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Integrated Delivery Systems: Reforming the Conflicts Among Federal Referral, Tax Exemption, and Antitrust Laws

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INTEGRATED DELIVERY SYSTEMS:
REFORMING THE CONFLICTS AMONG
FEDERAL REFERRAL, TAX EXEMPTION, AND
ANTITRUST LAWS

Amy L. Woodhall†

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THE HEALTH CARE INDUSTRY is undergoing frenzied and chaotic changes. The prospect of some type of health reform, the increasingly competitive environment, and the aggressive development of new delivery and financing modes have combined to produce a fundamental restructuring within the industry. This industry transition is particularly affected by three broad areas of federal law: (1) the laws governing Medicare and Medicaid fraud, abuse, and self-referrals; (2) the provisions of the Internal Revenue Code establishing the conditions by which hospitals and other providers may be exempted from federal taxes; and (3) the antitrust laws.

This Note will discuss the impact and interrelationships of these federal laws on the development of an integrated health care industry. At the micro-level, an integrated delivery system is "a network of organizations that provides or arranges to provide a coordinated continuum of services to a defined population and is willing to be held clinically and fiscally accountable for the outcomes and the health status of the population served." While extensive foundational literature is available on the theories, rationale, and legal and economic principles underlying each of the three areas of law that are the subjects of this Note, this Note analyzes the interrelationships among these areas and proposes several initiatives to improve the federal law governing health care providers.

This Note will analyze four problems for health care providers undertaking integrated delivery system development. First, each body of law contains inherent barriers to the development of new organizational models that are the centerpiece of private health care system reforms. Second, the application of rules to different types of health care organizations is not

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always consistent, and the differences are often not justified. Third, the laws themselves and the regulatory apparatus governing health care providers often result in tensions and inconsistencies in federal law. The lack of a coordinated regulatory agenda creates special problems for integrated delivery system development. Finally, proposed solutions to these problems are notably absent from the recent health reform debate.

In response to these problems, this Note identifies a process and a proposed agenda for resolving these conflicts. The ultimate goal of these proposals is to develop a process for harmonizing provider standards that identifies and elaborates upon the underlying value conflicts among federal health care laws while respecting the discrete rationale and legal principles in each area. Without regard to the timing or outcome of health reform at the national level, existing mechanisms may be used to improve the federal laws governing integrated system development.

I. BACKGROUND

The health care industry is undergoing a major realignment in its basic structures and assumptions. Historically, health care has been a fragmented industry characterized by legally separate provider entities and separate payor and provider organizations. Problems associated with industry fragmentation include duplication among providers, fragmented episodic care, the lack of economies of scale, gaps in insurance payments, and conflicting financial incentives among providers and between payors and providers.

Several interrelated factors have combined to propel the movement away from a fragmented industry toward an integrated industry. A new environment of "managed competition" has emerged in which brokers, including the government and

5. Id.
large employers, manage the process of informed consumer choices toward high-quality, economical health care plans.\(^7\) Although the 103d Congress did not pass major health reform legislation, President Clinton and Republican and Democratic leaders of Congress intend to continue the debate in the current Congress.\(^8\) The prospect of health reform at the federal level and the reality of private sector managed competition initiatives have further accelerated integrated delivery system development.\(^9\)

Purchasers are demanding performance measures for defined patient populations. Developing health status outcomes and demonstrating cost-effectiveness for large patient populations requires clinical integration of health care services from a patient-centered perspective, physician integration through economic linkages, governance, and management, and the functional integration of strategic planning and quality improve-


For a proposed classification and definition of managed care monikers, the reader is directed to the work of Weiner and Lissovoy. The development of managed care has been accompanied by a virtual alphabet soup of acronyms including HMOs (health maintenance organizations), PPOs (preferred provider organizations), POS (point-of-service plans), and IPAs (independent practice associations). Johnathan P. Weiner & Gregory de Lissovoy, *Razing a Tower of Babel: A Taxonomy for Managed Care and Health Insurance Plans*, 18 J. Health Pol. Pol’y & L. 75, 77-78 (1993) [hereinafter Babel].

While managed competition refers to the process of managing the competition among health plans, managed care refers to the methods used by plans and providers to manage the resources expended on patient care. *Id.* at 97-98.

\(^{8}\) Diane E. Kirrane, *Healthcare Reform: What the Future Holds*, HEALTHCARE EXECUTIVE, Jan.-Feb. 1995, at 6, 7. Meanwhile, state and local governments are introducing reforms, and absent federal reforms, providers will continue responding to the forces of managed competition. *Id.*

\(^{9}\) Stephen W. Bernstein, *Hospital Mergers, Acquisitions and Affiliations: The Anatomy of Motivations, Models, Process and Legal Considerations*, in *Health Care Law* 1993, at 77, 77-78 (PLI Com. L. & Practice Course Handbook Series No. A4-4428, 1993). Bernstein also notes other driving factors such as the conservation of limited resources, the elimination of duplication, and the conversion of acute care facilities toward outpatient care. *Id.*
ment. Further, health reform initiatives have accelerated integrated delivery system development as providers combine to facilitate contracts with qualified health plans or to become qualified health plans and contract with health care purchasing groups, the "power buyers" under managed competition. Health plans also must integrate horizontally to include enough providers to meet patient needs.

Other factors facilitating integration include Medicare reimbursement reforms giving hospitals and physicians financial incentives to manage the continuum of care, the need for reductions in the administrative costs of managing care, and the need for capital transfers between acute care and primary care organizations to meet community needs. Finally, as will be discussed later, the anti-kickback, self-referral, tax-exemption, and antitrust laws have to some extent encouraged integration, especially among physicians.

The movement toward an integrated industry includes affiliations among physicians, alliances between physicians and

12. Id. at 210.
15. Gerald R. Peters, Organizational and Business Issues Affecting Integrated Delivery Systems, Topics in Health Care Financing, Spring 1994, at 1, 2-3. Health care delivery is shifting from the inpatient to the outpatient setting. As a result, capital will be needed for new facility construction, information system development, and physician recruitment and retention. Id.
16. See generally James G. Wichl, "Physician Integration": The Legal Pressures for Consolidation of Health Care Services, 34 St. Louis U. L.J. 917 (1990) (discussing the pressures that anti-kickback, self-referral, and antitrust laws place on physicians to integrate with one another).
17. Id. at 919-22 (discussing the market pressures for physician integration). See also Alain Enthoven & Richard Kronick, A Consumer-Choice Health Plan for the 1990s:
hospitals, and combinations of health care financing and delivery. Various legal models have evolved based on the dominant central organization and the degree of provider integration. Within an integrated delivery system, one central organization typically manages the entire system. For example, different models include systems controlled by hospitals or physicians, HMO models, and the equity model owned by shareholders. Considerable conflict for control has ensued as hospitals, physicians, HMOs, and insurers vie for network leadership. The degree of integration differentiates the transitional or "entry models" of integration such as management service organizations, group practices without walls, and physician-hospital organizations (PHOs) from the fully integrated.

Universal Health Insurance in a System Designed to Promote Quality and Economy (pt. 2), 320 NEW ENG. J. MED. 94, 96 (1989) (noting that physician affiliations include IPAs and group practices).

18. Sally Berger & Susan K. Sudman, M.D.-Hospital Integration: Staying on Course, HEALTHCARE EXECUTIVE, May-Jun. 1994, at 9 (stating that 27% of hospitals have created physician-hospital organizational arrangements, and 97% expect to create such an arrangement within two years).

19. COILE, supra note 2, at 137-38; Enthoven & Kronick, supra note 17, at 95-96. National networks of HMOs also are being formed to decrease administrative costs and meet the needs of national employers. See Julie Johnsson, National HMO Networks Court Big Employers, HOSPS., Sept. 5, 1990, at 80.


22. HMOs encompass four basic organizational models depending on the relationship with physicians: the group-model, staff-model, network-model, and IPAs. INTRODUCTION TO ALTERNATIVE DELIVERY MECHANISMS: HMOs, PPOs, & CMPs 6-7, (Jeanie M. Johnson ed., 1986); Babel, supra note 7, at 96. Physicians are directly employed by staff model HMOs and typically receive a fixed salary and performance bonus. Group-model HMOs contract with a large multi-specialty practice on a fixed fee basis. Physician services are typically offered under a "closed panel" or exclusive basis in both staff- and group-model HMOs. In contrast, the network-model and IPA models are typically "open panel" and contract with a network of existing group practices ("the network model") or a physician association (the "IPA model"). Id.

Kaiser-Permanente, a closed-panel plan, also operates its own network of clinics and hospitals. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 322 (1982).


24. For a discussion of PHO organizational forms, see generally Peter M. Friend & Spence Meighan, Driving Forces Behind Integration: Weigh Your Options, HEALTHCARE
structures that include physicians, hospitals, and insurance products within one organization. These models often overlap, and hybrid models are common. Whatever integration model providers choose, the movement toward integration involves numerous transactions and arrangements that have important legal consequences. As the next section explains, the federal anti-kickback and self-referral, tax exemption, and antitrust laws place significant restrictions on integrated delivery system development.

II. FEDERAL RESTRICTIONS ON THE TRANSITION TOWARD INTEGRATION

As integrated delivery systems accept increased responsibilities for coordinating care among providers and assume accountability for financial results through integrated delivery and financing or risk-sharing arrangements, the economic incentives of fee-for-service health care are eroding. Federal laws regulating provider behavior historically have been designed to address the problems that arise in a fragmented industry. With the development of managed competition,
these same laws contradict the economic theories and foundations of recent health reform efforts. As a result, there are inherent barriers that anti-kickback, self-referral, tax exemption, and antitrust laws place before providers in the transition toward an integrated industry.

A. Anti-kickback and Self-referral Laws

The Medicare-Medicaid anti-kickback law prohibits the knowing and willful remuneration for Medicare and Medicaid patient referrals. The self-referral law prohibits physician financial interests in facilities that may profit from a Medicare or Medicaid referral for designated health services. Both laws were designed to safeguard the Medicare program assets from provider conflicts of interests that may result in unnecessary services. According to the former Department of Health and Human Services (HHS) Inspector General, the purpose of the anti-kickback statute was to prevent overutilization, contain Medicare and Medicaid costs, preserve patient choice among providers, and diminish the market distortion of referral fees. Similarly, the concerns that entities may lock-in physician re-

L.J., Jan. 24, 1994, at 26, 26 (arguing that antitrust, fraud and abuse, and self-referral laws run counter to virtually all of the reform proposals considered by Congress).


30. Self-referral Statute, 42 U.S.C. § 1395nn (Supp. V 1993) (prohibiting physician referrals of Medicare and Medicaid patients to entities furnishing designated health services with which the physician has a financial interest, including ownership or investment interests or compensation arrangements). See also Wiehl, supra note 16, at 933-35 (discussing the legislative history of the self-referral statute). Designated health services include clinical lab services, physical and occupational therapy, home health, radiation therapy, radiology services, durable medical equipment, parenteral and enteral nutrition, prosthetics and orthotics, outpatient prescription drugs, and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6) (Supp. V 1993).


32. Kusserow, supra note 29, at 52-53.
In integrated delivery systems, patients may not be referred to convenient facilities, unnecessary services may be ordered, and honest competition may be undercut were the impetus for physician self-referral proscriptions. Anti-kickback violators are subject to criminal sanctions and civil sanctions including Medicare program exclusion and monetary fines. Self-referral penalties include payment denial, program exclusion, and civil monetary penalties.

The HHS Office of Inspector General (OIG) has statutory authority for anti-kickback civil sanction enforcement and is mandated to promulgate “safe harbor” regulations regarding permissive practices not subject to criminal prosecution or exclusion. Although HHS has promulgated limited safe harbor exceptions, a proposed general rule would create a distinction between the substance and the form of health care transactions and prevent “sham transactions” from obtaining shelter under the safe harbors. Some argue that the proposed rule undercuts the statutory intent to delineate safe business practices and


35. 42 U.S.C. § 1395nn(g) (Supp. V 1993). Circumvention schemes by physicians or other entities also may be penalized with civil fines of $100,000. Id. § 1395nn(g)(4).


37. See 59 Fed. Reg. 37,202, 37,203, 37,208 (1994) (to be codified at 42 C.F.R. pt. 1001.545) (proposed July 21, 1994). The proposed rule states “[a]ny transaction or other device entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the transaction or device is not accurately reflected by the form will
“effectively guts” the existing safe harbors.\textsuperscript{38} HHS also enforces the self-referral statute, but there is no authority for safe harbors. Instead, statutory exceptions for self-referrals include referrals from among employees, prepaid plans, group practices, and rural providers, and personal service arrangements, physician recruitment, and hospitals owned by physicians.\textsuperscript{39}

The primary obstacle of the anti-kickback statute placed before providers who are interested in developing integrated delivery systems is the lack of clarity regarding lawful transactions. Courts have interpreted the statute broadly, casting a wide net for lawful health care transactions despite the egregious facts of the transactions found to be illegal.\textsuperscript{40} The safe harbors promulgated thus far have been too narrow.\textsuperscript{41} Public comments on the recently proposed “sham transaction” rule have been uniformly critical of the OIG’s inability to provide coherent, objective criteria for beneficial transactions.\textsuperscript{42} The OIG also has been criticized for its tendency to condemn broadly physician and hospital transactions without either re-


\textsuperscript{40} C. Kelly McCourt, Legislative & Regulatory Analysis: Recent Developments in Interpretations of Medicare's Illegal Remuneration Prohibitions, 4 MED. STAFF COUNSELOR 65, 67 (1990). For cases that broadly interpret the anti-kickback statute, see generally United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20 (1st Cir. 1989) (upholding the convictions of a hospital employee and the president of an ambulance company for receiving and providing automobiles and other compensation in return for recommending a hospital contract for ambulance company services); United States v. Kats, 871 F.2d 105 (9th Cir. 1989) (upholding the conviction of a physician for receiving a 50% kickback for referral of blood and urine samples to a laboratory); United States v. Greber, 760 F.2d 68 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985) (upholding the conviction of a cardiologist who paid interpretation fees to physicians referring patients for Holter monitoring because one purpose of the fees was to induce referrals); Inspector General v. The Hanlester Network, 1991 Medicare & Medicaid Guide (CCH) ¶ 39,566 (HHS Departmental Appeals Bd., Appellate Div., Sept. 18, 1991).

\textsuperscript{41} See King, supra note 31, at 670-71; Medicare, Medicaid Safe Harbor Rules Too Narrow, Restrictive, Comments Say, 1 Health Care Policy Rep. (BNA) No. 40, at 1691 (Dec. 6, 1993).

\textsuperscript{42} See Proposed ‘Sham Transaction’ Section Riles Commentators on Safe Harbors, supra note 38. See also supra notes 37-38 and surrounding text.
ferring to relevant facts or availing itself of the opportunity to understand integrated delivery systems better.48

Many business transactions considered customary in the commercial world are prohibited, resulting in a minefield for the health lawyer,44 traps for the unwary, and extensive transaction costs46 for providers undertaking integrated delivery system development. Clarity is also needed for integrated delivery system development to proceed because murky statutes protect the most devious of players.46

A principal reason that the anti-kickback and self-referral laws have been roundly criticized is that their basic assumptions and rationale grew out of concerns regarding the fee-for-service system that become less relevant in a managed competition environment.47 The anti-kickback statute was merely a means to the end of curbing the potential abuses of fee-for-service incentives and "was never intended to affect the structure of health care delivery in isolation from these goals."48


Similarly, courts do not consider defenses, such as cost-effectiveness, that may justify referral arrangements. King, supra note 31, at 669-70. As a result, anti-kickback and self-referral laws "unduly complicate" integrated delivery systems development. Schermer & Owens, supra note 28, at 26.

44. See Francis J. Hearn, Jr., Comment, Curing the Health Care Industry: Government Response to Medicare Fraud and Abuse, 5 J. CONTEMP. HEALTH L. & POL'Y 175, 176-77 (1989). The legal ambiguities have led to ethical issues for lawyers who must choose between advising clients to forego cost-effective transactions that improve health care delivery or to enter into illegal arrangements where the risk of prosecution is slight. Id.


47. See, e.g., Schermer & Owens, supra note 28, at 26 (arguing that anti-kickback and self-referral laws fail to recognize adequately the nature of managed care and provider economic risk sharing).

Commentators have requested that HHS promulgate additional safe harbors for managed care plans, and HHS has attempted to respond to these concerns with the development of the managed care organization safe harbors. However, none of the safe harbor regulations deal with integrated delivery systems that provide managed care, and HHS does not intend to update any of its pronouncements regarding illegal activities to account for integrated delivery systems development.

The managed care safe harbors afford little protection to providers and are incongruent with health reform efforts to promote networking among providers. Additional safe harbors have not been forthcoming, and as a result, commentators have recommended supplemental safe harbors where structural protections are present to protect against overutilization. The OIG has suggested that President Clinton's health reform task force was well aware of the problems surrounding integrated delivery system development, but the OIG does not have any


51. HHS Reiterates Conservative Approach in Response to AHA's Guidance Request, 5 Medicare Rep. (BNA) No. 11, at 276 (Mar. 8, 1994) [hereinafter HHS Reiterates]. The Chief Counsel for the OIG has stated that further updates are not necessary because the safe harbors, fraud alerts, and speeches by HHS staff provide more advice on the anti-kickback statute “than any other part of the U.S. Code.” Id.


53. See John J. Farley, Note, The Medicare Antifraud Statute & Safe Harbor Regulations: Suggestions for Change, 81 GEO. L.J. 167, 191 (1992) (recommending that HHS craft safe harbors for organizational arrangements that have sufficient external controls that “control costs, encourage efficiency and protect against overutilization”); Hyman & Williamson, supra note 48, at 1185-95 (recommending “generic” safe harbors for reasonable and legitimate health care transactions that do not harm the Medicare program or beneficiaries); King, supra note 31, at 671 (recommending Congress set guidelines and delegate enforcement authority to state government). The OIG prefers bright line rules due to the lack of objective guidance in generic safe harbors. Kusserow, supra note 29, at 52-53.
solutions to offer other than its lack of concern for enforcing the law on capitated systems or where prices for hospital and physician services are bundled.\textsuperscript{54} Presumably, the lack of OIG concern is due to the complication of proving a "knowing and willful" violation when the payment incentive structure alleviates the inducement for referrals. Certainly, supplemental protections would facilitate integrated delivery systems development.

The self-referral statute excepts referrals from physicians to hospitals that they own.\textsuperscript{55} A similar concept has been recommended for safe harbor protection under anti-kickback law.\textsuperscript{56} The rationale for this exception is that physician owners are subject to the financial incentives of hospital prospective payment\textsuperscript{57} and to hospital quality assurance and utilization review.\textsuperscript{58} As a result, the risk of overutilization is minimized.\textsuperscript{59} The same argument may be made for physician investment in integrated delivery systems. Since an integrated delivery system assumes fiscal and legal responsibility for the entire spectrum of care, the risk of overutilization by physician investors is minimized.

Two exceptions in the anti-kickback safe harbors and the self-referral statute may encourage physician integration. The group practice exceptions\textsuperscript{60} allow referrals among physicians in the same group. The employee exceptions\textsuperscript{61} allow physician

\textsuperscript{54} D. McCarty Thornton, Self-Referrals: A Recent History, Address Before the National Health Lawyers Association (Sept. 27, 1993), in HEALTHCARE FRAUD AND ABUSE: ENFORCEMENT IN THE 1990s, 1993, at 10-11 (abstract available from National Health Lawyers Association). Neither capitation nor bundling of hospital and physician fees reward providers for referrals of covered services. For definitions of these terms, see supra note 27.


\textsuperscript{56} See Farley, supra note 53, at 191.


\textsuperscript{58} Peer Review Organizations, or PROs, monitor the quality and utilization of services provided to Medicare patients in hospitals, HMOs, skilled nursing facilities, ambulatory surgery settings, and home health care agencies. 42 U.S.C. § 1320c-3, c-13 (1988). If the PRO determines that the service was not medically necessary, Medicare may deny payment.

\textsuperscript{59} A Florida Health Care Cost Containment Board study seems to support this supposition. Farley, supra note 53, at 190.


compensation arrangements where a bona fide employment relationship exists between the referring physician and the physician receiving the referral under the theory that employer liability for employee acts will provide sufficient protections against abuse. Group practice and employment exceptions have led to practice consolidation among physicians and employment of physicians by hospitals and HMOs.

Vertical integration of physicians with hospitals does not receive the same level of protection. Hospital integration arrangements typically include physician practice acquisition and subsequent physician employment, especially for the primary care physician component that is essential to success under managed competition. An anti-kickback safe harbor covers sales of practices to physicians but not sales to hospitals. In a letter to the IRS, the Chief Counsel to the Inspector General, D. McCarty Thornton, identified factors related to hospital acquisition of group practices and physician employment believed to be disguised inducement. In a footnote, Thornton commented that the employee safe harbor protected only the compensation received for covered services. While Thornton has criticized providers for overreacting to the letter, he also has acknowledged that the HHS arguments for limits on the employment exception are less than clear.

Given the present industry turbulence, the untimeliness of the regulatory process presents additional problems for providers. The rulemaking process is sluggish, despite congressional determinations that HHS promulgate timely anti-kickback safe harbors and self-referral implementation regulations.
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does not have the authority for an advisory opinion mechanism to allow providers to obtain prospective agency determinations on proposed transactions.\(^6\) While the OIG planned to issue interpretive rules explaining conflicts between safe harbors and providing general guidance,\(^7\) no such guidance has been presented, and providers must rely on the current regulatory scheme and publicly known agency prosecutorial priorities.\(^8\)

As a result, providers need a process for prospective determination of compliance with anti-kickback laws similar to the advisory opinion process provided by the IRS and the Federal Trade Commission (FTC).\(^9\)

During the 1980s, provider attempts to rationalize the chaotic and disorganized health care system with joint venture, service, and lease agreements were ineffective in solving delivery problems.\(^10\) Further, provider joint ventures with a legitimate purpose of promoting health or improving the delivery system, such as many integrated delivery systems, are arguably different from technology that tends toward overutilization such as MRI, CT, and physical therapy. As a result, providers are seeking more effective delivery structures.\(^11\)

\(^6\) Despite receiving comments that an advisory opinion mechanism would provide guidance to the industry, decrease illegal practices, and inform HHS of current industry trends, HHS concluded that such a mechanism would interfere with the Justice Department’s exclusive enforcement authority over criminal prosecutions and would be impossible to implement since a prospective determination of the motive for business transactions is impractical. 56 Fed. Reg. 35,952, 35,959 (1991) (commenting on regulations codified at 42 C.F.R. pt. 1001). Instead, HHS suggested that periodic updates of the safe harbors and OIG fraud alerts highlighting illegal conduct would be sufficient to ensure that the regulations “remain practical and relevant in the face of changes in health care delivery and payment arrangements.” Id.

\(^7\) Kusserow, supra note 29, at 63.

\(^8\) The factors used by the OIG in enforcement decisions include the amount of remuneration involved, regional workload demands, and the evidence available to establish a violation, including cooperative witnesses. HHS Reiterates, supra note 51, at 11. For a general discussion of the OIG enforcement process and priorities, see Kusserow, supra note 29, at 67-70.

\(^9\) See Tedrick, supra note 31, at 559. See also discussion infra notes 87, 154-56 (regarding IRS, FTC, and Justice Department prospective reviews).

\(^10\) See Peters, supra note 3, at 21-22.

\(^11\) Id.
B. Federal Tax Exemption

Section 501(a) of the Internal Revenue Code exempts charitable nonprofit organizations from federal income tax.\(^7\) To be eligible for exemption, section 501(c) of the Code requires that an organization organize and operate exclusively for an exempt purpose, including religious, charitable, scientific, literary, or educational purposes, subject to constraints on the distribution of profits and limits on political activities.\(^6\) The Internal Revenue Service enforces tax laws, and the primary penalty for noncompliance is loss of tax exemption. The IRS recently entered into a closing agreement with a tax-exempt hospital that obligates the hospital to pay more than $1,000,000 in penalties representing the hospital’s federal income tax liability had it been taxable.\(^7\)

Rationales for tax exemption are much disputed, yet none of the theoretical frameworks provide a comprehensive rationale.\(^8\) One of the oldest and most conventional theories, the subsidy-based theory, views tax exemption as a quid pro quo for the relief of governmental burdens.\(^7\) Hansmann’s capital

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76. I.R.C. § 501(c)(3) (1988). Exempt organizations must satisfy a two-part test to meet the exclusivity requirement of § 501(c)(3). Treas. Reg. § 1.501(c)(3)-1(a)(1) (as amended in 1990). The organizational test requires the charter to be limited to one or more exempt purposes and not empower the organization to engage, otherwise than as an insubstantial part of its activities, in activities not in furtherance of an exempt purpose and requires the assets to be dedicated to exempt purposes. Treas. Reg. § 1.501(c)(3)-1(b) (as amended in 1990). The operational test requires that the organization primarily engage in activities directed toward accomplishment of its exempt purpose. If more than an insubstantial part of its activities is not in furtherance of its exempt purpose or if the net earnings of the organization inure to private individuals, the organization will fail the operational test. Treas. Reg. § 1.501(c)(3)-1(c)(1) (as amended in 1990).

77. See Closing Agreement Raises Questions About Wider Application of Restrictions, 3 Health L. Rep. (BNA) No. 42, at 1531 (Oct. 27, 1994). Tax liability may be considerable for nonprofit hospitals that lose their exemption given that the value of federal tax exemption, including income tax, tax-exempt bonds, and deductible donor contributions, is estimated at 4.1% of net revenues. See Bradford Gray, Why Nonprofits? Hospitals and the Future of American Health Care, 6 EXEMPT ORG. TAX REV. 729, 731 (1992). Exemptions from state and local governments also have become the subject of increased scrutiny and account for an additional 3.7% of net revenues. Id.

78. Gray, supra note 77, at 734 (arguing that one reason any principled rationale for tax exemption is "up for grabs" is that tax policy accumulates separate policy decisions made by disparate political bodies over time); Developments in the Law—Nonprofit Corporations, Tax Exemption, 105 HARV. L. REV. 1579, 1612-14 (1992).

79. Gray, supra note 77, at 734. See also Bob Jones Univ. v. United States, 461 U.S. 574, 591 (1983) (relying upon a subsidy theory to uphold the IRS revocation of ex-
compensation theory is based on the economic rationale that prohibitions on profit distributions will protect nonprofit organization consumers against contract failure where, as with health care, they may be vulnerable and have difficulty evaluating the quality of complex personal services they receive. In his view, tax exemption compensates nonprofit organizations for the non-distribution constraint and resulting lack of access to equity markets. Atkinson's altruism theory argues that donors may want to subsidize the "metabenefit" of diversity and pluralism in the provision of goods and services by providers who forego profits. The donative theory of tax exemption argued by Hall and Colombo states that exemptions should be limited to charitable organizations able to demonstrate sufficient community support through philanthropic contributions. A much broader view taken from the law of charitable trusts broadly defines charity as a gift "for the benefit of an indefinite number of persons ... by relieving their bodies from disease, suffering or constraints" and supports the idea that the provision of health care is charitable per se. A modern twist on the per se theory is Gray's argument that health care is unique, and tax exemption simply represents a political preference for the nonprofit

empt status from a racially discriminatory private school); Utah County v. Intermountain Health Care, Inc., 709 P.2d 265, 267 (Utah 1985) (relying upon a subsidy theory to revoke the state property tax exemption of two hospitals).

The corollary to the subsidy theory, the tax expenditure doctrine, holds that the government may bestow or withhold privileges in exchange for any condition. Gray, supra note 77, at 730. Problems with the subsidy theory are that it does not explain why more direct, efficient subsidies should not be granted nor why for-profit organizations should not be exempted. Id. at 734. Moreover, the subsidy rationale results in substantive policy decision-making by ill-equipped tax committees and the IRS. Developments in the Law, supra note 78, at 1621.


Finally, both Marmor and Seay have described a utilitarian role of tax exemption in encouraging development of certain types of institutions.\textsuperscript{86}

The tax-exemption enforcement process is much more flexible and adaptive than anti-kickback and self-referral enforcement. One advantage that the IRS has over HHS in providing clarity to providers is that, besides regulations, the IRS publishes revenue rulings, revenue procedures, private letter rulings, and General Counsel Memorandums (GCMs).\textsuperscript{87} These documents are publicly available and give guidance to providers considering similar transactions.\textsuperscript{88} The IRS recently published an article on integrated delivery system tax-exemption requirements that provides unparalleled guidance on current agency positions.\textsuperscript{89}

Further, the IRS recognizes the importance of identifying and addressing the evolving organizational structures in health care. The IRS is considering a centralized determination process and increased use of revenue rulings to address these issues promptly at a national level.\textsuperscript{90}

To improve tax law enforcement,
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the Treasury Department also has proposed a reexamination of sanctions and the development of statutory alternatives to loss of tax exemption. The Treasury Department also has proposed a reexamination of sanctions and the development of statutory alternatives to loss of tax exemption. Intermediate sanctions, including taxation or monetary penalties, will reduce the risk of loss of tax exemption while ensuring that unlawful activity is penalized.

Although the IRS has been somewhat supportive of integrated delivery system development, it also is challenged by the abundance of new delivery and financing models. Industry criticism has revolved around the lengthy and extensive preparation needed to comply with what are being interpreted as de facto standards, the application of hospital-oriented standards to the newer models of delivery, and the restraints on physician roles that may alienate physicians in the operation of integrated delivery systems. More generally, several commentators have questioned the suitability of the IRS in establishing health policy and enforcing health care laws.

The initial IRS determination letters relating to integrated delivery systems focused on foundation-model integrated delivery systems. The IRS analyzed the factors traditionally used

92. Peters, Practical Examination, supra note 43, at 765 (stating that deviations are probably fruitless and may lead to exemption revocation).
94. Peters, Practical Examination, supra note 43, at 765-66. The integrated delivery system determination letters also have been criticized because the models approved by the IRS reduce the equity incentive for physician efficiency and decrease physician autonomy. See Harris Meyer, Foundation Model for Medical Groups Passes IRS Test, AM. MED. NEWS, Mar. 15, 1993, at 3, 11 (noting that the Friendly Hills physicians lost considerable autonomy and disgruntled physicians are investigating alternate practice arrangements).
96. See Kenneth L. Levine, IRS Enforcement of Health Care Laws, 6 EXEMPT ORG. TAX REV. 921, 928 (1992) (arguing that the IRS need not condition tax exemption on compliance with anti-kickback laws). See also infra note 293.
97. See Harriman Jones Medical Foundation, reprinted in 9 EXEMPT ORG. TAX REV. 719 (1994) (foundation model sponsored by regional health care system to acquire
to evaluate hospital exemptions and applied the hospital "community benefit" standard.\textsuperscript{98} The hospital factors the IRS applied to integrated delivery systems focused on limits to physician participation on the integrated system board, the provision of charity and emergency care, participation in Medicare and Medicaid, reasonable compensation to the physician group, medical education and research, open medical staff requirements, and the purchase of medical group assets at a fair market value.\textsuperscript{99}

The controversy in integrated delivery system tax policy surrounding the role of physicians in the integrated system revolves around private benefit and private inurement concerns. Exempt organizations must be operated for a public rather than a private purpose and not serve private interests.\textsuperscript{100}

\begin{itemize}
\item Facey Medical Foundation, reprinted in 7 EXEMPT ORG. TAX REV. 828 (1993) (foundation model sponsored by a regional health care system to acquire medical groups);
\item Friendly Hills Healthcare Network, reprinted in 7 EXEMPT ORG. TAX REV. 490 (1993) (foundation model sponsored by academic medical center) [hereinafter integrated delivery system determination letters].
\end{itemize}

The foundation model is a creative attempt by hospitals to circumvent state corporate practice of medicine statutes by establishing a nonprofit corporation that purchases the assets of formerly taxable medical practices and then contracts with the medical group to provide professional services to managed care populations. Robert S. Bromberg, The Foundation Model, 8 EXEMPT ORG. TAX REV. 335, 335-36 (1993).

\textsuperscript{98} See Colombo, supra note 93, at 240. The IRS has developed the community benefit standard through revenue rulings over the last several decades. The original test required indigent care to the extent of the hospital's financial ability. Rev. Rul. 56-185, 1956-1 C.B. 202. Rev. Rul. 69-545 relaxed this requirement and allowed an alternate community benefit test based on facts and circumstances. Community benefit factors included a full-time emergency room available without regard to ability to pay, Medicare and Medicaid participation, a community board, an open medical staff, and the return of profits to the hospital facility. Rev. Rul. 69-545, 1969-2 C.B. 117. In 1983, the IRS determined that emergency facilities were not required if community needs were already met or in specialty hospitals, such as cancer or eye hospitals, that are unlikely to provide emergency care. Rev. Rul. 83-157, 1983-2 C.B. 94.

\textsuperscript{99} For in-depth criticisms concerning the appropriateness of applying each of these factors to integrated delivery systems, see Bromberg, supra note 97, at 347-42; Peter N. Grant, IRS Approves Exemption for Medical Group Practices in Integrated Delivery System, 5 J. TAX'N EXEMPT ORG. 3, 5-6 (1993).

\textsuperscript{100} Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii) (as amended in 1990) (stating that the organization must demonstrate that it is not "organized and operated for the benefit of private interests"). Public benefit is based on common law principles that a charitable organization benefit a class adequately charitable. Treas. Reg. § 1.501(c)(3)-1(d)(2) (as amended in 1990). Traditionally charitable classes such as the poor and underprivileged are enumerated in the regulations. Id. Alternatively, common law notions of charity may encompass benefits to a broad, indefinite public. See Sound Health Ass'n v. Commissioner, 71 T.C. 158, 178 (1978), acq., 1981-2 C.B. 1. Private benefits must be incidental to public benefits and pass a two-part test to be incidental. Gen. Couns. Mem. 39,598 (Dec. 8, 1986). A private benefit is qualitatively incidental if the public benefit can be conferred
vate inurement is a subset of private benefit and is prohibited by the statute and the regulations. The private inurement prohibition is analogous to the nondistribution constraint and applies to "insiders" who exploit their position by influencing or controlling the distribution of net earnings. Physician representation in integrated delivery system governance has invoked private benefit concerns while physician compensation has invoked private inurement concerns.

The IRS limits physician membership to 20% of the governing board of an integrated delivery systems. The rationale only by conferring a private benefit, and a private benefit is quantitatively incidental if the public benefit outweighs an insubstantial private benefit. 

101. See Gen. Couns. Mem. 39,862 (Nov. 22, 1991). Exempt organizations are those entities "no part of the net earnings of which inures to the benefit of any private shareholder or individual." I.R.C. § 501(c)(3) (1988). If the net earnings of the organization inure to private individuals, the organization will fail the operational test. Treas. Reg. § 1.501(c)(3)-1(c)(I) (as amended in 1990). See also IRS 1994 TEXTBOOK, supra note 20, at 231 (discussing the IRS view on the differences between private inurement and private benefit).

102. BRUCE R. HOPKINS, THE LAW OF TAX-EXEMPT ORGANIZATIONS § 12.2 (5th ed. 1987) (stating that insiders include founders, directors and officers, and contributors). While net earnings are not simply limited to dividend distributions, Harding Hosp. v. United States, 505 F.2d 1068, 1072 (6th Cir. 1974), a reasonable compensation exception allows payments to insiders if the entire amount is reasonable in relation to the services provided, Gen. Couns. Mem. 39,498 (Apr. 24, 1986), comparable in cost to services negotiated at arms length from an outsider, and not merely a disguised profit distribution. See University of Mass. Medical Sch. Group Practice v. Commissioner, 74 T.C. 1299 (1980), acq., 1980-2 C.B. 2 (reversing an IRS denial of tax exemption to a faculty practice plan because the compensation was reasonable and subject to great public scrutiny and outside control); B.H.W. Anesthesia Found. v. Commissioner, 72 T.C. 681 (1979), nonacq., 1980-2 C.B. 2 (finding salaries of the Harvard Medical School anesthesiology group reasonable considering the nature of the work and the required skills). However, [w]here a doctor or group of doctors dominate the affairs of a corporate hospital otherwise exempt from tax, the courts have closely scrutinized the underlying relationship to insure that the arrangements permit a conclusion that the corporate hospital is organized and operated exclusively for charitable purposes without any private inurement. Lowery Hosp. Ass'n v. Commissioner, 66 T.C. 850, 859 (1976) (finding private inurement where the founding physicians so controlled the hospital that there was no line of demarcation between their private medical practice and the hospital). In Lowery, the defendant physicians had argued that a symbiotic relationship between the clinic practice and the hospital created mutual benefits. The court did not hold that a such a union would not be exempt, but held that "when it is predicated on the comprehensive integration of the two organisms, [the exempt organization] must offer convincing proof that the benefits were not unevenly distributed in favor of the private parties involved." Id. at 860 n.11.

Courts also have found private inurement where founding physicians exerted a virtual monopoly over hospital patients allowing private benefits to inure. Harding Hospital, 505 F.2d at 1078.

103. See IRS 1994 TEXTBOOK, supra note 20, at 227-32.

104. See id. at 227. According to the IRS, the key issue in the determination letters was the balancing of private benefit to physician members against the public benefit of
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for this position is that the agreements with physicians to provide professional services for the patients of the integrated system and the physicians' prior ownership of practice assets create a strong presumption of private benefit. However, this presumption has been subject to trenchant criticism for its lack of a statutory basis, its unenforceability, and its lack of appreciation for current realities.

In analyzing private inurement, the IRS presumes that physicians are insiders, but this interpretation also has been severely criticized. Nonetheless, the IRS assumes that any physician in the medical group providing professional services to an integrated delivery system is presumptively an insider. The IRS will examine the potential for inurement, but the insider presumption may be overcome if each physician does not have a "chance to employ inside influence." The IRS presumption effectively limits physician representation on an integrated system's compensation and fee committees to avoid potential inurement risks. The problem with imposing such limitations is that they prevent the "possibility of inurement" rather than the statutory prohibition of actual inurement, and appropriate safeguards can be developed to allow physician participation without creating an inurement problem.


105. IRS 1994 TEXTBOOK, supra note 20, at 227.

106. See Colombo, supra note 93, at 241-42; Grant, supra note 99, at 5; Peters, Practical Examination, supra note 43, at 765. Peters argues that the IRS criteria for determining integrated delivery system tax exemption are likely to be challenged because courts are not likely to uphold the application of criteria that was established for tax-exempt financing, not tax exemption in general. Id. The limits also conflict with integrated delivery objectives of improving health delivery through physician partnerships. Id. Further, the limits attack the possibility of inurement, while the statute prohibits actual inurement. Id.


108. See Colombo, supra note 93, at 241 (noting that the IRS position on physician control is based on its "historic paranoia about exempting entities that could benefit doctors"); Theodore T. Myre, Jr., Significant Tax Issues in Hospital Related Joint Ventures, 75 Ky. L.J. 559, 577-79 (1986).


110. Id.

111. See Peters, Practical Examination, supra note 43, at 767.

112. Id. (recommending that integrated delivery system boards use physicians only in an advisory capacity and use outside expertise to validate the physician compensation plan). See also infra note 183.
Like the anti-kickback law, tax law has been interpreted around the fundamental assumptions of a vanishing fee-for-service industry. In Lorain Avenue Clinic v. Commissioner, the court found private inurement and private benefit in the physician control over hospital policies because the physician compensation plan allowed competing physicians to set their own fees individually and was akin to the practice of medicine in a fee-for-service system. Unlike fee-for-service, physician compensation in an integrated delivery system is based on incentives for cost-effective delivery. Integrated systems need physician expertise to design appropriate cost-effective arrangements, but the integrated delivery system board should set individual physician compensation.

The IRS bases its presumption of physician control over health care institutions on assumptions of professional dominance in hospitals that are outmoded. Economic regulation of hospitals, hospital legal liability for quality care, and the ascent of professional hospital administrators have shifted the model of hospital decision making away from a "physicians' cooperative" toward a model of shared authority among hospital constituents. As a result, no single profession predominates the modern hospital, and widespread group participation is necessary for effective decision making. Further, due to the declining number of hospitals, the increasing number of physicians, and the constraints that managed care places on access to patients, physicians are becoming bound to particular hospitals.

The IRS emphasis on minor private benefit is overstated when balanced against the public benefit of integrated delivery systems and the role of these systems in the modern managed

117. Comm. on Implications of For-Profit Enterprise in Health Care, Inst. of Medicine, For-Profit Enterprise in Health Care 174 (Bradford H. Gray ed., 1986) (discussing the changing nature of physician influence in hospitals).
Resourceful hospitals with large capital reserves, refined marketing strategies, and sophisticated lawyers may take advantage of the fears that isolated physicians have of market exclusion and health reform uncertainties. Some hospitals also use the ambiguity surrounding private incurrence and private benefit to extract lower prices from physicians selling their practices. Instead, integrated delivery systems should be partnerships between hospitals and physicians to provide resources and expertise that improve delivery systems. Otherwise, fragmentation of service delivery will continue.

Finally, tax policy must be flexible toward evolving nonprofit forms or consumers will be left with only for-profit delivery choices. For-profit entities do not have the same restrictions on physician involvement in integrated delivery system development. In competitive managed care markets, many physicians are embracing the acquisition strategies of for-profit companies to obtain new patients, job security, and ownership interests. While both investor-owned acquisitions and nonprofit hospital acquisitions are subject to the anti-kickback, self-referral, and antitrust laws, tax exemption is a crucial issue for the nonprofit hospital.

Shared governance and decision making are appropriate under the risk-sharing realities of integrated delivery systems, and nonprofit entities are unnecessarily restricted from designing mechanisms that allow a reasonable level of physician autonomy and control. The result may be either the conversion to for-profit forms or the creation of nonprofit forms limiting physician participation, producing physician disillu-

118. A similar criticism has been noted in relation to tax policy on hospital and physician joint ventures. See Kurt A. Wagner, Commentary, Federal Income Taxation of Nonprofit Hospital Joint Ventures, 14 J. LEGAL MED. 479, 495-96 (1993).
120. Id.
121. Peters, Practical Examination, supra note 43, at 766.
sionment, and causing physicians to take advantage of the investor-owned appetite for physician practices. Again, federal regulatory efforts to control provider behavior may produce unintended consequences when applied under the new health care paradigm.

C. Federal Antitrust Laws

The primary rationale for federal antitrust laws is to foster and protect competition under the presumption that open markets enhance consumer welfare. This Note focuses primarily on section 1 of the Sherman Act prohibiting contracts, combinations, and conspiracies in restraint of trade. Section 1 governs many of the contracts and combinations that form the basis of integrated delivery systems development.

Congressional intent for section 1 is confusing because "restraint of trade" is ambiguous and the statute does not address whose interests the law is designed to protect. While courts have at times protected various political, social, and economic interests, the prevailing view is that the goal of antitrust law is to maximize consumer welfare as judged by the criteria of economic efficiency.


128. See BORK, supra note 125, at 55-66 (arguing that the statutory language and legislative history of the Sherman Act indicate a single congressional intent to maximize consumer welfare); Frank N. Easterbrook, Workable Antitrust Policy, 84 Mich. L. Rev. 1696, 1698 n.7 (1986) (noting that antitrust jurisprudence emphasizes economic efficiency and consumer welfare).
Antitrust analysis is inherently fact-specific and involves a two-pronged analysis. If the purpose of the agreement is likely to restrict competition or decrease output, courts will apply a per se analysis and will strike such agreements as illegal per se, despite any procompetitive benefits. Relevant exceptions to the per se rule include joint ventures that incorporate risk sharing or agreements to integrate that produce otherwise unobtainable benefits such as the production of a new socially useful product or a decrease in costs.

Courts consider agreements that are not per se illegal under a “rule of reason” analysis. After defining the relevant geographic and product market, courts will evaluate the purpose of the agreement and the anticompetitive effects and procompetitive benefits of the agreement. The anticompetitive effects and the procompetitive benefits are then balanced to determine whether the restraint is reasonable. Finally, the court will evaluate agreements ancillary to the main agreement to detect any illegitimate restrictions on competition.

129. See United States v. Trenton Potteries Co., 273 U.S. 392, 397-98 (1927). A per se analysis is generally used for price fixing, market division, and certain group boycotts and tying arrangements. Northern Pac. Ry., 356 U.S. at 5. See also Craig D. Bachman, Per Se Offenses, in ANTITRUST HEALTH CARE. ENFORCEMENT AND ANALYSIS 3, 3 (M. Elizabeth McGee ed., 1992) [hereinafter ANTITRUST HEALTH CARE].

130. Maricopa, 457 U.S. at 351; Northern Pacific Ry., 356 U.S. at 5; United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 224, n.59 (1940). See also FTC v. Indiana Fed’n of Dentists, 476 U.S. 447, 462-63 (1986) (holding that quality of care was not a defense to anticompetitive conduct under a rule of reason analysis).

131. See Maricopa, 457 U.S. at 356 (applying a per se analysis to a maximum fee schedule agreement among PPO network physicians with inadequate risk sharing).

132. This defense is also known as the “new product doctrine.” Wiehl, supra note 16, at 928. See also NCAA v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85, 101 (1984) (applying a rule of reason analysis to NCAA exclusive network agreements because horizontal restraints were necessary to market college football); Broadcast Music, Inc. v. CBS, 441 U.S. 1, 18-23 (1979) (applying a rule of reason analysis to licensing agreements among competitors which produced a new product). But see Maricopa, 457 U.S. at 351 (finding that a PPO product was not unique).


134. See Professional Eng’rs, 435 U.S. at 692; Chicago Bd. of Trade, 246 U.S. at 238.


136. See id. at 50-51; Robert J. Enders, An Introduction to Special Antitrust Issues in Health Care Provider Joint Ventures, 61 ANTITRUST L.J. 805, 821-24 (1993) (discussing ancillary restraints such as provider exclusion through selective provider participation, provider and payor exclusive participation in a network, and restraints on dealing with nonparticipating providers).
vant exemptions\textsuperscript{137} from federal antitrust law include the business of insurance,\textsuperscript{138} regulatory immunity,\textsuperscript{139} state action,\textsuperscript{140} the Health Care Quality Improvement Act of 1986,\textsuperscript{141} and the political action exemption.\textsuperscript{142}

\textsuperscript{137} For a discussion of exemptions common to the health care industry, see generally Martin J. Thompson & Samuel Hirsch, Exemptions and Immunities, in Antitrust Health Care, supra note 129, at 25.

\textsuperscript{138} McCarran-Ferguson Act, 15 U.S.C. §§ 1012(b), 1013(b) (1988). The act exempts conduct that is part of the "business of insurance" to the extent it is regulated by state law unless boycotts, coercion, or intimidation are involved. Ocean State Physician Health Plan v. Blue Cross, 883 F.2d 1101, 1107 (1st Cir. 1989), cert. denied, 494 U.S. 1027 (1990) (interpreting the McCarran-Ferguson Act). The business of insurance encompasses practices within the insurance industry that effect a transfer of risk and directly involve the insurer and insured policy relationship. \textit{Id.} (interpreting Union Labor Life Ins. v. Pireno, 458 U.S. 119, 129 (1982), to hold that a Blue Cross managed care product was covered under McCarran-Ferguson and exempt from antitrust scrutiny due to the nature of its marketing and pricing conduct). See also Group Life & Health Ins. Co. v. Royal Drug, 440 U.S. 205, 214 (1979), \textit{reh'g denied}, 441 U.S. 917 (1979) (providing a narrow interpretation of "the business of insurance" in a price-fixing agreement between Blue Cross and pharmacies).

\textsuperscript{139} This exemption is also known as "implied repeal" and protects activity that is required to comply with federal directives. See Bloch & Falk, supra note 11, at 220. However, this defense is not favored by courts and requires a "clear repugnancy between the antitrust laws and the regulatory system." National Gerimedical Hosp. & Gerontology Ctr. v. Blue Cross, 452 U.S. 378, 393 (1981) (holding that federal health planning laws did not immunize Blue Cross from antitrust scrutiny). See also Silver v. New York Stock Exch., 373 U.S. 341, 357 (1963), \textit{reh'g denied}, 375 U.S. 870 (1964). Thus, health care reform legislation would not provide an implied exemption unless explicitly recognized by the statute. However, several health reform proposals have called for express antitrust immunities. Robert E. Bloch & Donald M. Falk, \textit{Bids for Sweeping Antitrust Exemptions, Sought by Health Care Providers, Could Prove Poor Medicine for Consumers,} \textit{NAT'L L.J.} Jan. 24, 1994, at 27.

\textsuperscript{140} See Parker v. Brown, 317 U.S. 341, 351 (1943) (immunizing conduct mandated by state law). See also FTC v. Ticor Title Ins. Co., 112 S. Ct. 2169, 2176 (1992) (requiring state action to be active and participatory); California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97, 105 (1980) (requiring that the conduct clearly reflect state policy and be subject to active supervision by the state). See also Bloch & Falk, supra note 11, at 220.

\textsuperscript{141} Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (1988) (providing peer review committees with a qualified immunity from antitrust laws). Peer review activities must be conducted with a reasonable effort to obtain relevant facts, with the reasonable belief that they are warranted by the facts and further quality care, and with adequate procedural due process protections. See \textit{id.} § 11112(a). Immunity does not apply to actions brought by the Justice Department or state attorney generals. \textit{Id.} § 11111.

Antitrust laws are enforced by the Antitrust Division of the Justice Department, the FTC, and private parties. As with anti-kickback law, a violation of the antitrust laws may result in both criminal sanctions and substantial civil penalties. However, criminal liability requires proof of anticompetitive intent.

Since most joint provider activity is evaluated under a rule of reason analysis, the primary concerns with antitrust compliance are the ambiguity of the analysis, the need for detailed justification, and the risk of treble damages. While the Supreme Court has recently decided a significant number of health care antitrust cases, few integrated delivery systems transactions have been challenged. Antitrust has been less of a barrier to integrated delivery systems development than have other federal laws due to agency guidance and reasoned enforcement. In fact, one FTC official asserts "[m]anaged care owes its existence to effective antitrust enforcement" due to an...
agency focus on keeping markets open for the development of alternate plans.¹⁵³

Like the IRS, the Justice Department and the FTC have mechanisms other than regulations that provide prospective guidance to providers. In response to provider requests, the Justice Department will provide a business review letter stating its current enforcement intentions.¹⁵⁴ The FTC provides similar guidance through advisory opinions.¹⁵⁵ Business review letters and advisory opinions are then publicly available for other providers seeking guidance.¹⁵⁶

Additionally, both agencies issue “guidelines” that outline agency positions on antitrust analysis and enforcement. In trying to reduce uncertainty among providers, the Justice Department and the FTC developed policy statements in 1993 that afford safety zone protection in six areas: hospital mergers, joint ventures among hospitals for the provision of high-technology, collective provision of information to payors by physicians, hospital exchanges of price and cost information, provider joint purchasing, and physician-controlled networks.¹⁵⁷ Within a year of developing the policy statements, the antitrust enforcement agencies issued nine additional statements that expand upon the 1993 guidelines and also provide analytical principles used in analyzing multi-provider networks.¹⁵⁸ Except for

¹⁵³. Federal Agencies Set to Stay Course Pending Outcome of Health Care Reform, Health Care Daily (BNA) (May 24, 1993), available in WESTLAW, 5/24/93 HCD (quoting Mark J. Horoschak); David L. Meyer & Charles F. (Rick) Rule, Health Care Collaboration Does Not Require Substantive Antitrust Reform, 29 WAKE FOREST L. REV. 169, 170-71 (1994). See also Reazin, 899 F.2d at 963 (upholding a § 1 antitrust violation by Blue Cross as anticompetitive because it inhibited alternative delivery system development and reduced consumer options).


¹⁵⁸. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N. STATEMENTS OF ENFORCEMENT POLICY AND ANALYTICAL PRINCIPLES RELATING TO HEALTH CARE AND ANTITRUST (Sept. 27, 1994), reprinted in 67 Antitrust & Trade Reg. Rep. (BNA) No. 1682 (Supp. Sept. 29, 1994) [hereinafter 1994 ANTITRUST ENFORCEMENT GUIDELINES]. The 1994 guidelines were issued due to the concern that many procompetitive arrangements were curtailed by
hospital mergers and multi-provider networks, the agencies guarantee the health care provider community expedited business reviews and advisory opinions within ninety days of a completed application.¹⁶⁸

Provider networks generally will be evaluated based upon whether the collaboration is sufficiently integrated to share substantial risk or provide a new product that differs materially from individual activities.¹⁶⁰ Like the anti-kickback laws, the Sherman Act encourages physician integration.¹⁶¹ However, given the Supreme Court finding that the economic integration of the Maricopa PPO was insufficiently unique to afford a new product defense, health care antitrust attorneys still struggle with the lack of clarity in the requisite degree of integration.¹⁶²

The physician-network safety zones begin to address these issues. Safety zone protection is afforded to exclusive ventures if the physicians compose no greater than 20% of a specialty area with active hospital admission privileges in the local market and share "substantial financial risk."¹⁶³ Similar protection is afforded to nonexclusive ventures that compose no greater


¹⁵⁹. 1994 ANTITRUST ENFORCEMENT GUIDELINES, supra note 158, at S-5.

¹⁶⁰. Bloch & Falk, supra note 11, at 213-14. Discounts, capitation, and new products such as utilization review and plan administration may be sufficient, but a fact-specific analysis must be made into the network's purposes and its effect on competition. Id.

¹⁶¹. See Wiehl, supra note 16, at 923, 928. See also discussion supra notes 60-63 and surrounding text. Entities that are a part of a single enterprise are incapable of conspiring because Sherman § 1 prohibits a conspiracy or agreement among independent competitors. See Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 771 (1984) (holding that price fixing between a parent holding company and its subsidiary was not a conspiracy).

¹⁶². See Kevin E. Grady, A Framework for Antitrust Analysis of Health Care Joint Ventures, 61 ANTITRUST L.J. 765, 781-84 (discussing the inconsistencies among Justice Department, FTC, and court opinions) (1993); J. Thomas Rosch & Hajime Tada, The Antitrust Risks of Management Services Organizations, Medical Foundations, and Integrated Delivery Systems, 20 TOPICS IN HEALTH CARE FINANCING 37, 44 (1994) (noting however that the greater the provider integration, the greater the antitrust protection). Further, the degree of market power and foreclosure of competition are other significant questions. Id. at 44 (noting that courts are concerned that overinclusiveness of providers may lead to market power sufficient to reduce competition and foreclose development of alternative arrangements).

¹⁶³. 1994 ANTITRUST ENFORCEMENT GUIDELINES, supra note 158, at S-17. Financial risks are substantial if services are provided on a capitated basis or if the members are provided financial incentives such as a 20% withhold with distribution based upon achievement of cost containment goals. 1993 ANTITRUST ENFORCEMENT GUIDELINES, supra note 157, at 35.
than 30% of the market share and share substantial risk. A rule of reason analysis is afforded to ventures outside the safety zone if physicians share substantial financial risk or offer a new product with substantial efficiencies.

Nonetheless, the antitrust guidelines have been criticized for impeding physician network development in less populated areas, inadequately protecting integrated physician efforts to compete with insurance-sponsored alternatives, immunizing conduct not subject to challenge, and attempting to preempt legislative exemptions for the health care industry. While FTC Commissioner Owen dissented from the 1993 hospital merger guidelines as a departure from past practice and inequitable treatment for one industry, a former Justice Department official responsible for health care enforcement has stated that the current turbulent environment warrants special treatment of health care providers.

The statement on multi-provider networks applies to horizontal and to vertical networks such as PHOs. It sets forth only the analytical principles the agencies will use since the agencies have not yet obtained sufficient experience evaluating multi-provider networks to formalize the analysis. Many industry groups reacted favorably to the 1994 guidelines despite con-
cerns that additional guidance may become necessary. The lack of formal advice for multi-provider networks should concern PHO developers because the FTC Chairman has noted that these networks are more likely to raise agency concerns. However, the Justice Department should be applauded for its continuing attempts to solicit comments from providers undertaking innovative transactions and for keeping current with developing delivery models.

Thus, each of these areas of federal law presents both statutory and regulatory obstacles to health care industry integration efforts. The current regulatory framework is based on fundamental assumptions of a fee-for-service industry that separated financing from delivery and provided incentives to increase utilization of health care services. While federal agencies have undertaken incremental efforts to update the regulatory framework for current and future realities, these laws regulating provider behavior will require a thorough reexamination as the managed competition environment unfolds.

III. INCONSISTENCIES IN APPLICATION

The patchwork approach to health policy has led to concerns over special preferences and exceptions and clear inconsistencies in the application and enforcement of the laws governing health care providers. Despite arguments over relative differences among organizational forms, the real debate in health policy centers fundamentally upon the tension surrounding "whose interests should predominate." While the respective agencies acknowledge these exceptions, the rationales for distinguishing the various forms of treatment are often unclear, unstated, or unprincipled. As the health care environment be-

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174. See Agencies Clarify Reach of Health Care Guidelines, supra note 158, at 357 (discussing comments by Janet D. Steiger).

175. Marmor et al., supra note 86, at 319 (arguing that the debate over relative organizational forms should be replaced with the more important policy considerations of the types of services to be provided, the role of physicians, and the impact of governmental regulation on service delivery). See also Mark A. Hall, Managed Competition and Integrated Health Care Delivery Systems, 29 Wake Forest L. Rev. 1, 6 (1994) (noting the power struggle among hospitals, physicians, and insurers to control integrated delivery systems).
comes more competitive, major players have called for efforts to level the playing field.¹⁷⁶

A. Hospitals and Physicians

1. Referrals

Since self-referral legislation applies only to physicians, physicians are singled out for special treatment.¹⁷⁷ In this case, the rationale is principled due to the traditional role of physicians as the primary source of referrals and the conflict between physician fiduciary duties and the empirical data on self-referral.¹⁷⁸ As a result of self-referral proscriptions, physicians with investment interests not covered by an exception must sell their investments, often to eagerly awaiting hospitals and entrepreneurs.¹⁷⁹

Whether this same rationale should apply only to physicians or should extend beyond the fee-for-service environment is unclear. As insurance companies and other non-physician entities begin to arrange for referrals and as incentives change to reduce the financial benefits of overutilization by physicians, the rationale for prohibiting physician self-referrals while allowing non-physicians to refer to entities in which they have a financial interest is open to question.

2. Tax Exemption

The “hospital paradigm” for tax exemption neglects other components of the health care delivery system¹⁸⁰ and creates a preference for hospitals as an organizational form. Most non-profit hospitals are exempt from taxation because their charitable purpose is to promote health,¹⁸¹ but the IRS has historically refused to extend this rationale to physician groups.¹⁸² No legal


¹⁷⁷. However, the entity with which the physician has a prohibited financial relationship may not bill for services covered under the statute. 42 U.S.C. § 1395nn(a)(1)(B) (Supp. V 1993).

¹⁷⁸. See supra note 31 and surrounding text.

¹⁷⁹. See supra note 31 and surrounding text.


¹⁸¹. Colombo & Hall, supra note 95, at 29.

¹⁸². Sullivan, supra note 89, at 197.

¹⁸³. See Hall & Colombo, supra note 83, at 343 n.125 (arguing that if physicians accept patients without regard to the ability to pay, the distinction is unfounded). See
justification for this arbitrary distinction exists, and principled limitations on private inurement and private benefit can be developed to maintain equity.\textsuperscript{183}

While the IRS is considering whether the "operated exclusively for" requirement in the regulations may be reconciled with group practice medical clinics having the dual purposes of promoting health and practicing a trade or business,\textsuperscript{184} it has recently approved two alternatives to the foundation model. These alternatives involve formerly taxable medical groups such as a clinic subsidiary of a hospital-based health care system that employs physicians with privileges at hospitals within the system\textsuperscript{185} and a clinic that recently merged with a community hospital under a nonprofit parent holding company.\textsuperscript{186} These latest rulings demonstrate the IRS’s willingness to move beyond the foundation model approach to integrated delivery systems and may indicate a willingness to reconsider its position on group practices.

3. Antitrust

In contrast to tax exemption, anti-kickback, and self-referral laws, the recently issued antitrust guidelines protect physician control over integrated delivery systems. The new safety

\textit{generally} Robert S. Bromberg, \textit{The Tax-exempt Clinic}, 8 \textit{EXEMPT ORG TAX REV} 557 (1993) (discussing the difficulty that clinics have in obtaining tax exemption). Bromberg argues that the 20% limit is unfounded for existing tax-exempt clinics because these physicians relinquished substantial income and autonomy through the divestiture of property and future profits, accepted reasonable compensation limits, and often exhibit altruistic motives. \textit{Id.} at 560.

\textsuperscript{183} See John D. Colombo, \textit{Are Associations of Doctors Tax-Exempt? Analyzing Inconsistencies in the Tax-exemption of Health Care Providers}, 9 \textit{VA. TAX REV} 469, 472 (1990) (arguing that a rebuttable presumption of control test should replace the current private benefit and private inurement analysis). Alternatively, mechanisms similar to those used in nonprofit corporation law to protect board fiduciary obligations could be employed. \textit{See, e.g., REVISED MODEL NONPROFIT CORPORATION ACT} § 8.31 (1987) (regulating director conflicts of interests).

\textsuperscript{184} Sullivan, \textit{supra} note 89, at 210-11.

\textsuperscript{185} See the Detroit Medical Center exemption noted in Paul Streckfus, \textit{Clinic Operator Qualifies under Section 501(c)(3)}, 9 \textit{EXEMPT ORG TAX REV.} 12 (1994) (exempting a clinic subsidiary of hospital-sponsored integrated delivery system). The Detroit clinic was previously owned and operated by a for-profit hospital subsidiary. \textit{Id.}

zone for physician networks protects "physician-controlled" ventures, such as IPAs, PPOs, and similar entities because they "promise significant procompetitive benefits for consumers."187

The antitrust enforcement agencies have not yet developed similar safety zones for hospital-controlled networks. Doctors and hospitals compete for outpatient business, and a hospital-controlled network is a competitive alternative to a physician-controlled network. However, the enforcement agencies have provided the analytic principles for evaluating multi-provider networks, such as PHOs, because limited agency experience and the considerable variation in the type of restraints and likely efficiencies prevent the delineation of explicit safety zones.188 Since the competitive effects of integrated networks will be analyzed under a rule of reason analysis,189 hospital-controlled ventures may use a common sense approach to evaluate network development arrangements. In antitrust enforcement, the differences between hospitals and physicians are best explained by the agencies' familiarity with physician-controlled networks. The analytic principles show that the antitrust enforcement agencies intend to adapt to new delivery forms.

B. Health Plans

1. Referrals

HHS has developed a specific safe harbor for qualified HMOs.190 The managed care safe havens do not cover PPOs and IPAs not regulated by state insurance boards, hospital-physician networks, contracts between providers and employers, or any other network venture that includes referral incentives. Similarly, self-referral law exempts only qualified prepaid plans.191

One commentator argues that the distinction between referrals within an HMO and referrals among private practitioners is arbitrary because the substance of the referrals is the same and both involve compensation for the coordination of

187. 1994 ANTITRUST ENFORCEMENT GUIDELINES, supra note 158, at S-16. See also supra note 7 (discussing managed care acronyms).
188. See id. at S-21.
189. Id. at S-23.
190. See supra notes 50-51 and surrounding text.
care. The difference is that the HMO may retain the compensation for coordinating care.

While this criticism may not be appropriate for kickbacks and self-referrals among independent fee-for-service practitioners, IPA and PPO providers operate under different financial incentives that support industry efforts to coordinate care and reduce overutilization. As with health care provided by HMOs, care provided in hospitals, ambulatory surgery, outpatient, skilled nursing, and home health settings is subject to Medicare and Medicaid utilization review. Unnecessary care by physicians in any of these settings may result in physician payment denials. Thus, appropriate safeguards are in place to include nontraditional managed care plans in the safe harbor. The distinction between staff-model HMO organizational forms and IPAs and PPOs is unfounded and may lead to unprincipled, preferential treatment of traditional staff-model HMOs over newer health plan models.

2. Tax Exemption

Although Kaiser-Permanente, the nation's largest HMO, is tax exempt, two-thirds of HMOs are not exempt. Currently, most tax-exempt HMOs qualify under section 501(c)(4) of the Internal Revenue Code. However, tax exemption under section 501(c)(3) is preferable to section 501(c)(4) because while both allow exemption from the corporate income tax, section 501(c)(3) also allows access to tax-exempt bond

192. Frankford, supra note 45, at 1872.
193. Id.
194. See supra note 33 (regarding the empirical data on self-referrals).
financing, deductible donor contributions, and relatively fewer restrictions on capital transfers.\textsuperscript{198}

As with physician organizations, the hospital paradigm operates to discriminate against certain health plan organizational forms. Again, the IRS and the courts use the hospital community benefit factors\textsuperscript{199} to analyze HMO tax exemption under section 501(c)(3).\textsuperscript{200} In \textit{Geisinger Health Plan v. Commissioner},\textsuperscript{201} the Third Circuit applied the hospital community benefit test to determine whether a hospital-sponsored HMO benefitted the community as well as its subscribers and determined that the HMO did not merit section 501(c)(3) tax exemption. Important factors for obtaining exemption include the direct provision of services and membership that is open to the community.\textsuperscript{202} The Geisinger HMO did not merit exemption since it arranged for care instead of providing it directly and it served only its subscribers.

The \textit{Geisinger} decision has been roundly criticized for concluding that promoting health by "arranging for" health care delivery was insufficient for tax exemption\textsuperscript{203} and for applying the hospital community benefit standard inconsistently.\textsuperscript{204} The effect of the \textit{Geisinger} interpretation is to support the IRS preference for traditional staff-model HMOs\textsuperscript{205} and to exclude most non-staff HMOs from section 501(c)(3) qualification,\textsuperscript{206} forcing them to seek section 501(c)(4) status or forego tax ex-

\begin{thebibliography}{99}
\bibitem{198} Sullivan, \textit{supra} note 89, at 202.
\bibitem{199} \textit{See supra} notes 98-99 and surrounding text (discussing the facts and circumstances analyzed under the community benefit test).
\bibitem{200} \textit{See Frederick J. Gerhart \& Melissa B. Rasman, HMO Denied Section 501(c)(3) Status by Third Circuit, 4 J. TAX EXEMPT ORG. 17, 19 (1993); Sullivan \textit{supra} note 89, at 202.}
\bibitem{201} 985 F.2d 1210 (3d Cir. 1993).
\bibitem{202} \textit{See Geisinger Health Plan, 985 F.2d at 1217-18 (distinguishing Geisinger from \textit{Sound Health}); Carlson, \textit{supra} note 104, at 893.}
\bibitem{203} Thomas K. Hyatt, \textit{Recent Developments for Tax-exempt Healthcare Organizations, 2 ANNALS HEALTH L. 79, 80-81 (1993) (arguing that this interpretation is inconsistent with case law and private letter rulings).}
\bibitem{204} Kenneth L. Levine, \textit{Geisinger Health Plan Likely to Adversely Affect HMOs and Other Health Organizations, 79 J. TAX'N 90, 93 (1993) (arguing that the positive factors in hospital analysis also should be used as positive factors in HMO analysis as opposed to determinative reasons for exclusion).}
\bibitem{205} \textit{See, e.g., Gen. Couns. Mem. 39,828 (Sept. 30, 1990) (denying exemption to two non-staff model HMOs that arranged for health services). For a discussion of the differences between staff- and group-model HMOs, see \textit{supra} note 22.}
\bibitem{206} Gerhart \& Rasman, \textit{supra} note 200, at 21.
\end{thebibliography}
Likewise, the IRS generally will deny tax exemption to IPA-model HMOs. The IRS's reasons for denying exemption are that IPAs provide physicians with access to large pools of patients and thus primarily benefit member physicians rather than the community.

In 1986, Congress revised the treatment of Blue Cross and other plans providing health insurance in order to restrict tax exemption. Now, a section 501(c)(4) exempt social welfare organization that provides "commercial-type insurance" as a substantial part of its activities is not exempt. In contrast, health insurance customarily provided by an HMO as an incident to its plan offerings will not jeopardize tax-exempt status.

The preferential treatment of staff-model HMOs over group-model HMOs and IPAs should be reconsidered in light of today's realities and consumer preferences. As providers accept utilization controls or discounted pricing in order to join or form financing vehicles, the relative public-private benefit balance has been altered. While patients report higher satisfaction in fee-for-service outpatient care than prepaid care, they prefer prepaid multi-specialty group care over staff-model HMO care.

The organizational preferences of the IRS will affect consumer options in the future. Due to the profit potential of

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207. Hyatt, supra note 203, at 81.
208. See Sullivan, supra note 89, at 201.
212. Id. § 501(m)(3)(b).
214. For a discussion of the relative differences and the similarities between for-profit and nonprofit delivery systems, see generally BRADFORD H. GRAY, THE PROFIT MOTIVE AND PATIENT CARE: THE CHANGING ACCOUNTABILITY OF DOCTORS AND HOSPITALS (1991) (documenting the controversies surrounding the industry transformation from community service values to corporate values and the impact of the corporate culture on provider accountability).
HMOs in a managed care environment, many section 501(c)(4) HMOs are converting to for-profit status or alternatively, selling out to large for-profit chains. In a managed competition environment, consumer choices among nonprofit health plans may become limited.

3. Antitrust

In contrast with tax exemption, antitrust laws provide greater protection to commercial insurers through the McCarran-Ferguson limited antitrust exemption. The "business of insurance" exemption allows insurance companies to set rates collectively because unbridled competition among insurers might result in insolvency. But providers that undertake substantial financial risk, such as capitation, also could argue that without collective rate making, they too might establish capititated rates that are inadequate to meet patient requirements.

Hospitals, traditional HMOs, group practices, and their participating physicians may obtain a qualified immunity from private antitrust challenges such as boycott activities by complying with the Health Care Quality Improvement Act procedural requirements for peer review activities. In addition to following the formal peer review process, health care entities such as HMOs and group practices must provide health care services. Provider networks that do not provide services directly might not obtain the same level of protection that traditional HMO plans enjoy.

Thus, while antitrust law has been credited with protecting the development of managed care, within this framework, federal law immunizes rate-making activities of traditional insurance companies and certain boycott activities of hospitals and


216. See statute and cases cited supra note 139.


220. Compare to Geisinger Health Plan v. Commissioner, 985 F.2d 1210, 1217-18 (3d Cir. 1993), and supra notes 200-03 and surrounding text (noting the denial of an HMO's tax exemption because it did not provide services directly).
traditional HMOs. As providers begin to integrate health care delivery with health care fiduciary and as new integrated models emerge, the application of the antitrust laws does not afford similar protections. Since many providers are developing insured products to complement their delivery structures, they should be cautious when engaging in direct employer contracting or unprotected PHO, IPA, and PPO development if antitrust risks are present.

Established integrated delivery systems often receive preferential treatment over newer forms. For example, the Mayo Foundation is a physician-managed, nonprofit integrated health system that has developed a well-deserved reputation for low costs, high quality, and patient satisfaction. Understandably, this model could raise self-referral and exemption concerns. However, a self-referral exception grandfathers hospital arrangements with group practices established before 1989. Presumably, this exception would apply to the Mayo Clinic. Further, the Mayo Clinic and similar established health care entities are governed by physician-controlled boards without any apparent diminution in community benefit or problems with private inurement. The Mayo Clinic may be a model that Congress wishes to protect from self-referral proscriptions.

221. The "business of insurance" anomaly may be short-lived given current legislative efforts to require insurance companies to "operate in a normal antitrust environment." Insurance Group Backs Compromise that Would Modify Antitrust Exemption, 3 Health L. Rep. (BNA) No. 22, at 729, 729 (Jun. 2, 1994) (discussing proposals to repeal McCarran-Ferguson). See also Bloch and Falk, supra note 139, at 27.

222. Starr, supra note 22, at 211.

223. See generally April Hattori, Innovation in the Cornfields Makes the Mayo Foundation a Fast-moving Heavyweight in Both Finance and Medicine, 300 Bond Buyer 4 (1992) (noting that the Mayo Clinic is a low-cost provider whose drawing cards are high standards and a philosophy of patient-centered care); Gary Jacobsen, The Healthcare Biz: Alive and Kicking at the Mayo Clinic, 78 MGMT. REV. 10 (1989) (noting that from 1967-85, the Mayo Clinic’s annual prices increased at the same rate as the Consumer Price Index).

224. See 42 U.S.C. § 1395nn(d)(7) (Supp. V 1993). Services provided by groups and billed by hospitals are excepted if the arrangement was established before Dec. 19, 1989, has been in perpetual effect, the group furnishes “substantially all” of the inpatient services, and the compensation does not account for referral volume or value. Id.

225. See William J. Aseltyne & Gerald R. Peters, Tax Exemption and Integrated Delivery Systems, 20 Topics in Health Care Financing 46, 53 n.11 (1994) (noting that the IRS approach to new integrated delivery system development is more cautious than with established systems such as the Mayo Clinic); Colombo, supra note 93, at 241-42 (noting that the IRS differentiates between established and new delivery systems).
and that deserves tax exemption. However, newer integrated delivery models deserve to be treated similarly.

One explanation for this distinction between older and newer integrated delivery systems, particularly in the area of tax exemption, is a political bias for mainstream, well-established organizations. While politics will certainly pervade any federal initiatives surrounding provider standards, political choices today will affect consumers' health care delivery choices tomorrow. The federal government should become more sensitive to the impact these exceptions and privileges may have on the development and availability of innovative new delivery systems.

IV. TENSIONS AMONG THE LAWS

A. Conflicting Rationales

Tension among the fraud and abuse, self-referral, tax-exemption, and antitrust laws is inevitable given the different rationales of each statute. As previously mentioned, the purposes of anti-kickback and self-referral laws are to protect Medicare assets from overutilization as well as the referral fees associated with provider conflicts of interests. The primary rationale for federal tax exemption is disputed but several theories have been offered, including the subsidy theory, the capital compensation theory, the altruism theory, and the donor theory. The purpose of the antitrust laws is to promote consumer welfare through the protection of efficient markets.

Conflicts between the anti-kickback and self-referral laws and the antitrust laws occur when stewardship goals and standards for provider integrity are not economically efficient. Prohibiting physician investment in facilities to which they refer their patients saves hospitals from the menacing competition of physician-owned entities. The anti-kickback laws im-

226. See Marlis L. Carson, Brier and Mancino Address Health Care Tax Issues, 7 EXEMPT ORG. REV. 717, 718 (1993) (noting that revocation of the exempt status of established charities may be a political impossibility).
227. See also Marmor et al., supra note 86, at 348.
228. See supra notes 31-33 and surrounding text.
229. See supra notes 78-86 and surrounding text.
230. See supra notes 125-29 and surrounding text.
pede the development of competing cost-effective practices.\textsuperscript{232} If anti-kickback, self-referral, and tax-exemption laws also discourage development of provider-sponsored integrated delivery systems, consumers will be denied valuable competitive alternatives.\textsuperscript{233} Tax exemption also may reduce competition and allocate resources inefficiently by providing "preferential subsidies."\textsuperscript{284}

Conversely, pure competition may result in referral fiduciary conflicts and inadequate recognition of the public goods and the community benefit provided by tax-exempt providers. Physicians may have fundamentally different roles in their fiduciary relationship with patients than those found in ordinary consumer transactions, and antitrust law, by focusing on economic efficiency, may not account for non-economic harms caused by a fiduciary breach.\textsuperscript{285} Where tax exemption is predicated upon market failure, because consumer evaluation is difficult, or on governmental subsidies for public goods such as indigent care, tax exemption assumes that pure competition is not always desirable. However, it is difficult to justify tax exemptions for providers that do not relieve governmental burdens or are not distinguishable from for-profit commercial enterprises. An analysis of some typical transactions helps to explore the resulting tensions caused by these separate bodies of law.

\begin{itemize}
  \item \textsuperscript{232} King, supra note 31, at 667-69 (discussing conflicts between competition and anti-kickback law).
  \item \textsuperscript{233} See supra part III.B.
  \item \textsuperscript{235} But see E. Haavi Morreim, Blessed Be the Tie that Binds? Antitrust Perils of Physician Investment and Self-referral, 14 J. Legal Med. 359, 409-12 (1993) (arguing that despite the fiduciary relationship, vigorous antitrust enforcement and informed patient choice is preferable to proscriptions against self-referrals).
\end{itemize}
B. Examples of Conflicts

Each transaction in the development of an integrated delivery system must be thoroughly analyzed and justified for compliance with federal law. Sample transactions include provider joint ventures, physician recruitment, and hospital acquisition of physician practices. The entry models of integrated delivery systems typically rely upon joint ventures as a transitional vehicle to integration. Physician recruitment is a prerequisite for any model. Physician practice acquisition is a component of the more advanced efforts to integrate networks of providers. As providers analyze these transactions, they will encounter significant conflicts among federal agencies.

1. Provider Joint Ventures

Providers, primarily hospitals and physicians, have attempted to develop joint ventures in the transition toward integration. Joint ventures are often created strategically to develop a working alliance, minimize conflicting economic incentives, promote shared loyalties, enhance capital access, and generate additional revenues.

OIG's anti-kickback concern surrounding joint ventures is that the investment interest will affect a physician's choice of referral. The OIG is concerned about the manner in which investors are selected, the business structure of the joint venture, and the distribution of profits. Two limited safe harbors are available for investment interests: investments in a large,
publicly traded company and small entity investments that limit the percentage of investments by investors who may influence or make referrals and limit the gross revenue from referrals generated by interested investors. The self-referral law prohibits physician investment in ventures that provide designated health services, but unlike the anti-kickback laws, there are no joint venture safe harbors.

Joint ventures that involve sharing of nonprofit hospital ancillary revenues with physicians will jeopardize tax exemption. In GCM 39,862, the IRS held that the transfer of a hospital net revenue stream through a joint venture with physicians results in per se inurement because it amounts to a dividend distribution. The hospital benefit factors such as improved financial health or greater efficiencies were reinterpreted to hold that these hospital benefits exhibit only a "most tenuous relationship to the hospitals' charitable purpose of promoting health."

GCM 39,862 is the first agency attempt to acknowledge the relationship between anti-kickback violations and tax exemption. The IRS held that if a transaction violates the anti-kickback law, sufficient grounds exist for the loss of tax exemption. As the official link between tax exemption and anti-kickback laws, GCM 39,862 represents a maturing regulatory philosophy. However, the IRS examination and enforcement

246. See id. See also Paul Streckfus, Bromberg Speaks Out on Physician Recruitment by Tax-Exempt Hospitals, 7 EXEMPT ORG. TAX. REV. 714, 715-16 (1993) (arguing that Rev. Rul. 76-91 takes precedence over GCM 39,862 and that the distinction between a hospital benefitting itself and benefitting this community is revolutionary).
248. See also infra note 293 (discussing integrated delivery system determination letters).
the jurisdiction over tax law.\textsuperscript{249}

In contrast with self-referral proscriptions, antitrust law allows the development of provider joint ventures so long as the ventures do not amass sufficient market power to be anticompetitive. The FTC responded to HHS's request for comments on proposed anti-kickback regulations by outlining the procompetitive benefits of physician participation in joint ventures such as the unique input of physicians in determining community need, reducing costs through organizational efficiencies, increasing access to equity sources of capital, and improving quality by placing both the referral and the physician investment at risk for quality delivery.\textsuperscript{250}

Above a certain level of physician participation, self-referrals may create anticompetitive risks.\textsuperscript{251} To settle charges of anticompetitive conduct by a physician-owned medical equipment company, the FTC recently required a partial divestiture of referring pulmonologists.\textsuperscript{252} Roughly 60\% of the local referring pulmonologists were partners in the company, allowing the company to amass market power over home oxygen services since the pulmonologist partners could influence patient choice among home oxygen equipment.\textsuperscript{253} The divestiture agreement required the company to reduce the percentage ownership of pulmonologists to 25\% within eight months of the agreement or to risk total divestiture.\textsuperscript{254}


\textsuperscript{250} Theodore N. McDowell, Jr., Physician Self-referral Arrangements: Legitimate Business or Unethical 'Entrepreneurialism', 15 Am. J.L. & Med. 61, 70-73 (1989) (noting that the dangers of anticompetitive effects such as overutilization and increased costs also exist within non-prohibited practices).


\textsuperscript{253} Id. at 60,656.

\textsuperscript{254} Id. at 60,661.
Further, the antitrust enforcement agencies can distinguish between provider joint ventures with the legitimate competitive purpose of improving the delivery system and the anticompetitive joint ventures designed to create captive referral systems for ancillary services. According to the Justice Department, legitimate provider joint ventures that include economic risk sharing, integrated operations, and new products are not likely to be prosecuted.\textsuperscript{255} The new antitrust guidelines actually protect legitimate, procompetitive joint ventures like PHOs and physician networks by applying a rule of reason analysis to the competitive effects of integrated ventures.\textsuperscript{256} Despite provider perceptions, the antitrust laws do not erect significant barriers to joint venture development, and the enforcement agencies are not likely to contest legitimate joint ventures.

Whether self-referral law applies to physician-owned entities formed to contract with third parties to manage delivery is not clear.\textsuperscript{257} If so, self-referral law would prevent physicians from investing in IPAs and PHOs in which they provide care.\textsuperscript{258} Such an application would conflict with the antitrust guidelines designed to promote consumer welfare by allowing the development of physician-controlled networks that provide procompetitive benefits.

Thus, the antitrust guidelines may allow an investment interest that is proscribed under self-referral, jeopardizes tax exemption, and implicates anti-kickback violations. Since conduct aimed at competitor exclusion is anticompetitive and may raise per se antitrust violations,\textsuperscript{259} antitrust law is congruent with anti-kickback law for anticompetitive ventures that foreclose competition through a captive referral system. Since providers have been advised to proceed with caution,\textsuperscript{260} and at least one noted integrated delivery system expert has advised hospitals to


\textsuperscript{256} 1994 \textit{Antitrust Enforcement Guidelines}, supra note 158, at S-17, S-23.

\textsuperscript{257} Schermer & Owens, supra note 28, at 26. Examples of such entities would include IPAs and PHOs.

\textsuperscript{258} Arguably, an IPA may meet the group practice exception. \textit{See supra} notes 60-63 and surrounding text.

\textsuperscript{259} Grady, supra note 162, at 804.

"get rid of all joint ventures," the tension surrounding procompetitive integrated delivery ventures draws tighter.

2. Physician Recruitment

Physician recruitment by hospitals highlights the tension between tax exemption and the anti-kickback and self-referral laws. The OIG considers incentive programs such as income guarantees, physician office staff training, subsidized attendance at conferences or continuing medical education programs, discounted office space, and low interest loans suspect because they may inflate Medicare costs and interfere with appropriate referrals. Although HHS received many comments on the community benefits of physician recruitment and the need for a specific safe harbor protection, it has proposed only a very limited safe harbor for physician relocations to rural areas. The self-referral statute allows physician recruitment only if the physician relocates to a hospital service area, the amount of the inducement is not related to "the volume or value of any referrals by the referring physician," and the arrangement meets HHS regulatory requirements.

On the other hand, GCM 39,498 articulates the IRS policy on physician recruitment and allows recruitment under specified circumstances. Recruited physicians are presump-
tively "insiders" and therefore subject to proscriptions on in-
urement. However, GCM 39,498 allows a reasonable comp-
ensation exception determined by reference to hospital benefit,
including improved hospital productivity and efficiency. A
hospital may offer remuneration based upon the value of the
physician to the community in order to meet the reasonable
compensation test. Hospitals engaging in improper practices
such as providing unreasonable compensation or not linking
physician compensation to responsibilities for providing com-

Limits on physician recruitment may produce tension with
private sector initiatives to create a more efficient, competitive
marketplace. The safe harbors do not protect some legitimate
yet efficient recruitment initiatives that reduce costs. For exam-
ple, if a hospital's recruitment of a neonatologist is critical to
the development of its integrated system and a local neonatolo-
gist has an inadequate patient base to support her practice, the
hospital may not induce the local neonatologist to join its staff
without risking anti-kickback sanctions since her existing pa-
tients are likely to follow her. A rural hospital must forego this
local opportunity and recruit from over 100 miles away in or-
der to follow the proposed anti-kickback safe harbor. Moreover,
no safe harbor protects a suburban hospital or an urban
hospital in a medically underserved area. The local ne-
onatologist faces a restraint of trade imposed by the anti-kick-
back law.

Thus, an attempt by a nonprofit hospital to protect its tax
exemption by compensating the physician for his or her referral

267. See supra notes 107-08 and surrounding text.
269. Id. The arrangement must also pass the private benefit test. See discussion supra part II.B. (regarding determination of incidental private benefit). The transaction in question failed the private benefit test because it was impossible to determine whether this package of incentives was necessary to recruit the physicians, and the lack of caps on the income guarantee might lead to private benefit greater than the public benefit of promoting health through the recruited physician. Gen. Couns. Mem. 39,498 (Apr. 24, 1986).
270. See Closing Agreement, supra note 77 (discussing a voluntary closing agree-
ment between the IRS and Hermann Hospital that required the hospital to pay over one million dollars in penalties for engaging in questionable physician recruitment practices).
271. Johnsson, supra note 264, at 30 (discussing an example of neonatologist recruit-
ment). The recruitment of a local physician also would violate self-referral law as the stat-
ute requires that a recruited physician "relocate" to a hospital service area. See 42 U.S.C.
§ 1395nn(e)(s) (Supp. V 1993).
value may lead to both anti-kickback and self-referral violations. The conflicts among agencies are identified by commentators but not resolved by the agencies, and the resulting lack of clarity has led to inherent contradictions and the termination of physician recruitment programs by many hospitals. The foregone opportunities to recruit necessary physicians for a hospital network impede private-sector integrated delivery system development.

3. Hospital Acquisition of Physician Practices

In preparation for managed care contracting, all types of hospitals across the nation are acquiring physician practices. Needs for access to patients in managed care plans, capital for practice expansion, risk-sharing partners, and practice support systems are driving physicians to sell their practices. In order to develop competitive integrated delivery systems, most acquisitions involve primary care specialties such as family practice, internal medicine, and obstetrics and gynecology.

Self-referral law allows a one-time sale of a physician practice to any entity. The transaction must be consistent with fair market value, be commercially reasonable even if the physician did not refer to the acquiring entity, not relate to the future referral value, and meet HHS regulatory requirements. In contrast, the anti-kickback safe harbor applies only to practice acquisitions by other physicians because HHS believes that practice sales to hospitals may increase

273. See, e.g., William M. Copeland, Recruiting Physicians: Avoiding the Legal Minefield, 37 Hosp. & HEALTH SERVICES ADMIN. 269, 280 (1992) (noting that careful structuring of physician recruitment activities requires the balancing of "inherently contradicting requirements.").


275. COILE, supra note 2, at 162-63.

276. Id. at 165. Coile predicts that hospitals will focus on young physicians entering practice who generally desire personal security over autonomy and independence. Id. at 166.

277. Id. at 163 (citing a national survey of PHOs).


Medicare program costs and compensate physicians for referrals.280

The OIG and the IRS are beginning to coordinate their efforts to scrutinize physician practice acquisitions.281 Responding to an IRS request for anti-kickback guidance on hospital acquisitions of physician practices that result in the "common ownership or control" of both hospitals and physicians, the OIG reiterated its concern that such acquisitions may be sophisticated profit-sharing arrangements that violate the anti-kickback statute.282 In contrast, the IRS prefers physician practice acquisitions over leasing or licensing because the asset acquisition ensures hospital control over key assets such as patient records and managed care contracts.283 Both agencies have concerns that the acquisition price should reflect no more than fair market value,284 but the IRS allows the acquisition price to include intangible assets such as goodwill, non-compete agreements, HMO contracts, and patient records.285

In the area of antitrust, acquisition analysis may turn on whether a hospital is acquiring the practice of a competing physician.286 Physicians and hospitals are often competitors, and horizontal agreements between the two are disfavored, requiring increased justification for collaborative activity.287 In the analysis of anticompetitive effects, one commentator argues that the anti-kickback statute, in conjunction with antitrust law, erodes physician bargaining power, co-opts professional

282. See Thornton Letter, supra note 65, at 244.
283. IRS 1994 TEXTBOOK, supra note 20, at 217.
284. Id. at 219.
285. Id.
286. See Peters Address, supra note 43, at 47 (noting that horizontal mergers receive increased scrutiny over vertical mergers regarding the potential lessening of competition).
287. Frankford, supra note 45, at 1924-25. Frankford argues that the production of health care, like any other economic good, requires collective activity driven by market forces. Id. at 1862. Frankford believes that because regulatory prohibitions such as those encompassed within the anti-kickback statute channel these collective activities into institutional forms employing professional labor, independent professionals will be coopted by bureaucratic institutions that standardize health care delivery and reduce patient autonomy. Id. at 1863-64.
judgment, and enhances bureaucratic power at the expense of patient autonomy.\textsuperscript{288}

In its anti-kickback advice, the OIG also noted that a comparison of the acquired physicians' financial welfare before and after the acquisition would be revealing because physicians may improve their economic position.\textsuperscript{289} Such an inquiry is revealing because it contradicts the OIG's assumptions regarding the extent of such lucrative transactions. Due to the fear of being left out of the managed competition environment, many physicians are selling their practices at less than fair market value.\textsuperscript{290} Again, the paradigm shift in health care has altered many of the assumptions embedded into the current regulatory framework.

C. Lack of Interagency Coordination

The statutory goals underlying the regulation by these three agencies are not necessarily mutually exclusive. It is possible to maintain the custodial goals of the Medicare program while promoting charitable activities and protecting open markets. However, since notable conflicts exist among agency directives, efforts to coordinate directives have not been very effective in reconciling these statutory goals.

Although primitive attempts at agency coordination have been made, these efforts have not been successful in harmonizing standards for integrated delivery systems. For example, the FTC asked HHS to develop safe harbors for provider discounts to PPOs because anti-kickback liability is so ambiguous and the discounts are not designed to induce medically unnecessary referrals.\textsuperscript{291} Yet liability for provider-sponsored competitive alternatives still remains unclear.\textsuperscript{292}

A prime example of the lack of effective coordination among the agencies is the unresolved conflict between HHS and the IRS that effectively prevents advance tax-exemption determinations of compliance in transactions involving physician practice acquisitions. Due to the inability to determine

\begin{thebibliography}{99}
\bibitem{288} Id. at 1864.
\bibitem{289} Thornton Letter, supra note 65, at 245.
\bibitem{290} See Breisch & Johnsson, supra note 119, at 15 (emphasis added).
\bibitem{291} \textit{FTC Staff Urges HHS to Clarify Legality of Arrangements by HMOs, Other Providers, Antitrust & Trade Reg. Rep. (BNA) No. 1346, at 988 (Dec. 24, 1987).
\bibitem{292} See supra part III.B.1.
\end{thebibliography}
anti-kickback violations in advance, the IRS conditions integrated delivery system determination letters upon compliance with anti-kickback law. Although the IRS professes its reluctance to use a non-tax statute if courts and the responsible agency have not yet enforced integrated delivery system compliance, the conditional nature of the rulings is based on troublesome legal grounds because the broad nature of anti-kickback prohibitions often makes it impossible to determine if an arrangement violates the law. Many integrated delivery systems serve a public purpose and confer a public benefit, the ultimate tests for tax exemption. Further, an isolated violation of the ambiguous anti-kickback prohibitions, while potentially criminal, should hardly be considered a violation of a clearly enunciated legal norm and necessarily inconsistent with a charitable purpose.

Before a hospital vertically integrates with physicians holding managed care contracts, it cannot be assured of the anti-kickback consequences of combining managed care contracts into an integrated system, despite advance rulings from other agencies that the arrangement provides a public benefit and is procompetitive. Despite the need for provider guidance, the OIG has stated that the conflict with the IRS over whether payments for intangible assets represent inducement for referrals is not resolvable. Further, the conflict appears related to the inability of the IRS and HHS "to work in tandem" and

293. See IRS 1994 Textbook, supra note 20, at 234. See also Levine, supra note 96. The lineage of the conditional nature of these rulings may be traced to the Gen. Couns. Mem. 39,862 on provider joint ventures stating that Medicare anti-kickback violations may provide the grounds for revocation of exemption. J. Anthony Manger, Tax Developments: Do They Shed Light?, 10 Healthspan (P-H L. & Bus.) No. 6, at 2 (June, 1993).


295. Manger, supra note 293, at 2. IRS denial of exemption due to anti-kickback violations is based on common law notions that illegal activities are inconsistent with exempt purposes and on the Supreme Court decision in Bob Jones that activities violating a clearly enunciated public policy are likewise inconsistent. See Jean Wright & Jay H. Rotz, Illegality & Public Policy Considerations, in IRS 1994 Textbook, supra note 20, at 155-58, 163. However, the common law rationale is based on the notion that "a charitable trust fails if it violates public policy embodied in the criminal law or otherwise clearly enunciated as a legal norm" and the Bob Jones decision is based on the notion that charitable organizations must serve a "public purpose and confer a public benefit." John G. Simon, supra note 211, at 87-88 (emphasis added).


297. Id. at 755.
INTEGRATED DELIVERY SYSTEMS

has even been characterized as a "feud." One observer suggests that a factor in the conflict is that the IRS is closely attuned to federal health policy and that HHS has not yet "gotten the word." Whatever the resolution, the conflicts among agencies should be resolved openly.

The foremost reason that interagency coordination is needed is that each agency has established primary competencies in different areas. For example, proposals to allow HHS screening of mergers and joint ventures rather than the FTC or the Justice Department would allow HHS's familiarity with quality and access to influence policy making in this arena. However, HHS has no expertise in competition analysis. The IRS has suggested that antitrust violations also might be a basis for revocation of exempt status on the grounds that antitrust principles encourage increased numbers of competitors and antitrust violations are harmful to society. Like HHS, the IRS has no special competence in this area. Further, it is questionable whether the IRS or the FTC should be making decisions that require health policy expertise.

The expertise that each agency has developed bears on the resolution of the problems providers face in understanding and complying with federal law as they develop integrated delivery systems. For effective integrated delivery systems development within a private health care system, coordination of directives among the agencies charged with enforcing federal statutes is necessary. Instead, the regulatory apparatus itself creates a legal obstacle to the transition toward an integrated industry.

V. PROPOSED INTERVENTIONS

To the extent these laws have a chilling effect on competition, they must be recognized and reconciled with current health care policy. To the extent the laws protect patients, maintain the integrity of the medical profession, and success-

299. Streckfus, supra note 296, at 756.
300. Unfortunately, the conflict is expected to be resolved behind the scenes. Id.
303. Wright & Rotz, supra note 295, at 175.
304. See Colombo & Hall, supra note 95, at 31.
fully control costs, they should be strengthened and supported. Further, . . . legislative efforts should be directed at eliminating the inherent inconsistencies and creating a solid legal framework within which the health care industry can function.305

Separately developed legal rules regulating health care providers have resulted in a lack of vision in health policy and a “patchwork of separate responses to various problems, with each reform creating a new distortion.”306 Health care is an important issue demanding significant public attention as health reform at federal and state levels is debated. Most current reform efforts would continue to rely on private systems of health care delivery.307 A discussion of the chaotic impact of the existing regulatory framework on private health care providers has been missing from the debate. To ensure that rational responses are developed to solve health care delivery problems, reforms must include the reduction of interagency conflicts, the resolution of unjustifiable inconsistencies in the application and enforcement of federal law, and the expression of policy preferences and difficult choices among competing principles of health care cost, quality, and access.

A. Objectives for Interventions

Principled methods must guide the development of solutions for harmonizing provider standards, and unless objectives are set, the outcome will be beset with the same fundamental weaknesses as current law. For purposes of this Note, several objectives are proposed. The process and the outcomes must be congruent, rational, open, consistent, coherent, legitimate, and flexible. An intervention is congruent if it complements and is consistent with national health policy. If policymakers clearly

305. MacKelvie & McGuire, supra note 260, at 1 (discussing the legal conflicts between anti-kickback and tax-exemption over joint ventures and the resulting policy conflict with the Medicare prospective payment system).

306. Robert L. Dickman et al., An End to Patchwork Reform of Health Care, 317 New Eng. J. Med. 1086, 1086 (1987). Although Dickman advocates an examination of national health insurance and a national health service, this Note assumes that the paradigm shift in health care will evolve within a public or private managed competition framework. See supra part I.

identify and evaluate the underlying value conflicts and determine appropriate tradeoffs, the intervention will be more rational. An open process is one that is exposed to public scrutiny. Consistent solutions will avoid gaps and conflicts in the law and strive toward a more unified approach. Coherence may be assured through a straightforward mechanism to guide the interpretation and enforcement of the law. An intervention is legitimate if principled and developed by the rule of law. Finally, flexibility is necessary to allow the law to adapt to changing industry conditions.

B. Proposed Initiatives

Each branch of government has different powers and contributes distinctive competencies to improving federal law governing provider behavior, and avenues exist to begin the process of clarifying and harmonizing provider standards. This Note recommends a program of executive, agency, legislative, and judicial interventions to maximize the competencies of each branch and set the stage for regulatory reform.

1. Executive and Administrative Initiatives

Remarkably few statutory and regulatory changes in federal health law have occurred during the recent health reform debate. Absent new legislation, the relevant agencies may be expected to apply the existing regulatory framework and continue present policies. Several existing executive branch alternatives may provide an inexpensive, straightforward process for resolving policy conflicts among agencies or between agencies and federal health policy.

The President has vast authority to initiate and effect controls over administrative agencies through the process of appointment and removal and oversight of agency authority.


310. Myers, 272 U.S. at 117, 135 (construing Article II as the source of presidential authority to secure uniform execution of the laws through agency supervision and guidance).
Executive coordination of agency regulation is often accomplished by executive orders and is important because although Congress establishes the goals, it seldom legislates the details of every action taken in pursuit of these goals or makes the balancing choices that these decisions require. It has assigned this task to the regulatory agencies. Each regulatory agency, however, usually is given a set of primary goals, without specific regard for whether proposed actions in pursuit of those goals might conflict with the pursuit of other goals by other agencies. An effective mechanism is needed to coordinate agency decisions with the judgments of officials having a broader perspective, such as the President and Congress.\(^\text{311}\)

a. Interagency Task Forces

Interagency task forces could begin to study and report on effective mechanisms for coordinating agency activities and minimizing conflicting directives. HHS has recommended an interagency task force to examine the interrelationship between antitrust and health policy, and a staff-level working group from HHS and the antitrust enforcement agencies has begun to share information.\(^\text{312}\)

At higher levels, the executive branch should use interagency policy councils to provide agencies with policy guidelines. For example, senior officials from the Justice Department and the OIG have begun meeting formally to develop a national enforcement policy for health care fraud.\(^\text{313}\) The Executive Level Health Care Fraud Policy Group has discussed strategies for identifying and investigating fraudulent practices.\(^\text{314}\)

While interagency coordination is important for effective enforcement, such a policy group also could improve compliance with federal law by providing health care providers with clear and coherent guidance on the types of transactions com-

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312. HHS to Remain Neutral on Hospital Merger Enforcement, supra note 301, at 71.


314. Id.
mon to integrated system development. The Justice Department, an executive agency, and the FTC, an independent commission, used an interagency approach to develop the policies embodied in the health care enforcement guidelines. Although the guidelines are not exhaustive of all current delivery models, they do improve clarity for physician integration efforts and provide analytical guidance for hospital and physician integration. At the cabinet level, the Domestic Policy Council is charged with coordinating domestic policy and ensuring consistency with presidential goals, and the HHS Secretary, the Attorney General, and the Secretary of Commerce are all members. Thus, improved policy making through interagency initiatives may proceed under a variety of models. However, given the existing tensions among agencies, some type of interagency coordination may be warranted.

b. Superagency Oversight

A new agency could be created and charged with coordinating health policy. For example, the Clinton plan would have established an independent commission, the National Health Board (NHB), with responsibility for developing uniform provider quality and performance measures and defining requirements for qualified health plans. Federal administration of health care would have been divided among the NHB and existing federal agencies, but the NHB would have had access to all relevant information from executive agencies. While responsibilities for coordination of agency activities could be considered for an entity such as the NHB, Congress is unlikely to create new federal agencies to oversee health reform.

Instead of creating a new agency to harmonize and clarify provider standards, existing mechanisms for agency coordina-

315. See supra notes 157-58 and surrounding text.
317. WHITE HOUSE DOMESTIC POLICY COUNCIL. THE PRESIDENT'S HEALTH SECURITY PLAN 44-45 (1993) (discussing the authority of the National Health Board under the Clinton plan). See also H.R. 3600, 103d Cong., 1st Sess. § 1503 (1993) (outlining the general duties and responsibilities of the National Health Board).
318. H.R. 3600 § 1505(c).
tion could reform the rules that govern provider behavior. Coordination of agency policy making often is carried out centrally through the Office of Management and Budget (OMB). The Reagan administration frequently used executive orders to centralize executive oversight of agency policy making through OMB coordination. However, the OMB coordination process may lack integrity. The most noteworthy criticisms of OMB coordination have been its secrecy and lack of accountability, delays in rulemaking, and lack of expertise in the regulated area.

President Clinton has revoked President Reagan's executive orders dealing with centralized OMB coordination and replaced them with Executive Order 12,866. Executive Order 12,866 establishes principles to guide regulatory programs including the examination and modification of existing regulations, avoidance of regulations that are inconsistent or duplicate those of other federal agencies, and the assessment of alternate forms of regulation, including a preference for specifying performance objectives over means. OMB's role of ensuring consistency with presidential objectives and reducing interagency conflict is housed within the Office of Information and Regulatory Affairs (OIRA).

The authority of Executive Order 12,866 could be invoked to provide executive oversight for the regulatory process affect-

320. See, e.g., 44 U.S.C. §§ 3501, 3503 (1988) (establishing the Office of Information and Regulatory Affairs (OIRA) to review and approve agency regulations requiring the collection of information).

321. See Bruff, supra note 311, at 514 (discussing Executive Order 12,291 requirements for OMB review and clearance on proposed and final regulations and Executive Order 12,498 requiring OMB agenda coordination). Exec. Order 12,291 required agency use of cost-benefit analysis in preparing a regulatory impact statement, and Executive Order 12,498 required agencies to submit their regulatory program to OMB for coordination and review. See id.

HHS anti-kickback safe harbor regulations have been released from regulatory impact statements requiring OMB coordination under Exec. Order No. 12,291 or the Regulatory Flexibility Act because the safe harbors are "designed to permit ... business practices that encourage competition, innovation and economy." See, e.g., 57 Fed. Reg. 52,723, 52,728 (1992) (commenting on regulations codified at 42 C.F.R. pt. 1001).


324. Id. § 1(b).

325. Id. § 2(b).
ing health care providers. First, interagency conflict would be reduced by having each agency review its existing health care regulations for inconsistencies with other federal agencies. The knowledge and understanding of each agency’s statutory commands and regulatory priorities could emanate from the interagency task force meetings discussed above. A part of this process should include the identification of legislative mandates that may become outmoded or unnecessary in a managed competition environment. OIRA may then review “significant regulatory actions” that create a serious inconsistency or interfere with actions of other agencies or the President’s health policy. A Regulatory Working Group convened by OIRA may then serve as a forum for conflict resolution, and conflicts unresolved by OIRA and the agencies would be resolved by the President or Vice President with the relevant agency officials. Public disclosure of agency-OIRA correspondence and of OIRA communications with outside interests related to published health care regulations would improve public accountability. This process would force the agencies to work together and improve regulatory coordination.

c. Administrative Initiatives

Despite the need for direction from the legislative and executive branches, administrative agency decision making will always be important to administer the health care bureaucracy. Agencies have rulemaking responsibilities delegated by law, but these responsibilities should be carried out with a full appreciation for overall health policy. A straightforward process to guide the implementation and enforcement of the laws is needed, and flexibility is also necessary to adapt to evolving forms. Besides agency contributions to interagency

326. See id. § 5.
327. See supra notes 315-18 and surrounding text.
328. Recommendations for statutory changes then could be referred to Congress for legislative initiatives. See infra part V.B.2.
329. See supra note 322, § 3(f), 6(a).
330. Id. § 4(d).
331. Id. § 7.
policy making, each agency has distinctive competencies in its primary area of regulation. The turbulent changes in health care require that each agency's competencies include an awareness and understanding of evolving organizational forms.

The use of advisory opinions by the IRS and FTC and business review letters by the Justice Department has allowed these agencies to develop a sense of the types of innovative transactions that providers are undertaking to develop integrated delivery systems. The lack of such a mechanism for anti-kickback law enforcement by HHS is a liability and has reduced that agency's effectiveness in dealing with the multitude of new arrangements that require new analytical approaches.

A bill authorizing HHS to provide advisory opinions on whether a proposed arrangement violates either the anti-kickback statute or the self-referral statute was introduced in the last Congress. The OIG strongly opposed the bill on the grounds that sufficient advice is available, the application material would be inadequate for a conclusive determination of the parties' intent, and the OIG would be unable to respond to the voluminous requests predicted.

The OIG's logic is faulty and circular. The reason the OIG should anticipate voluminous requests is precisely because providers do not have adequate guidance to deal with the legal ambiguities of anti-kickback law. Further, adequate procedural protections can be developed to preserve prosecutorial discretion such as limiting the advisory opinion to factual matters and including the Justice Department in the review process.

If jurisdictional issues related to the enforcement of criminal laws concern the OIG, then it may develop enforcement guide-

334. See supra notes 87, 154-56.
337. See Ways-Means Votes to Require HHS Fraud and Abuse Advisory Opinions, 3 Health L. Rep. (BNA) No. 27, at 921 (July 7, 1994) (discussing committee amendments to limit advisory opinions). For example, the Justice Department analysis for business review letters necessarily involves a determination of the parties' intent regarding anti-competitive conduct. To minimize the risk of devious behavior, the business review process provides that requesters make full and true disclosure and comply with requests for additional relevant information. See 28 C.F.R. § 50.6(5) (1994). Business review letters state only current agency enforcement intentions, and the Justice Department remains free to prosecute future violations if required. 28 C.F.R. § 50.6(9) (1994).
lines for potentially criminal violations in cooperation with the Justice Department like those developed for antitrust enforcement. The development of advisory opinions would both improve HHS effectiveness and clarify provider expectations.

Other avenues are available to ensure that agencies are aware of industry trends. Notice and comment on proposed regulations provide agencies with information on provider concerns. Agencies also might consider using negotiated rulemaking procedures to allow more formal industry participation in rulemaking. Each agency should be current regarding industry trends, specific transactions providers contemplate, and the purposes and motives for provider development of integrated delivery systems. As each agency takes steps to inform itself, health care providers have the corollary obligation to provide full and frank disclosure and cooperation in ensuring that federal agencies adequately understand the problems they face.

2. Legislative Initiatives

One obvious avenue for intervention is Congress. As a matter of institutional competence, Congress is best suited to address broad policy issues not requiring special agency expertise. Yet, often it is difficult for Congress to implement its value choices effectively. Whatever reforms Congress may enact in the health care arena, the administrative structure for health care regulation should receive priority. Congressional interventions may be limited to congressional oversight functions,

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338. The antitrust enforcement guidelines include a qualification that physician ventures within the guidelines will not be challenged "absent extraordinary circumstances," but they also provide analytical guidance for ventures outside the safe harbors. 1994 ANTITRUST ENFORCEMENT GUIDELINES, supra note 158, at S-16 to S-17.

339. For notice and comment requirements in agency rulemaking, see Administrative Procedure Act, 5 U.S.C. § 553 (1988).


342. See James A. Morone, The Administration of Health Care Reform, 19 J. HEALTH POL'Y & L. 233, 236 (1994) (arguing that reformers who ignore administrative structure do so at their peril). Other than the conventional delegation of rulemaking authority, the President's health plan contained little guidance on how to reform agency policy making. See ADMINISTRATIVE CONFERENCE OF THE UNITED STATES. ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM (1994).
include specific reforms, or encompass a comprehensive statutory scheme. More important is the requisite guidance on important health policy choices.

a. Oversight functions

A relatively informal process for congressional intervention is through oversight functions. Besides the appropriations process, each agency is subject to congressional oversight by many standing committees.\textsuperscript{343} Joint committees also have held hearings in recent years to oversee conflicts among agencies.\textsuperscript{344} In addition, the House Government Operations Committee and the Senate Governmental Affairs Committee review the efficiency and economy of all governmental operations and activities.\textsuperscript{345}

Any of these committees could conduct hearings and investigations to oversee the regulatory agenda and to identify and resolve interagency problems or conflicts with health policy. However, congressional oversight is resource-intensive, often perfunctory, and better used to police agency performance.\textsuperscript{346} While these hearings may serve the important first step of obtaining information to monitor and control agency activity, they are an inefficient and ineffective tool for harmonizing provider standards.

b. Specific Proposals

Specific legislative interventions within each area of law have been recommended to address problems with anti-kickback and self-referral, tax exemption, and antitrust law. Congressional delegation of power to the OIG for development of safe harbors consistent with beneficial industry changes has

\begin{footnotesize}
\textsuperscript{343} Examples would include the Senate Judiciary Committee on Antitrust, Monopolization and Business Rights, the Senate Finance Committee on Medicare and Long-term Care, and the House Ways and Means and Senate Finance Committees.

\textsuperscript{344} See, e.g., the hearings held before the Joint Economic Committee's Subcommittee on Investment, Jobs, and Prices to review hospital merger policy inconsistencies between HHS and the Justice Department. Hudson, supra note 255, at 40; \textit{Officials Challenge Perception that Antitrust Law Hampers Hospital Efficiency}, 63 Antitrust & Trade Reg. Rep. (BNA) No. 1572, at 14, 15 (July 2, 1992).

\textsuperscript{345} \textit{Congressional Yellow Book}, at III-38, IV-47 (1993).

\end{footnotesize}
been ineffective in providing the industry with guidance on lawful arrangements. Congress has specified the anti-kickback arrangements it wishes to condemn, but direction on the types of organizational arrangements allowed is needed.\textsuperscript{347} Congressional intervention has been recommended in the area of tax exemption because tax subsidies are involved and because the IRS lacks expertise in health policy.\textsuperscript{348} As well, broad statutory antitrust exemptions for health care providers have been proposed.\textsuperscript{349}

However, piecemeal solutions to the problems enumerated in this Note will replicate existing problems and enshrine the current schizophrenia surrounding health care federal law. Given the potential for conflict among federal statutes and regulations governing provider behavior, a more comprehensive legislative direction on the desirability and extent of harmonizing provider standards may be needed.

c. Comprehensive Statutory Scheme

The lack of consistency and uniformity in health care provider regulation makes providers dependent upon attorneys for a thorough review and parsing of the numerous statutory requirements. For example, the development of physician-hospital joint ventures is "a lawyer's dream and a provider's nightmare" due to the elaborate regulatory framework.\textsuperscript{350}

One attorney argues that inconsistent standards for managed care products should be eliminated through the development of a uniform managed care code and that health lawyers should think of themselves as chattel mortgage lawyers before the Uniform Commercial Code (UCC) was developed.\textsuperscript{351} Al-

\textsuperscript{347} Frankford, \textit{supra} note 45, at 1877-78.
\textsuperscript{348} Colombo & Hall, \textit{supra} note 95, at 31-33.
\textsuperscript{349} See Bloch & Falk, \textit{supra} note 139, at 27 (criticizing broad exemptions for health care providers).
\textsuperscript{350} Donald L. Holmquest, \textit{Implementing Managed Care Opportunities through Physician/Hospital, and Provider/Insurer}, in \textit{MANAGED HEALTH CARE: LEGAL & OPERATIONAL ISSUES FACING PROVIDERS, INSURERS, AND EMPLOYERS} 145, 152 (PLI Com. L. & Practice Course Handbook Series No. 393, 1986). \textit{See also} Tedrick, \textit{supra} note 31, at 557 (describing the legal assistance required for anti-kickback protection as a "pot of gold" for attorneys).
\textsuperscript{351} Bruce S. Wolff, Keynote Address Before the National Health Lawyers Association (Jan. 6, 1994), in \textit{HEALTH LAW. NEWS REP.}, Jan. 1994, (Nat'l Health Lawyers Ass'n, Wash., D.C.), at 3 (commenting on the stringent obligations imposed on HMOs as compared with other managed care products).
though the UCC was developed as a model for uniform state legislation, the analogy is illustrative. The purposes of the UCC were to simplify, clarify, modernize, and unify the law of commercial transactions.\textsuperscript{52} Although the UCC took over a decade to draft and did not reduce the need for lawyers, commercial lawyers now can render clearer advice to clients on commercial transactions.\textsuperscript{53} Like commercial lawyers, health care lawyers need greater certainty and predictability in providing advice to clients, especially regarding integrated delivery transactions.

As Congress reconsiders reforms for the health care system, it should consider the specific policy goal of harmonizing and clarifying health care provider standards. Achieving uniformity would be difficult because Congress may experience inherent institutional difficulties in developing and codifying its expectations for provider behavior. A uniform code for health care providers would force political accountability for making the difficult trade-offs entailed by health care cost, quality, and access issues.\textsuperscript{54} Due to the tremendous activity in private sec-

\begin{itemize}
  \item \textsuperscript{52} U.C.C. § 1-102.
  \item Prior to the U.C.C.'s adoption, there were a wide variety of security devices, each with a different filing system for each security device which was subject to filing requirements. The recognition of so many separate . . . devices had the result that . . . each . . . had to be separately checked to determine a debtor's status. [D]espite the great number of security devices there remained gaps in the structure. The growing complexity of financing transactions forced legislators to keep piling new [statutes] on top of our inadequate and already . . . complicated . . . security law[s]. The results were increasing costs to [secured parties and debtors], and increasing uncertainty.
  \item Olivia F. Gallo, \textit{Conflict Between the Uniform Commercial Code and the Federal Tax Lien Act}, 7 \textit{Whittier L. Rev.} 1009, 1015 (1985) (internal quotation marks and citations omitted). The resulting lack of predictability and uniformity led to a crazy quilt of uniform statutes dealing with commercial law, including the Uniform Sales Act, the Uniform Negotiable Instruments Law, and the Uniform Warehouse Receipts Act. \textit{William D. Hawkland. U.C.C. Series} § 1-102:03 (1984). The UCC drafters realized that a comprehensive and systematic body of commercial law would be difficult because these areas of commercial law were intertwined, used different terms, and lacked uniformity and certainty. \textit{Id.}
  \item Interview with Spencer Neth, Professor of Law, Case Western Reserve University in Cleveland, Ohio (March, 1994).
\end{itemize}
tor market innovation, the delineation of statutory standards may be too rigid and proscriptive and lack the flexibility required by the dynamic health care environment. Further, it is doubtful that health care antitrust law could ever be reduced to a code because the competitive effects of an arrangement are an essential ingredient of the analysis. Nonetheless, by simply reconciling conflicting statutory obligations and improving the rulemaking procedures, Congress could begin to unify and clarify provider standards, improve policy outcomes, and reduce challenges of agency action.

d. Policy Agenda

As Congress attempts to develop a consensus on the proper structure of the nation's health care system, the time-consuming nature of a comprehensive code may be impractical and unnecessary. However, if Congress fails to provide clear guidance to the regulatory process, the regulation of health care providers may be incongruent with national health policy. The need for congressional debate surrounding the problems identified in this Note bears directly on developing health care policy and is critical to any reform initiatives that rely upon private sector organization and delivery. The following questions are important issues to place on the congressional agenda:

1. What are the proper roles for federal agencies in structuring the reformed health care industry? What legislation is necessary to improve interagency coordination? How may agency coordination contribute to the congressional goals of health reform?

2. Is there a desirable level of provider integration? Or should federal law support multiple integration options as a vehicle to promote pluralism and increase consumer options?

3. Should the federal government encourage or discourage development of for-profit forms of integrated delivery systems? Should it encourage or discourage integrated delivery systems development at all? Do integrated delivery systems provide benefits that are worthy of tax exemption and that protect sufficiently against potential fiduciary conflicts and Medicare program abuse?

4. Should changes in provider behavior, including physicians, be effected by changes in financial incentives? If so, can these changes be made without creating fiduciary conflicts? What
are the appropriate limitations on physician compensation and risk sharing under health plans designed to constrain utilization?

Answering these broad policy questions is outside the scope of this Note. These questions simply provoke discussion surrounding the issues identified in this Note and highlight the unresolved policy choices available to the next Congress. Nonetheless, congressional debate surrounding these issues and legislation to modernize the laws governing health care providers would inform federal agencies, providers, and the public and would begin to align health care policy with the new health care marketplace.

3. Judicial Interventions

Judicial interventions involve using the courts to challenge the legal basis of agency actions. Challenging regulatory actions through the courts has limited effectiveness in securing harmonized provider standards because of the time and expense involved in litigation and appellate advocacy and because the outcome is very uncertain. In the absence of clear congressional intent, agency interpretations of law are entitled to great deference. The Court will defer to reasonable agency constructions of statutes that involve conflicting policies. Thus, because Congress has not provided a clear legal framework for the laws regulating providers, agencies often will have considerable discretion in interpreting federal law and are protected somewhat from judicial challenges by providers.

Yet, judges are still the "final arbiters of statutory meaning," and courts can provide a safety net for resolution of interagency conflicts and inconsistencies in the application of federal laws. Factors influencing judicial deference include longstanding or consistent application of the agency's construction, statutory authority for rulemaking, public reliance on

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356. Id. But see Rosenblatt, supra note 341, at 452-56 (illustrating that the lack of congressional clarity results in inconsistent judicial approaches).

357. Natural Resources Defense Council, Inc. v. EPA, 725 F.2d 761, 767 (D.C. Cir. 1984) (discussing the tension between the deference rule and judicial intervention).

agency interpretations, and a subject matter requiring special expertise.\(^\text{359}\) Inconsistencies in application of the law and inter-agency conflicts surrounding broad policy goals not requiring any special agency competence appear most vulnerable to judicial intervention. For example, Peters argues that the inconsistencies in application and lack of a statutory basis for limits to physician governance of tax-exempt integrated delivery systems is likely to cause a legal challenge to the IRS rules.\(^\text{360}\)

This Note has identified numerous other issues that may subject agencies to judicial challenge given the irregularities identified, the lack of a consistent framework, and the broad health policies involved. Further, the increasingly competitive nature of the market accentuates disparities that may have been disregarded in a more stable era. As the market tightens and providers perceive that the rules of the game are irrational or bestow unfair advantage to competitors, providers likely will use the courts to challenge the regulatory framework. To avoid protracted litigation, the executive and administrative branches would be well-served by initiatives to clarify and harmonize provider standards that will withstand judicial scrutiny.

VI. CONCLUSION

This Note has reviewed the effects federal laws governing Medicare and Medicaid anti-kickback and self-referrals, health care provider tax exemptions, and antitrust have on the efforts of health care providers to develop integrated delivery systems. In particular, these federal laws place many restrictions on provider efforts to integrate with one another and to integrate health care delivery with financing. As providers integrate and develop transitional delivery and financing vehicles, the distinctions among providers and between delivery and financing are beginning to blur. As a result, historical approaches to regulation produce many inconsistencies. In combination, these federal laws also produce conflicting directives.

Regulatory approaches, designed for an earlier era, need to be revamped. This process will not be easy and will require deliberate policy choices among cost, quality, and access goals.


However, since private sector health care delivery is the centerpiece of most reform efforts, health care providers necessarily need clarity and direction on the types of arrangements considered lawful and legitimate under federal law.

To begin this process, each branch of the federal government has an important role to play. Executive and administrative agencies should begin to develop an open and inclusive process for improving consistency and reducing interagency conflicts. Solutions should avoid gaps and conflicts in the law and strive toward a unified approach through the coordination of interagency policy making. Executive Order 12,866 provides the means for the executive branch to perform this function. A straightforward, inexpensive process also is needed to guide the interpretation and enforcement of administrative law and support a flexible approach to new and evolving organizational forms. Congress is best suited to ensure that harmonized provider standards are consistent with national health policy goals. Congress must begin to identify and evaluate clearly the underlying value conflicts to guide agency policy making. In this way, Congress may ensure that agency reforms reflect broad political support and include the consideration of diverse and often conflicting policy goals. Finally, courts play an important role in assuring the accountability of the other branches and providing a forum for providers to challenge regulatory inconsistencies. The transformation of health care delivery and financing warrants this comprehensive reexamination of the legal and regulatory framework governing health care providers.