

The Health Insurance Portability and Accountability Act of 1996: A Medicare Fraud Advisory Opinion Mandate Sends the Inspector General “Shopping for Hats”

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Congress responded to the problem of Medicare and Medicaid provider fraud by strengthening its anti-kickback statute to reduce collusive referrals between health care professionals. An unintended result was uncertainty for joint-venturing providers wishing to conduct their practices in accordance with the law. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) attempted to remedy this dilemma. By requiring the Office of the Inspector General (OIG) of the Department of Health and Human Services to issue advisory opinions concerning inquiring physicians' conduct, HIPAA aimed to simplify physicians' compliance with the anti-kickback statute. The author explores the realities of issuing federal agency advisory opinions: the ineffectiveness of prior agency attempts to advise, the burden placed on OIG in providing advisory opinions, and the conflicting advisory roles the agency must juggle in responding to Congress's mandate. Trying to reconcile its mandated advisory and enforcement duties has left OIG "shopping for hats." The author concludes with suggestions for reforming the advisory opinion process.

Since its creation in 1965, the Medicare program has helped millions of people by providing health care services to those who could not otherwise have afforded it. Medicare was born in an era in which health care policy was struggling to address inequities in the health care system, both in terms of access and cost distribution.¹ By 1950, private health insurance plans covered fifty-one percent of the population, but unfortunately this system excluded many types of services and failed to provide coverage for large segments of the population, particularly the poor and the elderly.² Congress created the Medicare and Medicaid programs to increase access to health care to these underprivileged groups.³ Medicare and Medicaid were predicated under a policy of containing the ever-increasing costs of health care.⁴ Unfortunately, the

* I would like to express my gratitude to Professor Sharon Davies for her inspiration. I would also like to thank Professor Art Greenbaum, Robert Johnson, and Don Kacmar. My parents and family have my deepest thanks for their support throughout my education.

¹ See Theodore N. McDowell, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 691 (1987).

² See McDowell, *supra* note 1, at 695.

³ See *id.*

⁴ See Raymond G. Davis, *Congress and the Emergence of Public Health Policy*,

structure of the programs (and the health care system in general) created cost-enhancing incentives, and consequently cost-enhancing behavior by providers and beneficiaries alike.⁵ The perverse financial incentives inherent in the system have been cited as a driving force behind the exponentially inflating costs of health care.⁶

One of the most problematic aspects of the system is its tendency to induce fraud. Since the inception of Medicare and Medicaid, fraud by health care providers has been a gross thorn in the side of the program's efforts to achieve cost efficiency. Currently, it is estimated that fraud and abuse account for up to ten percent of all national health care expenditures.⁷ In 1994, federal spending for the Medicare program totaled \$162 billion and is expected to double in the next ten years.⁸

Congress's response to the burgeoning health care fraud crisis has been to strengthen the Medicare and Medicaid anti-fraud and abuse statutes. These statutes create a complex statutory and regulatory scheme providing for a wide range of criminal, civil, and administrative sanctions.⁹ Of particular controversy is the so-called "anti-kickback" statute.¹⁰ This statute places limits on the extent providers can refer Medicare and Medicaid patients to other providers, a practice that is widely believed to increase cost to the system by encouraging overutilization of goods and services.¹¹ At tension with the

HEALTH CARE MGMT. REV., Winter 1985, at 61, 67-69.

⁵ See McDowell, *supra* note 1, at 691.

⁶ See *id.* at 699. Between 1965 and 1983, national health care expenditures increased from \$42 billion to \$355 billion. See also Robert M. Gibson et al., *National Health Expenditures, 1983*, 6 HEALTH CARE FIN. REV. 1, 7 (1984). In 1983, Medicare and Medicaid financed 29% of all expenditures on personal health care. The rhetoric of crisis became prominent in the late 1960s and early 1970s. *Fortune* magazine described the health care system as "on the brink of chaos." *It's Time to Operate*, FORTUNE, Jan. 1970, at 79.

⁷ See John R. Munich, *The Medicaid Anti-Fraud Amendments of 1994: Attorney General's Newest Weapon in the Fight Against White Collar Crime*, 52 J. MO. B. 26, 26 (1996).

⁸ See Ellen L. Janos & M. Daria Niewenhous, *White Coat Crime or Hospital-Physician Financial Relationships in the 90s*, BOSTON B.J., May-June 1996, at 8. The Government Accounting Office (GAO) estimates Medicare and Medicaid fraud and abuse account for 10% of health care expenditures. See *id.* If GAO spending estimates are accurate, federal spending for Medicare will top \$300 billion by the year 2004. Unless improvements are made in fraud reduction, fraud and abuse could cost the government over \$30 million annually.

⁹ See *id.*

¹⁰ 42 U.S.C. § 1320a-7b (1995).

¹¹ The Health Care Financing Administration believes that it has been conclusively proven that a physician who has a financial interest in the entity providing patient services will offer more tests and services. See Janos & Niewenhous, *supra* note 8, at 8. A hypothetical demonstrates the potential risk to the Medicare system. Imagine Dr. John, whose practice has just been purchased by a mega health care conglomerate. Dr. John sees Sally Patient, who is

statute's kickback and referral prohibitions is a trend among providers to engage in joint ventures to become more competitive in today's changing market.¹² These joint ventures typically involve some form of referrals among the venturing entities, which worries the parties involved that they may be in violation of the anti-kickback statute. The result of this tension has been a back-and-forth dialogue between health care providers and the Department of Health and Human Services (HHS) regarding the scope and reach of the anti-kickback provisions. Providers who engage in joint ventures desire certainty that they will not be prosecuted under what has proved to be an uncertain statute. HHS, like any other agency, wants to maintain a flexible approach to enforcing the statute.

Congress significantly altered the battlefield with the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹³ Among HIPAA's provisions is an advisory opinion mandate which forces HHS's Office of the Inspector General (OIG) to provide on-demand guidance to venturing providers regarding the application of the anti-kickback statute. This Comment will examine the mandate in light of the current health care regulatory environment. Part I will examine today's health care environment, including the trend toward joint ventures and integrated delivery systems, and the impact of the anti-kickback provision on this trend. Part II will examine in detail the mandates of HIPAA. Part III will examine the advisory opinion mandate under established principles of administrative law. Part IV suggests better alternatives to the advisory opinion system to assuage the fears of the industry, while preserving the potency and legitimacy of OIG's enforcement mechanisms.

I. THE CURRENT HEALTH CARE ENVIRONMENT

A. *Shift in Goals from Accessibility to Cost Containment*

As mentioned before, Medicare and Medicaid were enacted to address problems of inequity of access to health care services. As more and more people utilize professional health services, overall expenditures have escalated

a Medicare recipient. Dr. John will be tempted to order more tests, to be performed at his new hospital, in the hope that the benefits will trickle down. This rather alarmist hypothetical is all too reflective of reality. *See id.* Courts have also noticed this phenomenon. *See, e.g., United States v. Ruttenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980) ("Congress need not spell out obvious truisms . . . [that] kickback schemes . . . misdirect program funds . . . and . . . can erect strong temptations to order more drugs and supplies [and services] than needed.").

¹² *See infra* Part I.A.

¹³ Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in scattered sections of 26, 29, and 42 U.S.C.).

dramatically.¹⁴ Predictably, in light of the escalating costs of health care, the debate has shifted focus in recent years from promoting access and quality to finding ways to contain the cost and overall expenditures of health care.¹⁵ While concerns about access still exist, the new focus seems to emphasize establishing proper market incentives to conserve public monies and slow the rapid inflation of health care costs.¹⁶

Despite wide public and governmental concern, cutting health care costs has proved to be an uphill battle. A major contributor to the problem is the structure of the system itself, which tends to promote cost-enhancing behavior on the part of providers. This is partially because our system of health care has, to date, existed outside of pure-competitive economic models.¹⁷ Historically, price-conscious consumers have not met with competitive suppliers.¹⁸ The fact that a large portion of costs are supplemented by third-party payers (insurance) reduces consumer cost consciousness and further removes the health care market from typical supply-demand markets.¹⁹ Add to this the nature of the doctor-patient relationship, where the patient typically submits to whatever tests or treatments the doctor might prescribe,²⁰ and you have a system ripe for cost-enhancing behavior.²¹ One of the cost-enhancing behaviors engaged in by

¹⁴ See James F. Blumstein & Frank A. Sloan, *Redefining Government's Role in Health Care: Is a Dose of Competition What the Doctor Should Order?*, 34 VAND. L. REV. 849, 850-51 (1981).

¹⁵ See *id.* at 851.

¹⁶ See *id.* at 852.

¹⁷ The structure of the health services market deviates significantly from classic competitive market models. The purely competitive model, in which price is set by supply and demand, is not reflected in the health care market. In essence, the health care market has been dominated by cost-enhancing, noncompetitive structures and incentives. See McDowell, *supra* note 1, at 700; T.R. Marmor et al., *Medical Care and Procompetitive Reform*, 34 VAND. L. REV. 1003, 1003 (1981).

¹⁸ See McDowell, *supra* note 1, at 700.

¹⁹ See *id.* Broad, comprehensive insurance coverage for both routine and complex medical care is seen as encouraging the provision of services without a balancing of the costs and benefits of such services. This situation undercuts rational economic decisionmaking by consumers. See also Rand E. Rosenblatt, *Health Care, Markets, and Democratic Values*, 34 VAND. L. REV. 1067, 1088-1103 (1981).

²⁰ See Randall R. Bovbjerg, *Competition Versus Regulation in Medical Care: An Overdrawn Dichotomy*, 34 VAND. L. REV. 965, 967-68 (1981) (discussing the view that medical care is a technical process in which providers are experts and consumers are largely ignorant). The bottom line of the market structure is not healthy from a cost control perspective. The doctor can influence a patient to drive up costs which increase the doctor's profits.

²¹ Studies confirm that physicians have the ability to "create demand" for their services. See McDowell, *supra* note 1, at 702.

providers is fraudulently taking advantage of the Medicare system.²² By some estimates, the Medicare system loses up to one billion dollars a year to fraud.²³

Congress's main tools for battling fraud in the Medicare system are the anti-fraud and abuse amendments, introduced in 1972.²⁴ Among these provisions, the paramount tool for combating modern Medicare fraud tactics is the anti-kickback statute.²⁵ In keeping with the times, these statutes are focused on reducing costs because a stream of referrals is generally assumed to lead in overutilization of services, which in turn drains the Medicare system. Despite aggressive enforcement efforts under the anti-kickback statute, the federal government believes that its fraud and abuse controls have failed to keep pace with the industry's more complicated financial arrangements which often cleverly disguise kickback arrangements.²⁶ The tendency for some providers to commit fraud derogates from the government's overall goal of cost containment in health care.

B. *The Industry Trend Toward Managed Care: Joint Ventures*

It is easy to see that the health care industry is changing dramatically. One

²² See *id.* at 713–14. History teaches us that it has been easy for health care providers to take advantage of the system. When Medicare was started, it operated on a retrospective payment system (meaning Medicare reimbursed the reported cost of services) which encouraged providers to increase both the quantity and scope of services and created few incentives to economize. See *id.* An important step was taken in 1983 toward the goal of cost containment when Medicare switched from a retrospective to a prospective payment system. See *id.* at 703. While this system does introduce cost-saving incentives into the market, it does little to combat fraud.

²³ See Martha J. Yoakum, Comment, *Physician Fraud in the Medicare-Medicaid Programs—Kickbacks, Bribes, and Remunerations*, 10 MEM. ST. U. L. REV. 684, 685 (1980) (citing 123 CONG. REC. S16011 (1977)).

²⁴ See Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972).

²⁵ Kickbacks have become the prevalent form of fraud in part due to a switch in reimbursement systems. In 1983, Congress went from the retrospective payment system to the prospective payment system, which reimburses providers only for the reasonable costs associated with their patients' particular maladies. See Social Security Amendments of 1983, Pub. L. No. 98-21, §§ 601-607, 97 Stat. 65, 149–72 (codified at 42 U.S.C. § 1395 (1994)). This system encourages providers to keep costs down. But the opportunity for fraud now exists in volume and kickbacks, not in classical overbilling. Physicians will pay (or get paid) money to send referrals to other physicians or to hospitals, which increases the volume of business of the beneficiary of the referral and creates opportunities to collect Medicare funds. There is strong evidence that referring physicians receive benefits in various forms (e.g., kickbacks) for those referrals. See Janos & Niewenhaus, *supra* note 8, at 8. This financial incentive encourages overutilization. Thus, fraud and abuse control now focuses on shutting down these streams of referrals for kickbacks. See 42 U.S.C. § 1320a-7a (1994).

²⁶ See Janos & Niewenhaus, *supra* note 8, at 8.

commentator notes:

"The health care industry has totally changed. What started with the Clinton bear market a couple of years ago in drugs is now a managed-care revolution in the U.S., and it's beginning to spill over into Europe. . . . We have, really, a worldwide revolution occurring in health care, which is a \$2.5 trillion industry. And that revolution is the economic rationalization of the health-care industry. Every company has to change its ways to live in an environment of cost containment, consolidation, and rationalization. It's the biggest thing that has happened to health care in our lifetimes."²⁷

Physicians and health care organizations are rapidly forming joint ventures²⁸ to compete for valuable managed care contracts.²⁹ Diverse suppliers have united by pooling capital and sharing space, equipment, and personal or managerial services.³⁰ The individual players in the health care industry have started to realize that they can better survive by cooperating, rather than by competing.³¹

A look at the increasingly competitive market uncovers the advantages of cooperation.³² Health care providers (hospitals and physicians) seek joint ventures for a myriad of reasons. Among the most common are new revenues, increase in market share through streams of referrals, establishment of multi-

²⁷ Kathryn M. Welling, *Going Bottom Fishing: To Do Otherwise Is to Miss the Health-Care Reform Boat, Analyst Insists*, BARRON'S, Nov. 25, 1996, at 26 (quoting David H. Talbot, president of HealthReform Partners).

²⁸ The term "joint venture" is normally defined quite broadly to include relationships ranging from simple contracts to complex multi-party arrangements. Under federal tax law, a joint venture has four elements: an express or implied agreement to form, the contribution of money or services, an agreement for joint control, and profit sharing agreements. See Robert A. Metry, *Physician Ventures*, C472 ALI-ABA Course of Study 509, 511 (1990).

²⁹ See Latham Williams, *Structuring Managed Care Contracts*, HEALTH CARE FIN. MGMT., Aug. 1, 1995, at 32.

³⁰ See David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1865-66 (1989).

³¹ One commentator notes: "In the health-care industry, in general, there's a lot of very needless and senseless allocation of resources in competing with each other as opposed to rationally figuring out what's in the best interest of the community." Angela Gonzales, *Merger Means Mega Health-Care Network*, BUS. J. PHOENIX & VALLEY SUN, Nov. 15, 1996, at 25 (quoting Kaylor Schemberger, president and CEO of East Valley Regional Health System of Chandler, Arizona).

³² Traditionally, hospitals were at the core of health care expenditures. Today, hospitals are now experiencing a threat to their financial stability due to Medicare's prospective payment system, price competition from alternative delivery systems such as HMOs, and an overall decrease in the demand for inpatient treatments. See McDowell, *supra* note 1, at 706-07.

disciplinary practices, access to expertise, and general economies of scale.³³ A properly managed joint venture can drastically decrease administrative overhead.³⁴ These cost savings are crucial to health care providers as the regulatory environment clamps down on costs, and providers have to shift to increased volume and cost-control to maintain profitability. As the market gets tighter, it is logical to assume that joint ventures will continue to proliferate, and eventually will be the dominant structure for health care providers.

C. The Impact of the Anti-Kickback Statute on Joint Ventures

As one might expect, the anti-kickback statute has a very direct effect on joint ventures between health care providers. One of the prominent reasons physicians and hospitals enter into joint ventures is to gain access to a pool of patients—a stream of referrals³⁵ to increase the volume of their business. Because the anti-kickback statute has been less than clear in its application, joint venturers have had a difficult time assessing their risk of prosecution under the statute.

1. The Development of the Anti-Kickback Statute

Unveiled in 1972, the original anti-kickback statute made it a crime to solicit, receive, offer, or pay any kickback, bribe, or rebate in return for referrals.³⁶ Battling adversaries quickly convinced the courts that ambiguities existed, upon which developed a split of authority, engendering immediate

³³ See Metry, *supra* note 28, at 512.

³⁴ This results from economies of scale in physical plants (e.g., medical buildings), maintenance, insurance, and administrative assistants (e.g., secretaries). When physicians form joint ventures, senseless duplication of these cost factors can be reduced. See Cathy Tokarski, *Learning from Experience: Mercy Health System, a Regional System, Bought More than 200 Physician Practices to Fend Off Competition*, AM. MED. NEWS, Dec. 9, 1996, at 21.

³⁵ Referral streams (e.g., between physicians and hospitals or specialists) that carry potential kickbacks may seem innocuous enough at first glance. However, referral streams carry significant cost-enhancing potential. See Hugh E. Aaron, *Application of the Medicare and Medicaid Anti-Kickback Statute to Business Arrangements Between Hospitals and Hospital-Based Physicians*, 1 ANNALS HEALTH L. 53, 55-57 (1992). First, they can result in the provision of unnecessary medical services, known as "overutilization," which drives up costs to the patient, and thus Medicare. See *id.* at 56. This can often have detrimental effects on patients' health, as patients are exposed to tests and treatments that they may not really need. See *id.* Second, referral-kickback arrangements add another layer of "profit" to the cost of an item or service, which gets passed on to the patient, and thus to Medicare. See *id.* Finally, these arrangements tend to restrict patients' freedom of choice, as doctors refer patients to co-venturers for services. See *id.*

³⁶ Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972).

confusion as to the reach of the statute.³⁷ In early cases, courts primarily focused on the definitions of the terms "bribe" and "kickback." The federal circuits differed as to whether the terms should be construed narrowly (e.g., cash only, obviously for a referral)³⁸ or broadly (to include all forms of remuneration).³⁹

The 1972 statute was ultimately unsuccessful in reducing fraud in the Medicare and Medicaid systems. A series of hearings conducted after its enactment found that shocking levels of fraud were still rampant within the system.⁴⁰ The congressional findings, coupled with public outrage over fraudulent activities, resulted in what one commentator described as a "fraud and abuse crisis."⁴¹ Conviction under the anti-kickback statute tended to turn on whether the court adopted a narrow or broad view of the terms "bribe" and "kickback."⁴² The uncertainty of the statute's application, coupled with the

³⁷ For the description of the development of anti-kickback laws, this author draws heavily from a recently published treatise on the subject. See TIMOTHY S. JOST & SHARON L. DAVIES, *MEDICARE AND MEDICAID FRAUD AND ABUSE* 81-169 (1997) (discussing the history and development of the anti-kickback laws).

³⁸ See, e.g., *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979). In its first case under the statute, the court in *Porter* adopted a narrow view of the terms. The case involved a doctor who referred Medicare patients' blood samples to a particular lab. See *id.* at 1051. The lab paid the doctor a "handling fee." See *id.* The court found no basis for characterizing the payments as bribes and defined "kickback" as the "secret return to an earlier possessor of part of a sum received." *Id.* at 1054. See also *United States v. Zacher*, 586 F.2d 912 (2d Cir. 1978) (relying on a narrow interpretation of the term "bribe" to reverse a conviction under the anti-kickback statute).

³⁹ In *United States v. Hancock*, the Seventh Circuit rejected the *Porter* opinion and instead adopted a broad interpretation of the word "kickback." *United States v. Hancock*, 604 F.2d 999, 1002 (7th Cir. 1979). In *Hancock*, the defendant chiropractors sent blood and tissue samples to a certain lab for testing and received payments for the referrals. See *id.* at 1001. They claimed that the payments they received were "handling fees" based on *Porter*. See *id.* The court affirmed the conviction, finding "kickback" to include "a percentage payment . . . for granting assistance by one in a position to open up or control a source of income." *Id.* at 1002 (citing *Webster's Third New International Dictionary* (1966)). The defendants opened up a source of income to the labs, and the labs paid them, which was enough for the court. "The potential for increased costs to the . . . system . . . is plain, where payments for the [referrals] are added to the legitimate costs of the transaction." *Id.* at 1001. This "potential for increased costs" rationale was followed in *United States v. Ruttenberg*, 625 F.2d 173 (7th Cir. 1980).

⁴⁰ Congress found that so-called "medicaid mills," clinics that provided services to essentially anyone armed with a Medicaid number, accounted for a disproportionate amount of Medicaid claims and were major cost centers for the program. H.R. REP. NO. 95-393, pt. 2, at 45-46 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3047-48.

⁴¹ Harvey E. Pies, *Control of Fraud and Abuse in Medicare and Medicaid*, 3 AM. J. L. & MED. 323, 328 (1977).

⁴² See McDowell, *supra* note 1, at 718.

rampant fraud problem, led to a revision of the statute in 1977.⁴³ The amendments reflect the Seventh Circuit's approach, replacing the terms "bribe" and "kickback" with the catch-all term "remuneration."⁴⁴ Also, the amendments added a "knowingly and willfully" requirement.⁴⁵

While the amendments did away with the controversy over kickback definitions, the scienter requirement created yet another split of authority in federal courts. The Third Circuit ruled that if at least *one* purpose of a payment was to induce referrals, then the "knowing and willful" requirement was satisfied.⁴⁶ The First Circuit held, on the same issue, that in order to satisfy the "knowing and willful" requirement for a conviction, the government must prove that the *primary* purpose of the payment was to induce referrals.⁴⁷ The Ninth Circuit recently adopted a completely different approach to scienter in *Hanlester Network v. Shalala*.⁴⁸ Creating a high hurdle for the government to clear on its way to winning convictions under the anti-kickback statute, the court held that the defendants must (1) know that the statute prohibits the payment made for referral, and (2) engage in the prohibited conduct with the specific intent to break the law.⁴⁹ This heightened threshold may hinder prosecutions under the anti-kickback law, as it possibly makes ignorance of the law a viable defense. Moreover, a defendant may in good faith rely on the advice of counsel and immunize himself from prosecution.⁵⁰

Congress amended the statute once again in 1987. The most significant aspect of these amendments is Congress's order to the Department of Health and Human Services (HHS) to develop "safe harbor" regulations specifying certain payment practices not subject to criminal prosecution under the anti-kickback law.⁵¹ Congress ordered these regulations in response to the uncertain interpretation of the statute that was developing in the courts.⁵² In response to Congress's directive, HHS's Office of the Inspector General (OIG) promulgated regulations containing eleven safe harbor provisions.⁵³ If conduct

⁴³ See Medicare-Medicaid Fraud and Abuse Amendments, Pub. L. No. 95-142, §§ 4(a), 4(b), 91 Stat. 1175, 1181 (1977).

⁴⁴ See 42 U.S.C. § 1320a-7(a)(1) (1994).

⁴⁵ See *id.* at § 1320a-7(a)(2).

⁴⁶ See *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

⁴⁷ See *United States v. Bay State Ambulance*, 874 F.2d 20 (1st Cir. 1989).

⁴⁸ 51 F.3d 1390 (9th Cir. 1995).

⁴⁹ See *id.* at 1400.

⁵⁰ See *Janos & Niewenhous*, *supra* note 8, at 9.

⁵¹ See *id.*

⁵² See *id.*

⁵³ The safe harbor provisions give protection to the following arrangements: (1) "Investment [i]nterests," (2) "Space [r]ental," (3) "Equipment rental," (4) "Personal services

complies with every element of a safe harbor provision, then it will not be subject to criminal prosecution.⁵⁴ Arrangements not completely in compliance are not guaranteed protection, but of course are not guaranteed to be in violation either.⁵⁵ Most business arrangements will not mechanically fulfill all of that given safe harbor provision's elements.⁵⁶ This means that most joint venturers, while they may be close to fulfilling all of the elements of a safe harbor, will seldom be guaranteed freedom from prosecution.

2. *The Special Problem with Joint Ventures*

As discussed above in Part I.B, there is a major migration in the health care industry toward managed care, which involves *inter alia* the formation of joint ventures between hospitals and physicians. One obvious benefit and motivating factor for hospitals to establish these agreements is the likelihood that the physician will increase the use of her partner hospital as she sends her patients there for services. The problem in terms of the anti-kickback statute is that often an acknowledged intent of these ventures is to increase the hospital's referral stream.⁵⁷ The conflicting and sometimes quite broad interpretations of the statute leave many potential joint venturers wondering if they are about to break the law.⁵⁸ The dilemma confronting venturing parties is this: Is there any meaningful way to distinguish between fraudulent practices and legitimate business agreements? The unresolved split on the scienter requirement ("knowing and willful") adds to the uncertainty.⁵⁹ Experience with "safe harbors" has showed the industry that "providing clear, authoritative guidance as to what payment practices are permitted under [the anti-kickback provisions is] . . . a more difficult and tedious task for OIG than Congress may have

and management contracts," (5) "Sale of practice," (6) "Referral services," (7) "Warranties," (8) "Discounts," (9) "Employees," (10) "Group purchasing organizations," and (11) "Waiver of beneficiary coinsurance and deductible amounts." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35984-87 (1991) (to be codified at 42 C.F.R. pt. 1001) [hereinafter Anti-Kickback Provisions]. While a detailed discussion of each of these provisions is outside the scope of this Comment, suffice it to say that these do not begin to cover the myriad of structures that are used in creating joint ventures today.

⁵⁴ See Aaron, *supra* note 35, at 63.

⁵⁵ See *id.*

⁵⁶ See *id.*

⁵⁷ See McDowell, *supra* note 1, at 739.

⁵⁸ See Aaron, *supra* note 35, at 53-54 (noting that "the anti-kickback statute could easily be interpreted to prohibit a wide range of traditionally accepted business arrangements involving healthcare providers").

⁵⁹ See *supra* notes 45-49 and accompanying text.

anticipated.”⁶⁰

All of this uncertainty under the anti-kickback statutes leaves potential joint venturers to twist in the wind. Many payment practices, while not appearing to violate the spirit of the anti-kickback statute, will still fall outside the guarantees of safe harbor protection, leaving providers in a legal gray area where it is difficult to assess their exposure to prosecution.⁶¹ The health care industry is concerned that the anti-kickback statutes have a chilling effect on the formation of new, honest, legitimate business enterprises.⁶²

II. OIG'S ATTEMPTS TO ADVISE, LEADING TO THE PASSAGE OF THE ADVISORY OPINION MANDATE IN HIPAA

A. OIG's Early Guidance Efforts

One can hardly blame the health care industry for being confused about the anti-kickback statute. The statute itself is a challenging read even for those with a legal education and has been subject to various interpretations by the courts.⁶³ The existing safe harbor provisions are equally complex and are widely known to be narrowly applied.⁶⁴ The industry is concerned that a joint venture, formed in good faith to comply with the statute, may nevertheless violate the technical terms of the statute and expose the venturing parties to criminal sanctions. With the increasingly rapid formation of joint ventures, it is clear that further guidance to the health care industry from the relevant authorities⁶⁵ is desirable in order to protect good faith actors.

OIG has had some difficulty providing guidance. Some early advisory opinions were written on OIG's own initiative in 1980 and 1981. In 1991, however, OIG announced that it would stop issuing advisory opinions on the ground that the interpretation of criminal statutes was a matter best left to the

⁶⁰ Richard S. Saver, *Proposed Safe Harbor Regulations Clarify a Few Issues, Leave Others Unresolved*, 11 HEALTHSPAN 20, 20 (1994). The safe harbor provisions have been criticized for their failure to provide meaningful guidance on the reach of the anti-kickback statute. *See id.* at 22.

⁶¹ *See id.* at 22.

⁶² *See* McDowell, *supra* note 1, at 727.

⁶³ To this day, federal courts are still divided over what the requisite level of intent must be to convict a person or entity under the anti-kickback statute. *See supra* notes 45–49 and accompanying text.

⁶⁴ Only full compliance with each element of the safe harbor provisions guarantees freedom from prosecution. *See* Aaron, *supra* note 35, at 63.

⁶⁵ The relevant authorities are the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS), the Attorney General, and the Department of Justice (DOJ).

judiciary.⁶⁶ The early advisory opinions have been explicitly rendered dicta by HHS. HHS has made it known that no person associated with HHS, intermediaries, or carriers has ever been authorized to permit a practice that is illegal under the anti-kickback statute.⁶⁷ HHS has also made it clear that HHS is unable to render legal advice on the application of the statute to individual fact situations.⁶⁸ The agency has explicitly stated that “the so-called advisory letters may not be regarded in any way as authoritative.”⁶⁹

According to HHS, to render responses to requests (possibly with a binding effect) on the application of the criminal anti-kickback statute to individual businesses would violate the exclusive authority vested in the Department of Justice (DOJ) to enforce all criminal laws of the United States.⁷⁰ HHS also pointed out that any response would be of limited value due to the fact-intensive and inherently subjective nature of any inquiry into a party’s intent to violate the statute.⁷¹

OIG also tried to issue informal advice in the form of “intermediary letters” which were sent to fiscal intermediaries to help them understand the statute. One letter is of particular relevance in the realm of joint ventures. In this particular letter, OIG set up a hypothetical agreement between a durable medical equipment supplier and a physician.⁷² The agreement involved payment of “finders fees” to the physician for referrals to the supplier of patients in need of durable equipment.⁷³ The letter concluded that the arrangement violated the statute.⁷⁴ A few months later OIG withdrew the letter,

⁶⁶ See Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,959, 35,960 (1991) (to be codified at 42 C.F.R. pt. 1001).

⁶⁷ See *id.* at 35,959.

⁶⁸ See *id.*

⁶⁹ *Id.* at 35,960.

⁷⁰ See *id.* at 35,959. Courts have consistently ratified this rule. See *United States v. Wong Kim Bo*, 466 F.2d 1298, 1302 (5th Cir. 1972) (holding that the decision to prosecute is the exclusive responsibility of the Attorney General); *United States v. Kysar*, 459 F.2d 422 (10th Cir. 1972); *Smith v. United States*, 375 F.2d 243, 247 (5th Cir. 1967). If HHS immunized a particular agreement, the resulting conflict with DOJ’s authority to initiate or decline to initiate charges is clear.

⁷¹ See Anti-Kickback Provisions, 56 Fed. Reg. at 35,959.

⁷² See *Payments to Respiratory Therapists by Double Medical Equipment Supplier and the Illegal Remuneration Provisions of the Social Security Act*, OIG intermediary letter No. 84-9 (Sept. 1984), reprinted in *Suppliers of Durable Medical Equipment Offering “Finders” and “Referral” Fees*, [May 1984–Dec. 1984 Transfer Binder, New Developments] MEDICARE AND MEDICAID GUIDE (CCH) ¶ 34,127 (Oct. 1984).

⁷³ See *id.*

⁷⁴ See *id.*

explaining that the legality of particular arrangements could not be determined without consideration of the relevant factors and practice patterns.⁷⁵ The short life of this letter is a testament to the inherent difficulty in determining a party's subjective intent.⁷⁶

HHS has struggled to provide guidance to the industry regarding the reach of the anti-kickback statute.⁷⁷ The statute is particularly relevant to hospitals and physicians wishing to engage in a joint venture.⁷⁸ Given the explosive growth of joint venture agreements in the modern managed-care environment, the industry wants for guidance more than ever.⁷⁹

B. Congress to the Rescue?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁸⁰ primarily deals with portability. The statute refers to "portability" in its dictionary sense—something that can be carried around from place to place. The statute seeks, *inter alia*, to make health insurance "portable" for Americans who switch jobs. Under the statute's portability provisions,⁸¹ when individuals

⁷⁵ See OIG memorandum No. B-85-2 (Apr. 1985), reprinted in *Suppliers of Durable Medical Equipment Offering "Finders" and "Referrals" Fees*, [Dec. 1984–July 1985 Transfer Binder, New Developments] MEDICARE AND MEDICAID GUIDE (CCH) ¶ 34,544 (Apr. 1985).

⁷⁶ In a 1988 solicitation for ideas to improve the anti-fraud scheme, OIG noted the problems associated with trying to give pre-dispute advice on the anti-kickback statute in an advisory opinion-type mechanism:

We should note that questions have been raised regarding the practicality and effectiveness of such an approach given that often an assessment of circumstances (1) cannot be accurately made based solely on a written presentation, (2) could divert limited resources from enforcement efforts, and (3) could be used to impede subsequent cases against other parties.

53 Fed. Reg. 51,856, 51,857 (1988).

⁷⁷ See discussion *supra* Part II.A.

⁷⁸ See *supra* note 57 and accompanying text.

⁷⁹ See *supra* Part I.B.

⁸⁰ Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in scattered sections of 26, 29, and 42 U.S.C.) [hereinafter HIPAA].

⁸¹ See HIPAA tit. I (codified in scattered sections of 29 and 42 U.S.C.). Congress's chief concern in passing HIPAA was portability. Increased portability has several advantages for working Americans:

Above all, the goal of the Health Insurance Portability and Accountability Act continues to be the implementation of the very basic reforms of portability and limits on pre-existing conditions. These reforms represent what we all support and are important to the many people who experience a sense of job-lock or pre-existing conditions.

change jobs, their health insurance should go with them. HIPAA was designed with a specific goal in mind: to create portability despite having pre-existing conditions, being fired, or otherwise changing jobs.⁸² Fraud reduction is also one of the purposes of HIPAA, as evidenced by its preamble: "An act to . . . improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery"⁸³ As part of HIPAA's fraud and abuse control scheme, Congress created an advisory opinion mandate requiring OIG to give advice to providers on a number of issues, including whether any activity constitutes grounds for the imposition of a sanction under the anti-

142 CONG. REC. S10564-65 (daily ed. Sept. 13, 1996) (statement of Sen. Frist)

The "job-lock" effect, that a worker will be afraid to change jobs for fear of losing health insurance, was one of the main problems HIPAA was designed to remedy:

Victory can be expressed by workers, who currently can see a new opportunity for themselves and their families by moving up in terms of the employment opportunities but hesitate to do so. They hesitate to attempt to fulfill the great American dream because they wonder whether that job which is out there and offered to them in which they feel they can do a superior job may not provide that degree of [health care] coverage for a member of their family, for their [spouse] or for one of their children. As a result, they turn down that opportunity. The American dream becomes somewhat more remote and distant to them.

142 CONG. REC. S9501-02 (daily ed. Aug. 2, 1996) (statement of Sen. Kennedy).

⁸² Most of the debate on this bill focused on the portability provisions. This is an interesting phenomenon because the portability provisions were given universal support. Why would members of Congress continually and repetitively speak during debate on an uncontested issue? Most likely the legislators wanted their names attached on the right side of a politically popular issue. A very politically favorable piece of legislation, HIPAA was heralded as a victory for working Americans. *See, e.g.*, 142 CONG. REC. E1485 (daily ed. Aug. 2, 1996) (statement of Rep. Bentsen). Representative Bentsen heralded HIPAA as

exactly the kind of assistance the American people want and need to address the challenges they face in their daily lives. . . . [HIPAA] will give peace of mind to millions of families without imposing new costs on businesses and government This is an example of what Congress can do when we put common sense and the public interest first.

Id. Indeed, most of the record consists of legislators lauding the portability provisions as a major health care breakthrough, despite the fact that not a single member of either house of Congress raised a single objection to the bill's portability provisions. Thus, the debate was relatively fruitless and pointless from a substantive point of view. Not focused on clearing up disagreements, the debate was more useful to individual members as a chance to impress their constituents. Apparently, it was a positive political move in the 1996 election year to jump on the portability bandwagon. In the end, the bill passed the House 421-2 and the Senate 98-0. *See, e.g.*, 142 CONG. REC. S9501 (daily ed. Aug. 2, 1996).

⁸³ HIPAA pmb1., 110 Stat. at 1936.

kickback provision.⁸⁴ Though the record is sparse in relation to the motivation behind this provision, it is clear that the advisory opinion mandate was designed, at least in part, to provide guidance to joint-venturing parties.⁸⁵ The statute reads, in relevant part:

(b) *ADVISORY OPINIONS.*—

(1) *ISSUANCE OF ADVISORY OPINIONS.*—The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

(2) *MATTERS SUBJECT TO ADVISORY OPINION.*—The Secretary shall issue advisory opinions as to the following matters:

(A) What constitutes prohibited remuneration within the meaning of section 1128(B)(b).

....

(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1128, 1128A, or 1128B.

....

(4) *EFFECT OF ADVISORY OPINIONS.*—

(A) *BINDING AS TO SECRETARY AND PARTIES INVOLVED.*—Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) *FAILURE TO SEEK OPINION.*—The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or

⁸⁴ See HIPAA tit. II, § 205(b), 42 U.S.C.A. § 1320a-7d (West Supp. 1997).

⁸⁵ Trying to define the rationale behind HIPAA's advisory opinion mandate is speculative, as the legislative history is relatively barren of discussion of the issue. Not a single member of Congress spoke to the issue of why the mandate was a positive step in the fight against fraud and abuse. The few comments on the provision were negative, focusing on the negative impact the mandate would have on fraud and abuse control efforts. See, e.g., 142 CONG. REC. H9790 (daily ed. Aug. 1, 1996) (statement of Rep. Dingell). See also *infra* Part III. One possibility is that the Medicaid lobby was in favor of the provision and influenced its passage. Considering the trend in the health care industry toward joint venture arrangements, see *supra* Part I.B, combined with the uncertain application of the anti-kickback statute to those arrangements, see *supra* Part I.C, it is easy to envision the health care lobby clamoring for help from Congress. See 142 CONG. REC. S9477, S9478 (daily ed. Aug. 2, 1996) (statement of Sen. Heflin) ("This measure enjoys . . . support . . . from a host of organizations, including . . . the American Medical Association, [and] the American Hospital Association Virtually every medical group in the country has endorsed this bill"). Special interests have power to influence legislation, and it is possible that special interests provided the impetus for the advisory opinion mandate. For a commentary on the potency of special interest groups in the legislative process, see WILFRED E. BINKLEY & MALCOLM C. MOOS, *A GRAMMAR OF AMERICAN POLITICS* 7-8 (2d rev. ed. 1952). In the end, those special interests are bound to be disappointed by the advisory opinion mandate. While the advisory opinions may seem to provide meaningful guidance to joint venturers, the forthcoming analysis will reveal the mandate's darker side.

1128B.⁸⁶

The statute requires that the advisory opinion be issued no later than sixty days after the request is received.⁸⁷ Viewed solely from the point of view of joint venturing parties, this statute is a great deal. Joint venturing parties can get speedy yet binding advice from the agency.⁸⁸ They can get this advice at relatively little expense.⁸⁹ Upon their request, the providers will know whether the agency will have grounds to prosecute them. They may to some extent be able to rely on these opinions against prosecution by the Department of Justice.⁹⁰ At first glance, the statute seems to give potential joint venturers what they want.

III. THE NEGATIVE REGULATORY IMPACT OF HIPAA'S ADVISORY OPINION PROCESS

A. *Financial Burden and Other Familiar Agency Objections to Issuing Advisory Opinions Under the Anti-Kickback Statute: The Obvious Dangers*

While at first glance this mandate may seem to properly address a growing concern in the health care industry, this provision is certainly not as innocuous

⁸⁶ HIPAA tit. II, § 205(b), 42 U.S.C.A. § 1320a-7d (West Supp. 1997).

⁸⁷ See HIPAA tit. II, § 205(b)(5)(B)(i), 42 U.S.C.A. § 1320a-7d (West Supp. 1997).

⁸⁸ This receipt of advice contrasts with waiting for the agency to promulgate more detailed rules according to the strict procedural requirements of the Administrative Procedure Act. See *infra* Part III.B.

⁸⁹ OIG can recover no more than its actual cost. See HIPAA tit. II, § 205(b)(5)(B)(ii), 42 U.S.C.A. § 1320a-7d (West Supp. 1997).

⁹⁰ Other agencies have procedures that allow for advisory opinion-type guidance mechanisms. One example is the Securities and Exchange Commission (SEC) no-action letter. SEC may issue a no-action letter where it feels it is appropriate. A no-action letter is one where an authorized SEC Staff Official indicates that the Staff will not recommend any enforcement action to the Commission if the proposed transaction described in the incoming correspondence is consummated. See Richard H. Rowe, *Reliance on SEC Staff "No Action" Letters—A Shield or a Sword?*, in *OPINIONS IN SEC TRANSACTIONS* 667, 679-80 (PLI Corp. Law & Practice Handbook Series No. 896, 1995). Commentators have suggested that there is often a reliance defense available based on published no-action letters, even to third parties. See *id.* at 681-88 (analyzing a "hierarchy" of no-action positions and the varying degree to which the public can rely on no-action positions). From the SEC example, it would stand to reason that reliance theories may be spun from advisory opinions. Thus, Inspector General of HHS June Gibbs Brown's fears that advisory opinions may lead to third party reliance and same party reliance to avoid criminal prosecution appear to have some substance. See Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15158, S15159 (daily ed. Oct. 13, 1995).

as it may seem. First of all, it requires a speedy response to every request from the public, which will put quite a drain on OIG's budget.⁹¹ Also, HIPAA did not address HHS's reasoning for abandoning the issuance of advisory opinions back in 1981. The advisory opinions contemplated by HIPAA are the same as the advisory opinions issued under the anti-kickback statutes in the early 1980s, which HHS found to be totally inadequate to provide meaningful advice on the intent-based anti-kickback statute.⁹² Despite these well-known concerns, the provision caught the attention of very few members of Congress during HIPAA's debates. The few meager minutes that were spent on the issue simply regurgitated the fears brought to light by OIG during the past fifteen years. Not a single legislator put forth a theory in defense of the advisory opinion mandate.⁹³

Sporadically during HIPAA's debate, as well as in debates on earlier forms of the bill, a member of Congress would attempt to directly face the issue of the advisory opinions. More than once, the comments either directly referred to or mirrored concerns that were expressed by HHS's Inspector General in a letter

⁹¹ See *infra* notes 94–96 and accompanying text.

⁹² See *supra* notes 66–69 and accompanying text.

⁹³ The curious state of affairs in Congress at the time of the bill's debates may have had an impact on this provision's successful passage. August 2, 1996 was approximately ninety days before the election. This bill was a very public affair—a major success to help our nation's health care crisis, just in time for November's popularity contest. As a result, a substantial amount of election-year politics infiltrated the debate. In the House, for example, the greatest amount of attention was paid to the advisory opinion mandate on a motion to recommit the bill to committee. See 142 CONG. REC. H9786 (daily ed. Aug. 1, 1996) (statement of Rep. Stark). The charge to recommit was led by Representative Stark, who is one of the leading authorities in Congress on Medicare and Medicaid fraud and abuse. See *id.* "The bill's anti-fraud provisions are bad. The advisory opinions on intent based fraud cases are unprecedented, and the Justice Department-HHS's Inspector General strongly oppose them. . . . [The mandate's lack of funding for OIG's advisory role] devastates the agency's ability to fight fraud that they talk about." *Id.* Another representative attacked the provision as an attempt at logrolling by the Republican Party: "While this legislation does some good things, at least one of the things it does needs to be examined. My good Republican friends have tucked away a couple of nice little provisions here which will hinder the fight against fraud and abuse." 142 CONG. REC. H9790 (daily ed. Aug. 1, 1996) (statement of Rep. Dingell, discussing the advisory opinion mandate). When the motion to recommit was called to question, it failed by a relatively narrow margin, 228–198. This shows there was some real concern with the issues raised. But when the conference report itself was called to question, those fears took a back seat to the political pressure of getting behind popular health care reform. It seems that although many members of Congress had misgivings about some provisions, only two legislators (in both houses) could resist jumping on the bandwagon. The bill passed the House 421–2, and passed the Senate 98–0. It seems that election politics may have played a role in the advisory opinion mandate passing so easily, with so little meaningful debate. Though 198 legislators felt the bill needed significant revision, only two would dare go on record as voting against the popular health care reform measure.

to Senator Tom Harkin.⁹⁴ This letter nicely summarizes the arguments against advisory opinions that have been considered to date. According to the letter, industry efforts to make OIG issue advisory opinions have been staunchly resisted by both OIG and DOJ. There is no guarantee under HIPAA that the fees paid by requesters will get back to OIG, which could result in a serious drain on OIG's budget. The letter states the following as major problems with advisory opinions under HIPAA:

Advisory opinions on intent-based statutes (such as the anti-kickback statute) are impractical if not impossible. Because of the inherently subjective, factual nature of intent, it would be impossible for HHS to determine intent based solely upon a written submission from the [requester]. Indeed, it does not make sense for a [requester] to ask the Government to determine the [requester's] own intent. . . .⁹⁵

None of the 11 existing advisory opinion processes in the Federal Government provide[s] advisory opinions regarding the issue of the [requester's] intent. An advisory opinion process for an intent-based statute is without precedent in U.S. law.

The advisory process . . . would severely hamper the Government's ability to prosecute health care fraud. Even with appropriate written caveats, defense counsel will hold up a stack of advisory opinions before the jury and claim that the defendant read them and honestly believed (however irrationally) that he or she was not violating the law. The prosecution would have to disprove this defense beyond a reasonable doubt. This will seriously affect the likelihood of conviction of those offering kickbacks.⁹⁶

The letter goes on to highlight the financial problems OIG will experience.⁹⁷ HHS is permanently downsizing, even as it faces massive program and structural changes. The result of the advisory opinion mandate would be to divert hundreds of already busy anti-fraud workers from their cases

⁹⁴ See Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15159 (daily ed. Oct. 13, 1995).

⁹⁵ This problem becomes even worse when the split of authority over the intent element of the statute is considered. Because the courts have differed, *see supra* notes 45-49 and accompanying text, a finding of intent or no intent from the agency could be different than a court's interpretation. If DOJ wished to prosecute an arrangement that HHS had immunized (perhaps for a favorable result in a circuit that requires less intent than did the author of the advisory opinion), then DOJ would likely meet a reliance defense based on the advisory opinions.

⁹⁶ Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15158, S15159 (daily ed. Oct. 13, 1995).

⁹⁷ "The Congressional Budget Office scored this advisory opinion provision as costing taxpayers \$280 million over the next 7 years." 142 CONG. REC. at S9542, S9544 (statement of Sen. Harkin).

to handle preparation of advisory opinions.⁹⁸ The few comments that were made in HIPAA's debates regarding advisory opinions mostly raised concerns that paralleled this letter.⁹⁹ Thus, it should be noted that Congress was aware of these particular concerns. However, these concerns were not enough to derail the politically charged HIPAA. Whether the mandate would have passed on its own merits is a question that involves trying to decipher what goes on in the minds of members of Congress (a horrific exercise). It seems that in this case, though the problems were occasionally referred to, the advisory opinion section passed on the coattails of popular portability provisions that cut across party lines.¹⁰⁰ It is also clear that Congress failed to realize the position into which it was forcing OIG. Not only does the mandate place a serious financial burden on the agency, but it calls on an uncertain and uncomfortable mix of agency functions, which will lead to results that are wholly at odds with fundamental principles of administrative law.

B. *The Strange Mixture of Agency Functions Called Upon by HIPAA's Advisory Opinion Mandate Sends OIG "Shopping for Hats"*

The arguments against issuing advisory opinions mentioned above (as expressed in the letter from HHS's Inspector General to Senator Harkin)¹⁰¹ have been communicated to Congress since 1981. Despite these objections

⁹⁸ See *id.*

⁹⁹ See, e.g., 142 CONG. REC. S9501-01, S9511 (daily ed. Aug. 2, 1996) (statement of Sen. Cohen).

¹⁰⁰ The record is littered with legislators lauding the bipartisan efforts to bring the portability measure to fruition. For example:

[HIPAA] will reduce many of the existing barriers to obtaining health insurance coverage by making it easier for people who change jobs or lose their jobs to maintain adequate coverage. As many as 25 million Americans will be helped by this legislation, since it protects portability and against losing insurance due to preexisting medical conditions.

....

This measure enjoys wide bipartisan support in Congress and from a host of organizations. . . .

....

....

. . . [HIPAA] . . . is an example of the kind of incremental changes that can be enacted step-by-step in a bipartisan, collegial manner. Hopefully, this will serve as a model for future legislative reforms to our health care system and prompt the two sides of the aisle to seek more ways of working together for the betterment of the Nation.

142 CONG. REC. S9477 (daily ed. Aug. 2, 1996) (statement of Sen. Heflin).

¹⁰¹ See *supra* Part III.A.

Congress passed HIPAA with the advisory opinion mandate intact, and without the mandate being carefully scrutinized. A closer look at the implications of HIPAA reveals a larger, more serious flaw in Congress's command to OIG: a lack of theoretical and practical support for the type of action Congress is forcing OIG to take.

To appreciate the counter-theoretical results that flow from HIPAA's advisory opinion mandate, one must first attempt to classify the type of agency action it requires, and then see if that action can be harmonized with the principles that have legitimized that type of action in other situations. HIPAA's advisory opinion mandate forces action that seems to exist outside of all major legitimate paradigms for agency actions.¹⁰² The difficulty in characterizing the action HIPAA requires leads to difficulty in harmonizing the action with rule of law principles.¹⁰³ It is the lack of harmony between the action required by HIPAA's mandate and the theories that usually support those actions that will force OIG to go "shopping for hats."

1. *Advisory Opinions as Traditional Rulemaking*

It is fairly obvious that as it issues advisory opinions under HIPAA, OIG cannot comfortably wear the hat of the rulemaker.¹⁰⁴ The advisory opinions cannot be seen as being part of HHS's traditional rulemaking function. First and foremost, rulemaking is supposed to be general and prospective, applying across the board to all potentially affected parties. Such rules aspire toward the

¹⁰² This author has identified three major agency functions: rulemaking, adjudication, and advice-giving. Each function will be considered in turn. In the end, it will be clear that HIPAA's mandate calls on a mixed bag of agency functions, exposing the agency to all of the pitfalls inherent in those functions, yet providing few of the safeguards needed to harmonize those functions with the rule of law principle.

¹⁰³ Agency rulemaking comports with rule of law principles when the agency making the rule complies with the Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.) (APA), and makes rules prospectively and with public participation. Agency adjudication can be consistent with the rule of law if the process ensures stable and accurate fact-finding, such that parties know what to expect. *See generally* ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, *ADMINISTRATIVE LAW* (1993). Agencies have also developed advice-giving models that are consistent with the rule of law, in that the more binding a given piece of advice will be, the more process (such as hearings and publication) is involved. *See* Rowe, *supra* note 90, at 681 (explaining that the most reliable breeds of no-action letters are published in the *Federal Register* or independent sources). A mandate like HIPAA, which calls on a strange mix of agency functions, carries the danger that the safeguards that usually bring that function within the rule of law will be lacking, and thus the action itself will be "out of sync" with the rule of law principle.

¹⁰⁴ This author envisions a crown, as if worn by a king making rules for all his loyal subjects.

rule of law principle,¹⁰⁵ a fundamental theory of American government. As

¹⁰⁵ An integral part of the nature and theory of American government is that it aspires to govern by the rule of law. By definition, the rule of law posits “government according to *standing rules* [and principles] that [more] *impartially* distribute the burdens and benefits of government.” AMAN & MAYTON, *supra* note 103, at 67 (emphasis added). The United States Supreme Court has explicitly recognized the rule of law as fundamental to our theory of government:

When we consider the nature and theory of our institutions of government, the principles upon which they are supposed to rest, and review the history of their development, we are constrained to conclude that they do not mean to leave room for the play of action of purely personal and arbitrary power.

Yick Wo v. Hopkins, 118 U.S. 356, 369–70 (1886).

The most obvious—and oldest—manifestation of this principle is the doctrine of separation of powers. Separation of powers promotes the rule of law because it militates against concentration of power in any one person or body. A combination of power in the same hands (for example, if a legislator also had adjudicative and executive powers) approaches tyranny. See THE FEDERALIST NO. 47 (James Madison). Under this view, when one person or governmental body “wears too many hats” “it admits to *ad hoc* rule making, not permanent and general laws but orders cut for the occasion . . . [which often spring] from partial motives and [are] directed at private ends.” AMAN & MAYTON, *supra* note 103, at 69–70. Separation of powers, on the other hand, helps to move government within the rule of law.

The eighteenth century has come and gone. Our complex and growing society has outgrown a government of wholly discreet powers. To keep pace with the increasing demands of modern government, agencies have assumed much of the duty of administering policies. See *id.* at 68. “And so, government power has been combined in agencies for a more efficient development of various government programs.” *Id.* The courts have sanctioned this delegation of power. See Wayman v. Southard, 23 U.S. 1, 15–16 (10 Wheat.) (1825) (stating that “Congress can certainly delegate . . . powers it may rightfully exercise itself”). This delegation is proper, particularly where the legislature has imperfect knowledge of a substantive area and wants the policy to be developed by experts within an agency. This delegation of legislative authority necessarily means that agencies must be given quasi-legislative powers to promulgate rules. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 (1984). Of course, agencies also must have adjudicative power to resolve disputes under the rules they promulgate. This combination of powers provides the opportunity for *ad hoc* action (particular laws made for particular cases) that separation of powers and the rule of law seek to retard. See AMAN & MAYTON, *supra* note 103, at 68.

This modern commingling of powers in agencies does not necessarily mean that agency action will violate the rule of law principle. “[F]reedom . . . under government,” John Locke said, “is to have a standing rule to live by, common to every one of that society. . . .” JOHN LOCKE, SECOND TREATISE OF GOVERNMENT 17 (Hackett 1980).

This statement of the rule of law principle shows that the theory has two basic components: “The first part is the practical capacity of people to order [their] life and business” around a readily available set of published rules. See AMAN & MAYTON, *supra* note 103, at 69. The second part is that the rules should be general, equally applicable to all,

agencies take on a more prominent role in administering policy, it is desirable that their actions comport with the rule of law principle as well.¹⁰⁶ While it is

rather than according to the will of an official. *See id.*

The first part of this definition regarding capacity to plan has been recognized throughout history as a fundamental aspect of the rule of law. *See* THE FEDERALIST NO. 62 (James Madison) ("Law is defined to be a rule of action; but how can that be a rule, which is little known and less fixed."). The Second Circuit had this principle in mind when it stated that the Federal Trade Commission "owes a duty to define the conditions under which conduct . . . would be unfair so that business will have an inkling as to what they can lawfully do rather than be left in a state of complete unpredictability." *E.I. du Pont de Nemours & Co. v. FTC*, 729 F.2d 128, 139 (2d Cir. 1984).

The second part of Locke's definition deals with equality. Rules should be made generally and apply equally to all members of society. When all similarly situated people and enterprises—regardless of their relative political pull—are subject to a general rule, the rulemaker must necessarily proceed with care and circumspection, with due regard to many different interests outside of his own, in making the rule. *See Railway Express Agency v. New York*, 336 U.S. 106, 112–13 (1949) (praising legislative generality). The requirements of the APA can be viewed as Congress's attempt to make sure agencies take action according to rule of law principles. *See supra* note 103 and *infra* note 106 and accompanying text.

¹⁰⁶ Congress and the courts have kept rule of law aspirations in mind when delegating to agencies, and safeguards have been established to protect that principle. *See Railway Express Agency*, 336 U.S. at 112–13. Congress has done a good deal to legitimize agency actions by passing the APA. *See* 5 U.S.C. § 552(a) (1994). The APA prescribes certain procedures to accompany agency rulemaking. It requires rules to be open to the public for comment, then published in the *Federal Register*. *See id.* It also provides that "a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register* and not so published." *Id.* This part of rulemaking, as recognized by the Supreme Court, is responsive to rule of law values. It "provides notice of what . . . will be sanctioned and promotes equality of treatment among similarly situated [persons]." *Dixon v. Love*, 431 U.S. 105, 115 (1977). Thus, despite the concentration of power in agencies (both to make and apply rules), agency action is brought closer to rule of law principles by the stringent rulemaking requirements of the APA.

When an agency takes action according to the rulemaking procedures in the APA, several concerns are addressed. Rulemaking, through the notice-and-comment requirements, assures that a variety of interests will focus on a proposed policy shift and bring issues to the political forefront. *See Jim Rossi, Making Policy Through the Waiver of Regulations at the Federal Energy Regulatory Commission*, 47 ADMIN. L. REV. 255, 294 (1995). In addition to increasing public participation and fairness, notice-and-comment rulemaking procedures assure that the agency is adequately informed as to the issues inherent in any proposed rule, much like the deliberative process of legislators assures adequate coverage of issues. *See Committee on Fed. Regulation of Sec., Report on the Task Force on SEC Settlements*, 47 BUS. LAW. 1083, 1143 (1992). Agency action through rulemaking also serves to legitimize the agency action in the eyes of the public. *See Chamber of Commerce of United States v. OSHA*, 636 F.2d 464, 470 (D.C. Cir. 1980) (stating that public participation by those to be affected by a rule "helps dispel suspicions of agency predisposition, unfairness, arrogance, improper influence, and ulterior motivation"). So, although concentration of power in the hands of an agency may appear to violate rule of law standards by inviting ad hoc policy development, the APA helps bring agency action within the ambit of the rule of law.

true that our government is not always able to reach its goal of governance according to the rule of law, one should view with skepticism a statute that forces agency action which has no hope of aspiring to the rule of law principle.

Generality, as opposed to specificity, is one of the chief factors legitimizing the rulemaking process.¹⁰⁷ The specificity of the advisory opinion process, applying law to specific parties in specific fact situations, quickly removes a HIPAA-style advisory opinion from the realm of traditional rulemaking. Moreover, HIPAA mandates that advisory opinions be issued without the notice-and-comment procedures specified in the APA for rulemaking.¹⁰⁸

HIPAA's advisory opinion mandate does not even attempt to harmonize the issuance of advisory opinions with the APA's rulemaking requirements. This casts serious doubt on any attempt to characterize the mandate as calling on HHS's and OIG's rulemaking function. Also, the specificity to certain parties, along with the retroactive nature of the opinions, tends to remove the advisory opinion process from the traditional rulemaking model. With all of these factors present, it is impossible to logically justify the advisory opinions as traditional agency rulemaking. When issuing advisory opinions, OIG cannot hope to bring us closer to any discernible rule of law via the traditional mechanics of agency rulemaking. Clearly, OIG cannot comfortably don the rulemaker's hat as it attempts to comply with HIPAA's advisory opinion mandate.

2. HIPAA Advisory Opinions as Ad Hoc Rulemaking

Apart from standard notice-and-comment rulemaking envisioned under the APA, agencies can also engage in a breed of de facto rulemaking by adjudication on a case-by-case basis.¹⁰⁹ When proceeding to make rules in a

¹⁰⁷ Promulgated under the notice-and-comment procedures delineated in the APA, traditional rulemaking is particularly suited to determining legislative facts and policy of general, prospective applicability. Specificity is more suited to trial-like procedures for retrospective determination of specific facts about individual parties. See AMAN & MAYTON, *supra* note 103, at 101. HIPAA advisory opinions are specific determinations of the facts in individual cases. Thus, they lack the requisite generality to be legitimate agency rulemaking.

¹⁰⁸ See 5 U.S.C. § 553 (1994).

¹⁰⁹ Just as there are clear advantages to rulemaking, there are disadvantages as well. The disadvantages are primarily from the agency's perspective. "In large part, the disadvantages are in terms of substantive rationality"—instead of being bound by rigid rules, an agency may be better able to effectuate its policy goals through ad hoc "orders cut for the occasion . . . It would [rather] treat each case [on] its own merits" than try to fit it into an ill-fitting rule. AMAN & MAYTON, *supra* note 103, at 71. This "idea is shown in a probation officer's remarks about sentencing guidelines and new bureaucratic methods in his profession, that he was now a 'bean counter' and that 'the probation officer's knowledge, experience, and judgment are no longer [a] crucial [part of] the sentencing process.'" *Id.* (quoting Eugene D. Natali, *The Probation Officer, Bean Counting and Truth in Sentencing*, 4 FED. SENTENCING

case-by-case manner, the agency must wear the hat of the adjudicator, carefully attending to the adversarial process to ensure fairness and accurate fact-finding.¹¹⁰

The Supreme Court, which has traditionally championed formal rulemaking to attain administration by the rule of law, has recognized that under certain circumstances it may be more appropriate for an agency to make policy on a case-by-case basis.¹¹¹ The Court countenanced ad hoc agency action in *SEC v. Chenery*.¹¹² The Court noted that “the function of filling in the interstices of [the Holding Company Act] should be performed as much as possible through the quasi-legislative promulgation of rules to be applied in the future,”¹¹³ consistent with rule of law principles. The Court then tempered this statement with the following caveat: “[P]roblems may arise which the agency could not reasonably foresee . . . [or] the problems might be so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule.”¹¹⁴ The Court went on to conclude that an agency should ordinarily regulate by means of rules, but it may at times regulate ad hoc. An agency may, in its “informed discretion,” resort to case-by-case adjudication to address orders to the issue at hand.¹¹⁵

Rulemakers are not omniscient and the language of rules is at best imperfect. Situations are bound to arise in which the application of a rigid rule makes no sense, and indeed may even frustrate the policy behind the rule. Thus, courts have countenanced ad hoc approaches to rulemaking when the

REP. 102 (1991)).

The adjudicative function of agencies has been around even longer than the rulemaking function. See David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921, 942-57 (1965) (discussing agency reluctance to convert from adjudicatory models to rulemaking models). It is no surprise that Congress addressed adjudication in the APA. The APA basically promotes rule of law principles within agency adjudication by ensuring the process of an adversarial-type hearing. The role of the adversarial process in adjudication is to promote fair determination of the rights of parties based on truth-tested evidence. A good process, coupled with adequate containment principles, can help preserve predictability in the rules and can help agencies adjudicate equitably, while still adhering to the spirit of the rule of law principle.

¹¹⁰ For illustration's sake, this author envisions the proper hat for the adjudicative function as the white powdered wig, historically worn by judges in English courts.

¹¹¹ See *AMAN & MAYTON*, *supra* note 103, at 71.

¹¹² 332 U.S. 194 (1947).

¹¹³ *Id.* at 202.

¹¹⁴ *Id.* at 202-03.

¹¹⁵ *Id.* at 203. It is important to note that in recognizing the need for agency discretion to proceed ad hoc, the Court was not turning its back on the rule of law. It was simply acknowledging that sometimes the most efficient and practical way to achieve the eventual rule of law was to proceed case-by-case.

agency decides, in its informed discretion, that it is best to proceed ad hoc rather than by formal rulemaking processes.¹¹⁶ When such a situation arises, it is appropriate for an agency to trade the crown of the rulemaker for the powdered wig of the adjudicator. An agency may choose to proceed ad hoc for a variety of reasons.¹¹⁷

Whatever a particular agency's reasons may be for wanting to proceed ad hoc, it is clear that HHS has not made that choice here. In fact, HHS has specifically rejected this approach.¹¹⁸ Under HIPAA, Congress has simply made the choice for the agency.¹¹⁹ This is an important factor that distinguishes HIPAA's breed of ad hoc decisionmaking from traditional forms of ad hoc rulemaking. If HHS had chosen to proceed ad hoc, it would have done so because it felt that better policy could be made case-by-case. After choosing the adjudicatory route, HHS would put on the adjudicator's wig, would have to comply with the process requirements of the APA, and could engage in thoughtful disposition of the cases before it.¹²⁰ But HHS has specifically

¹¹⁶ *See id.*

¹¹⁷ For example, the agency may be faced with far-flung factual situations that do not inure themselves to traditional rulemaking. Sometimes trying to make prospective rules will result in more inconsistent policy than by proceeding on a case-by-case basis. *See AMAN & MAYTON, supra* note 103, at 71.

¹¹⁸ Advisory opinions were one of the first methods the agency tried when it started developing its policy under the anti-kickback statute. It was also one of the first methods abandoned by HHS after it proved unworkable. *See supra* Part II.A.

¹¹⁹ By forcing HHS to issue advisory opinions on request, which will interpret the law in a specific factual situation to particular parties, with binding effect, Congress has essentially forced HHS to proceed with administering the anti-kickback statute ad hoc. *See infra* note 120 and accompanying text. It has made this choice without careful thought as to its consequences. The *Chenery* Court countenanced ad hoc rulemaking when the agency determined that it was the better course to proceed case-by-case rather than by general rules. *See Chenery*, 332 U.S. at 203; *supra* notes 112–16 and accompanying text. Contrary to proceeding ad hoc by its own discretion, the agency has been forced to proceed ad hoc by Congress's uninformed discretion. *See also* *WAIT Radio v. FCC*, 418 F.2d 1153, 1157 (D.C. Cir. 1969) (“The agency’s *discretion* to proceed in difficult areas through general rules is intimately linked to the existence of a safety valve procedure for consideration of an application for exemption based on special circumstances.”) (emphasis added).

¹²⁰ HIPAA's advisory opinion process calls on a function that somewhat resembles agency adjudication. First, the opinions would apply law to specific facts, with specific parties, and with binding effect. This resembles agency adjudications. *See AMAN & MAYTON, supra* note 103, at 199–201. Adjudications, under the APA, must be determined on the record after an opportunity for an agency hearing. *See* 5 U.S.C. § 554(c)(2) (1994). Obviously, the advisory opinion provides for no such process. Congress may not have intended for advisory opinions to be adjudicatory proceedings. Unfortunately, an opinion rendered under the mandate will have many characteristics of an adjudication, *vis-à-vis* simple advice-giving. Thus, at least in part, the mandate calls on the adjudicative function of agencies, but does not provide any of the procedural safeguards required by the APA. Moreover, agencies should

abandoned this case-by-case route, at least through the use of advisory opinions. Recall the difficulties outlined in Part III.A with trying to render advice on an intent-based statute from only a written submission from the parties in interest. OIG has called the issuance of advisory opinions on intent-based statutes "unprecedented."¹²¹

The questionable mechanics of HIPAA's advisory opinion mandate (determining intent from nothing but a written submission), the wide range of results that will come out of the process (due to the inherently subjective nature of intent), and the lack of procedural process usually present in adjudicative actions makes HIPAA's mandate impossible to defend as calling for ad hoc rulemaking. Thus, in attempting to comply with the mandate, it is clearly not proper for the agency to wear the wig of the adjudicator.

It is also clear that these adjudicative-type decisions will not bring OIG any closer to a rule that comports with the rule of law ideal. The completely subjective nature of the inquiry would produce such inconsistent results that any hope of distilling a clear rule out of the individual cases would be lost. When one considers the practicality of how these opinions will be rendered, the hope for emergence of a rule becomes bleaker still. The mandate forces OIG to respond, upon request, within a limited period of time, and with only a written submission from the requesting party with which to render an advisory opinion.¹²² HHS and OIG are already facing a fiscal nightmare.¹²³ The

seek to avoid advice-giving from an adjudicatory pose. *See Burnele V. Powell, Sinners, Supplicants, and Samaritans: Agency Advice Giving in Relation to Section 554(e) of the Administrative Procedure Act*, 63 N.C. L. REV. 339, 355 (1985). Advice-giving actions by agencies do not have to meet stringent procedural requirements, because most of the time advice-giving is informal. HIPAA basically calls for action that has the relaxed process of informal advice-giving, but all the binding results of an adjudication. Congress wants to have its cake and eat it too, but cannot have it both ways if it hopes for the action to lead to administration consistent with the rule of law.

¹²¹ *See* Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15159 (daily ed. Oct. 13, 1995). Other commentators agree with this assessment:

Although advisory opinions are an appropriate means of giving guidance to the industry on some issues, it is clearly unwise to have the agencies in the positions of opining on the intent of the person requesting the opinion. To have a Government agency make an independent determination of what is in someone's head, based solely upon what the person chooses to tell the agency, is a highly questionable Government function.

142 CONG. REC. S9501, S9511 (daily ed. Aug. 2, 1996) (statement of Sen. Cohen).

¹²² In asking OIG to divine a provider's intent solely from a written submission from the inquirer, it seems Congress asks OIG to put on the mythical hat of a wizard or a psychic. The problems inherent in this intent-based inquiry have been put before Congress, but have been largely ignored. *See supra* note 93 and accompanying text.

practical implication of this is that it will be impossible for HHS to commit the resources necessary to handle the requests in a careful manner.¹²⁴ The emergence of a discernible rule from a quagmire of quickly written advisory opinions, based only on a written submission from the parties, no doubt cleverly crafted by counsel, is unlikely at best.

Thus, it is difficult to justify the advisory opinion process under HIPAA from either a formal or an ad hoc rulemaking standpoint. The opinions will lack the generality and prospectivity necessary to formulate general rules, and are completely lacking the process necessary to be formal, prospective rulemaking.¹²⁵ The advisory opinion process cannot be justified as ad hoc rulemaking, either. First, it completely lacks the process elements necessary to ensure that the opinions are the result of careful fact-finding and the adversarial process.¹²⁶ Also, the fact that the statute is based on intent means that every advisory opinion will be inherently subjective, and thus will not get HHS any closer to a rule that applies across the board.

In fact, these opinions collectively would have only a negative effect. Both OIG and DOJ have made their fears evident that defendants will try to build reliance theories based on the opinions. Despite the appropriate caveats, defense counsel can hold up a stack of advisory opinions and claim that the client acted in good faith.¹²⁷ Since criminal convictions must be “beyond a reasonable doubt,” such a theory could hurt DOJ’s chances of winning convictions under the statute.¹²⁸ Thus, the only “rule” that may come out of

¹²³ See Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15158, S15159 (daily ed. Oct. 13, 1995) (stating “[a]s a result of downsizing, OIG has had to close 17 OIG investigative offices and [now lacks] an investigative presence in 24 states. The OIG has only about 140 investigators for all Medicare cases nationwide. By way of contrast, the State of New York gainfully employs about 300 persons to control Medicaid fraud in that State alone.”).

¹²⁴ Even if unlimited resources were available, more money will not change the fact that discerning intent is a factual inquiry that requires the truth-testing tools of the adversarial process to be utilized with accuracy. It is possible that OIG could do a more complete and thorough analysis if it had more resources, which may improve the quality of a given advisory opinion. But the fact is that HHS is low on resources, which means that what little HHS can expend on advisory opinions will effectively go to waste.

¹²⁵ Here, “process” refers to the notice-and-comment procedures under the APA. See 5 U.S.C. § 553 (1994).

¹²⁶ See *supra* note 120 and accompanying text.

¹²⁷ An informal dissemination process has developed with other advisory processes. Organized members of the public likely to be affected by an agency advisory opinion regularly send couriers to public information rooms to dig up these opinions so they can build good faith reliance theories. See Powell, *supra* note 120, at 352.

¹²⁸ See Letter from June Gibbs Brown, Inspector General of HHS, to Sen. Tom Harkin (Sept. 29, 1995), in 141 CONG. REC. S15158, S15159 (daily ed. Oct. 13, 1995).

this process is a de facto reliance rule, something to which the agency surely would not have subjected itself had it been given the choice.

3. *Advisory Opinions as Advice-Giving*

It might be possible to rationalize the HIPAA advisory opinions as administrative advice-giving, were it not for several characteristics that take HIPAA's process out of the realm of traditional advice-giving models. Most agencies tend to view their advice-giving actions as an aspect of their rulemaking function.¹²⁹ Thus, advice-giving takes place outside of the adjudicative realm, which typically involves specific parties with fixed interests that are directly and immediately at risk.¹³⁰ Immediately, HIPAA's mandate disagrees with the model because it involves specific parties who, in the context of joint ventures, have fixed interests at stake. Further, the intent-based nature of the statute means that any advice-giving could not apply to anyone else, as intent is entirely subjective. The specificity inherent in HIPAA's advisory opinions is at tension with the generality with which agencies prefer to give advice. The type of specific findings demanded by the advisory opinion mandate beg for some sort of adjudicatory process to insure accuracy and fairness in their determination.

Advice-giving tends to be general and is much less formal by way of process than adjudication. The hat worn by agencies while dispensing advice under traditional models is an informal, common, everyday type of hat. By way of illustration, it is more like a broken-in baseball cap, turned around backwards, than it is like the crown or powdered wig worn by agencies in their

¹²⁹ See Powell, *supra* note 120, at 348-49.

¹³⁰ See *id.* This is a characteristic of adjudicatory proceedings, which have been viewed by agencies as somewhat divorced from their advice-giving activities. There are practical reasons why. Normally, advice-giving is very informal, with interested parties communicating with low ranking staff members by telephone or in writing. See *id.* It is generally understood that informal advice is not binding on the agency. See *id.* The agency may sometimes choose to give advice in a more formal manner, and the public can rely on this advice to a greater extent. See *id.* It generally costs less (in terms of staff expenses) for an agency to offer informal advice than to offer formal, binding advice. Formal advice-giving takes time, and requires higher levels of authority to make it valid. See *id.* at 353. Cost savings translate into resources available for other matters, and the fact that lower level employees have rendered non-binding advice gives the agency flexibility to change its position later. See *id.* Because of the practical way that agencies give advice (keeping costs in mind), it is questionable to order them to give advice that will bind the parties in the same way an adjudication would. Thus, agencies try to avoid advice-giving from an adjudicatory posture, and advice-giving is generally not viewed as encompassing determinations having specific effects on individualized matters and specific parties. See *id.* at 354. Since the advisory opinions have such adjudicatory ingredients, they are not within traditional advice-giving models.

more formal capacities. Unfortunately, HIPAA's mandate has characteristics that make it inappropriate for OIG to approach advisory opinions while wearing this informal hat.

One of the major ingredients in an agency advice-giving scheme is flexibility. In particular, "agencies seek control over the timing of their responses and the significance that the public is allowed to attach to [them]."¹³¹ HIPAA's mandate is at odds with this model in that the agency cannot pick and choose when it will respond, and has no control as to the significance of its responses. Agencies also, in general, like "to avoid advice giving from an adjudicatory posture,"¹³² because it amounts to pre-adjudication adjudication with no formal process to ensure stability and accurate fact-finding. The fact that these letters are binding on the agency makes them similar to summary adjudications, at least from the agency's perspective. The model advice-giving scheme that can be generalized from contemporary administrative government is, in a word, calculated.¹³³ It envisions that advice can be provided to the public, but only under the circumstances and to the degree that the agency itself believes appropriate.¹³⁴ Clearly, HIPAA's mandatory advisory opinion provision runs against this model. Thus, it is difficult to justify the mandate as calling on an agency advice-giving function. Consequently, it seems inappropriate for OIG to wear the advice-giver's cap while attempting to comply with HIPAA's advisory opinion mandate.

¹³¹ *Id.* at 353.

¹³² *Id.* at 355. Illustratively, it would amount to playing the role of the adjudicator while wearing the broken-in baseball cap of the everyday advice-giver.

¹³³ An example of a more sound advice-giving model is SEC's use of no-action letters. *See Rowe, supra* note 90. This model is distinct from HIPAA's mandate in several ways. First, there is usually more communication than one written submission. *See id.* at 678. Second, SEC is not required to respond by congressional mandate, but has instead developed this model at its own discretion, and may choose not to respond. *See id.* at 708. Third, the agency has at least some control over how much reliance the public can place on a given no-action letter, and how binding the letters will be on the parties involved. *See id.* at 681-95 (suggesting a hierarchy of reliance on no-action letters).

¹³⁴ *See id.* Efficiency is one of the chief factors that leads agencies to develop this sort of advice-giving scheme. The agency knows that it has limited resources, so it wants to give advice cheaply and quickly, involving as few higher level staff members as possible. The sheer volume of advisory opinion requests may inundate OIG staff and make efficiency impossible. The binding nature of the opinions will motivate OIG to involve senior members in drafting them, which leads to more costs and less efficiency. *See supra* notes 123-24 and accompanying text. The flexibility in terms of timing and importance that is preserved in traditional advice-giving models helps agencies give advice within their budgets. That flexibility is lost under HIPAA's advisory opinion mandate and further removes the mandate from traditional advice-giving models.

4. *A Mandate Without a Leg on Which to Stand*

It seems that no matter which way you slice it, HIPAA's mandate is out of step with traditional agency functions, and in discord with the legal principles that legitimize those functions. The mandate cannot be justified as rulemaking, either formal or ad hoc.¹³⁵ It lacks the process, prospectivity, and neutrality that legitimizes formal rulemaking by harmonizing it with rule of law principles. The mandate lacks the process needed for legitimate ad hoc rulemaking, and a choice by the agency to proceed ad hoc is conspicuously absent. It is also clear that HIPAA calls for action that lacks the agency discretion in terms of response and reliance needed to fit the mandate within an advice-giving model.¹³⁶ All in all, it seems that HIPAA calls for agency action that has no theoretical leg on which to stand. This lack of theoretical support leaves OIG in a position of wondering which hat it should don when attempting to comply with the mandate.¹³⁷ Since none of the hats in OIG's wardrobe is fit for the occasion, HIPAA's mandate will force OIG to go "shopping for hats."

This author is sensitive to the need for guidance under the anti-kickback statute, particularly in light of the rapid expansion of managed care and joint ventures in the health care industry. Industry actors must be concerned that, though they set up an agreement in good faith, they may nonetheless risk sanction. The complexity of the statutory scheme, coupled with the persistent split of authority in federal courts on the intent requirement, adds even more uncertainty. However, HIPAA advisory opinions are not a legitimate answer to the problem. What good is guidance if it leads to unprincipled and illegitimate administration by the agency? Congress has literally forced OIG to adopt a practice that has no hope of aspiring to the rule of law. Thus, the need for a different solution to this problem is paramount.

IV. SUGGESTIONS FOR REFORM

As the previous discussion suggests, the advisory opinion mandate is not a proper solution to the problems experienced by joint venturers under the anti-kickback statute. This is not a problem without a solution, however. There are a few possibilities that could serve to protect good faith venturers, yet still call for agency action that can be legitimized by accepted practices and theories of

¹³⁵ See *supra* Parts III.B.1-2.

¹³⁶ See *supra* Part III.B.3.

¹³⁷ To some degree, the uncomfortable mixture of functions called upon by HIPAA's mandate would ask OIG to wear all three hats (rulemaker, adjudicator, and advice-giver) all at once. The absurdity of the picture of June Gibbs Brown standing there, with a powdered wig, a turned-around baseball cap, and a crown on her head all at once is an apt analogy to the absurd and unprincipled administration that HIPAA's mandate will foster.

administrative law.

A. Repeal the Mandate and Tailor Application of the Anti-Kickback Statute Through Administrative Equity

First, Congress could repeal HIPAA section 205(b) (the advisory opinion mandate)¹³⁸ wholesale. This is the most obvious solution to the problem.¹³⁹ It is not certain how an initiative to repeal would fare on Capitol Hill.¹⁴⁰ Since the mandate was overshadowed by the bill's enormously popular portability provisions, and there was so little congressional attention paid to the matter,¹⁴¹ it is difficult to predict how this mandate would have fared on its own merits.

The repeal of the advisory opinion mandate would still leave intact other HIPAA provisions that call for more regular solicitation of public opinion on enacting safe harbors and special fraud alerts.¹⁴² Of course, it may take some time before the dialogue between the public and the agency results in a solution. But at least when that solution comes, it will have been born of the notice-and-comment procedures in the APA's rulemaking guidelines,¹⁴³ and thus will be more in harmony with the theory of the rule of law.

If the mandate were repealed, providers would be forced to face life without the instant advice granted them under HIPAA. To assuage industry concerns for protecting good faith actors, a formal system of exceptions should be in place to protect good faith actors under a theory of "administrative

¹³⁸ See *supra* Part II.B.

¹³⁹ It is probable that the health care industry will object to this solution, because its members would be put back at square one. Yet, perhaps now is the time to question the industry's complaints in general. How legitimate are the fears of joint venturers that OIG will come after good faith actors with guns blazing? The fears look even less substantial when it is considered that there is no evidence on the record to indicate that any trivial cases have ever been pursued under the statute. See 142 CONG. REC. S9541, S9543 (daily ed. Aug. 2, 1996) (statement of Sen. Harkin, discussing the letter written to him by Inspector General June Gibbs Brown).

¹⁴⁰ President Clinton began advocating the advisory opinion mandate's repeal almost as soon as he signed HIPAA into law. As yet, his efforts have been unsuccessful. However, Clinton attempted the repeal as part of the Health Care Financing Administration's 1998 budget agreement. Thus, it is still difficult to say with certainty how the advisory opinion process would fare, standing completely alone. See JOST & DAVIES, *supra* note 37, at 167-68.

¹⁴¹ See *supra* note 82.

¹⁴² See HIPAA §§ 205(a), (c) (safe harbors; special fraud alerts), 42 U.S.C.A. § 1320a-7d (West Supp. 1997). These mandates force OIG to step up its dialogue with the public concerning the reach of the anti-kickback provision.

¹⁴³ See 5 U.S.C. § 553 (1994) (specifying rulemaking notice, comment, and publication procedures).

equity."¹⁴⁴ Systems of administrative equity are at use in other agencies.¹⁴⁵ While overusing exceptions may inadvertently swallow the rule,¹⁴⁶ administrative equity can be appropriately contained so that granting exceptions in appropriate cases will not necessarily violate the rule of law.¹⁴⁷ A look at the implications of the anti-kickback statutes on joint venturers suggests that a good faith actor who is nonetheless exposed to criminal sanctions may be able to qualify for a recognized and containable category of administrative equity, such as "economic hardship" equity or "reasonableness" equity.

Exceptions to rules based on economic hardship begin with the idea that "[e]quity will not allow the application of a particular regulation to force a firm out of business or render a piece of property valueless unless the social benefits of compliance with that regulation outweigh the severe costs to the petitioner."¹⁴⁸ A joint venturer could conceivably be faced with the threat of economic extinction if he is sanctioned for setting up a particular structure.¹⁴⁹ Even if a joint venturer is not sanctioned, but is simply told "no, you cannot do that" by OIG, the economic pressures in the market that prompted the joint venture in the first place may end up forcing the joint venturer out of

¹⁴⁴ What some commentators have dubbed "administrative equity" is nothing more than allowing exceptions to provide a safety valve to agencies, when enforcing a rule by its four corners would work an injustice in a particular case. Criteria and processes can be established under which administrators can do justice in individual cases, when the rule fails to do so by itself. See Alfred C. Aman, Jr., *Administrative Equity: An Analysis of Exceptions to Administrative Rules*, 1982 DUKE L.J. 277, 278. Under administrative equity systems, the agency casts off the crown of the general rulemaker, and dons the powdered wig of the adjudicator, crafting specific exceptions in specific cases.

¹⁴⁵ One example is the Federal Energy Regulatory Commission. See generally Rossi, *supra* note 106.

¹⁴⁶ This fear is very speculative. Given the relative infrequency of agency sanctions, coupled with the lack of actual attempts at prosecution, see *supra* note 139, the need to grant an exception to a perhaps erroneously prosecuted individual would be rare indeed.

¹⁴⁷ Containment principles are what keep actions in administrative equity from violating the rule of law. If exceptions to rules are freely and easily granted, with little or no regard for principle, the inner morality of law may be jeopardized. "Exceptions to administrative rules need not be granted or denied on a random basis For the most part, [exceptions are limited by] certain equitable principles and the norms that underlie those principles Three broad categories of exceptions relief emerge. These are hardship exceptions, fairness exceptions, and policy exceptions." See Aman, *supra* note 144, at 292-93.

¹⁴⁸ *Id.* at 294-95.

¹⁴⁹ Violations of the statute can result in heavy fines, and a violation of the anti-kickback statute results in automatic exclusion from the Medicare program. See McDowell, *supra* note 1, at 725-26. Exclusion from the program could spell economic death for many providers such as nursing homes who derive a great deal of revenue from Medicare patients.

business.¹⁵⁰ It seems that a joint venturer who acted in good faith does not present such a threat to society that the societal costs of letting him continue would outweigh the costs of forcing him out business. Thus, joint venturers should be able to qualify, in some cases, for an exception to the anti-kickback statute under a theory of economic hardship administrative equity.

Another relevant form of administrative equity is a reasonableness exception. At the heart of a reasonableness exception is the notion that “[e]quity may allow an exception when compliance with a rule either does not further the goals of the statute or minimally advances those goals at a cost to the petitioner wholly disproportionate to the benefits produced.”¹⁵¹ In the case of the good faith joint venturer, who inadvertently violates the technical terms of the anti-kickback statute, it seems this equitable exception would provide safety. The goals of the anti-kickback statute are to put those who intentionally defraud the system in jail and exclude them from the program. While putting innocent venturers in jail will not further this goal, neither will excluding them from the system. The cost of prosecuting them, or excluding them, is great: either they will be imprisoned or suffer great economic damage. It seems that a good faith actor would qualify for this sort of administrative equity.

To provide some guidance under the system of exceptions, HHS could promulgate specific factors that it will consider in deciding whether to grant an exception. These factors could be made pursuant to notice-and-comment rulemaking procedures consistent with the APA, and consequently with the rule of law principle.¹⁵² Publishing criteria by which equitable claims should be considered would help give prospective guidance to joint venturers, and would add legitimacy to HHS enforcement under the anti-kickback statute.

B. *Make Response Discretionary*

In the alternative to a wholesale repeal, Congress could amend the word “shall” to “may,” making issuance of the advisory opinions discretionary. This may seem a simplistic solution, but it has the elegance of putting the agency action (rendering an advisory opinion) into a more traditional advice-giving model. With this added discretion, OIG could carefully choose when it wants to respond, and can more carefully control the public’s ability to rely on the opinions. This would also give the agency freedom to utilize its resources in a more efficient manner.¹⁵³ To help empower the industry to obtain agency

¹⁵⁰ See *supra* Part I.A.

¹⁵¹ Aman, *supra* note 144, at 311.

¹⁵² Here, OIG can comfortably wear the crown of rulemaker.

¹⁵³ See *supra* notes 123–24 and accompanying text. One drawback to this solution is that it would still call on the agency to give advice to specific parties with already fixed interests. However, by enabling OIG to turn down a request, the possibility is created that OIG can

review, Congress could provide that OIG at least respond to a request with an explanation as to why it feels giving an advisory opinion on that inquiry would be inappropriate.

C. *Make Advisory Opinions Non-Binding*

Alternatively, Congress could simply make the advisory opinions non-binding. This would have two positive effects. First, it would greatly reduce the possibility of third parties building reliance theories on opinions rendered to strangers. This would help avoid the negative de facto reliance rule that the current advisory opinion mandate makes imminent.¹⁵⁴ In addition, making the advisory opinions non-binding would serve to give the agency more discretion in allocating its scarce resources. If the letters are non-binding, many requests can be confidently handled by lower level, lower paid staff employees.¹⁵⁵ This brings the process more in line with traditional advice-giving models by letting the agency decide how high up the chain of command a particular inquiry will go, and likewise to what extent a third party can rely on that information.¹⁵⁶ This solution leaves the power to initiate the advice-giving process in the hands of the interested joint venturers, but reduces the negative impact that the flood of requests will have on OIG's efficiency.

V. CONCLUSION

While it seems that Congress had admirable intentions when it passed HIPAA's advisory opinion mandate, it also seems clear that Congress chose a questionable vehicle for realizing those intentions. The advisory opinion mandate does more to hurt the overall problem than it does to help it. Any

wait for a question to be asked by several parties, then respond with a general and prospective advisory opinion that would apply across the board. Thus, changing "shall" to "may" would create a more traditional system of advice-giving.

¹⁵⁴ See *supra* notes 127-28 and accompanying text.

¹⁵⁵ These lower level employees are undoubtedly suited for wearing the turned-around baseball cap of the informal advice-giver. They may not, however, be well suited for the crown or the powdered wig which they will effectively be forced to wear under the mandate in its current form, given the adjudicatory aspects of the mandate.

¹⁵⁶ See Powell, *supra* note 120, at 353. "In particular, agencies seek control over the timing of their responses and the significance that the public is allowed to attach to those responses. Ideally, they seek resolutions that resolve inquiries . . . at the lowest practicable level of authority. Cost savings [from utilizing lower levels of authorities] translates into resources available for other matters, and lower-level resolutions promote flexibility by preserving the option of altering the decision at higher levels if events warrant." *Id.* at 353-54.

guidance under such a mandate would be questionable as to reliability,¹⁵⁷ and would force the agency to compromise traditional theories of administrative law in the process. The curious mixture of agency functions called upon by the mandate will leave OIG in the uncomfortable position of wearing multiple hats, all at once, or go shopping for an entirely new hat that it has never worn before. The clear solution to the quandary created by HIPAA's advisory opinion mandate is for Congress either to repeal the mandate and formulate exceptions to the anti-kickback statute, or to amend the mandate to make the advisory opinions discretionary or non-binding on the agency

¹⁵⁷ See *supra* Part III.A, and the discussion of why it is basically impossible to render sound advice under an intent-based statute based solely on a written submission from the inquirer.

