.

No matter where on the vertical ladder of delivery an excluded provider may stand, reimbursement is not permissible for anyone, and violations may result in potential criminal penalties.[25] This includes those administrative and management services that are not directly related to health care but are nonetheless a necessary component in the ultimate delivery of health care services. Services performed by excluded parties such as nurses, pharmacists, ambulance drivers, social workers, claims processors, or even the person who sells, delivers and/or refills an order for a medical device are thereby prohibited.[26] Failure to follow these rules closely exposes a health care provider to potential civil money penalties of $10,000 for each item or service that bears some nexus to an excluded individual, treble damages for the amount of each specific claim, and possible exclusion for the health care provider him or herself, who may have been unaware of the circumstances rendering his or her treatment problematic in the eyes of the government.[27]

It should thus come as no surprise that under the Affordable Care Act, participation in the Medicare program may require a heightened level of advanced screening, such as criminal background checks, fingerprinting, licensure verification and unannounced visits.[28] As of March 25, 2012, these procedures will apply to nearly everyone involved in the delivery of care under the Medicare program, either directly or indirectly.[29] While this may on the surface appear to be somewhat disruptive, its intent is to protect providers from unwittingly collaborating with excluded parties who may cause them not only to forfeit their right to

reimbursement, but also incur substantial penalties. Although typically associated with criminal law cases, the legal metaphor "fruit of the poisonous tree"[30] provides an excellent analogy for the ways in which the slightest oversight can lead to substantial financial penalties.

The Fraud and Abuse Labyrinth

In an attempt to curtail the ever-present specter of medical fraud, both state and federal governments have created a series of provisions designed to police providers and highlight areas where conflicts of interest may arise. Fraught with complexity and comprised of volumes upon volumes of information in the form of statutory authority, case law decisions, and secondary references, Stark laws, Anti-Kickback statutes and laws governing outpatient referral[31] give the Commerce Clause[32] a run for its money in terms of complexity. And yet, it is not the nature of the laws that are problematic from the viewpoint of a business lawyer, but rather the 28 pages of double-columned regulatory exceptions (also known as "Safe Harbors")[33] to the criminal penalties for acts involving federal health care programs.[34] When used accordingly, these statutory exceptions can potentially insulate a health care provider from liability under the Stark and Anti-Kickback laws, not to mention the few hundred advisory opinions generated by the Office of the Inspector General.[35]

Some of the more common Safe Harbor provisions include investment interests, office space and equipment rental, personal services and management contracts, the sale of a practice, referral services, discounts, employees, group purchasing organizations, waiver of beneficiary coinsurance and deductible amounts, physician recruitment, investments in group practices, ambulatory surgical centers, ambulance replenishing, and electronic health records.[36] Outside of the health care context, many such transactions are considered ordinary at best, and there are without question other specialty areas among business lawyers that also include higher standards of care. However, with health care expenditures (NHE) accounting for almost 18% of the nation's gross domestic product, amounting to approximately $2.5 trillion as of 2009[37], it is not entirely unexpected that health care law is trying to keep pace, and the physical and mental demands such labyrinthine legislation may impose upon the unwary business lawyer should never be underestimated. With such an expansive regulatory reach and potential liability emanating from so many possible points of origin, extreme vigilance and an ever-present eye to copious, sometimes seemingly unreasonable or unfair details must serve as the foundation for any health care law practice.

Health Care's Version of the Recall

It is not uncommon for federal or state laws to mandate that businesses notify their customers in certain events, such as during product safety recalls in automobiles, potential health threats relating to food products, and substantive or technical concerns in the pharmaceutical industry. Due to concerns over patient privacy, the health care industry must take the idea of patient notification to a whole new level. Under the Health Information Technology for Clinical and Economic Health (HITECH) Act,[38] any "covered" entity that maintains "unsecured" protected health information (PHI) and "discovers" a "breach of such information" must notify each individual whose PHI "has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach."[39] This rule also applies to business associates working with an entity for which disclosure is required under the HITECH Act.[40]

The regulations provide for the method of notification (mail, email, or telephone, in certain instances),[41] establish protocol should the issue involve more than ten individuals, and set forth further requirements for issues involving more than 500 individuals.[42] Federal regulations also specify what the notice must include for each type of infraction.[43] Finally, there is often a fine when a breach is proven, and neither HITECH nor HIPAA (Health Insurance Portability and Accountability Act of 1996)[44] offer exceptions. With civil penalties ranging from $100 to $50,000 for each HIPAA or HITECH related violation, cumulative penalties can amount to as much as $1,500,000 in any calendar year.[45] Where there is an "intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the penalty may not exceed $250,000, imprisonment up to 10 years, or both."[46]

We Cannot Refuse the Right to Serve

In an effort to counteract "patient dumping," wherein hospitals refuse to treat people due to lack of insurance or inability to pay, Congress passed the Emergency Medical Treatment and Active Labor Act (EMTALA) in 1986.[47] EMTALA requires every hospital that receives federal funding to treat any patient with an emergency condition in such a way that, upon the patient's release, no further deterioration of the condition is likely. No hospital may release a patient with an emergency medical condition without first determining that the patient has been stabilized, even if the hospital properly admitted the patient. Under EMTALA, patients requesting emergency treatment can only be discharged under their own informed consent

or when their condition requires the services of another hospital better equipped to treat the patient's concerns.[48]

There has been an abundance of debate regarding the propriety of these requirements, specifically regarding their impact on the emergency health care system in the United States.[49] Simply put, the idea behind EMTALA places a considerable burden on participating emergency departments by allowing a buyer of certain goods (i.e., the patient) to obtain certain goods (i.e., medical care) from a seller of certain goods (i.e., the hospital), though the seller must still perform his or her duties regardless of whether the buyer is able to pay, and there exists no viable remedy to prevent such a scenario from happening repeatedly. While other industries have specific remedies for addressing such issues,[50] these methods rarely apply in the health care sector.[51] Even provisions to protect business transactions upon seller's discovery of buyer insolvency do not translate well in the realm of health care law,[52] placing providers in the unenviable position of having to provide their services atop a business model too weak to allow for continued sustainability.

Health care law is by no means exclusive, and opportunities abound for an able practitioner hoping to transition at any stage of his or her career. In today's climate of reform, it is essential that those practicing American health care law honor and obey the hierarchy surrounding its discipline as it struggles to stay afloat amid a rising tide of constitutional challenges. It comes as no surprise that even after the Supreme Court's landmark decision in June confirming the constitutionality of the Affordable Care Act,[53] health care law continues its reign in the spotlight. Even though Chief Justice Roberts set the stage for the November elections while casting uncertainty for the future of the Affordable Care Act[54], health care lawyers are sure to remain standing.

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[1] Cal. Rules of Prof'l Conduct R. 3-110 (C); *see also* N.Y. Rules of Prof'l Conduct R. 1.1(b); Colo. Rules of Prof'l Conduct R. 1.1; Ala. Rules of Prof'l Conduct R. 1.1; Tex. Disc. Rules of Prof'l Conduct R. 1.01.

[2] *Camarillo v. Vaage*, 105 Cal. App. 4th 552, 561 (2003) (quoting *Smith v. Lewis*, 13 Cal. 3d 349, 356 (1976)); *see also McIntyre v. Commission for Lawyer Discipline*, 169 S.W.3d 803, 807-08 (Tex. App. 2005); *In re Jayson*, 832 N.Y.S.2d 696, 698 (N.Y. App. Div. 2007); *Davis v. Alabama State Bar*, 676 So.2d 306, 310 (Ala. 1996); *Disciplinary Counsel v. Hoppel*, 129 Ohio St. 3d 53, 54 (Ohio 2011).

[3] *But see Catholic Health Initiatives v. Sebelius*, 841 F. Supp. 2d 270 (D.D.C. 2012) ("Picture a law written by James Joyce and edited by E.E. Cummings. Such is the Medicare statute, which has been described as 'among the most completely impenetrable texts within human experience.'" (quoting *Rehabilitation Ass'n of Va. V. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)). The District Judge also noted: "The Court clarifies, however,

that by making this analogy, it is referring not to Joyce's early work, such as Dubliners or A Portrait of the Artist as a Young Man, but his later period, specifically Finnegan's Wake." *Id.* at n.1.

[4] *See, e.g.*, Cal. Corp. Code.

[5] *See, e.g.*, Md. Corps. & Ass'ns Code.

[6] *See, e.g.*, N.Y. Gen. Bus. Law.

[7] *See, e.g.*, Cal. Health & Safety Code, Welf. & Inst. Code, Ins. Code, Lab. Code, and Gov't Code, among others.

[8] *See, e.g.*, N.Y. Ins. Law, N.Y. Pub. Health Law, N.Y. Mental Hyg. Law, N.Y. Retire. & Soc. Sec. Law, N.Y. Vol. Ambul. Workers' Ben. Law and N.Y. Workers' Comp. Law, among others.

[9] *See, e.g.,* Tex. Health & Safety Code and Tex Loc. Gov't Code, among others.

[10] *See also* Title 42 of the United States Code (Public Health and Welfare); Title 25, Chapter 18 of the United States Code (Indian Health Care); Title 31 of the United States Code (Money and Finance); Title 38, Chapter 73 of the United States Code (Veterans Health Administration). In addition to these state and federal statutes, there exists an equally expansive body of state and federal regulatory authority. *See, e.g.*, Title 8 of the California Code of Regulations (Industrial Relations); Title 17 of the California Code of Regulations (Public Health); Title 28 of the California Code of Regulations (Managed Health Care); *see also* Titles, 25, 38 and 42 of the Code of Federal Regulations.

[11] Pub. L. 111-148.

[12] Pub. L. 111-152.

[13] *United States v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (quoting Senate Judiciary Committee, False Claims Amendments Act of 1986, S. Rep. No. 345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266).

[14] 31 U.S.C. § 3729(a)(1)(A).

[15] 2 Stat. 696 (Mar. 2, 1863).

[16] 42 U.S.C. § 1320a-7k; *see also* 18 U.S.C. § 1035 (false statements relating to health care matters); 18 U.S.C. § 1001 (false statements as to matters under federal jurisdiction); 31 U.S.C. § 3729(a)(1)(6) (the Fraud Enforcement and Recovery Act). *Cf.* Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (proposed Feb. 16, 2012) (to be codified at 42 C.F.R. pts. 401, 405) (clarifying the requirements for providers and suppliers receiving funds under the Medicare program to report and return overpayments).

[17] *See generally* 42 U.S.C. § 1320a-7b.

[18] *Buckner v. Heckler*, 804 F.2d 258 (4th Cir. 1997).

[19] *See In re Slater Health Center*, 398 F.3d 98, 100 (1st Cir. 2005).

[20] *Carleson v. Unemployment Ins. Appeals Bd.*, 64 Cal. App. 3d 145, 153 (1976); *see also Holy Cross Hosp. of Silver Spring, Inc. v. Maryland Employment Sec. Admin.*, 288 Md. 685, 689-90 (Ct. App. 1980).

[21] *See generally Robert F. Kennedy Med. Ctr. v. Department of Health Srvs.*, 61 Cal. App. 4th 1357 (1998).

[22] This includes Medicare and Medicaid.

[23] The Federal Government, and specifically the Office of the Inspector General, is required by law to exclude from participation in all federal health care programs individuals or entities convicted of certain offenses, such as Medicare or Medicaid fraud, patient abuse or neglect, or felony convictions for other health care related fraud or misconduct. *See, e.g.,* 42 U.S.C. § 1320A-7(a). The OIG also has discretion to exclude from participation in all federal health care programs individuals or entities with misdemeanor convictions related to health care fraud, fraud in a non-health care program that is funded by a federal, state or local government agency, or for providing unnecessary or substandard service. *See, e.g.*, 42 U.S.C. § 1320A-7(b).

[24] *See, e.g.,* 42 C.F.R. § 1001.1901.

[25] 42 U.S.C. § 1320a-7b.

[26] *See, e.g.,* 42 U.S.C. § 1395x(b) (defining inpatient hospital services).

[27] *See, e.g.,* 42 U.S.C. § 1320a-7a; 42 C.F.R. § 1001.3002.

[28] 42 U.S.C. § 1866j(2).

[29] 76 Fed. Reg. 5862, 5865 (Feb. 2, 2011).

[30] *See Nardone v. United States*, 308 U.S. 338, 341 (1939) (first use of the phrase "fruit of the poisonous tree"); *Silverthorne Lumber Co. v. United States*, 251 U.S. 385 (1920) (first articulation of the concept behind the phrase).

[31] Stark (the Medicare self referral prohibitions, codified at 42 U.S.C. § 1395nn), AKS (the Federal Anti-Kickback statutes, 42 U.S.C. § 1320a-7b(b), and PORA (California's Physician Outpatient Referral Act, Cal. Bus. & Profs Code § 650, *et seq*.).

[32] U.S. Const. art. I, § 8, cl. 3 ("To regulate commerce with foreign nations, and among the several states, and with the Indian tribes.").

[33] *See* 42 C.F.R. § 1001.952.

[34] *See, e.g.,* 42 U.S.C. § 1320a-7b.

[35] The OIG issues advisory opinions about the application of its fraud and abuse authorities to the requesting party's existing or proposed business arrangement. 42 U.S.C. § 1320a-7d(b) and 42 C.F.R. § 1008.

[36] *See* 42 C.F.R. § 1001.952.

[37] United States Department of Commerce, Bureau of Economic Analysis; Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. The NHE calculates total annual spending for health care in the United States (goods and services), in addition to total administrative spending each year, as well as the net cost of private health insurance, among other things. *See* Micah Hartman, Anne Martin, Olivia Nuccio, Aaron Catlin, *Health Spending Growth at a Historic Low in 2008*, 29, No. 1 Health Affairs 147 (Jan. 2010) (citing Centers for Medicare & Medicaid Services, National health expenditure accounts: definitions, sources, and methods used in the NHEA 2008).

[38] Pub. L. 111-5 (Feb. 17, 2009).

[39] 42 U.S.C. § 17932.

[40] 42 U.S.C. § 17931(a).

[41] 42 U.S.C. § 17932(e).

[42] 42 U.S.C. §§ 17932(e)(3), (e)(4).

[43] 42 U.S.C. § 17932(b), (f).

[44] Pub. L. 104-191.

[45] 42 U.S.C. § 1320d-5(a)(3).

[46] 42 U.S.C. § 1320d-6(b)(3).

[47] Pub. L. 99-272.

[48] 42 U.S.C. § 1395dd. Notwithstanding the requirements of EMTALA, including an undisputed obligation to treat undocumented or illegal aliens, the Affordable Care Act does not provide for any mechanism to insure this same category of individuals.

[49] *See, e.g.*, Renee Y. Hsia, M.D., *Factors Associated with Closures at Emergency Departments in the United States*, 305 (19) JAMA 1978 (May 18, 2011); S. Trzeciak and E.P. Rivers, *Emergency Department Overcrowding in the United States*, 20 Emerg. Med. J. 402-05 (2003).

[50] *See, e.g.*, Cal. Penal Code § 487 (grand theft larceny); Minn Stat. § 609.52 (theft); Fla. Stat. § 812.012 (theft, robbery and related crimes); U.S. Const. amend. V (Takings Clause).

[51] A recent California Supreme Court decision held that emergency department physicians who do not contract with a health maintenance organization (HMO) may not bill the HMO's members for any amounts that remain unpaid by the HMO, an industry practice commonly known as "balance billing." *Prospect Med. Grp. v. Northridge Emerg. Med. Grp.*, 45 Cal. 4th 497 (2009); *but see* Cal. Penal Code § 484b ("Any person who receives money for the purpose of obtaining or paying for services, labor, materials or equipment and willfully fails to apply such money for such purpose . . . and wrongfully diverts the funds to a use other than that for which the funds were received, shall be guilty of a public offense. . . .").

[52] *Compare* Cal. Com. Code § 2702 *and* Ind. Code § 26-1-2-702 ("Where the seller discovers the buyer to be insolvent he may refuse delivery except for cash including payment for all goods theretofore delivered under the contract, and stop delivery. . . .") *with* Christopher Palmeri, California Faces Cash Shortfall by March on Low Receipts, Controller Says, Bloomberg, Jan. 31, 2012, http://www.bloomberg.com//news/2012-01-31/california-faces-cash-crisis-by-march-controller-chiang-says.html ("Unlike 2009, when [Controller John Chiang] was forced to issue IOUs to creditors, the controller said the current cash shortfall can be managed through payment delays, as well as external and internal borrowing.").

[53] *National Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

[54] Although the Affordable Care Act survived the Supreme Court ruling, it remains to be seen whether it will escape the effects of partisan politics unscathed. In his conclusion, Chief Justice Roberts aptly set the stage for what is to come in November: "[T]he Court does not express any opinion on the wisdom of the ACA. Under the Constitution, that judgment is reserved to the people." *Id*. at 2608.

The Supreme Court Opens the Road to Health Care Reform, But Will California Meet the Challenge?

By Craig B. Garner, Esq. and Julie A. Simer, Esq.
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Almost 28 months after President Barack Obama signed the Affordable Care Act ("ACA")[1] into law, the United States Supreme Court upheld the constitutionality of health care reform.[2] Though the underlying arguments set forth in the 59-page majority slip opinion venture deep into the labyrinth of constitutional law and test the traditional boundaries of federalism, the holding itself is clear and concise: (1) the ACA's individual mandate is constitutional;[3] and (2) the Medicaid expansion provisions found within the ACA survive, but the Federal Government is prohibited from penalizing "[s]tates that choose not to participate in [the Medicaid expansion] by taking away their existing Medicaid funding."[4] The decision promises to have a dramatic effect on California, as the country's most populous state.

In ruling that the individual mandate is constitutional, the Court rejected the Commerce Clause[5] and the Necessary and Proper Clause[6] in the Constitution as bases for upholding the mandate. The Court held that the Commerce Clause failed to provide a sufficient nexus between the requirement to purchase health insurance and its anticipated effect on interstate commerce to validate the individual mandate:

> No matter how "inherently integrated" health insurance and health care consumption may be, they are not the same thing: They involve different transactions, entered into at different times, with different providers. And for most of those targeted by the mandate, significant health care needs will be years, or even decades, away. The proximity and degree of connection between the mandate and the subsequent commercial activity is too lacking to justify an exception . . . .[7]

Chief Justice Roberts noted that the Commerce Clause does not give Congress the authority to compel an individual "to become active in commerce by purchasing a product, on the ground that … failure to do so affects interstate Commerce." [8] Likewise, the Court rejected the Necessary and Proper Clause as a means to sustain the individual mandate, finding it was not "an essential component of the insurance reforms."[9] The Court distinguished previous decisions upholding laws under the Necessary and Proper Clause, because the laws at issue in those cases "involved exercises of authority derivative of, and in service to, a granted

power." Whereas, the individual mandate would give Congress the ability to create the "necessary predicate to the exercise of an enumerated power." The Court added: "Even if the individual mandate is 'necessary' to the Act's insurance reforms, such an expansion of federal power is not a 'proper' means for making those reforms effective.[10]

Instead, the Court upheld the constitutionality of the individual mandate through Congress's authority to "lay and collect Taxes."[11] In so doing, the Court did acknowledge that Congress's taxing authority can exceed its power to regulate commerce, but the Court made the subtle distinction that the power to tax affords Congress less control over individual behavior than its power to regulate commerce.[12] Under its taxing power, Congress can only require that "an individual to pay money into the Federal Treasury, no more."[13]

California stands to gain more than any other state when its seven million[14] of the nation's estimated 50 million uninsured comply with the individual mandate in 2014,[15] although it remains to be seen how Californians will satisfy the ACA's most publicized provision in their quest for "minimal essential coverage."[16] The role employer-sponsored plans will play in providing health insurance throughout the state remains to be seen, especially as many businesses consider abandoning their own health plans in favor of the statutory penalty under the ACA.[17]

Under the ACA, beginning in 2014, individuals and small businesses will be able to "shop" for insurance through exchanges. California was the first state in the nation to create a health benefit exchange,[18] and its California Health Benefit Exchange is an independent public entity with a five-member board and 36 employees. It is the intention of California's Health Benefit Exchange to ensure that the state will be capable of plugging any holes that may sprout within the system. According to Peter V. Lee, executive director of the California Health Benefit Exchange: "We know buying insurance is really complicated. We want to make it as easy as buying a book on Amazon."[19] Such a tall order for America's most populous state will no doubt resonate throughout all major industries, and it will be incumbent upon California attorneys to guide their clients through any number of corporate, employment, insurance, constitutional and financial hurdles, not to mention the obvious health care uncertainties that remain in the wake of the Supreme Court's historic decision.

The second part of the Court's decision confirmed the constitutionality of the ACA's Medicaid expansion provisions, though this came at a price. The Court held that Congress has the authority to offer funding for states to expand Medicaid by 2014,[20] but that Congress will not be entitled to surprise states "with postacceptance or 'retroactive' conditions."[21]

This limitation on the Medicare expansion provision prevents the Federal Government from withdrawing existing Medicaid funding should a state refuse to participate in the expansion provisions under the ACA.[22]

Chief Justice Roberts summarized the Court's ruling on the Medicaid expansion provisions as follows:

> The Court today limits the financial pressure the Secretary may apply to induce States to accept the terms of the Medicaid expansion. As a practical matter, that means States may now choose to reject the expansion; that is the whole point. But that does not mean all or even any will. Some States may indeed decline to participate, either because they are unsure they will be able to afford their share of the new funding obligations, or because they are unwilling to commit the administrative resources necessary to support the expansion. Other States, however, may voluntarily sign up, finding the idea of expanding Medicaid coverage attractive, particularly given the level of federal funding the Act offers at the outset. [23]

For California, Medicaid expansion means that the Federal Government will cover 100 percent of the state's costs for insuring new Medi-Cal[24] beneficiaries accessing the program under the ACA in 2014, 2015 and 2016. Coverage under the ACA drops by one percentage point between 2017 and 2020, and after 2020 the Federal Government will cover 90 percent of California's new expenses under Medicaid.[25] Given the state of health care in California, coupled with the state's tenuous economy and current budgetary concerns, it would be difficult to imagine a scenario where California would reject this offer.[26]

At a minimum, Medicaid expansion would reduce the financial burden on hospitals in California hit hard by the fact that they must treat the uninsured. Too many of the state's residents, emergency departments serve as a major, if not the only point, of access to health care, and under federal law hospitals are limited in the ways in which they can respond.[27] The 1986 Emergency Medical Treatment and Active Labor Act ("EMTALA")[28] requires nearly all hospitals in California to provide a specified level of care to anyone presenting for emergency medical treatment, regardless of citizenship, legal status, or ability to pay, or risk the imposition of hefty fines or loss of participation in federal health care programs such as Medicare and Medicaid.[29]

The California Hospital Association reacted favorably to the decision, announcing that the expansion of Medicaid "could extend coverage to an estimated 2 million low-income uninsured Californians," and that full implementation of the California Health Benefit Exchange is expected "to provide coverage to more than 2 million additional California residents."[30] The reaction from the California Medical Association ("CMA"), however, was mixed. While the CMA applauded the extension of insurance coverage to uninsured Californians, CMA President James T. Hay, M.D. remarked that the ACA "does not guarantee that these newly insured patients will have access to doctors because the Medicare and Medicaid programs were left grossly underfunded." According to Dr. Hay: "Expanding coverage to more Californians, putting an end to insurance industry abuses, and support for primary care are essential for our patients and the future of medicine." Dr. Hay added: "Despite these wins, the ACA builds reform on the broken foundations of Medicare and Medicaid without addressing the underlying problems and inadequate funding. CMA will continue to work to fix those ills."[31]

While health plans recognized the benefit of increasing numbers of enrollees, America's Health Insurance Plans' President and CEO, Karen Ignagni, expressed concerned about cost:

> The law expands coverage to millions of Americans, a goal health plans have long supported, but major provisions, such as the premium tax, will have the unintended consequences of raising costs and disrupting coverage unless they are addressed. [32]

With Medicaid's expansion comes greater responsibility on the part of the state. California faces the unenviable task of establishing health insurance exchanges to accommodate an unknown number of beneficiaries seeking coverage in 2014. Health care service plans that wish to participate in California's exchange must "fairly and affirmatively offer, market, and sell in the Exchange at least one product within each of the five levels of coverage" required by the ACA.[33] Adherence to the federal requirements will be no easy task. Last March, the Federal Government issued its final rule on the implementation of health insurance exchanges, and every state would be wise to carefully analyze all 166 pages of codified health care reform.[34] Though the Federal Government will certainly promulgate additional regulations, California's window to have its insurance exchange operational closes on December 31, 2013, because directs ACA directs the Secretary of the Department of Health and Human Services to establish and operate an exchange within States that do not have an operational exchange by January 1, 2014.[35]

Uncertainty remains as to what constitutes the "essential health benefits package" referenced by the Court in connection with its discussion of the Medicaid expansion, particularly for the purpose of satisfying an individual's obligations under the individual mandate.[36] While federal guidance will be ongoing throughout the balance of 2012 and into 2013, California's legislature may need to make some important independent decisions on California's road to reform, and the state has little time to endure the partisan delays inherent in much of the state's fiscal planning. While budget timeliness seems to be a fluid concept in California politics, the State has little control over the deadlines and requirements under the ACA.[37]

Yet California differs from other states in many respects. The Stanford Center on Longevity reports: "California may be the sixth youngest state right now. But it has an outsized population of Baby Boomers." The Center predicts doubling of California's elderly population over the next 20 years, meaning that the state's population will be slightly older, and consequently less healthy, than the nation as a whole.[38] Anthony Wright, Executive Director of Health Access, a non-profit coalition that advocates for consumers, points out that "Californians are more likely to be uninsured, less likely to get coverage at their job, less likely to be able to afford coverage on their own, and more likely to be denied for pre-existing conditions."[39] California's large population, its experience with models of integrated care delivery, and its two separate insurance regulators (the Department of Insurance and the Department of Managed Health Care) make implementation of the ACA in California especially difficult.

However, implementation of some of the core tenets of the ACA has already taken place. In point of fact, many such tenets would be difficult to excise from health care regardless of the Court's decision. As with the rest of the nation, in California health insurance will remain available for dependents until the age of 26,[40] the prohibition of using preexisting conditions as a basis for excluding health care coverage will continue,[41] issuers of health insurance will continue to be required to make meaningful and reasonable disclosures detailing the benefits and premiums relating to coverage,[42] health plans will not be permitted to limit lifetime or annual benefits (a concept to be gradually phased in between now and 2014),[43] and certain measures of preventive health services will continue to apply under both group and individual health insurance coverage.[44]

Tax credits are still available for qualifying small businesses with no more than 25 full-time employees for up to 35% of the employer's contribution toward an insurance premium, and as of 2014 this will apply for participation in California's health insurance exchange.[45]

Small businesses can still take advantage of federal grants when they offer workplace wellness programs, and all businesses are eligible for federal assistance in establishing employer-based wellness programs.[46] For the 27 approved accountable care organizations currently participating in the Medicare shared savings program,[47] including two in California, this means that their sizeable investment of time and money in becoming participants in that program will not have been in vain.

While health care reform may have survived its encounter with the Supreme Court, notwithstanding the above its future is anything but certain. Though it is probable that many of the programs referenced in this article will endure whatever iterations of health care reform the future holds, the true legacy of the ACA faces one more daunting challenge in November. Whether or not the ACA will escape partisan politics unscathed remains to be seen and concluding words of the Chief Justice aptly set the stage for what is to come: "[T]he Court does not express any opinion on the wisdom of the ACA. Under the Constitution, that judgment is reserved to the people."[48] By the ballot their voice will soon be heard.

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[1] All references to the ACA include the 2010 Patient Protection and Affordable Care Act, Pub. L. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act, Pub. L. 111-152 (Mar. 30, 2010).

[2] *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012).

[3] The individual mandate creates an obligation on the part of most Americans to maintain "minimum essential coverage" beginning in 2014. *See* 26 U.S.C. § 5000A (2010).

[4] *National Federation of Independent Business*, at 2607. Specifically, the Court's holding restricts the ways in which the Federal Government can apply 42 U.S.C. section 1396c to such states.

[5] U.S. Const., Art. I, § 8, Cl. 1.

[6] § 8, Cl. 18.

[7] *National Federation of Independent Business*, at 2591.

[8] *Id*. at 2573 (emphasis in original).

[9] *Id*. at 2592.

[10] *Id*.

[11] *Id*. at 2593 (quoting U.S. Const., Art. I, § 8, Cl. 1). The Court also addressed challenges to justiciability, and in particular whether the Anti-Injunction Act [26 U.S.C. § 7421(a)] prevented a ruling on the merits of the case. The Court held that the ACA did not require the penalty provisions to be treated as a tax for violations of the individual mandate, and as such the Anti-Injunction Act did not apply. *Id*. at 2594-95. In their dissenting opinion, Justices Scalia, Kennedy, Thomas and Alito disputed that Congressional taxing authority should control, but nonetheless took issue with the Government's position that "the very same textual indications that show this is *not* a tax under the Anti-Injunction Act show that it *is* at tax under the Constitution. That carries verbal wizardry too far, deep into the forbidden land of the sophists." *Id*. at 2656 (Scalia, Kennedy, Thomas and Alito, JJ, dissenting) (emphasis in original).

[12] *Id*. at 2600 ("Once we recognize that Congress may regulate a particular decision under the Commerce Clause, the Federal Government can bring its full weight to bear. Congress may simply command individuals to do as it directs. An individual who disobeys may be subjected to criminal sanctions.").

[13] *Id*. The Court also noted that the ACA waives any criminal penalties in the event a taxpayer fails to comply with the penalty imposed by the individual mandate. *See* 26 U.S.C. § 5000A(g)(2)(A).

[14] *The California Health Care Landscape*, Henry J. Kaiser Family Foundation, (December 2011), *available at* http://www.kff.org/medicaid/8268.cfm.

[15] The individual mandate exempts prisoners and undocumented aliens from compliance, *see* 26 U.S.C. § 5000A(d), and vitiates any penalty for individuals with income below a certain threshold. *See* 26 U.S.C. § 5000A(e).

[16] "Minimal essential coverage" includes coverage under Medicare, Medicaid or other federally funded health care programs, employer-sponsored plans, health insurance through the soon-to-be established health insurance exchanges, "grandfathered" plans, and certain approved high risk pools established under the ACA. 26 U.S.C. § 5000A(f)(1).

[17] Under the ACA, businesses with more than 50 full-time employees must offer health insurance that satisfies the minimum essential coverage requirements or pay an annual penalty in the amount of $2,000 for each employee (reduced by 30 employees solely for the purpose of calculating the penalty). 26 U.S.C. § 4980H (2010).

[18] Assem. B. 1602 (Perez) (Cal. 2010); *see also* Cal. Gov't Code § 100500 (2011); Cal. Health & Safety Code § 1366.6 (2011).

[19] Victoria Colliver, *Health Care Exchange Will Offer Policies*, SF Gate, San Francisco Chronicle, (June 29, 2012) at page 2, *available at* http://www.sfgate.com/health/article/Health-care-exchange-will-offer-policies-3675063.php.

[20] The expansion includes covering "*all* individuals under the age of 65 with incomes below 133 percent of the federal poverty line" and establishing health insurance programs for new Medicaid beneficiaries that satisfy the threshold requirements under the individual mandate. *National Federation of Independent Business*, at 2601 (emphasis in original); *see also* 42 U.S.C. § 1396a(k)(1) (2012).

[21] *National Federation of Independent Business*, at 2606 (quoting *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 25 (1981)).

[22] *Id*. at 2607.

[23] *Id*. at 2608. In essence, the Court held that the ACA lacked the constitutional authority to obligate state acquiescence in response to the Congressional edict. Rather, "Congress may offer the States grants and require the States to comply with accompanying conditions, but the States must have a genuine choice whether to accept the offer." *Id*.

[24] California's version of Medicaid is "Medi-Cal."

[25] 42 U.S.C. § 1396d(y) (2011).

[26] Justices Scalia, Kennedy, Thomas and Alito noted the following in their dissenting opinion: "Congress never dreamed that any State would refuse to go along with the expansion of Medicaid. Congress well understood that refusal was not a practical option." *National Federation of Independent Business*, at 2665 (Scalia, Kennedy, Thomas and Alito, JJ, dissenting).

[27] *See generally* Hsia, Renee Y., M.D., Factors Associated with Closures at Emergency Departments in the United States, 305 (19) JAMA 1978 (May 18, 2011).

[28] Pub. L. 99-272, 100 Stat. 164 (1986).

[29] 42 U.S.C. § 13955dd (2011). Also under EMTALA, any hospital "that negligently violates a requirement of this section is subject to a civil money penalty of not more than $50,000 (or not more than $25,000 in the case of a hospital with less than 100 beds) for each such violation." § 1395dd(d)(1)(A).

[30] C. Duane Dauner, President of the California Hospital Association, *California Hospitals Pleased by Supreme Court Decision Upholding Access to Coverage Under ACA* (June 28, 2012), *available at* http://www.calhospital.org/media-statement/california-hospitals-pleased-supreme-court-decision-upholding-access-coverage-under.

[31] *California Medical Association Responds to United States Supreme Court Ruling* (June 28, 2012), *available at* http://www.cmanet.org/news/press-detail/?article=california-medical-association-responds-to0

[32] *AHIP Statement on Supreme Court Ruling* (June 28, 2012), *available at* http://www.ahip.org/News/PressRoom/2012/AHIP-Statement-on-Supreme-Court-Ruling.asp.

[33] Cal. Health & Safety Code § 1366.6(b) (2011).

[34] *See* 77 Fed. Reg. 18310 (Mar. 27, 2012) (to be codified at 45 C.F.R. Parts 155, 156 and 157).

[35] *Id* at 18311.

[36] *National Federation of Independent Business*, at 2580. Essential health benefits must include at least the following health care services: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventative and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. *See* 42 U.S.C. § 18022(b)(1) (2010).

[37] In her dissenting opinion, Justice Ginsburg discussed the challenges states may face in coordinating benefits that conform to threshold requirements under the ACA. "[T]he minimum coverage provision, along with other provisions of the [ACA], addresses the very sort of interstate problem that made the commerce power essential in our federal system. . . . The crisis created by the large number of U.S. residents who lack health insurance is one of national dimension that States are 'separately incompetent' to handle." *National Federation of Independent Business*, at 2628 (Ginsburg, J., dissenting).

[38] *California's Aging Population: Not Forever Young; Stanford Center on Longevity, available at* http://longevity.stanford.edu/blog/2012/06/californias-aging-population-not-forever-young/.

[39] Rachel Myrow, *Californians Have a Big Stake in the Health Care Decision*, KQED News (June 28, 2012) *available at* http://www.kqed.org/news/story/2012/06/28/99522/californians_have_a_big_stake_in_the_health_care_decision?category=bay+area.

[40] 42 U.S.C. § 300gg-14(a) (2010).

[41] § 300gg-3.

[42] § 300gg-9.

[43] § 300gg-11.

[44] § 300gg-13.

[45] 26 U.S.C. § 45R (2010).

[46] 42 U.S.C. § 280l (2010).

[47] *See* § 1395jjj.

[48] *National Federation of Independent Business*, at 2608.

The Evolving Relationships Between Hospital, Physician and Patient in Modern American Healthcare

By Craig B. Garner and David A. McCabe
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Introduction

Today's healthcare climate is one of uncertainty, with the longstanding bond between doctor and patient growing ever more tenuous as the nation reacts to fundamental changes within its healthcare structure. Since March 2010, when President Obama signed into law the Patient Protection and Affordable Care Act[1] as amended by the Health Care and Education Reconciliation Act[2] (collectively referred to as the Affordable Care Act or "ACA"), the federal government has continued to release information aimed at clarifying and expanding upon the original 2,700 pages of codified reform. At its core, ACA seeks to prohibit health insurers from denying coverage or refusing claims based on pre-existing conditions, expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to offer healthcare benefits, and increase support for medical research.

As the implementation of these new programs, partnerships, preventative care measures, competitions and grants steals headlines daily, ACA's ramifications underscore the ways in which the Federal government has increased its presence in healthcare in an effort to ensure that the allocated trillion dollars in federal funding remains accountable. Arguments made by both critics and supporters of ACA have become all too familiar in the ongoing debates, with each side citing the nation's growing economic crisis as a major factor in ACA's future.

Meanwhile, both patients and providers are unsure how to respond to this bevy of changes as they wait to discover what impact ACA may have on their coverage and bottom line. To fuel this growing fire, both parties must remain in harm's way while they endure the collateral damage that seems set to accompany such dramatic restructuring of our system's foundations.

How Did We Get Here?

Thanks largely to the media's continued focus on the changes to our healthcare's structure since the passage of ACA, it is easy to forget the importance of history in understanding the nation's present day system. For starters, it has grown exponentially, both in terms of coverage and cost. In 1960 approximately 5.2 percent of the nation's $526 billion gross domestic product ("GDP") went toward national healthcare expenditures ("NHE" or national healthcare expenditure accounts ("NHEA")).[3] The NHE calculates total annual spending for healthcare in the United States (goods and services), in addition to total administrative spending each year, as well as the net cost of private health insurance, among other things.[4] By 2009, that same number had escalated to 17.6 percent of a $14.1 trillion GDP.[5] NHE increased from $74.9 billion in 1970 to $2.5 trillion in 2009, or from $356 per capita to $8,086 per capita.[6] Such a rate of growth points to fundamental changes within the structure of healthcare itself, which may explain the difference between the $3.5 billion budget for the United States Department of Health and Human Services ("HHS") in 1962 and the estimated $1.2 trillion projected for 2016.[7]

Representing a fundamental component of federal healthcare spending for nearly fifty years is Medicare, the public health insurance program that has been both a source of political contention and a beacon of hope from which to gauge the changes in American healthcare as a whole since it first passed in 1965 as part of the Social Security Amendments. [8] Medicare had as its original focus individuals sixty-five years of age and older,[9] with a similar yet state-run program, Medicaid, addressing the medical needs of people with certain disabilities and low-income families.[10] And yet, at a cost of $10,075 per beneficiary in 2010, Medicare has over the years grown to represent the backbone for the entire nation's healthcare system, which is a far cry from its humble origins and initial cost of $593 per beneficiary in 1967.[11] Indeed, 2009 figures show that Medicare consumed $502 billion, or 20 percent of total NHE, creeping that much closer to the $801.2 billion (32 percent of total NHE) spent the same year on private health insurance. Medicare kept its respectable lead over the $373.9 billion (15 percent of total NHE) directed toward Medicaid and the $299.3 billion (12 percent of total NHE) from out-of-pocket spending.[12]

In 1967, for its 19.5 million enrollees, Medicare reimbursed hospital services (including inpatient care, skilled nursing facility services, home health agency services, and hospice services, (referred to today as Part A) the sum of $4.24 billion.[13] For the 47.7 million Medicare enrollees in 2010, this figure increased to $176 billion.[14] For physician services and other healthcare

needs that eventually came to comprise what is known today as Part B, the Medicare program paid $1.27 billion in 1967 (for 17.9 million enrollees) and $154 billion by 2010 (for 44 million enrollees).[15]

Through the 1980s, physician compensation followed an upward trajectory more consistent with inflation than healthcare,[16] even if the slope of this elevation was not as steep as the overall growth in Medicare payments. Between 1982 and 1989, the average annual income for physicians increased by 24 percent to $155,800, with surgeons enjoying a 33 percent increase to $220,500.[17] The most recent information for a twelve-month period (2010) from the United States Department of Labor, Bureau of Labor Statistics estimated the mean annual wage at $189,480 for internists, $173,860 for family and general practitioners, and $225,390 for surgeons.[18]

The role of the modern hospital has also changed considerably over the last 20 years, as more and more facilities have had to struggle to keep their doors open. According to the latest data published by CMS, in 1990 there were an estimated 6,552 hospitals (including short stay, critical access, and non-short stay facilities); by 2010 that number had dropped to 6,169,[19] a nearly six percent decrease in comparison to the 16 percent increase in Medicare enrollees during that same twenty year time period.[20] The combined increase in utilization and decrease in number of hospitals is especially significant in California, where healthcare spending has grown exponentially over time. California's population has continued to increase even as the number of hospitals statewide has decreased,[21] resulting in close to a 10 percent reduction in the number of hospital beds in California between 2002 and 2009.[22]

Even against such odds, hospitals have remained a major point of access to American healthcare, in large part because of the availability of their emergency departments. The 1986 Emergency Medical Treatment and Active Labor Act ("EMTALA")[23] requires hospitals to provide a specified level of care to anyone presenting for emergency medical treatment regardless of citizenship, legal status, or ability to pay, or risk the imposition of hefty fines or even loss of participation in federal healthcare programs. As a result, the great bulk of responsibility for America's uninsured has fallen to the nation's hospitals, who must now shoulder approximately 60 percent of uncompensated medical care.[24] Such a mandate to provide treatment to the uninsured weighs heavily on facilities striving to stay afloat amid an ocean of often-conflicting regulations.

In 2008 alone, uncompensated medical care in the United States approached an estimated $57 billion, of which nearly $43 billion was paid by federal, state, and local governments from funds earmarked for this very purpose through Medicare. This included disproportionate share hospital ("DSH") payments, indirect medical education ("IME") payments, and Medicaid (including DSH payments and supplemental provider payments, for example).[25] Although the Federal Government typically foots close to half of this annual bill, its contribution equals only 2 percent of federal healthcare spending yearly.[26]

In addition to EMTALA's influences, ACA contains certain mechanisms for CMS to evaluate both patient satisfaction and hospital quality measures. As a result, within the next few years hospitals may face a one percent reduction overall on Medicare payments under the Inpatient Prospective Payment System ("IPPS"), as these funds are now earmarked to cover performance bonuses. By 2015, hospitals that continue to show poor performance ratings will not only be excluded from this bonus pool, they will also face additional cuts in reimbursement.[27]

2012 proved to be an interesting year now that the United States Supreme Court has confirmed the Constitutionality of ACA [28] While interest in the Supreme Court's landmark decision, as well as the Presidential elections in the United States, served to keep ACA in the limelight, it seems unlikely that any single action will put an end to the debate over healthcare reform.[29] While speculating about the direction in which the majority will rule, it thus becomes increasingly important to pay particular attention to the dissenting opinion(s), as they may prove in the long run to be akin to a modern-day oracle concerning the future of reform.[30]

The Present Day Impact on Doctors and Hospitals

The proposed legislation creating the Medicare program initially sought to include an array of physician services as well as hospital care. Attempting to placate both sides of the partisan debate, legislators divided the Medicare program into a series of sections, each of which was to reign over a specific aspect of healthcare. The program's cornerstone was "Part A," which provided health insurance coverage for qualified individuals requiring hospitalization.[31] As a concession to the demands of physician lobbying efforts and public fears, Congress then created "Part B," a set of optional benefits addressing medical necessities such as doctor services, outpatient care, and home health maintenance.[32] Over the years, Congress has

carefully defined the term "hospital" under its Medicare program[33], while at the same time closely guarding the rates at which hospitals are reimbursed under the program. Although Part B did provide limited coverage for physician and other similar services, it imposed no restrictions on what physicians could charge, thereby creating a fundamental rift between doctors and hospitals, each now having different incentives in the way they approached the delivery of healthcare.[34]

Ironically, almost 50 years after the fact this rift has begun to come together under certain provisions within ACA. Two years after Medicare was passed, it expanded the scope of coverage under Part B to include additional services such as durable medical equipment, podiatric care, and outpatient physical therapy.[35] The federal Government also extended Medicare eligibility to people under the age of 65 with certain long-term disabilities and others with chronic kidney disease.[36] The 1973 Health Maintenance Organization Act[37] created a partnership of sorts between the Federal Government and certain healthcare providers, again changing the dynamic between hospitals and physicians by extending medical oversight authority to non-clinicians.

Perhaps the most dramatic change to Medicare since its formation was the creation of a classification system designed to standardize patient care by devoting a set price to a given procedure. Known as the diagnosis-related group ("DRG"), this prospective payment system did away with reimbursing providers for the actual cost of their services, creating instead a predetermined rate per illness based on a patient's diagnosis.[38] The introduction of the DRG system was in part responsible for an exodus of procedures that had traditionally been done in the hospital on an "inpatient" basis. Relying on advances in medical technology, many hospitals began to bridge the gap between Part A and Part B by working with physicians in outpatient facilities in an attempt to avoid whenever medically feasible the disparate reimbursement systems inherent in Parts A and B.[39]

Today's healthcare structure favors a new dynamic, as ACA emphasizes performance as a means to save money and increase efficiency, rather than the cost-based initiatives that had traditionally been the hallmark of American health care.[40] As such, it marks a dramatic shift in government policy as it relates to both regulation and funding.[41] While performance measures in healthcare have historically focused on individual clinicians rather than systems, ACA legislation now encourages the formation of accountable care organizations ("ACO"s), a concept designed to overhaul the nation's health care system by implementing structures that monitor the quality and efficiency of entire groups of medical practitioners in an effort

to assess performance and create standards for compensation. This Hospital Value-Based Purchasing Program is another step toward shifting the reimbursement infrastructure from the cost of services to improvements in patient health and performance.[42]

Such federal encouragements toward bundling[43] and the effects of these newly formed ACOs [44] may soon rule the day, providing comprehensive incentives for physicians and hospitals to realign in the interest of healthcare sustainability. Providing further motivation for hospitals and physicians to join forces, the federal government has recently eased up on the traditionally strict healthcare regulatory framework. In an initial step, the Office of the Inspector General has clarified the limited implications of physician self-referral laws and federal anti-kickback statutes.[45] Likewise, the Federal Trade Commission has confirmed that entry into ACOs will not require a mandatory antitrust review, while at the same time creating an antitrust "safety zone" for ACOs approved by CMS.[46] Finally, the Internal Revenue Service has provided participation guidelines for charitable organizations without compromising any tax-exempt status.[47]

From the Patient's Point of View

While the Federal Government has attempted to create a new system that will finally mend the rift that occurred in 1965, this does not necessarily mean that physicians and hospitals will elect to play in the same proverbial sandbox. What is perhaps more significant is that such new provisions within ACA do little to reassure patients that healthcare is headed in the right direction,[48] especially as the health insurance market has begun to spiral out of control well in advance of the 2014 effective date on certain restrictions.[49]

The relationship between health insurance and health care spending over the past fifty years illustrates another potential reason as to why patients have yet to fully embrace healthcare reform in its most recent incarnation. Although out-of-pocket expenses made up close to 50 percent of all national health expenditures in 1960, this same category plummeted to approximately 12 percent in 2009, due largely to the role that Medicare and Medicaid played in American healthcare.[50] While historically such influence tended to work in a patient's best interest, the last five years have shown a disturbing upward trend in the amount of money individuals and families have been forced to spend on healthcare insurance.[51]

Further exacerbating the situation, in 2006 only 6 percent of covered workers in small companies (those consisting of 3-199 employees) chose to enroll in a high deductible plan of $2,000 or more for individual coverage although by 2011 that number had increased to 28 percent.[52] Large companies (those consisting of 300 or more employees) saw a modest increase in $2,000 or more high deductible plan enrollment from one percent in 2006 to five percent in 2011. Individuals enrolled in deductibles of $1,000 or more increased from 16percent in 2006 to 50 percent in 2011 for small companies, while large firms increased from 6 percent in 2006 to 22 percent in 2011.[53] And while the average percentage of premiums paid by employees for individual and family coverage remained relatively flat between 1999 and 2011 (holding between 26 percent and 30 percent for family coverage and between 14 percent and 19 percent for individual coverage),[54] the actual amounts to be paid out of pocket proved anything but stable. In 1999, the average premium for individual coverage was $2,196, but by 2011 that figure had increased to $5,429. Similarly, family coverage averaged $5,791 in 1999, but jumped to $15,073 by 2011.[55]

Reevaluating the Doctor/Patient Relationship

Healthcare has seen its fair share of shifts in strategic alliances over the years, as its structure has been forced to adapt to fluctuations in the marketplace as well as repeated recalibrations of government regulations, including those pertaining to issues of reimbursement.[56] As the amount of money our nation spends on healthcare continues to increase at alarming rates, patients, doctors, and hospitals will most likely have greater struggles than before. This inherent disconnect between the changes in our healthcare system and the satisfaction of patients and providers leaves much to be desired and considered.[57]

To most Americans in the modern age, healthcare is considered a right rather than a privilege, particularly when it comes to emergency medical care. To date there is no prerequisite granting entitlement to its benefits save that of U.S. citizenship, and even the highest level of neglect will not bar any claim to services. But if health care remains a right that one cannot forfeit through abuse, who should be made responsible for picking up the tab? In the past, the business of healthcare has often operated outside the parameters of fiscal consideration, and it is this lack of financial control that has now come to threaten health care's very existence. At its core, the new system proposed by reform seeks to address these inequities, recognizing that its survival relies on its sustainability.

For healthcare reform to succeed, individuals must come to accept the harsh truth that the present path on which this country is headed may ultimately lead to the abolition of unrestrained entitlement to care. Since the establishment of parameters that may one day lead to individual loss of this basic right is not presently up for consideration, now is the perfect opportunity for the creation of an alliance that recognizes not only our right to comprehensive care, but also our responsibility to ourselves and the system in which we trust. Mutual compromise is our only hope for the resurrection of the doctor/patient relationship.

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[1] Pub. L. 111-148.

[2] Pub. L. 111-152.

[3] United States Department of Commerce, Bureau of Economic Analysis; Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads//tables.pdf.

[4] *See* Micah Hartman, Anne Martin, Olivia Nuccio, Aaron Catlin, *Health Spending Growth at a Historic Low in 2008,* 29, No. 1 Health Affairs 147 (Jan. 2010) (citing Centers for Medicare & Medicaid Services, National health expenditure accounts: definitions, sources, and methods used in NHEA 2008).

[5] *Id*.

[6] *See* Micah Hartman, *et al*., *Health Spending Growth at a Historic Low in 2008*, at 147-48; Centers for Medicare & Medicaid Services, National Health Expenditure Data 2009.

[7] Figures from the Federal Government's Office of Budget and Management ("OBM") and the U.S. Government Printing Office ("GPO").

[8] Social Security Amendments of 1965, Pub. L. No. 89-97.

[9] 42 U.S.C. § 1395c.

[10] 42 U.S.C. § 1396a.

[11] *See* Centers for Medicare & Medicaid Services, Office of Information Services; Centers for Medicare & Medicaid Services, Officer of the Actuary; Centers for Medicare & Medicaid Services, National Health Expenditure Data 2009.

[12] *Id*.

[13] *Id*.

[14] *Id*.

[15] *See* Centers for Medicare & Medicaid Services, Office of Information Services.

[16] *See* U.S. Department of Labor, Bureau of Labor Statistics, *available at* http://www.bls.gov/home.htm.

[17] GC Pope and JE Schneider, *Trends in Physician Income*, 11 Health Affairs 1, 181, 183 (1992).

[18] According to the U.S. Department of Labor, annual wages are calculated by multiplying the hourly mean wage by a "year-round, full-time" hourly figure of 2,080 hours, unless a particular occupation does not have an hourly mean wage published, in which case the annual figure comes from survey data. *See* U.S. Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, 2010.

[19] *See* Centers for Medicare & Medicaid Services, Center for Strategic Planning, 2011 CMS Statistics, p. 2, *available at* www.cms.hhs.gov/home/rsds.asp.

[20] *See* Centers for Medicare & Medicaid Services, Office of the Actuary, *available at* www.cms.gov/MedicareEnrpts/.

[21] In California between 2002 and 2009, healthcare spending increased by 34%, but there were 40 fewer hospitals available to treat approximately 2.7 million additional residents. *See* U.S. Census Bureau's annual survey of state and local government finances.

[22] *See, e.g.*, Hsia, Renee Y., M.D., *Factors Associated with Closures at Emergency Departments in the United States*, 305 (19) JAMA 1978 (May 18, 2011) (noting that emergency department visits in the U.S. have increased by as much as 30%).

[23] Pub. L. 99-272.

[24] *See id.; see also The Uninsured: A Primer*, The Henry J. Kaiser Family Foundation (Oct. 2011).

[25] *See, e.g.*, Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248 (TEFRA directed HHS to study the need to adjust hospital rates for treating low-income patients, and was the origin of the DSH adjustment); 76 Fed. Reg. 148 (Jan. 3, 2011) (Medicaid DSH Payments); Consolidated Omnibus Reconciliation Act of 1985, (Pub. L. 99-272 (COBRA mandated explicit adjustments for hospitals treating low-income patients); 42 C.F.R. Parts 447 and 455 (Medicaid DSH payments); *but see* Balanced Budget Act of 1997 (Pub. L. 105-33) (reducing DSH payments); *see also* J. Hadley, *Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs*, Health Affairs, Web Exclusive pp. W399–W415 (Aug. 25, 2008).

[26] National Healthcare Expenditures ("NHE") approached $2.5 trillion in 2009. *See* notes 4 and 5, *supra*.

[27] ACA § 3022; 42 C.F.R. § 425 (proposed rules as of Apr. 7, 2011); *see also* Berwick, Donald M., M.D., *Launching Accountable Care Organizations — The Proposed Rule for the Medicare Shared Savings Program*, New Eng. J. Med. (Mar. 31, 2011).

[28] *National Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

[29] *But see id.* at 2608. In his conclusion, Chief Justice Roberts aptly set the stage for what is to come in November: "[T]he Court does not express any opinion on the wisdom of the ACA. Under the Constitution, that judgment is reserved to the people."

[30] *See Douglas v. Independent Living Ctr. of S. Cal., Inc.*, 132 S. Ct. 1204, 1211 (2012).

[31] Greenfield, Margaret, *Health Insurance For the Aged* (Institute of Governmental Studies, University of California, 1966).

[32] *Id.*

[33] *See* 42 U.S.C. § 1395x(b).

[34] U.S. General Accounting Office, *History of the Rising Costs of Medicare and Medicaid* (1976).

[35] 42 U.S.C. § 1395x.

[36] Pub. L. 92-603.

[37] Pub. L. 93-222.

[38] *See* Wilensky, Gail R., *The Economics of DRG-Based Physician Reimbursement* (Center for Health Affairs, 1985).

[39] *See* Mayes, Rick, *Origins, Development, and Passage of Medicare's Revolutionary Prospective Payment System*, J. Med. & Allied Sci., Vol. 61, No. 1 (Jan. 2007).

[40] *See* 42 C.F.R. Parts 412, 413, 424 and 476.

[41] ACA § 3022.

[42] *Id; see also* Berwick, Donald M., M.D., *Launching Accountable Care Organizations – The Proposed Rule for the Medicare Shared Savings Program*, New Engl. J. Med. (Mar. 31, 2011).

[43] *See* ACA § 3023.

[44] *See* 42. C.F.R. Part 425.

[45] 76 Fed. Reg. 67992 (Nov. 2, 2011).

[46] *See Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, Federal Trade Commission (2011).

[47] *See* 2011-16 I.R.B. 652 (Apr. 18, 2011).

[48] As just one example, a Medicare fee-for-service beneficiary is assigned to an ACO when the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology. CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided by a physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined. Assignment will be updated quarterly based on the most recent 12 months of data. Final assignment is determined after the end of each performance year, based on data from that performance year.

[49] *See, e.g.*, Colliver, Victoria, *Health insurance premiums to rise soon for many*, SF Gate (Mar. 31, 2012) *available at* www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2012/03/30/BUQS1NS6C3.DTL; Aaron, Henry J. and Frakt, Austin B., PhD., *Why Now Is Not the Time for Premium Support,* 366 N. Engl. J. Med. 877 (Mar. 8, 2012).

[50] *See* Centers for Medicare & Medicaid Services, office of the Actuary, National Health Statistics Group; U.S. Department of Commerce, Bureau of Economic Analysis; U.S. Bureau of the Census.

[51] *Id.* Out of pocket spending has increased from $263.4 billion in 2005 to $299.7 billion in 2010. At the same time, one study concluded that lower income families in high deductible health plans are more likely to delay or even forgo medical care due to the expense. *See* Grann, Victor R., MD, MPH, *High-Deductible Plans: What If You Can't Afford Your Share?* 170 (21) Arch. Intern. Med. 1925 (Nov. 22, 2010).

[52] *See* Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2011.

[53] *Id*.

[54] *Id*.

[55] *Id*.

[56] In its 2011 fiscal year (ending September 30, 2011), the Department of Justice procured settlements and judgments in its civil fraud division in excess of $3 billion, capping the largest three-year streak in the department's history at a total of $8.7 billion since January 2009. *See Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011*, U.S. Department of Justice, Office of Public Affairs (Dec. 19, 2011). For years 2010 and 2012, HHS' discretionary budget for health care fraud and abuse control was $311 million and $581 million, respectively. See HHS Budget, 2011. This $270 million increase in discretionary funding is designed to save $10.3 billion over ten years by preventing and prosecuting health care fraud. HHS' mandatory funding through the Health Care Fraud and Abuse Control (HCFAC) account is $6.5 billion between 2012 and 2016.

[57] Recently the OIG has focused its attention on hospitals and the need to improve internal reporting systems that capture instances of patient harm. Of the 189 hospitals surveyed by the OIG that use and often rely heavily upon incident reporting systems to identify patient harm, the outcomes were disturbing:

> Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. Of the events experienced by Medicare beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent. In the absence of clear event reporting requirements, administrators classified 86 percent of unreported events as either events that staff did not perceive as reportable (62 percent of all events) or that staff commonly reported but did not report in this case (25 percent).

Hospital Incident Reporting Systems Do Not Capture Most Patient Harm, Department of Health and Human Services, Office of the Inspector General (Jan. 2012). Other federal agencies were no more fortunate in escaping the watchful eye of the OIG. In a December 2011 report it criticized CMS, claiming that they reimbursed as much as $15.1 million under Medicare Part D to providers who were excluded from federal health care programs between 2006 and 2008. *See Review of Excluded Providers in the Medicare Part D Program*, Department of Health and Human Services, Office of the Inspector General (Dec. 2011). The OIG has also set its sights on the Medicare Recovery Audit Contractors (RACs) and Medicaid Integrity Contractors (MICs). Citing an abundance of inaccurate workload data and an overall lack of uniformity, the OIG criticized CMS once again for what the OIG considers substandard oversight in relation to these integrity contractors. *See Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors*, Department of Health and Human Services, Office of the Inspector General (Dec. 2011).

60 Days to Pay – Has Medicare Reached the Point of No Return?

COMPLIANCE TODAY (a publication of the Health Care Compliance Association) (Sept. 2012)

In February the Centers for Medicare & Medicaid Services ("CMS") clarified an oft quoted existing rule: Providers must return overpayments to Medicare within 60 days "after the date on which the overpayment was identified," or in the alternative, "the date any corresponding cost report is due, if applicable."[1] For providers of any size, failure to report and return Medicare overpayments pursuant to these temporal requirements may result in potential liability under the Federal False Claims Act[2], resulting in substantial monetary penalties and the risk of being denied future claims for reimbursement.

Dating back to the American Civil War, the False Claims Act (FCA) has over time become the "primary litigative tool for combating fraud" for both federal and state governments.[3] At its core, the FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[4] While most providers have worked within a similar time frame after identifying an overpayment, it appears that the statutory requirements under the 2010 Patient Protection and Affordable Care Act [5], as amended by the Health Care and Education Reconciliation Act[6] (collectively referred to as the Affordable Care Act or health care reform) were not enough.[7] In reaction, the February 2012 regulations now leave nothing to chance, imposing upon the health care industry detailed definitions with numerous examples to assist providers in determining exactly when the 60-day clock begins.[8]

To ensure that the seriousness of its resolve is understood, the Federal Government plans to soon have the authority to enforce this 60-day requirement for overpayments that have occurred up to 10 years in the past:

> In § 401.305(g), we are proposing that overpayments must be reported and returned only if a person identifies the overpayment within 10 years of the date the overpayment was received. We selected 10 years because this is the outer limit of the False Claims Act statute of limitations. We believe that the proposed 10-year lookback period is appropriate for several reasons. First, we believe that providers and suppliers should have certainty after a reasonable period that they can close their books and

> not have ongoing liability associated with an overpayment. We also believe that the length of the lookback period is long enough to sufficiently further our interest in ensuring that overpayments are timely returned to the Medicare Trust Funds.[9]

Held to a standard of actual knowledge or "reckless disregard or deliberate ignorance" for purposes of identifying an overpayment under the new regulations, CMS notes these new requirements provide for "an incentive to exercise reasonable diligence to determine whether an overpayment exists,"[10] or more specifically, did exist at any time within the past 10 years. While this decade-long requirement may seem excessive in the context of accidental and unidentified overpayments, especially in instances when the provider was not knowingly at fault, it is an essential component in the arsenal of the U.S. Department of Health and Human Services (HHS), and factors highly in its $1.2 trillion projected budget for 2016.[11] Though at first glance they may seem heavy handed, such tools have grown from the necessity inherent in dealing with the oversight of national health expenditures (NHE) that have reached $2.5 trillion as of 2009.[12]

In the current climate of health care reform, providers would be wise to embrace industry innovations designed to improve upon overall integrity, efficiency and performance, especially since the same infrastructure with its 21st century precision may help to identify unintentional overpayments dating as far back as 2002. Federal encouragements toward bundling[13] and the Medicare Shared Savings Program[14], more commonly referred to as accountable care organizations or ACOs, offer opportunities for providers to keep up with these mounting regulatory burdens just as the national push toward electronic health records reaches "stage two." What remains to be seen is how many of the nation's estimated 6,100 hospitals[15] will embrace ACOs, with their multi-million dollar price tag, and be willing to dive into the 455 pages of codified "Stage Two" requirements.[16] Perhaps the better question is how many of these same hospitals have satisfied the meaningful use requirements from Stage One.

Of course, the Federal Government and its record-breaking enforcement efforts stand ready to address any industry resistance. In its 2011 fiscal year[17], the Department of Justice procured settlements and judgments in its civil fraud division in excess of $3 billion. Capping the largest three-year streak in the department's history at a total of $8.7 billion since January 2009,[18] the Federal Government owes its recent success in part to a strategic alliance with beneficiaries.[19] In November 2011, HHS announced a $9 million award from CMS to Senior Medicare Patrol ("SMP") programs designed to tackle fraud by increasing awareness of

Medicare beneficiaries and enabling them to spot Medicare fraud sooner. The OIG has even focused its attention on hospitals and the need to improve internal reporting systems to identify patient harm, the outcomes were disturbing:

> Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. Of the events experienced by Medicare beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent. In the absence of clear event reporting requirements, administrators classified 86 percent of unreported events as either events that staff did not perceive as reportable (62 percent of all events) or that staff commonly reported but did not report in this case (25 percent). [20]

Early adopters of the finest technological advances the industry has to offer may avoid the looming threat of health care's newest, most ominous acronyms: RACs, MACs, MICs and ZPICs. Under the aegis of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA)[21], Congress directed HHS to conduct a three-year demonstration program using Recovery Audit Contractors ("RACs") to detect and correct improper payments within Medicare. By all government accounts, the original RAC demonstration program was successful, ending with more than $1.03 billion recovered. According to CMS, approximately 96% of these payments were overpayments collected from providers (85% of which were collected from hospital providers), and the remaining 4% were underpayments.

The Deficit Reduction Act of 2005 (DRA)[22], took the partnership between the CMS and the States to a new level by introducing RAC-like audits for Medicaid. The Medicaid Integrity Program (MIP) offers a unique opportunity to identify, recover and prevent inappropriate Medicaid payments. Medicaid Integrity Contractors ("MICs") work with CMS to carry out this program. It is also designed to support the efforts of State Medicaid agencies through a combination of oversight and technical assistance.

Recently introduced Medicare Administrative Contractors (MACs) conduct medical reviews to prevent improper payment of inpatient hospital claims, while Zone Program Integrity Contractors (ZPICs) look at billing trends and patterns in an attempt to uncover Medicare fraud and inefficiencies. CMS has organized the seven jurisdictional zones for ZPICs to comport with the multiple MAC jurisdictions, hoping that ZPICs will assist in preserving the integrity of Medicare.[23]

There is a certain degree of irony in the fact that the nation's preeminent health care system, which was originally designed to protect America's aging population, may end up killing the very infrastructure from which it has sprung. In April 1959, the U.S. Department of Health, Education, and Welfare ("HEW") first raised the fundamental question that remains unanswered 53 years later, as health care reform enters its third year:

> The rising cost of medical care, and particularly of hospital care, over the past decade has been felt by persons of all ages. Older persons have larger than average medical care needs. As a group they use about two-and-a-half times as much general hospital care as the average for persons under age 65, and they have special need for long term institutional care. Their incomes are generally considerably lower than those of the rest of the population, and in many cases are either fixed or declining in amount. They have less opportunity than employed persons to spread the cost burden through health insurance. A larger proportion of the aged than of other persons must turn to public assistance for payment of their medical bills or rely on "free" care from hospitals and physicians. Because both the number and proportion of older persons in the population are increasing, a satisfactory solution to the problem of paying for adequate medical care for the aged will become more rather than less important. In our society the existence of a problem does not necessarily indicate that action by the Federal Government is desirable. The basic question is: Should the Federal Government at this time undertake a new program to help pay the costs of hospital or medical care for the aged, or should it wait and see how effectively private health insurance can be expanded to provide the needed protection for older persons?[24]

Before Medicare, federal funds flowed across the nation as states made much-needed disbursements consistent with Congressional requirements. In many ways Medicare's predecessor, the Hospital Survey and Construction Act (the "Hill Burton Act"), forced communities and their local hospitals (many of which were doctor owned at the time) to work together, pooling these government grants as well as their own resources and equipment in order to stay in business.[25]

At the time, providers viewed this infusion of capital in the context of communities, rather than individual hospitals. If a local hospital needed new equipment, its leadership went to other nearby facilities or the community as a whole to fill the gap, and collectively these institutions could share in the federal funds disbursed under the aforementioned Act.[26] In many ways,

1965 found Medicare leaving the totality of America's hospitals as isolated as critical access hospitals appear today, gradually eliminating the ability for sharing clinical resources, at least to the extent an expectation of compensation was concerned.

In the past, it was initially America's rural hospitals that predicted Medicare's prospective payment system would be its ultimate demise. In a statement by Republican Congressman Norman D. Shumway from California: "One area of particular concern is the impact of the prospective payment system on rural hospitals. Such hospitals have frequently complained that the prospective payment system does not accurately reflect the increased hospital market basket since [fiscal year] 1984." Congressman Shumway noted that many experts in the industry concluded "with chilling thought that if inadequate Medicare reimbursement is allowed to continue, hospitals will be forced to go out of business, jeopardizing the health care – and economic stability – of rural America."[27]

Twenty-five years later, Medicare finds itself going through a transformation that rivals the impact of its formal introduction on the existing health care structure in 1965, and not just rural and community hospitals, but also some of their larger, urban counterparts, still wait on "life support" across the nation. Medicare may not bear the ultimate blame over the decades, but the ways in which the program has served as a weathervane for the health care industry make it an easy target. Moreover, the Federal Government's recent well-publicized determination to eliminate health care fraud and waste has sent a message to the industry, and clarification of the 60-day overpayment reimbursement requirement underscores the speed with which the OIG intends to deliver its message.

Unfortunately, health care has never been known for responding quickly to problems. This latest cluster of fraud and abuse regulations, combined with the nationwide push toward reimbursement based upon performance rather than cost does not bode well for smaller facilities (rural and community hospitals). Indeed, a hospital's chance of survival in Medicare's new world may ultimately depend on the sophistication and implementation of its core systems, both technical and practical, with little room for error. In this vein, Medicare's Hospital Value-Based Purchasing Program may create a disadvantage for freestanding community and rural hospitals that lack the resources of larger, better funded institutions, making it difficult for them to both implement and monitor the components established by Medicare to be eligible for reimbursement based on quality and performance.

Technology may in the long run provide an opportunity to level the playing field, but such implementations in health care can run years behind practical advances. For example, though both the Federal Government and California have recognized telemedicine as a way to reverse the declining health of the rural health system, such recognition occurred well over a decade ago,[28] and existing laws governing telemedicine today are still not entirely "hospital friendly."[29] Such hindrances are especially important in today's world of electronic health records, where straddling the fence between harmless information and sensitive data is no longer an easy task, and the repercussions for the slightest transgression can be severe.[30]

Even as technology provides opportunities, corresponding HIPAA violations can be devastating. If a provider had no prior knowledge that a HIPAA violation occurred, the civil penalty may range from $100 to $25,000 for each violation.[31] When a HIPAA violation has been due to reasonable cause, the civil penalty may range from $1,000 to $100,000.[32] In the case of a willfully negligent HIPAA violation, the penalty may range from $10,000 to $250,000.[33] In fact, HHS may impose cumulative penalties for all violations "of identical requirement or prohibition during a calendar year," up to $1,500,000.[34] And finally, in the case of an "intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the penalty may not exceed $250,000, imprisonment up to 10 years, or both."[35]

The systemic problems facing the Medicare system today should not be underestimated, especially when escalating health care expenses threaten the system's future sustainability. Institutional survival, however, is also an undeniably critical component in the delivery of health care, especially if future Medicare beneficiaries intend to access the health care services to which they are entitled under any Federal health program. Fully understanding the alternative deviates slightly from tenets of medicine and science, and perhaps is better phrased by philosopher George Berkeley: "But, say you, surely there is nothing easier than for me to imagine trees, for instance, in a park [...] and nobody by to perceive them. [...] The objects of sense exist only when they are perceived; the trees therefore are in the garden [...] no longer than while there is somebody by to perceive them."[36]

[1] 42 U.S.C. § 1320a-7k(d)(2).

[2] 42 U.S.C. § 1320a-7k(d)(3).

[3] *United States v. Boeing Co*., 9 F.3d 743, 745 (9th Cir. 1993) (quoting Senate Judiciary Committee, False Claims Amendments Act of 1986, S. Rep. No. 345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266).

[4] 31 U.S.C. § 3729(a)(1)(A).

[5] Pub. L. 111-148.

[6] Pub. L. 111-152.

[7] *See* Section 6402(a) of the Affordable Care Act, entitled "Reporting and Returning of Overpayments."

[8] 77 Fed. Reg. 9179, 9181-82 (Feb. 16, 2012).

[9] *Id.* at 9184. The proposed regulations offer several examples to assist providers in understanding when an overpayment has been identified, including the discovery of an excluded individual providing services on behalf of the provider, the fact that a patient death occurred prior to the serve date on a claim, or in the instance of an internal audit that uncovers an overpayment, *id*. at 9182, at any time within the past ten years. *Id.* at 9184.

[10] *Id.* at 9182.

[11] Figures from the Federal Government's Office of Budget and Management (OBM) and the U.S. Government Printing Office (GPO).

[12] *See* Micah Hartman, Anne Martin, Olivia Nuccio, Aaron Catlin, *Health Spending Growth at a Historic Low in 2008*, 29, No. 1 Health Affairs 147-48 (Jan. 2010) (citing Centers for Medicare & Medicaid Services, National health expenditure accounts: definitions, sources, and methods used in the NHEA 2008).

[13] *See* Affordable Care Act § 3023.

[14] *See* 42 C.F.R. Part 425.

[15] In 1990 there existed an estimated 6,522 hospitals (including short stay, critical access, and non-short stay facilities), whereas by 2010 that number had dropped to 6,169, a nearly 6% decrease in comparison to the 16% increase in Medicare enrollees during that same twenty year time period. See Centers for Medicare & Medicaid Services, Office of the Actuary. The combined increase in utilization and decrease in number of hospitals is especially significant in California, where health care spending has grown exponentially over time. California's population has continued to increase even as the number of hospitals statewide has decreased, resulting in close to a 10% reduction in the number of hospital beds in California between 2002 and 2009. *See, e.g.*, Hsia, Renee Y., M.D., *Factors Associated with Closures at Emergency Departments in the United States*, 305 (19) JAMA 1978 (May 18, 2011) (noting that emergency department visits in the U.S. have increased by as much as 30%).

[16] 77 Federal Register 13697 (Mar. 7, 2012).

[17] The Federal Government's fiscal year ended September 30, 2011.

[18] *Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011*, U.S. Department of Justice, Office of Public Affairs (Dec. 19, 2011).

[19] In May 2009, the DOJ and HHS created the Health Care Fraud Prevention and Enforcement Action Team (HEAT). *See* Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention and Enforcement Action Team, HHS Press Release (May 20, 2009). For years 2010 and 2012, HHS' discretionary budget for health care fraud and abuse control was $311 million and $581 million, respectively. This $270 million increase in discretionary funding was designed to save $10.3 billion over ten years by preventing and prosecuting health care fraud. HHS' mandatory funding through the Health Care Fraud and Abuse Control (HCFAC) account is $6.5 billion between 2012 and 2016. *See* HHS Budget, 2011.

[20] *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, Department of Health and Human Services, Office of the Inspector General (Jan. 2012).

[21] Pub. L. 198-173.

[22] Pub. L. 109-171.

[23] *See, e.g., Reporting Issues Hinder CMS Oversight of Program Integrity Contractors*, 44 Gov't Contractor ¶ 384 (Nov. 22, 2011).

[24] U.S. Department of Health, Education, and Welfare (Apr. 1959) (emphasis added).

[25] *See generally* Hochban, Jacquelyn, *The Hill Burton Program and Changes in Health Services Delivery*, Inquiry 8 (Spring 1981); Lave, Judith R., *The Hospital Construction Act: 1948-1973* (American Enterprise Institute for Public Policy Research 1974).

[26] *See generally id.*

[27] Prepared statement of Representative Norman D. Shumway to the Honorable Edward R. Roybal, Chairman of the House Committee on Aging (1987).

[28] *See* Roberts, Ann David, *Telemedicine: The Cure for Central California's Rural Health Care Crisis?* 9 San Joaquin Agric. L. Rev. 141 (1999).

[29] California law, for example, has numerous obstacles with which providers must comply before employing the technology of telemedicine. Section 2209.5(c) of the California Business and Professions Code provides:

> Prior to the delivery of health care via telemedicine, the health care practitioner who has ultimate authority over the care or primary diagnosis of the patient shall obtain verbal and written informed consent from the patient or the patient's legal representative. The informed consent procedure shall ensure that at least all of the following information is given to the patient or the patient's legal representative verbally and in writing: (1) The patient or the patient's legal representative retains the option to withhold or withdraw consent at any time without affecting the right to future care or treatment nor risking the loss or withdrawal of any program benefits to which the patient or the patient's legal representative would otherwise be entitled. (2) A description of the potential risks, consequences, and benefits of telemedicine. (3) All existing confidentiality protections apply. (4) All existing laws regarding patient access to medical information and copies of medical records apply. (5) Dissemination of any patient identifiable images or information from the telemedicine interaction to researchers or other entities shall not occur without the consent of the patient.

[30] *See, e.g.,* Cal. Bus. & Prof. Code § 2290(f) ("The failure of a health care practitioner to comply with this section [2290] shall constitute unprofessional conduct.").

[31] 42 U.S.C. § 1320d-5(a)(3)(A).

[32] 42 U.S.C. § 1320d-5(a)(3)(B).

[33] 42 U.S.C. § 1320d-5(a)(3)(C).

[34] 42 U.S.C. § 1320d-5(a)(3)(D).

[35] 42 U.S.C. § 1320d-6(b).

[36] George Berkeley, *A Treatise Concerning the Principles of Human Knowledge* (1734).

Redefining the Valuation Methods of Modern Day Hospital Care

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Due to the sensitive nature of the industry it services, the American hospital must rightfully operate under copious federal and state regulations, in addition to volumes of rules and ordinances established by separate, non-governmental entities. Though policing policies such as accreditation, certification and periodic review come from a variety of both public and private sources, the goal is generally consistent: develop uniform standards to ensure that hospitals in the U.S. operate at an acceptable safety level while delivering quality patient care.

The Many Paths to Accreditation

Though its primary function is without question the delivery of accurate and effective medical treatment, health care is also big business.[1] In an attempt to promote constant vigilance among America's hospitals, any one institution may be subject to accreditation review at any time from private, non-governmental organizations such as the Joint Commission,[2] the Healthcare Facilities Accreditation Program (HFAP),[3] Accreditation Commission for Health Care (ACHC),[4] Community Health Accreditation Program (CHAP),[5] the Compliance Team, Inc.,[6] Healthcare Quality Association on Accreditation (HQAA),[7] or DNV Healthcare, Inc. (DNV),[8] among others.[9]

By and large, each private entity governs through its own set of rules. For example, the Joint Commission surveys hospitals by following more than 276 standards and reviewing 1,612 elements of performance. HFAP does largely the same thing pursuant to its 1,100 or more individual standards. Focusing on home medical equipment as well as durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"), HQAA has developed a review process consistent with federal standards.[10]

Hospital Accreditation and the Joint Commission

Should a hospital wish to treat Medicare beneficiaries (with the expectation of payment), it must first enter into a provider agreement with Medicare. As a condition precedent to such participation, hospitals must meet certain requirements established by the Social Security

Act[11] or imposed by the Secretary of the Department of Health and Human Services (HHS), more commonly referred to as "conditions of participation" (CoPs)[12]. Hospitals can satisfy this statutory requirement by certification through a state agency, or alternatively the provider can seek "accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded."[13] The federal government recognizes the Joint Commission – as well as certain other organizations that have been confirmed as capable of providing appropriate oversight – as a national accreditation program for hospitals participating in Medicare or Medicaid.[14]

Formed December 15, 1951, as an independent, non-profit entity, the Joint Commission (known until 2007 as the Joint Commission on Accreditation of Hospitals) began as a collaboration between the American College of Physicians, the American Hospital Association, the American Medical Association, the Canadian Medical Association, and the American College of Surgeons.[15] The Joint Commission started its process of administering hospital accreditations in January 1953, evolving over the years from a one-page set of requirements in 1919 (known as "The Minimum Standard") to a 152-page manual for standards in 1970 (known as the 1970 Accreditation Manual for Hospitals)[16] to the approximately 500-page manual that exists today.[17]

The Joint Commission provides the following mission statement for the organizations with which it partners: "To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value."[18] As with all acute care hospital accreditation entities,[19] the Joint Commission must confirm that these providers meet specific and extensive criteria set forth by the federal government.[20]

As part of the rigorous set of standards reviewed in any hospital survey, the Joint Commission integrates performance measures in hospital accreditation oversight through its ORYX® initiative (a term unique to the Joint Commission). First deployed by the Joint Commission in 1997, ORYX core measure data are among the key data elements included in the Joint Commission's focus on improvement.[21] In its original form, ORYX had no industry standard detailing the type or amount of data hospitals should collect, and in fact more hospitals initially resisted than participated in this approach. Today, however, this institutionalized method for garnering information based on quality measures is a federal requirement, and the Joint Commission now accumulates data from hospitals for approximately 60 different inpatient measures.[22] Moreover, not only does the federal government penalize hospitals for non-compliance,

the 2010 Patient Protection and Affordable Care Act (PPACA)[23] may soon emphasize quality and performance as the core foundation of health care's future reimbursement structure.[24]

In November 2010, the Joint Commission outlined a five-year plan to continue its monitoring of the changing health care climate as the organization addresses areas for improvement:

- Refinement of the process for electronic receipt of high quality standardized performance measure data that cover all aspects of care delivery within and across the various types of health care organizations (e.g., hospitals, long term care, home care, etc.). Approaches to refining this process will include exploration of the potential to expand the capability of the electronic health record to capture measured data as a byproduct of the health care delivery process.

- Expansion of the scope of measure sets available for selection by health care organizations. This includes increasing the complement of measure sets for hospitals to provide a broader menu for measure selection.

- Creation of sophisticated applications of measurement data use for accreditation, accountability and public reporting purposes.

- Coordination of data demands and prioritization of critical measurement areas by the various public and private sector entities to minimize data collection burden and eliminate redundancies for health care organizations, while maximizing the consistency and usefulness of the data. Coordination activities will focus on the amalgamation of data demands by large national entities including CMS, the QIOs, NQF, AHRQ, IOM and others.

- Continued, proactive support for the leadership role of the National Quality Forum in the identification of national measurement objectives and the establishment of a long-term collaborative relationship.

- Continued proactive support for, and participation in, the work of the Hospital Quality Alliance, the AQA, and their combined efforts to harmonize these activities.[25]

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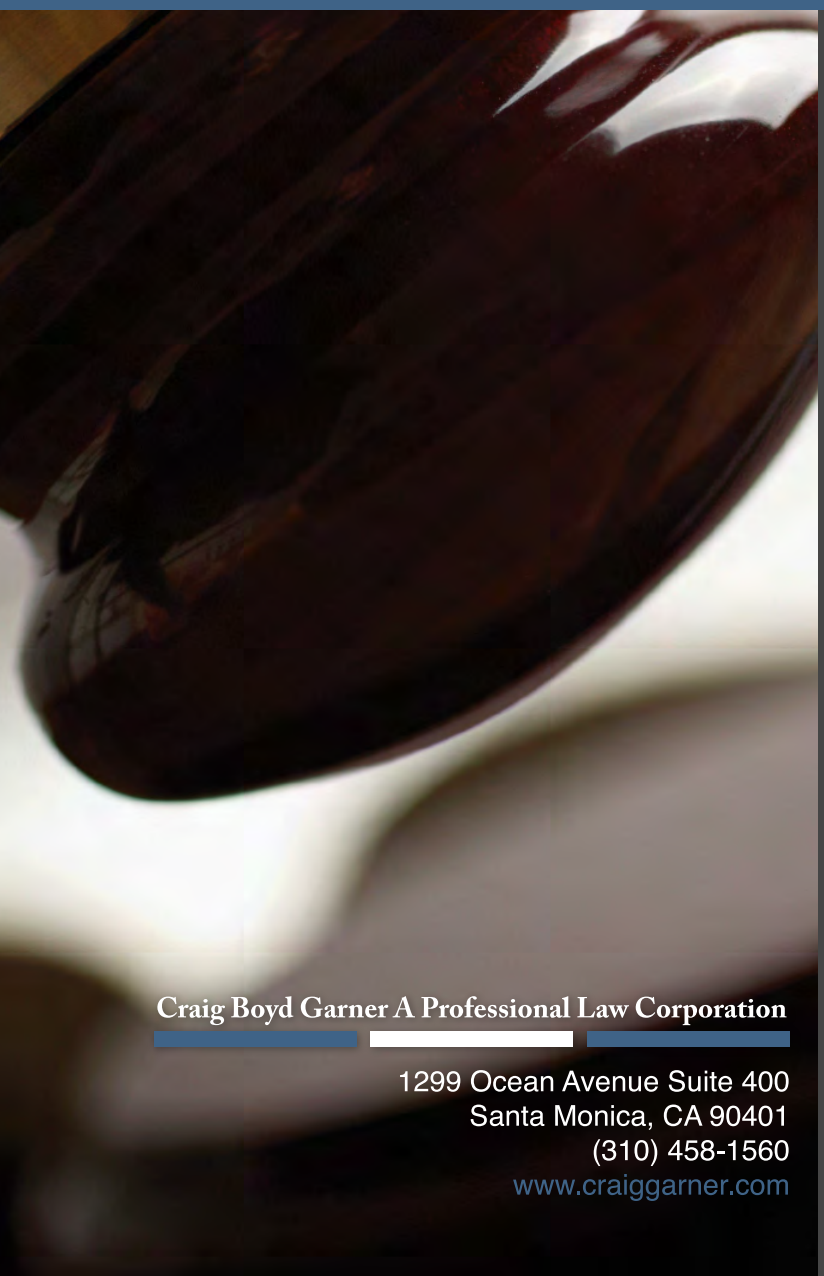

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Contemporary Performance Standards in the Context of Modern Health Care

Today, the Joint Commission requires hospitals to collect and submit certain data that falls under its "core measure sets," including but not limited to heart attacks and heart failure, pneumonia, and the Joint Commission's Surgical Care Improvement Project. Last month, the Joint Commission released its Annual Report on Quality and Safety entitled Improving America's Hospitals (the "Report") as a means to showcase the commendable achievements of hospitals identified by the Joint Commission as "Top Performers on Key Quality Measures," as well as to provide a comprehensive analysis on how those hospitals accredited by the Joint Commission fared for all measures.[26]

Joint Commission accountability measures connect evidence based care with positive patient results. The Joint Commission contends that implementation is more effective when it relates to certain programs wherein the public or even an outside regulatory agency holds the provider accountable, similar to the proposed federal regulations for value-based purchasing.[27] The Joint Commission has established four criteria in assessing the success of these evidence based examples, including:

> **Research:** Strong scientific evidence demonstrates that performing the evidence-based care process improves health outcome (either directly or by reducing risk of adverse outcomes).
>
> **Proximity:** Performing the care process is closely connected to the patient outcome; there are relatively few clinical processes that occur after the one that is measured and before the improved outcome occurs.
>
> **Accuracy:** The measure accurately assesses whether or not the care process has actually been provided. That is, the measure should be capable of indicating whether the process has been delivered with sufficient effectiveness to make improved outcomes likely.
>
> **No Adverse Effects:** Implementing the measure has little or not chance of inducing unintended adverse consequences.[28]

The tables in Appendix A summarize the Report in three areas: (1) heart attack care accountability composite[29]; (2) pneumonia care accountability composite[30]; and (3) joint

replacement, just one example contained within the surgical care accountability composite. [31] These tables show a steady increase in the care measure results (the "Care Composite") for each medical condition and surgical procedure.

When taken at face value in relation to the examples set forth in Appendix A, it is difficult to find fault with the Report and the ways in which hospitals have improved the delivery of care in these areas.[32] And yet, while viewing these successes in the context of health care in its totality does not in itself undercut the Report and its significance as a means to gauge the effectiveness of the accreditation process, it does portray somewhat of a different image.

The United States spent an estimated $2.6 trillion on national health in 2010 (17.6 percent of the U.S. GDP).[33] Some estimates expect this figure to be as high as $4.64 trillion by 2020 (nearly 20% of the U.S. GDP).[34] Singling out the nation's biggest spender, trends in California are of special concern as health care expenses continue to grow steadily along with the state's population, even though California lost approximately 10% of its hospital beds between 2002 and 2009.[35]

While few dispute the statistical information proving that we as a nation spend more on health care every year, the nexus between health care spending and actual revenue trends calls into question the sustainability of a system that finds itself locked into a self-perpetuating spending binge in its bid for survival.

A Comparison Between the Report and Correlating Medicare DRGs

With respect to tables 1 and 2 in Appendix A (heart attack care measure results), the Joint Commission's Care Composite was compared with the Medicare diagnostic related groups (DRGs) information in 2006 and 2007 for DRG numbers 127 (heart failure and shock) and 140 (angina pectoris), and in 2008 and 2009 for MS-DRG numbers 291 (heart failure and shock with major complication/comorbidity (MCC), 292 (heart failure and shock with complication/comorbidity (CC), 293 (heart failure and shock without CC or MCC), and 311 (angina pectoris).[36]

The Medicare revenue percentage for each respective DRG description was extracted from the DRG data relating to its annual revenue consistent with national data for suchacute care, divided by the number of patient days for the same year. This data was taken from the

Medicare Provider Analysis and Review (MEDPAR) files, which contain information pertaining to 100% of Medicare beneficiaries using hospital inpatient services national data for short stay, inpatient DRGs. From these figures, Appendix A, Table 1 compares the Medicare revenue percentage for heart failure and shock with the Report's Care Composite in the area of heart attack care for years 2006 through and including 2009.[37] Appendix A, Table 2 compares the Medicare revenue percentage for angina pectoris with the Report's Care Composite in the same area, and for the same time frame (2006 to 2009).

A similar approach was employed to create Appendix A, Table 3, comparing the Joint Commission's Pneumonia Care Composite with the appropriate DRGs. For 2006 and 2007, DRG numbers 89 (simple pneumonia and pleurisy (18 years and older in age)) with CC), 90 (simple pneumonia and pleurisy (18 years and older in age)) without CC, and 91 (simple pneumonia and pleurisy (under 18 years in age)) were used for the study, and for 2008 and 2009 MS-DRG numbers 193 (simple pneumonia and pleurisy with MCC), 194 (simple pneumonia and pleurisy with CC), and 195 (simple pneumonia and pleurisy without CC or MCC). The Medicare revenue percentage for each respective DRG description was extracted from the DRG data relating to its annual revenue consistent with national data for such acute care, divided by the number of patient days for the same year. The source of the data is also the MEDPAR files.[38]

Appendix A, Table 4 (addressing joint replacement, a single example from the Report's surgical care composite) was created through a compilation of data from within the Report (page 22, Table 6). Using information from three separate line items – (1) Antibiotics within 1 hour of first cut – For hip joint replacement surgery," (2) "Appropriate Prophylactic Antibiotics – For hip joint replacement surgery," and (3) "Stopping Antibiotics within 24 hours – For hip joint replacement surgery," Appendix A, Table 4 represents the average. The Care Composite for joint replacement was then compared with the appropriate MS-DRGs numbers from 2008 and 2009, including 469 (major joint replacement or reattachment of lower extremity with MCC) and 470 (major joint replacement or reattachment of lower extremity without MCC).[39] The Medicare revenue percentage for each respective MS-DRG description was extracted from the MS-DRG data relating to its annual revenue consistent with national data for such acute care, divided by the number of patient days for the same year. The source of the data is also the MEDPAR files.[40]

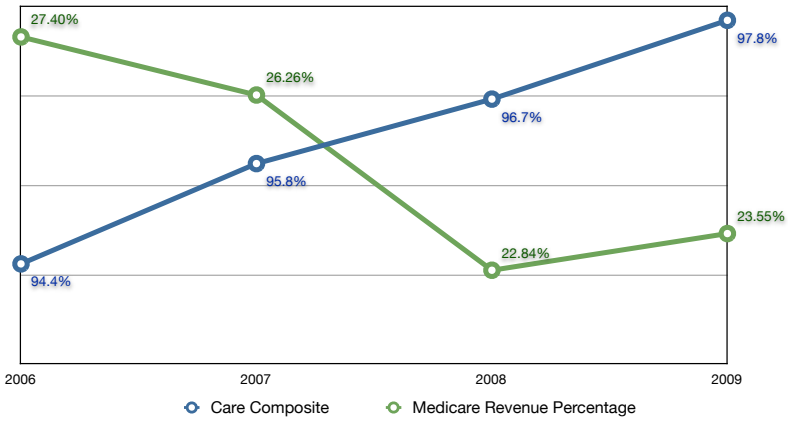
Conclusion

If our nation's track record on health care funding since the inception of Medicare is any indication, it should come as no surprise that hospital reimbursements do not share the same trajectory as Joint Commission quality standards. Indeed, factoring into the equation additional variables such as annual inflation and a struggling economy only serves to further distinguish the historical paths of performance and payment.[41] As Medicare prepares for a massive shifting from cost to performance-based reimbursement[42], a move likely followed in quick succession by other payer groups, the contradictory manner in which health care regulations reward annual improvement by reducing reimbursements speaks volumes about a system not just in transition, but in a state of confusion.

To be certain, the evolution of the reimbursement system has been shaped as much by innovation and advancements as it has by politics and a constantly changing definition of public interest. But in this age of technology, it may be prudent to take stock in the collections of data we have amassed as a means to understand and refine the delicate infrastructure of health care in the U.S. Ultimately, future congressional focus should be directed toward creating a self-sustaining system that improves the delivery of health care throughout the nation and is fair to both the individuals and institutions that participate therein. This hardly seems like an unreasonable place to start.

Appendix A, Table 1

Joint Commission Heart Attack Care Measure Results Compared with Medicare Revenue for Heart Failure and Shock, 2006 to 2009



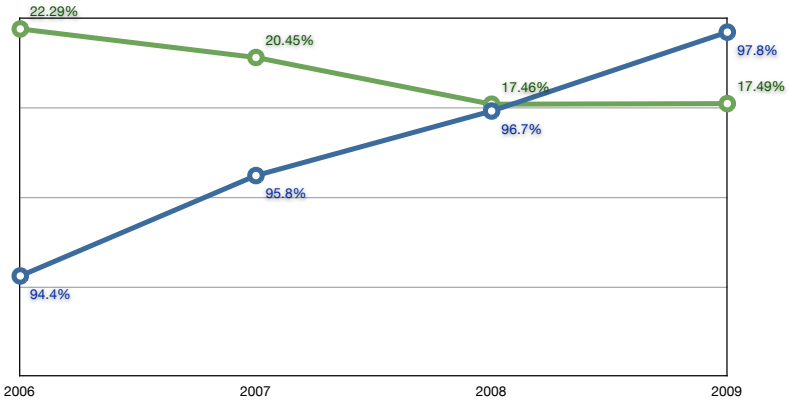
Average Medicare Revenue Per Day For Select DRGs (combined)*

2006	2007	2008	2009
$1,101.90	$1,138.49	$1,066.52	$1,170.16

*Years 2006 and 2007: DRG 127
Years 2008 and 2009: MS-DRGs 291, 292 and 293

Appendix A, Table 2

Joint Commission Heart Attack Care Measure Results Compared with Medicare Revenue for Angina Pectoris, 2006 to 2009



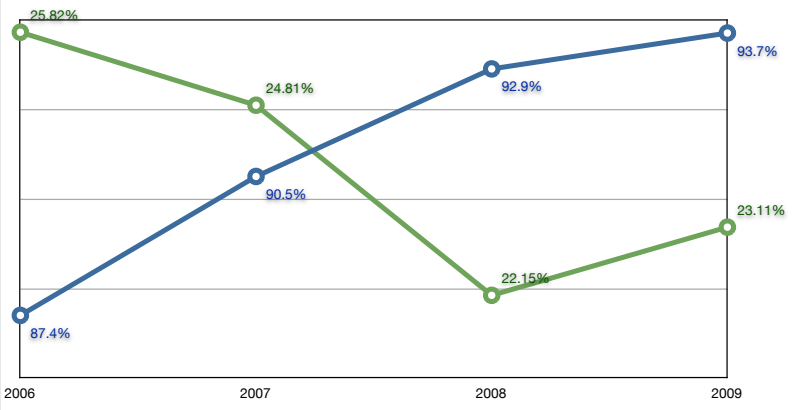
Average Medicare Revenue Per Day For Select DRGs (combined)*

2006	2007	2008	2009
$976.61	$997.35	$916.28	$933.87

*Years 2006 and 2007: DRG 140
Years 2008 and 2009: MS-DRG 311

Appendix A, Table 3

Joint Commission Pneumonia Care Measure Results Compared with Medicare Revenue for Pneumonia and Pleurisy, 2006 to 2009



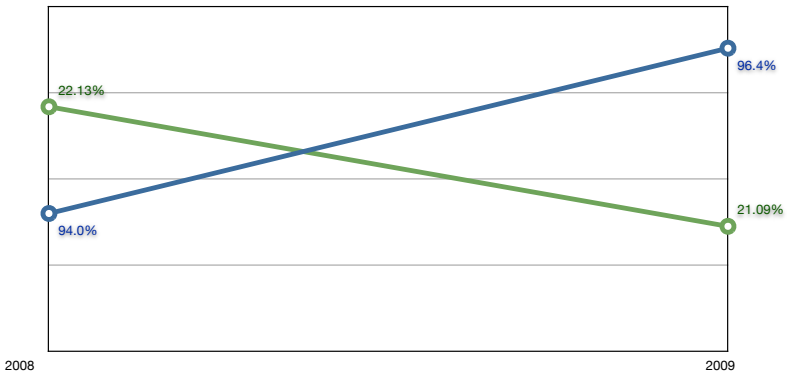
Average Medicare Revenue Per Day For Select DRGs (combined)*

2006	2007	2008	2009
$966.43	$1,001.54	$966.28	$1,068.81

*Years 2006 and 2007: DRGs 89, 90 and 91
Years 2008 and 2009: MS-DRGs 193, 194 and 195

Appendix A, Table 4

Joint Commission Surgical Care Measure Results (Joint Replacement) Compared with Medicare Revenue for Joint Replacement, 2008 to 2009



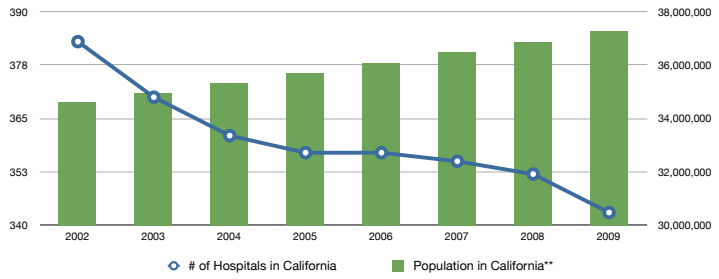
Average Medicare Revenue Per Day for Select MS-DRGs (combined)*

2008	2009
$966.28	$1,068.81

*MS-DRGs 469 and 470

APPENDIX B

Hospitals in California (2002 to 2009)



Year	No. of Hospitals in California	No. of Hospitals in U.S.*	California's % of Total Hospitals in U.S.	Change from 2002	Population in California**	% Increase in Population from 2002	Health Care Spending in California***	% Increase in Spending from 2002
2002	383	4927	7.8%	0	34,595,700	0	$41,100,000,000	0
2003	370	4895	7.6%	(13)	34,963,509	1.1%	$44,400,000,000	7%
2004	361	4919	7.3%	(22)	35,335,229	2.1%	$48,800,000,000	16%
2005	357	4936	7.2%	(32)	35,710,901	3.1%	$52,000,000,000	21%
2006	357	4927	7.2%	(26)	36,090,567	4.1%	$53,000,000,000	22%
2007	355	4897	7.2%	(28)	36,474,270	5.1%	$57,900,000,000	29%
2008	352	5010	7.0%	(31)	36,862,052	6.1%	$63,200,000,000	35%
2009	343	5008	6.8%	(40)	37,253,956	7.1%	$62,200,000,000	34%

*Number of community hospitals only, which represent 85% of all hospitals according to American Hospital Association data for each year. Federal hospitals, long-term care hospitals, psychiatric hospitals, and other similar institutions are not included.

**Numbers based on 2010 U.S. Census, 2000 U.S. Census, and estimates based on a comparison data from the years 2001 through 2009.

***U.S. Census Bureau's annual survey of state and local government finances.

[1] According to Congressional Budget Office estimates, major health programs accounted for 2.9 percent of the nation's GDP between 1971 and 2010 (averaged). Under the 2010 Patient Protection and Affordable Care Act, this figure may increase to as much as 7.1 percent by 2021. *See, e.g.,* Presentation by Douglas W. Elmendorf, Director, Congressional Budget Office, Federal Budget Math: *We Can't Repeat the Past* (June 16, 2011).

[2] The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 19,000 health care organizations and programs in the United States. *See* www.jointcommission.org.

[3] Established in 1945 to conduct objective reviews of osteopathic hospitals and the services they provide, HFAP surveys hospitals for compliance with the Medicare Conditions of Participation and Coverage. *See* www.hfap.org.

[4] ACHC is a national health care accrediting organization designed to create a system catering to small providers. *See* www.achc.org.

[5] CHAP is an independent, not-for-profit accrediting body for community based health care organizations. *See* www.chapinc.org.

[6] Since 2006, the Compliance Team, Inc. has been a nationally recognized, CMS-approved accrediting body for providers of durable medical equipment, prosthetics, orthotics, and supplies. *See* www.exemplaryprovider.com.

[7] HQAA provides home medical or durable medical equipment accreditation programs. *See* www.hqaa.org.

[8] The newest accreditation organization for hospitals, DNV received deemed authority from the Centers for Medicare & Medicaid Services in 2008. *See* www.dnvaccreditation.com.

[9] This regulatory infrastructure exists in addition to the labyrinth of federal and state laws. *See, e.g.*, 42 U.S.C. Section 1395x(e)(ii).

[10] *See* 42 CFR § 424.58. The 2003 Medicare Prescription Drug, Improvement, and Modernization Act (Pub. L. 198-173) required the Federal Government to implement quality standards for DMEPOS.

[11] Originally P.L. 74-271, approved August 14, 1935, 49 Stat. 620, and all subsequent amendments thereto.

[12] *See, e.g.*, 42 U.S.C. §§ 1302, 1395hh, 1395rr; 42 C.F.R. part 482.

[13] *See* 74 Federal Register (227) 62333 (Nov. 27, 2009).

[14] *Id*. (approving the Joint Commission's status through July 15, 2014); *see also* Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), § 125 (Pub. L. 110-275) (changing the process of accreditation in 2008 by revoking the Joint Commission's statutorily-guaranteed "deeming authority" for hospitals and requiring that the Joint Commission apply to, and obtain approval from, the Centers for Medicare & Medicaid Services (CMS)).

[15] *See* Roberts, James S., MD, Coale, Jack G., MA, and Redman, Robert R., MA, *A History of the Joint Commission on Accreditation of Hospitals*, 258 (7) JAMA 936, 938 (Aug. 21, 1987). The article notes that in 1958, the Canadian Medical Association withdrew from the Joint Commission. *Id*.

[16] *Id*.

[17] Comprehensive Accreditation Manual for Hospitals: The Official Handbook, (Joint Commission Resources, Inc., Mar. 2011).

[18] *See id*. at FW-1 (the Joint Commission revised its mission statement in 2009).

[19] The author neither addresses nor opines upon the scope of the Joint Commission's influence in the hospital accreditation process, and does not attempt to compare the Joint Commission with other entities providing similar and/or comparable oversight. Between 2002 and 2011, the author was the chief executive officer of an acute care hospital in Norwalk, California, accredited at all times by both the Joint Commission and HFAP.

[20] *See, e.g.*, 42 C.F.R. §§ 482.1, 482.2, 482.11, 482.12, 482.13, 482.21, 482.22, 482.23, 482.24, 482.25, 482.26, 482.27, 482.28, 482.30, 482.41, 482.42, 482.43, 482.45, 482.51, 482.52,482.53, 482.54, 482.55.

[21] *Id*. at PM-1 ("ORYX measurement requirements are intended to support Joint Commission – accredited hospitals in their quality improvement efforts. Performance measures are essential to the credibility of any modern evaluation activity for hospitals.").

[22] *See* Chassin, Mark R., M.D., Loeb, Jerod M., Ph.D., *et al*., *Accountability Measures – Using Measurement to Promote Quality Improvement*, 363 (7) New Engl. J. Med. 683 (Aug. 12, 2010).

[23] Pub. L. 111-148.

[24] PPACA, § 3022; 42 C.F.R. § 425 (proposed rules as of Apr. 7, 2011).

[25] *Evolution of Performance Measurement at the Joint Commission 1986-2010*: A Visioning Document (available at www.jointcommission.org/assets/1/18/SIWG_Prologue_web_version.pdf)

[26] *Improving America's Hospitals: The Joint Commission's Annual Report on Quality and Safety*, p. 4 (2011).

[27] *See supra,* note 24.

[28] The Report, p. 29.

[29] The Report, p. 20, Table 3.

[30] The Report, p. 21, Table 5.

[31] The Report, p. 22, Table 6.

[32] *But cf.*, McCannon, Joseph, AB, Berwick, Donald M., MD, MPP, *A New Frontier in Patient Safety*, 305 (21) JAMA 2221 (June 1, 2011)(concluding that despite the investment into the nation's healthcare system since the 1999 report *To Err Is Human*, medical errors continue to harm hospital patients to such an extend that further change is necessary); Wachter, Robert M., *Patient Safety at Ten: Unmistakable Progress, Troubling Gaps*, 29 (1) Health Affairs 165, 172 (Jan. 2010) (summarizing the success in efforts to enforce safety standards over the past five years as slightly above average).

[33] *See* Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; Department of Commerce, Bureau of Economic Analysis and Bureau of the Census; Keehan, Sean P., Sisko, Andrea M., *et al*, *National Health Spending Projections Through 2020*, 30 (8) Health Affairs 1594 (Aug. 2011).

[34] Keehan, *supra,* note 33*, National Health Spending Projections Through 2020*, p. 1595.

[35] *See* Appendix B: Hospitals in California – 2002 to 2009. Between 2002 and 2009, health care spending increased by 34%, and there were 40 fewer hospitals available to treat approximately 2.7 million additional residents.

[36] As of fiscal year 2008, CMS changed the Medicare inpatient prospective payment system by introducing Medicare Severity Diagnosis Related Group ("MS-DRGs"), thereby creating an entirely new numbering system for DRGs in 2008 and 2009. *See* 42 U.S.C. § 1395ww; TMA, Abstinence, Education, and QI Programs Extension Act of 2007, P.L. 110-90 (approved Sept. 29, 2007, 121 Stat. 984), § 7(a). Information for DRG and MS-DRG descriptions obtained from the CMS website for fiscal years 2008 and 2009 (https://www.cms.gov/Medicare-FeeforSvcPartsAB/).

[37] *See, e.g., id.*

[38] *See, e.g., id.*

[39] *See, e.g., id.*

[40] *See, e.g., id.*

[41] A recent study of the growth in family income in the U.S. over the past decade concluded that the estimated increase from $76,000 in 1999 to $99,000 in 2009 was practically erased by the increase in household spending on monthly health insurance premiums, out-of-pocket health care costs, and tax-related expenses directed toward health care. *See* Auerbach, David I., Kellerman, Arthur L., *A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average U.S. Family*, 30 (9) Health Affairs 1630 (Sept. 2011).

[42] *See supra*, note 24.

Book Review: "Obamacare on Trial"

Los Angeles DAILY JOURNAL (Nov. 9, 2012)

With 225 years separating the ratification of the Constitution of the United States and the landmark United States Supreme Court decision National Federation of Independent Business v. Sebelius, 132 S. Ct. 2566 (2012), the Constitutional impact of Chief Justice John Robert's majority opinion will resonate down the labyrinth of Federalism for decades to come.

As it relates to the 2010 Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act, the holding is clear and concise, even as the legacy of the Affordable Care Act has yet to be determined. Few scholars will disagree on the meaning of the Court's ruling – that the Affordable Care Act's individual mandate is constitutional and the Medicaid expansion provisions will survive – although the way in which the Court reached its conclusion remains the subject of heated debate.

Einer Elhauge's Obamacare on Trial approaches the Supreme Court decision much like the Phythia at Delphi, although sadly this latest collection of high profile, widely published essays conclude where the real story begins. The task itself is in many ways thankless, as the fluidity of the modern health care structure makes the art of prediction all but impossible. Just as no matter how hard we try to project the intent of the framers into our twenty-first century economy, it is unlikely that Washington, Madison or Hamilton could have predicted companies like Facebook, Amazon or Apple, today's health care experts are in no position to act as oracles until President Obama's fledgling program has had a chance to mature.

While theoretical discussions about the Affordable Care Act are fascinating in their own right, Professor Elhauge and his fellow health care scholars should always be mindful of the market that benefits most from such intellectual calisthenics. Let's face it, most Americans simply do not understand why Chief Justice Roberts held that the individual mandate is not a tax under the Anti-Injunction Act but is instead a tax under the Constitution, why four of the Justices on the bench referred to such logic as "verbal wizardry," and exactly when they will need to pay $695 for not having health insurance. Such a collection as his must target those who are both mindful of and intrigued by the myriad changes to the very structure of our nation's health care system brought about by a host of new programs and regulations.

While this most recent collection may not cater to the correct audience, the author does ask the appropriate questions. In discussing the individual mandate, Professor Elhauge uses logic and a Nobel laureate to convey the fact that its inherent flaw lies not in its existence, but rather its destined target. "In short, the Obamacare mandate targets expensive treatments that would likely be unaffordable without insurance," Elhauge explains. "The real debate is (or should be) over whether the mandate to pay for these treatments should be shifted from society at large to those who receive them."

Health care in America is anything but static, and the solutions to its problems will not come from Supreme Court opinions or academic collections. The answers will instead come from the very same trenches where these crises originated. And yet, like those hospitals that make up its backbone, the health care market is only ever as sound as the climate in which it finds itself. With all of the technological advances to be found in the twenty first century, America's oldest hospital, Bellevue Hospital in New York City, offered much the same service in October 2012 when Hurricane Sandy forced the evacuation of the hospital's 700 patients as it did in 1736 when the New York City Almshouse designated six bedrooms as Bellevue's first "ward." The ways in which we weather fluctuations in our health care climate are the true tests of any health care system in modern society, and often success is a result of the very relationships Professor Elhauge's Nobel laureate did not consider in his economic analysis.

Post-Acute Care and Vertical Integration After the Affordable Care Act

JOURNAL OF HEALTHCARE MANAGEMENT (Jan. 2013)

This Practitioner Application is a response to the findings and recommendations of the main article.

In his classic tale "The Sneetches," Theodor Seuss Geisel (Dr. Seuss, 1961) created a society divided by entitlement in which the lines of separation were removed, thrusting its members together. A satire about discrimination, "The Sneetches" offers children an early introduction to the arbitrary walls that those forces governing society can build and destroy at their whim.

Shay and Mick may be said to describe a similar scenario as they apply provisions of the 2010 Affordable Care Act (ACA) to post-acute care and vertical integration under the Medicare Shared Savings Program (also known as accountable care organizations or AC Os) and to bundled payment systems. They note that these are the areas in which the influences of the ACA are most apparent. In the process, Shay and Mick remind us that perception is formed largely on the basis of factors lurking beneath the surface that care little for public opinion. For example, much like Dr. Seuss's Sneetches, Hurricane Sandy, which struck the East Coast shoreline in October 2012, rendered the "haves" and "have nots" almost indistinguishable. Bellevue Hospital, the oldest hospital operating in the United States, was capable of offering roughly as much care during and immediately following the hurricane as it was in 1736, when the New York City Almshouse designated six bedrooms as Bellevue's first "ward."

During my 9-year tenure as CEO of a community hospital in Los Angeles County, California, bundling was still considered a pejorative term and vertical integration was lost somewhere in the abyss between Stark I and Stark III. As ours was a small hospital with a busy emergency department and no managed care contracts, patients usually left soon after stabilization, either own their own two feet or when transferred by the payer to a contracting facility. Vertical integration had little impact on my day-to-day operations. I cannot say how I would have reacted to ACOs or even this article then— at least until I took the time to review the application to become an ACO (see below).

In today's healthcare climate, however, I hold hope that patients will come to expect a full continuum of services for an entire care episode in a single institution or ACO. While most acute care facilities now focus attention on the Hospital Value-Based Purchasing program in an attempt to reduce the number of readmissions and unexpected outcomes, the final narrative question contained in the ACO application remains too important to be ignored by anyone in the healthcare sector:

> Submit a narrative describing how the ACO defines, establishes, implements, evaluates, and periodically updates its care coordination processes. Also describe: a. The ACO's methods and processes to coordinate care throughout an episode of care and during care transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO) . . .

Absent from this final section is any hint of concern about the dangers resulting from vertical integration, not to mention the economic and sociological directions an organization may be forced to follow as it integrates. While the authors raise pertinent questions relating to the future of modern American healthcare, the answers they seek may not be available until the ACA has had time to mature and align itself with the unspoken demands of the industry.

Biographical Information

Craig B. Garner is an attorney and health care consultant, specializing in issues surrounding modern American health care and the ways in which it should be managed in its current climate of reform. Craig's established law practice focuses on health care mergers and acquisitions, regulatory compliance and counseling for providers in all matters pertaining to contemporary health care in the United States. Craig is admitted as an attorney and counselor at law in the state of California (1995), District of Columbia (1996) and the state of New York (2001).

Formerly the CEO of Coast Plaza Hospital in Norwalk, California, from 2002 to 2011, Craig is a Fellow designate of the American College of Healthcare Executives, and an adjunct professor of law at Pepperdine University School of Law, where he teaches courses on Hospital Law and the Affordable Care Act.

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