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Resolving Conflicting Laws and Policy in Integrated Delivery Systems Development

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RESOLVING CONFLICTING LAWS AND POLICY IN INTEGRATED DELIVERY SYSTEMS DEVELOPMENT

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I. INTRODUCTION

Historically, health care services in the United States have been delivered by providers organized as separate economic and legal entities. Hospitals, physicians and various allied health professionals all had distinct roles in a system of care that was rarely a model of efficiency.

In light of the ever-increasing costs of health care however, health care purchasers, including public and private organizations, are demanding that

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costs be reduced and quality be improved.\(^4\) The financial incentives that existed under traditional health insurance programs rewarded providers for the increased utilization of services. The current impetus for cost reduction has resulted in the organization of systems that function successfully in an environment where the delivery of care and the reimbursement of that care are both managed.

Payers have encouraged this development of managed care systems, in which health care consumers are given access to care but only after consultation with and often the approval of a \emph{gatekeeper} physician or other professional. Payers are also increasingly asking providers to accept some of the financial risk associated with the delivery of care to a defined population, as a way of controlling if not predicting costs. Once separate provider groups are now joining forces to develop systems that address payer concerns about cost and quality.

As a result of these pressures, cataclysmic changes are transforming the health care industry. In the 1990's for example, we have seen extensive restructuring of health care delivery systems. In terms of delivery, the health care industry is evolving away from hospital centered systems. In terms of payment, the industry is shifting away from traditional fee-for-service reimbursement to a sharing of financial risk with providers.

Hospitals and physicians are forming networks that integrate certain delivery and insurance functions and thereby enable the providers to sell their services directly to employers and other payers. Even if networks decide to allow insurers and others like HMOs to market the network's services, providers are in a better bargaining position for their compensation. These efforts may result in some level of integration; however, the parties often end up with a transitional system that lacks total integration and delivers less than the full range of services while engaging in some insurance functions.

Against this backdrop, health care continues to be subject to extensive yet ever changing regulations at both the federal and state levels. As the industry responds to these changing regulatory forces and the industry's efforts to control health care costs, the traditional roles played by providers and payers are being reconsidered and often restructured into new configurations. The restructuring of any industry as large and complex as health care sometimes brings to light conflicting laws as well as public policies that underpin the laws and regulations governing this sector of the U.S. economy.

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\(^4\)Until recently, the conventional wisdom has been that health care costs are on the rise in this country at an alarming rate. See Randolph S. Jordan, \textit{Regulation of Provider Risk Sharing and Other Limitations on Risk Bearing Provider Networks}, § 2300:101 (BNA'S \textit{HEALTH LAW & BUS. SERIES} No. 2300, 1996) (citing Katharine R. Levit et al., \textit{National Health Spending Trends 1960-1993}, 13 \textit{HEALTH AFFAIRS} 14 (1994) ("In 1960, $27.1 billion was expended in the U.S. for health care services, compared to $884.2 billion in 1993"); \textit{but see} Clark C. Havighurst, \textit{Contract Failure in the Market for Health Services}, 29 \textit{WAKE FOREST L. REV.} 47 (1994) (Professor Havighurst finds much of the evidence regarding health care overspending to be inconclusive.).
Health care legal advisors are often called on to rationalize and synthesize these conflicting laws and policies while assisting clients to meet current market demands in developing competitive integrated delivery systems ("IDS"). This article explores the myriad of laws and regulations that affect integrated delivery systems development and proposes a practical approach for reconciling conflicting laws and policies. Some legal practitioners may recognize the proposed method as the process they already follow. For others, the suggestions in this article will hopefully challenge them to see conflicts of law and policy as opportunities to engage in creative thinking.

Part II of this article provides an overview of the models being used to develop integrated delivery systems and briefly discusses the continuum of integration. Part III proposes a businesslike framework for resolving and synthesizing conflicting laws and policies in the context of hypothetical IDS that is used to illustrate certain conflicts. Part IV provides an overview of the laws, regulations, and public policies implicated in developing an IDS. Using the example IDS and other integration models, Part V identifies and analyzes several conflicts created by existing laws and regulations.

II. INTEGRATED DELIVERY SYSTEMS

A. The Impetus For the Development of the Integrated Delivery System

Due to the aging of the baby-boom generation and the ever-increasing costs of health care, both public and private payers are concerned they will be unable in the future, as they have in the past, to provide basic health care coverage to older Americans. Although the federal government has been unsuccessful to date in passing comprehensive health care reform legislation, the private sector (motivated in part by the fear that the government will become overly involved in the restructuring of the health care system if the private sector fails to implement reform) continues to restructure in order to address the dual concerns of cost and quality.

As a result of the governmental attention and industry initiatives, many Americans are now familiar with the terms managed care or managed competition. The managed competition theory has been associated recently with the Clinton administration's efforts to develop and implement reform legislation.\(^5\) Under managed competition, consumers are given a wide range of enrollment options among different private health plans which compete in the marketplace to provide the maximum value for the subscriber's dollar.\(^6\)


\(^6\)See Catherine T. Dunlay & Peter A. Pavarini, Managed Competition Theory as a Basis for Health Care Reform, 27 AKRON L. REV. 141, 142 (1993). (The managed competition theory posits that costs will be controlled because the consumer will have choices among these competing plans. The primary goals under managed care and managed competition policies are to increase the quality of health care services and at the same time reduce (or at least slow the increase of) the overall cost of health care.)
Both the configuration and competitiveness of gestational IDSs are critical to the success of this market-oriented approach to reforming. Competitive reformers believe that IDS's will constitute the organizational framework for controlling health care costs in the managed competition environment. First, IDS's will develop governance mechanisms and incentive systems to control provider behavior. Second, competitive interaction among rival systems will ensure that systems do not stray from the goal of cost containment.

An IDS is an organization that furnishes patients with all levels and types of health care services from affiliated providers and that clinically integrates through coordinated case management and inter-provider information systems. The movement towards an integrated industry includes affiliations and alliances among physicians and hospitals (and in some instances insurers) as market forces cause previously fragmented providers to consolidate. An IDS typically involves the merger of physician and hospital services in an effort to align economic incentives often under a common parent or system.

IDS's often provide a package of hospital, physician, and ancillary health services designed to offer payers one stop shopping for all their health care needs and a single entity to engage for managed care contracts. To succeed in today's managed care environment, the system must assist the patient in making an informed health care decision and provide the service in an efficient, economical manner. The more common integration models for physicians

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7Thomas L. Greaney, National Health Care Reform on Trial, 79 CORNELL L. REV. 1507, 1508 (1994) (The term "integration" refers to the creation of clinical and economic relationships between providers in an effort to increase the availability, efficiency and quality of services as well as decrease the cost of services.).

8Id.

9See Carl H. Hitchner et al., Integrated Delivery Systems: A Survey of Organizational Models, 29 WAKE FOREST L. REV. 273 (1994); see also Woodhall, supra note 3, at 184. (Clinical integration occurs through the integration of health services delivered by the system from the patient's viewpoint. Economic integration occurs by developing linkages among the providers in the health care system through common ownership, governance and management. Functional integration occurs through common strategic planning and quality improvement.).

10Id.


12Hitchner et al., supra note 9, at 274.

13Id.

14Demetriou & Dutton, supra note 3, at 1300:101-1300:102 (Recognized goals of integrated systems include managed care contracting directly with payers; providing direct health care services to patients; accepting some risk for the costs of services to be provided; developing information systems to manage risk; conducting utilization review and quality assurance; developing joint treatment protocols and standards to improve the delivery of care; creating efficiencies and economies of scale to reduce costs; and providing greater access to capital.).
and hospitals include physician-hospital organizations, management services organizations, medical foundations, fully integrated delivery systems and at the far end of the integration spectrum, integrated organizations that offer both a licensed insurance product as well as a full-service provider organization.  

B. Integration Strategies

1. Physician-Hospital Organizations

One of the least integrated of the models is the physician-hospital organization, or PHO. In this model, a hospital and a local group of physicians affiliate in an effort to attract managed care contracts. The PHO may be formed as a separate legal entity, or the relationship may be purely contractual. The PHO provides certain basic managed care organization functions including the negotiation of managed care contracts, utilization review and quality assurance.

The PHO may have authority to enter into managed care contracts with payers which require the PHO’s physician and hospital members to provide services to the payer’s plan beneficiaries. Unlike other integration models, the PHO is not directly responsible to the payer for the delivery of the services. Additionally, PHOs are often not substantially capitalized by its members as the hospitals and physicians do not contribute their assets to the PHO.

2. Management Services Organizations

The management services organization, or MSO, provides management services to physicians or physician groups. MSOs are typically affiliated with an IDS or hospital system and may be operated as a service of a hospital or a wholly owned subsidiary of the hospital. They are often investor-owned or

15A complete discussion of the various forms and levels of integration is beyond the scope of this article. Each model offers varying degrees of clinical and economic integration. The form of the IDS varies as a function of the business realities of the situation tempered by existing federal and state legal constraints which make it difficult to categorize with any precision all the models being used. Conflicts, however, are inherent in varying degrees regardless of the model chosen. See Demetriou & Dutton, supra note 3, at 1300:102-1300:107 (discussing the various integration models in use today; see also Hitchner et al., supra note 9, at 274).

16Id.

17Managed care contract refers to any contract with a payer to provide services at a contract rate that includes some type of risk sharing for the delivery of services by the provider. Common forms of risk sharing include significant financial withholdings of premium amounts which are divided by the providers and if certain cost incentives are reached and capitation whereby providers are typically given a per-member-per-month amount to provide all the contract services to the plan beneficiary.

18Demetriou & Dutton, supra note 3, at 1300:103.

19Id.
jointly owned by hospitals and physicians. The MSO may be organized as a corporation, a partnership, a nonprofit corporation, or a limited liability company.

MSOs can be organized to offer complete "turnkey" management services to physicians, or physicians can be given the option of selecting various services as needed from a menu of management services provided by the MSO. The primary advantages of the MSO model for physicians is that MSOs relieve physicians of their day-to-day administrative burdens, and the physicians continue to establish their own compensation and retirement plans.

3. The Foundation Model

In the foundation model, the attributes of the PHO and the MSO are combined. The foundation can be established as a nonprofit corporation. It may own and operate one or more large clinics that offer complete ambulatory care, including both primary and specialty physician services. Foundations may employ physicians directly or staff facilities with independent contractor physicians. The foundation may be independent, affiliated with a hospital, or part of a larger IDS. A hospital or hospital system is typically the sponsor and owner of the foundation.

Like the PHO, the foundation provides managed care contracting, utilization review and quality assurance, and like the MSO also provides management services and a vehicle for acquiring physician practices. The primary difference between the foundation model and the lesser integrated models is the foundation contracts directly with payers to provide comprehensive health

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20 Hitchner et al., supra note 9, at 274. Hitchner and his co-authors posit that an MSO is subject to several definitions and understandings of its meaning and also may be referred to as a managed service organization or a medical services organization. In turnkey MSOs, the MSO acquires the physician's practice assets and agrees to employ all of the practice's non-physician personnel. The physicians, however, continue to own their own practices and the revenues generated thereby. The primary advantage to the IDS is that the MSO can be used to induce physicians to participate in the IDS. Like the PHO, the MSO can negotiate managed care contracts on behalf of the physicians it serves. Moreover, physicians can be encouraged to participate in the IDS through "lock-in" covenants in the MSO's management and acquisition agreements. Post-termination covenants including non-compete agreements, asset buy-back provisions and retention of office space agreements can be used by the MSO to discourage physicians from terminating the MSO and therefore from disassociating with the IDS. Id.

21 Id.

22 Demetriou & Dutton, supra note 3, at 1300:104.

23 Id.

24 Hitchner et al., supra note 9, at 297.

25 Id. at 297-98.
care services to the payer's plan beneficiaries. Physician groups and hospitals become subcontractors to the foundation to provide the health care services to beneficiaries.

4. The Fully Integrated Model

In a fully integrated system, physicians and hospitals consolidate their assets under common ownership held by hospitals, physicians, investors, or a combination of any of the above. Physicians can be employed directly by the IDS or in states like Ohio that continue to follow the corporate practice of medicine doctrine, physicians can be employed through an IDS-controlled clinic. The providers in the IDS are under common governance and control by one board which ensures the alignment of the providers' economic and other incentives. The IDS can be organized as a taxable, for profit entity or a tax-exempt, nonprofit entity.

5. Payer-Provider Model

The payer-provider model, as its name implies, combines the financing of health care with the delivery of care. This model is like the fully integrated model in that the providers of health services are integrated under a common parent; however, this model also includes an insurance component that can be directly marketed to consumers. The payer-provider model is often formed when an HMO acquires a health care delivery system or when a provider system organizes as either a staff or group model HMO.

26 Demetriou & Dutton, supra note 3, at 1300:105 (Because the foundation contracts directly with payers to provide services, the foundation owns the managed care contracts and can internally divide the managed care revenues with and create risk pools for the subcontract hospital and physician providers. This direct contracting function can subject the foundation to state insurance regulations if the foundation assumes the insurance risk, as defined under state law, of providing health care benefits to the plan's beneficiaries.) Id.

27 Id. As discussed further in Part III, tax-exemption raises several issues for the IDS or its members including limitations on physician representation on the governing board and physician ownership of the IDS. The benefits of tax-exemption include access to capital at favorable rates through the tax-exempt bond market and savings from the avoidance of federal and state taxes. Id.

28 Id. at 1300:106. If the IDS is formed as a for profit entity and a nonprofit, tax-exempt hospital or other entity contributes assets, issues concerning the conversion of charitable assets to for profit uses and the private use of tax-exempt financed facilities must be analyzed. Id.

29 Hitchner et al., supra note 9, at 302.

30 Demetriou & Dutton, supra note 3, at 1300:106 (The staff model HMO is one in which the physicians are employed by the HMO, while under the group model, the physicians belong to a group that is affiliated with the HMO.).
III. FRAMEWORK FOR RESOLUTION

A. The IDS

The first step in the conflict resolution process set forth below is to identify the client's objectives for the transaction. For purposes of discussion, assume that a nonprofit, tax-exempt hospital client and a group of physicians are considering developing an IDS formed as a limited liability company.

The hospital client is concerned with developing an IDS that will improve the health care services delivered to residents in its primarily rural service area. The hospital's board desires that the IDS be subject to local control and sustain a community orientation consistent with the hospital's tax-exempt purposes. The board wishes to provide health care that is accessible, affordable, and state of the art to prevent further out-migration of the hospital's patient base.

The hospital's payers would like the hospital to assume risk under managed care contracts. Although the hospital board wants to maintain some control over the IDS, it recognizes that physician participation, especially primary care physicians, is critical to the success of the IDS in a managed care environment. With these objectives in mind, the hospital board and the physicians in the community are considering the development of an IDS. The IDS will engage in such things as managed care and traditional fee-for-service contracting, health care services delivery, risk sharing among providers, information systems development, utilization review, quality assurance, and the development of joint treatment protocols.

The hospital will own 50% of the Class A membership interests and the physicians will own the other 50% of the Class A membership interests. The hospital will also own all of the Class B membership interests. The Class B membership interests will be created to give the hospital a preferred interest in profits and liquidating distributions in return for the hospital providing the bulk of the capital for creating the IDS.

The governing board will consist of ten managers. Five managers will be elected by the physician Class A members, and five managers will be appointed by the hospital board. Ordinary IDS board actions require the approval of both the physician managers and the hospital managers with each group voting as a class. The affirmative vote of 3 of the 5 managers in a class of managers is required to approve an action. If the classes are deadlocked on a strategic issue, the Class B member's vote will break the deadlock.

A professional corporation would be formed to employ or contract with individual physicians to provide physician services to the IDS. The IDS will enter into services agreements with both member and non-member physicians as well as the hospital and the physician corporation. These agreements authorize the IDS to engage in contracting on behalf of the member and bind the participants to the IDS's clinical protocols. Physicians may also participate

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31 Defined as an issue that will affect the continued viability of the entity as an ongoing business concern (e.g., merger, large expenditures, sale of assets, dissolution).
in other provider networks, but currently no other networks are forming in the area.

Compensation arrangements for physicians will be developed to emphasize efficiency and eliminate unnecessary services. Productivity bonuses will be provided based on patient satisfaction surveys, achievement of cost goals, provision of charity care, and productivity.

B. Resolving Conflicts

Although each of the integration models discussed in Part II provides unique legal challenges, the hypothetical IDS will be used to illustrate certain conflicts. One of primary challenges facing legal counsel to the IDS is to develop a strategy for reconciling conflicts in a manner that not only satisfies the client, but also satisfies conflicting legal requirements.

1. Traditional Conflicts Resolution

Courts continue to be the final arbiter in resolving conflict of law issues whenever a state's legislature has not done so by specific mandate. Legislators and regulatory agencies, however, because of a lack of time and resources, may not anticipate or consider how various regulations and policy decisions affect the application of other existing laws and regulations. Accordingly, courts are often left to their own devices in resolving conflicts. The conflicts of law problem is exacerbated as the influence of the administrative state will continue to grow in the future.

The rules and doctrines courts follow to resolve conflicts have been described as confusing, unpredictable, and even incoherent. Conflicts doctrines typically address the resolution of conflicts between the laws of two separate sovereigns, often two states. Under traditional rules, the state where the last significant event concerning the dispute occurred is often the state whose law controls. If the conflict involves federal and state law and an actual conflict exists such that compliance with both is not possible, federal law prevails under the supremacy clause. Federal law also prevails if the state law stands as an

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33 *Id.* at 985. (This theory is often referred to as the vested rights doctrine).

34 One classic conflict of law example is in tort law. If a resident of State A is injured by a product manufactured in State B, does State A or State B's law control assuming they are in conflict? If State A's law favors recovery and State B's does not, a court's determination becomes crucial to the outcome of the case. Courts decide what law to apply based on various conflicts of law rules and doctrines.

35 Trachtman, *supra* note 32, at 999.

36 U.S. Const. art. VI, cl. 2. "This Constitution, and the laws of United States ... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or laws of any State to the Contrary notwithstanding."
obstacle to the accomplishment and execution of the full purposes and objectives of the federal scheme[37] or if Congress has expressly or implicitly preempted the field.[38]

The implicit preemption doctrine derives from the supremacy clause and provides that federal law preempts state law if a federal regulatory scheme is so pervasive that Congress left no room for the States to supplement federal regulation of the field.[39] Preemption only applies, however, in limited situations and only if compliance with both federal and state law is impossible.[40]

Traditional doctrines and rules may not be helpful to counsel in resolving conflicting laws or policies in IDS development, however, because many of the identified conflicts occur between two federal laws or policies. Only limited guidance exists regarding the courts' resolution process for conflicts among two federal laws or policies. One approach may be to determine if any federal agencies have considered the conflict. Courts may be inclined to defer to agency discretion[41] unless the interpretation is contrary to the plain meaning of the statute or the court believes resolution of the conflict is outside the agency's area of expertise.[42]

Courts have also said that one federal law cannot violate another federal law and that if two federal laws are in irreconcilable conflict, the later one merely repeals the earlier law.[43] Other courts have used a sort of balancing test to resolve conflicting laws and policies.[44] One theory that has been discussed in the context of resolving conflicts among separate sovereigns may, by analogy,

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[38] A good example of Congressional express statutory preemption of a field is in the area of the ERISA laws. See 29 U.S.C. § 1144(a).


[41] See Sullivan v. Everhart, 494 U.S. 83 (1990) and K Mart Corp. v. Cartier, Inc. 486 U.S. 281 (1988) (as examples of situations where the Rehnquist court has deferred to agency interpretations of statutes the agency administers). There is also a strong presumption in the law that an agency's interpretation of its own regulations is correct. Mullins Coal Co. of Virginia v. Director, OWCP, 484 U.S. 135 (1987). Whether this presumption extends to an agency's interpretation of the interaction between its statute and another's is debatable.


[44] See Trachtman, supra note 32, at 1011. (Professor Trachtman describes Professor Leflar's Better Law Factor approach as a balancing of interests test that courts use to resolve conflicts of law).
provide insight as to how a court could resolve conflicting law or policy between agencies of the same sovereign.

This theory involves the weighing of the conflicting policies pursuant to certain principles, which are set forth below under step four in the recommended approach. The law which reflects the more important of the two policies is chosen by the court (or by counsel providing pre-transaction analysis) as the law that must be observed.

2. Recommended Approach

Although traditional conflicts theory may not provide all the answers, a review of this theory helps to identify certain principles counsel can follow when resolving conflicts in IDS development. At the front end of the transaction, it is always better to avoid potential agency challenges to the IDS structure and its activities rather than risk litigation that may provide a resolution to the conflict but only after the expenditure of great time and expense.

Many conflicts can be reconciled if counsel follows a systematic approach in analyzing the potential problem. In some situations, counsel may ask the IDS’s developers to modify the proposed IDS structure or transaction in a way that harmonizes the conflicting laws but is also consistent with the client’s objectives. The following outline sets forth one approach which counsel can follow when faced with conflict of law situations.

1. Analyze the structure and the goals for developing the IDS or engaging in the particular transaction based on the client’s description of the proposed activity.
2. Identify the legal issues involved in developing the IDS and the apparent conflicts in law or policy.
3. Reconsider and prioritize the client’s objectives in developing the IDS in light of the conflict and any legal barriers created by the conflict.
4. Promote the more important law or policy after considering the relative importance of the conflicting laws and their underlying policies according to the following principles:
   a. a law or policy that is strongly held by the legislature should be encouraged;
   b. choose an emerging law or policy over one embodying an outdated or regressive policy;
   c. specific laws and policies have priority over more general ones; and
   d. select the law best designed to effectuate an underlying policy.45

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45See Eugene F. Scoles & Peter Hay, Conflict of Laws, § 2.8 (1984). (These principles have been set forth as guidelines that courts may use in weighing and comparing of the merits of two conflicting law’s underlying policies. These principles
5. Reconfigure the IDS's business arrangement after considering:
   a. any exceptions to the law or regulation at issue;
   b. agency interpretations concerning the transaction at issue or similar transactions such as advisory opinions, business review letters, and private letter rulings; and
   c. alternative organizational structures or operational arrangements that not only accomplish the client's goals but also meet the legal requirements of the laws or policies implicated.

6. If a particular conflict cannot be reconciled in this manner, determine and comply with the law that will allow the client to satisfy its most important objectives and advise the client regarding the legal risks associated with satisfying lesser objectives.

IV. REGULATORY OVERVIEW OF LAWS AFFECTING IDS DEVELOPMENT

A. Federal Tax Laws

Laws relating to tax-exempt organizations are often implicated because the IDS may seek tax-exemption or, like the hypothetical IDS, the driving force behind the development of the IDS is the sole tax-exempt, nonprofit hospital in the community. Historically, nonprofit hospitals have been given tax exemption because they provide charitable health care services to the indigent. To achieve tax exemption, the IDS or the hospital must generally be organized to promote the health of the community and be operated for charitable purposes as defined by IRS regulations and agency interpretations.

No part of the tax-exempt's net earnings may inure to the benefit of any private individual or shareholder, the exempt organization may only serve public rather than private interests, and any private benefit conferred must only be incidental. These requirements are commonly referred to as the "private inurement" and the "private benefit" prohibitions.

are suggested as analytical tools only. It is very difficult if not impossible, to determine how a particular court might in the future reconcile conflicting policies.)

46 See John R. Washlick, Nonprofit Healthcare Organizations: Federal Income Tax Issues, 873 TAX MANAGEMENT PORTFOLIOS, p. A-2 (Tax Management Inc., 1996). (Providing such health services has long been considered a charitable purpose under the general law of charitable trusts. Although modern hospitals generally receive some form of reimbursement from the government for providing care to the financially needy, the availability of private entities willing to provide services to needy persons is of concern to the government and provides a strong justification for the exemption.); see also Nina J. Crimm, Evolutionary Forces: Changes in For-Profit and Not-For-Profit Health Care Delivery Structures; A Regeneration of Tax Exemption Standards, 37 B.C.L. REV. 1 (1995).

47 I.R.C. § 501(c)(3); Treas. Reg. § 1.501(a)-1(c).


If a tax-exempt hospital contributes assets to the IDS, the hospital must consider the conversion of some or all of its assets from charitable to for profit uses which do not warrant exemption. Not for profit conversions have received increased scrutiny by the Attorneys General of several states. Any violations of the aforementioned doctrines could result in the hospital participant in the IDS losing its exempt status or the IDS itself failing to attain exempt status.

Instead of revoking the tax-exempt status of an organization, the IRS may now impose intermediate sanctions against "disqualified persons" who engage in "excess benefit" transactions with exempt organizations. Disqualified persons are insiders to the tax-exempt organization who exercise substantial influence over the exempt organization. Penalty excise taxes may be imposed in the range of 25% to 200% of the excess benefit.

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1986); Gen. Couns. Mem. 39,598 (Dec. 2, 1986). (The I.R.S. has developed a two-part test for determining compliance with private inurement prohibition. First, the non-exempt person participating in the transaction must be a shareholder or a person with a personal or private interest in the activities of the exempt organization. Second, the net earnings or benefit provided for the benefit of the private person must represent a dividend like benefit because the benefit is more than fair market value for any property given or more than reasonable compensation for services.).

50 See Gen. Couns. Mem. 37,789 (Dec. 18, 1978); Gen. Couns. Mem.39, 598 (Dec. 2, 1986); Gen. Couns. Mem. 39,862 (Nov. 21, 1991) (The I.R.S. has developed a two-part test for determining compliance with the private benefit prohibition. First, the private benefit provided by the transaction must be necessary in order to obtain the benefits to the public at large from the transaction. Second, the private benefit must be insubstantial in light of the public benefit conferred by the transaction.).

51 See Michael W. Peregrine, State Attorneys General Increase Enforcement of Charitable Trust and Fiduciary Duty Laws, HEALTH LAW DIGEST, v. 24, n.12, p.3 (December 1996) (Mr. Peregrine provides examples of actions in several states to enforce charitable trust and fiduciary duty laws as they apply to nonprofit health care corporations. State Attorney General actions have been initiated to block (a) the whole hospital joint venture in Michigan between Columbia/HCA and Michigan Affiliated Health care Systems, Inc. (b) the conversion of nonprofit assets to for profit uses through the sale of the assets of the tax-exempt Blue Cross/Blue Shield of Ohio to Columbia/HCA, and (c) the sale of community hospitals such as Boca Raton Community Hospital, Inc. in Florida); see also Ohio H.B. 824 (Rep. Van Vyven) and it companion Ohio S.B. 334 (Sen. Drake), and Ohio H.B. 825 (Rep. Netzley) (These three bills were introduced in the Ohio legislature on October 29, 1996. Generally, the proposed legislation requires public disclosure and hearings regarding the terms of the transaction and clarifies that the Attorney General must review and approve any proposed charitable asset conversion transactions.).


53 Id. Excess benefit transactions are defined to include any transaction in which an economic benefit is provided to, or for the use of, any disqualified person if the value of the economic benefit provided, directly or indirectly, by the organization to such person is greater than the value of the consideration (including the performance of services) received by the organization for providing such benefit. Excess benefit transactions also include any transaction, to the extent provided in Treasury Department Regulations (to be published), in which the amount of any economic benefit provided to, or for the use of, any disqualified person is determined in whole or in part
B. Anti-Kickback and Self-Referral Laws

The federal anti-kickback statute prohibits the offer, solicitation, payment or receipt of any remuneration, in cash or in kind for in return for, or to induce, the referral of a patient for any service that may be paid by Medicare or Medicaid. Remuneration has been defined to include almost anything of value and includes both direct and indirect offers or payments.

The primary consideration under the anti-kickback statute is whether the remuneration was paid or received as an inducement to refer. To find a violation of the statute, the inquiry necessarily turns on whether an intent to refer can be inferred under the circumstances. Unlike the Stark II laws discussed below where intent is irrelevant, if an exception or safe harbor to the anti-kickback statute is not completely satisfied, the transaction may not violate the statute unless the requisite unlawful intent is proven.

Federal law ("Stark I") prohibits physicians from referring Medicare and Medicaid patients to entities with which they have a financial relationship for the furnishing of "designated health services." The threshold inquiry under Stark I requires the revenues of the tax-exempt organization, provided the transaction constitutes prohibited private inurement under existing law.

54 42 U.S.C.A. § 1320a-7(b).

55 The statute has been interpreted quite broadly. In United States v. Greber, the court held that if one purpose of the payment made by an entity to a physician for services rendered was to induce future referrals to that entity, the statute is violated. 760 F.2d 68, 69 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). This holding has been narrowed by the court in The Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995). The court in Hanlester held that the anti-kickback statute requires the person (1) to know the statute prohibits offering or paying illegal remuneration and (2) to engage in prohibited conduct with the "specific" intent to violate the law. Id. at 1400. The District Court for the Southern District of Ohio has refused to follow Hanlester. In U.S. v. Neufeld, a physician accused of violations of the anti-kickback statutes argued that the statute was unconstitutional. 908 F.Supp. 491, 493 (S.D. Ohio 1995). The court refused to require that a specific intent to violate the statute be proven. Id. at 497. The court said that the mental state required to find a "willful" violation is sufficient if it "takes into account the purpose to commit a wrongful act." Id. The court recognized there is a heightened mental state requirement in the statute but refused to provide an exact definition of the standard. Although the intent required to violate the anti-kickback statute is unclear in light of Neufeld and other decisions, these courts may be signaling a movement away from Hanlester's specific intent requirement.

56 42 U.S.C. § 1395nn ("Designated Health Services" under Stark II include: clinical laboratory services; physical and occupational therapy services; radiology services including MRI; CAT and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients equipment and supplies; prosthetics; orthotics and prosthetic devices and supplies; outpatient prescription drugs and inpatient and outpatient hospital services).

A recent interpretation of the federal physician self-referral prohibition is a final rule issued by the Health Care Financing Administration ("HCFA") on August 14, 1995. Even though this rule specifically addresses only the referral prohibition concerning clinical laboratory services ("Stark I"), HCFA indicated that this rule also affects how
Stark II is whether designated health services are being provided. If designated health services are identified, the next inquiry is whether a financial relationship exists between the referring physician and the entity. A financial relationship exists if the physician has an ownership or investment interest in the facility or otherwise has a compensation arrangement with the entity.

The primary distinction between the two statutes is the situations they apply to and the scienter requirement for finding a violation of the statute. In many instances, both the anti-kickback and the Stark laws apply; however, the Stark law does not apply in every situation where the anti-kickback statute applies. Before Stark can be implicated in a transaction, physicians and designated health services must be involved. Additionally, the anti-kickback statute includes a scienter requirement whereas Stark could be violated regardless of the parties' intentions.

The anti-kickback laws and the Stark laws are designed to prevent the overutilization of services and to contain Medicare and Medicaid costs\(^5\). Providers who are compensated whenever they refer patients may have an incentive to overrefer, which increases utilization and overall costs to the government\(^5\). Other important goals are the preservation of competition and the freedom of patient choice\(^5\).

C. Antitrust

One of the most significant regulatory hurdles which an IDS faces is compliance with the antitrust laws. Both the federal and state statutes address antitrust issues. Under Section 1 of the Sherman Act, "[e]very contract, combination ... or conspiracy in restraint of trade or commerce among the several states ... is declared to be illegal ..."\(^6\)

Antitrust laws are enforced by both federal and state agencies,\(^6\) but the most significant enforcement occurs through federal agencies, namely the Federal

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\(^5\) Providers who are compensated whenever they refer patients may have an incentive to overrefer, which increases utilization and overall costs to the government.

\(^6\) Similar to the federal restrictions, Ohio's Valentine Act proscribes any combination of capital, skill or acts by two or more persons to create or carry out restrictions in trade or commerce. O.R.C. § 1331.01(B) (Baldwin Supp. 1997). Presumably, a provider
Trade Commission and the Department of Justice. Recent debate regarding the application of the anti-trust laws in the health care industry has centered around whether the laws have been applied to defeat necessary integration and consolidation occurring in the industry.\(^6\)

The policy that underlies the antitrust laws is the promotion of free and fair competition in the marketplace through the elimination of practices which interfere with such competition.\(^6\) The antitrust laws are designed to promote a vigorous and competitive economy in which each business enterprise has a full opportunity to compete on the basis of price, quality, and service, and consumers can choose among a variety of suppliers.\(^6\)

In developing an IDS, one of the primary antitrust concerns is always whether the IDS will restrict competition in the relevant market.\(^5\) Restricted competition can lead to increased prices, lower quality, reductions in services offered, or reductions in technological innovation.\(^6\) Depending on the participants in the network, these concerns may be heightened. For example, IDS's that result in horizontal integration among previously competing providers (e.g., the IDS includes only hospitals or a physician's group with substantially all of the physicians in the market) raise significant concerns because of the direct loss of competition.\(^7\)

network which complies with federal antitrust requirements will also comply with Ohio's Valentine Act. See Richter Concrete Corp. v. Hilltop Basic Resources, Inc., 547 F.Supp. 893, 920 (S.D. Ohio 1981), aff'd sub nom, Richter Concrete Corp. v. Hilltop Concrete Corp., 691 F.2d 818 (6th Cir. 1982).

\(^6\)See Frederic J. Entin et al., Hospital Collaboration: The Need for an Appropriate Antitrust Policy, 29 WAKE FOREST L. REV. 107 (1994) (Entin and his colleagues argue that the federal antitrust statutes, court decisions, and federal merger guidelines have created barriers to necessary consolidation in the hospital industry. The failure of the federal agencies to articulate a clear antitrust policy of enforcement for the health care industry also contributes to perceived, if not real, barriers to integration among hospitals.); but see David L. Meyer and Charles F. (Rick) Rule, Health Care Collaboration Does Not Require Substantive Antitrust Reform, 29 WAKE FOREST L. REV. 169 (1994) (Meyer and Rule argue that federal antitrust laws and current enforcement policy provide a great deal of flexibility for hospital and other provider collaboration and integration. They urge that sensible enforcement, not immunities or other special treatment, is the key to ensuring the health care industry continues to reform consistent with the antitrust laws.).

\(^6\)Phillip A. Proger et al., Health care Networks and Managed Care: Antitrust Aspects of Integration and Exclusion, at 2500:201 (BNA's Health L. & Bus. Series No. 2500).

\(^6\)Id.

\(^6\)Id. at 2500:401.

\(^6\)Id.

\(^6\)See, Proger, supra note 63. (If the IDS only results in vertical integration (e.g., the IDS consists of one hospital and one physician group with a small percentage of the physicians in an area), the IDS cannot reduce competition directly, but other issues might be raised. Proger and his colleagues point up that vertically integrated IDSs may raise concerns if the network affects competition between network and nonnetwork providers or the IDS may restrict the ability of competing networks to form.).
In analyzing horizontal networks, the federal agencies' major concerns involve agreements on price made by otherwise competing providers. The federal agency Policy Statements indicate that naked agreements among competitors that fix price or allocate markets are per se illegal. Courts have found through experience that certain types of conduct are per se illegal because they are so anticompetitive regardless of the surrounding circumstances that the court will not examine them in detail, and the court will presume the conduct is anticompetitive and unjustified.

Under the more flexible Rule of Reason analysis, the Agencies identify the markets where the network affects competition and determine if the providers' integration is likely to produce significant efficiencies that benefit consumers.

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68The Policy Statements indicate that if competing providers in a multiprovider network engage in joint pricing or marketing (e.g., the members collectively agree on prices or other significant terms of competition), such a joint decision must be related to significant economic integration among the providers. Sharing substantial financial risk evidences such economic integration. The Agencies have formally recognized four situations in which network members share substantial financial risk: (i) providing services to a health plan at a capitated rate (ii) providing services to a health plan for a predetermined percentage of premium or revenue (iii) providing significant financial incentives for network members to achieve specified cost-containment goals (e.g., compensation withholds or cost/utilization targets which may be distributed or used as rewards (or penalties) if goals are met), and (iv) using "global fees" or "all inclusive case rates" whereby the IDS agrees to provide a complex or extended course of treatment for a fixed, predetermined payment. See Policy Statements, supra note 60.

69"Combination[s] formed for the purpose and with the effect of raising, depressing, fixing or stabilizing the price of a commodity in interstate or foreign commerce" have been held to be illegal per se. Arizona v. Maricopa County Medical Society, 457 U.S. 332, 347, 73 L.Ed.2d 48, 60 (1982) (quoting United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 223, 84 L.Ed. 1129). In Maricopa, the Supreme Court held an agreement among competing physicians setting, by majority vote, maximum fees for payment from participants in specified insurance plans to be per se illegal. The physicians in Maricopa, however, were not financially integrated. A network that has no purpose other than to reduce competition among its participants will always be found to be per se illegal. See, e.g., United States v. Healthcare Partners, Inc., No. 395-CV-09146 RNL (D. Conn. Sept. 13, 1995) (consent decree).

70The Supreme Court has stated that a geographic market is the "area of effective competition." United States v. E.I. duPont de Nemours & Co., 353 U.S. 586, 593 (1957). The Agencies rely on their own "Horizontal Merger Guidelines" in defining relevant markets. A geographic market is defined as the area in which a hospital would be able to raise prices by a small but significant and lasting amount if it were the only hospital in that area. DOJ and FTC, Horizontal Merger Guidelines, § 1.0 (1992). Two recent hospital merger cases show that courts may be taking a more expansive view in defining relevant markets. In FTC v. Freeman Hosp., 69 F.3d 260 (8th Cir. 1995), aff"g 911 F. Supp. 1213 (W.D. Mo. 1995), the Eighth Circuit court of Appeals affirmed a district court finding that the relevant geographic market for a hospital located in Joplin, Missouri, included all parts of 13 different counties in Missouri, Kansas and Oklahoma. The court rejected the FTC's narrow view of the relevant market and concluded the more likely market included the area where consumers could practically turn for alternative care and included 17 hospitals up to 54 miles from Joplin in the relevant market. In United
If price or other agreements that would otherwise be *per se* illegal among network providers are reasonably necessary to realize those efficiencies, the network will not be viewed as being *per se* illegal. Rather, the network may be justified as being reasonably related to supporting the network’s procompetitive activities and therefore, not violative of the antitrust laws. The Agencies evaluate substance over form, however, and networks whose purpose is merely to impede or prevent competitive forces from operating in the market continue to be illegal.

**D. Corporate Practice of Medicine**

The corporate practice of medicine doctrine generally prohibits corporations from engaging in the practice of medicine by employing physicians who provide professional services on behalf of the corporation. Under this doctrine, corporations and other entities not controlled by medical professionals may not hold or otherwise exercise those rights that are vested only in licensed physicians. The policy behind the law is to prevent any tension

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States v. Mercy Health Services, a U.S. District Court in Iowa rejected the DOJ’s request to enjoin the merger of the only two hospitals in Dubuque, Iowa. 902 F. Supp. 968 (N.D. Iowa 1995) *vacated, remanded*, 107 F.3d 632 (8th Cir. 1997). The court defined the geographic market to include other competing hospitals that were as much as 100 miles away. Although this last case was appealed, it too shows that courts are now more perceptive to the dynamics of the modern health care industry and agree that patients are increasingly willing to travel reasonable distances to achieve cost-savings. After the relevant product and geographic markets are determined, the Agencies will analyze market share because high market shares will affect the ability of payers to switch among competing provider networks. Where other networks offering the same or similar types of services exist or could be formed, third party payers will have the opportunity to switch between networks if the network’s prices become too high or quality becomes too low.

*One of the major concerns addressed in the Policy Statements is that networks will foreclose competition by impeding the formation of competing networks. Networks which restrict the ability of members to participate in other networks or plans are more likely to be deemed anticompetitive. Indicia of a non-exclusive network include: (i) viable competing networks or plans with adequate provider participation in the market; (ii) members actually participate in other networks or contract individually with other payers, or are willing to do so; (iii) members earn substantial revenue outside the network; (iv) absence of substantial departicipation from other networks in the market; (v) absence of coordination among members regarding price or other competitively significant terms of participation in other networks or plans. Supra Policy Statements, note 56.*

*See Pacific Employers Ins. Co. v. Carpenter, 10 Cal. App. 2d 592, 595 (Cal. Dist. Ct. App. 1935) (In California for example, it has been stated as a general rule of law that a corporation may not engage in the practice of medicine directly or indirectly by “engaging [physicians] to perform professional services for those [who] the corporation contracts to furnish such services.”); see also Demetriou & Dutton, *supra* note 3, at 1300:701.*
between the professional standards and obligations of physicians and the profit motives of corporations.\textsuperscript{74}

The policy is based on the assumptions that (i) corporate involvement in the practice of medicine creates a potential for divided physician loyalty between the corporation and the patient; (ii) a lay person should not have control over medical decision making; (iii) a corporation lacks the ability to establish and maintain the trust requisite to the physician/patient relationship; and (iv) a corporation may concern itself more with profit levels than with the patient’s quality of care or personal well-being.\textsuperscript{75}

Many states have abolished the doctrine or do not enforce it, although some states, including Ohio, continue to observe the doctrine.\textsuperscript{76} Many states have statutory exceptions which allow professional corporations or associations, non-profit health organizations,\textsuperscript{77} and foundations\textsuperscript{78} to employ or make other arrangements with physicians so that the corporation or other entity can hold itself out as a provider of medical services.\textsuperscript{79}

\textbf{E. Employee Benefits}

The organizers of the IDS, as well as its participants, may become subject to the IRS’s \textit{aggregation} rules which would require that the separate employee benefit plans among the IDS participants be treated as a single employer for purposes of determining if the separate plans qualify for favorable tax treatment. Generally, to receive favorable tax treatment as a qualified plan, the single employer’s benefits plan must not discriminate against lower paid employees with respect to eligibility or benefits in favor of highly compensated employees.

\textsuperscript{74}Id.


\textsuperscript{76}See, e.g., OHIO REV. CODE ANN. § 4731.41(B) (Baldwin Supp. 1997); TEX. REV. CIV. STAT. ANN. art. 4495b, §§ 3.08(12) and 3.08 (15) (Vernon’s 1997); CAL BUS. & PROF. CODE § 2400 (West Supp. 1997).

\textsuperscript{77}OHIO REV. CODE ANN. § 1785.01 (Baldwin Supp. 1997); TEX. REV. CIV. STAT. ANN. art. 1528f, §§ 2 and 9 (Vernon’s 1997).

\textsuperscript{78}TEX. REV. CIV. STAT. ANN. art. 4495b, § 5.01 (Vernon’s 1997).

\textsuperscript{79}CAL BUS. & PROF. CODE § 2032 (West Supp. 1997).

\textsuperscript{80}In those states that follow the doctrine, care must be taken to ensure that the IDS meets one of the exceptions to the doctrine or is structured to avoid violating the prohibition. Some of the factors to consider in determining whether the doctrine applies include the following: (i) whether the corporation (or other form of entity) influences the physician’s freedom to make clinical decisions; (ii) whether the corporation employs physicians; (iii) whether any unreasonable fee splitting arrangements may occur; and (iv) whether the corporation holds itself out to the general public as a provider of medical services.
If the IDS contracts with, rather than employs, physicians or a physician's group to provide physician services, the physicians or physician's group and the IDS may be treated as an affiliated service group or a controlled group. If so, these otherwise legally separate groups will be treated as a "single employer" for purposes of applying the minimum participation, coverage and non-discrimination tests.

F. Insurance Regulations

As IDSs become more financially integrated and combine traditional payer functions with delivery of service functions, IDSs begin to resemble health insurance companies. Health insurers are subject to a myriad of laws and regulations primarily at the state level.

Lawmakers are concerned primarily with ensuring that insurers remain sufficiently capitalized to avoid insolvency and leaving plan subscribers without health care coverage. To protect consumers, states typically require that insurance companies maintain substantial capital reserves and submit a hefty deposit to the state's department of insurance. The concern is particularly acute for provider run organizations because their experience in actuarial matters may be insufficient to accurately determine what level of premium is required to cover a particular risk. Like regulations for health insurers, HMO regulations are designed to protect the HMO's members by ensuring that the

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81 I.R.C. § 414(m)(2), (5).

82 See I.R.C. § 414(c) (discussing different types of controlled groups).

83 I.R.C. §§ 414(b), 414(c), 414(m) (Under the minimum participation test, at least 70 percent of an employer's non-highly compensated employees must be covered by the plan, or the percentage of non-highly compensated employees covered by the plan must be at least 70 percent of the percentage of highly compensated employees covered by the plan. If the plan does not pass the minimum participation test, it can still be a qualified plan if it passes the coverage test. Under this test, the plan is qualified if i) the contributions or benefits provided under the plan do not discriminate in favor of highly compensated employees and ii) the average benefit percentage for non-highly compensated employees is at least 70 percent of the average benefit percentage for highly compensated employees.).

84 Jordan supra note 4, at 2300:206-07 (Health insurers are mostly regulated at the state level. However, HMOs that contract to provide coverage to Medicare enrollees are subject to various federal regulations. Likewise, self-insured employers that sponsor health plans for their employees are subject to ERISA laws. ERISA preempts state regulation of these health plans.).


86 Jordan supra note 4, at 2300:204-05 (Insurance laws vary from state to state but some common areas of state regulatory interest include: i) the organizational structure of the insurer; ii) a review of the insurer's financial statements and financial capability; iii) propriety of reserves and investments; iv) adequacy of proposed premiums; v) policy forms and other material distributed to consumers; and vi) sales practices and advertising.).
HMO remains financially solvent and able to deliver care as promised to the member.87

Determining who engages in the business of insurance for purposes of applying insurance laws is often debatable, unless an IDS is clearly organized as an HMO or otherwise offering a health plan directly to payers. Health care insurance risk undoubtedly involves some acceptance of responsibility for future losses.88 For many IDSs, however, the applicability of insurance regulations is unclear. State regulators are taking a close look at health organizations to see if they are acting as insurers by accepting the financial risk of delivering care.89 Some states, including Ohio, have proposed or passed legislation to clarify how insurance regulatory concepts apply in the context of managed care.90

87 \textit{id. at 205} (Typically, states attempt to regulate HMOs in the following areas: i) form of entity and governing body provisions; ii) capital reserve and other financial requirements; ii) quality assurance; iv) sales and marketing to members; and v) member and provider grievances.).

88 Jordan \textit{supra} note 4, at 2300:201.

89 \textit{See generally id. note 85 at 2300:3106, Working Papers Section} (In Ohio, the Department of Insurance reviews several factors that are outlined in a letter dated July 28, 1994 from the State of Ohio Department of Insurance to the Ohio Hospital Association, \textit{reproduced in} the Working Papers Section. The Department review the following factors in determining whether an entity is engaged in the business of insurance: i) whether the insured has an insurable interest; ii) whether the insured's interest is subject to a risk of loss upon the happening of some outlined peril or contingency; iii) whether the insurer assumes the risk of loss; iv) whether the assumption is part of a scheme to distribute the losses among a group with similar risks; v) whether the insured pays a premium as consideration for the insurer's promise to pay; vi) whether the risk of loss is transferred and spread; vii) whether the practice is an integral part of the policy relationship between the insurer and the insured; and viii) whether the insurance is an integral part of the policy relationship between the insurer and the insured.).

90 The Ohio Department of Insurance unveiled a legislative proposal in 1996 which was adopted by the Ohio Legislature and is codified in Title 17, Chapter 51 of the Ohio Revised Code. This law makes Ohio one of the first states to authorize a uniform system of licensure for all managed care entities. This initiative regulates certain managed care entities that were not previously within the Department's jurisdiction, including preferred provider organizations, physician hospital organizations, and point-of-service plans. According to David Randall, Deputy Director for the Department of Insurance, "The purpose of the act is to capture within the scope and jurisdiction of the Department the financial regulation and oversight of all ... organizations which engage in what amounts to the business of insurance." The law requires managed care organizations which accept risk for payment or delivery of services under a subscriber contract to obtain a certificate of authority from the Department to conduct business in Ohio (the same licensure now required for HMOs). Managed care organizations that offer both basic and supplemental services must have total admitted assets equal to at least 110% of liabilities and a net worth not less than $1.5 million. In addition, the Health Insurance Corporation must maintain a deposit with the Superintendent of Insurance or an approved custodian of not less than $400,000. On the other hand, organizations which do not bear risk, but which merely market their services on a purely discounted
G. Reimbursement regulations

One of the most significant limitations to the formation of any IDS is the regulations and agency interpretations governing reimbursement for services provided to Medicare and Medicaid recipients. There are two primary issues to address in developing the IDS: i) whether the IDS can qualify to receive a Medicare provider number; and ii) whether the IDS can take reassignment of a physician’s right to Medicare or Medicaid reimbursement pursuant to one of the exceptions to the reassignment prohibition.91

Generally speaking, beneficiary’s may assign their right to reimbursement to physicians or other providers of service (e.g., physician groups, hospitals, or other recognized suppliers).92 However, if a provider is entitled to receive assignment, there are only limited instances when the provider may reassign that right to a third party.93 This limitation was implemented to discourage factoring whereby the provider would assign its right to reimbursement to a third party at a discount. Congress found these arrangements abusive, and decided to eliminate the activity.94

If the IDS qualifies as a Medicare provider, it can accept assignment directly from a beneficiary.95 Otherwise, the IDS may be able to receive Medicare reimbursement if individual providers in the IDS are authorized to reassign their rights to reimbursement.96 Medicare will pay reassigned benefits to health care delivery systems,97 a physician’s employer,98 and an inpatient facility where services are delivered.99

V. IDENTIFYING AND RECONCILING CONFLICTING LAWS AND POLICIES

After considering the IDS clients objectives and reviewing the laws applicable to the IDS’s development, counsel to the IDS begins identifying and reconciling any conflicting laws and policies. Although the recommended approach sets forth a series of steps in an ordered sequence, the process is fluid.

fee-for-service basis, will be required only to register with the Department (a process which is significantly less involved than obtaining a certificate of authority).

91 Demetriou & Dutton, supra note 3, at 1300:701.
92 42 C.F.R. Part 424, Subpart D.
93 42 C.F.R. § 424.73(a).
94 See Medicare and Medicaid Guide § 14,925 (CCH) (“Factoring” or the sale of accounts receivable to a third party collection organization led to fraud and abuse and is, therefore, prohibited through the Medicare and Medicaid reassignment rules).
95 Demetriou & Dutton, supra note 3, at 1300:901, n. 9.
96 Id.
97 42 C.F.R. § 424.80(b)(3).
98 42 C.F.R. § 424.80(c).
99 42 C.F.R. § 424.80(b)(3).
Certain steps may be taken out of order or not at all, as applicable. Counsel should, however, attempt to comply with each of the laws or policies implicated before resorting to step six or recommending that the client avoid the transaction or activity. Accordingly, this article focuses primarily on steps four and five in resolving any conflicts. The ensuing discussion provides but a few examples of this process.

A. Employing Physicians

1. Corporate Practice v. Employee Benefits

   a. The Conflict

   In order to fulfill its obligations under managed care contracts, an IDS must provide or arrange for the provision of a variety of physician services. An IDS, like the one described in Part II, may have a physician group organized as an independent practice association ("IPA") affiliated with it to provide these services. IPAs may be formed as an independent network of physicians or the IPA itself may be associated with other types of providers to form an IDS. In forming IPAs, the corporate practice of medicine doctrine and the employee benefits laws may conflict if the physicians members of the IPA desire to maintain employee benefits packages in addition to those of the IPA.

   The corporate practice of medicine doctrine prohibits corporations from providing medical services unless the corporation is controlled by licensed physicians. The doctrine therefore encourages physicians to form physician groups as professional corporations. An IPA established as a professional corporation could, therefore, employ its physician owners and employ or contract with other physicians to provide services to the IPA's managed care patients.

   Pursuant to the Employee Retirement Income Security Act, the IPA formed as a professional corporation and its physician owners might be treated as a single employer in determining whether the IPA physician owners' employee benefit plans qualify for favorable tax treatment. As a single employer, the physician owners' separate plans could be aggregated to determine if the separate plans meet the nondiscrimination tests.

   If the physicians are willing to forego their separate retirement plans upon joining the IPA, this conflict is not an issue. On the other hand, if the physician owners of the IPA wish to maintain equity participation in the IPA and maintain

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100 See supra text accompanying notes 73-80.
101 See supra text accompanying notes 81-83.
102 See I.R.C. §§ 404(a), 402(a) and 401(a). Some of the ramifications for unqualified plans are: (i) contributions are taxed to the employee in the year in which they vest; (ii) the earnings of the trust holding the assets of the plan are taxable; and (iii) distributions are not eligible for certain favorable income averaging rules or IRA rollovers.
separate retirement plans, compliance with the two bodies of law creates a conflict.

b. Reconciling the Conflict

To give physicians certain benefits of ownership as well as avoid the aggregation issues, some commentators advocate establishing the IPA as a nonprofit mutual benefit corporation. Under this approach, the IPA's physician members can participate in liquidating distributions but cannot participate in profit or dividend distributions. In states where the only exception to the corporate practice ban is the professional corporation, this approach may not work however.

An argument can be made that such a nonprofit corporation does not violate the corporate practice ban because the structure comports with the policies that underlie the corporate practice prohibition. If only physicians are members of the entity, then arguably only licensed professionals will be delivering medical care. Likewise, if the entity is operated not for profit, then judgment concerning patient care decisions should not be clouded by profit motives.

Another way to reconcile this conflict is to establish the physician organization as a sole shareholder physician organization. Under this approach, all the physicians interested in participating in the IPA merely do so as independent contractors but not as equity holders. Independent contract physicians are at less risk than physician owners of being aggregated with the IPA as a single employer. Accordingly, physician contractors might be able to maintain separate qualified employee benefits plans for accumulating retirement assets.

Although this structure may reconcile the conflict between the corporate practice ban and the employee benefits laws, the sole shareholder model must be analyzed to ensure consistency with the IPA's and its physicians' objectives. For example, physicians may want to participate in the benefits of owning the IPA. Under the proposed structure, only the sole shareholder could receive dividends and liquidating distributions.

2. Corporate Practice v. Self-Referral

a. The Conflict

The potential for the IDS to employ physicians highlights another conflict with the self-referral laws. The physician self-referral laws generally would

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104 Id. at § 1200.04.B.3.1. (Grant et al. point up that the inability to distribute profits or dividends to the members is not an issue to the extent that the IPA distributes all of its earnings as compensation to its physicians.)

105 Id. at § 1200.04.B.3.a.

106 Id. at § 1200.04.B.
prohibit employed or independent contractor physicians from referring patients to the IDS or other providers within the IDS because of the physician's compensation arrangement with the IDS. If structured to comply with the anti-kickback safe harbor and the Stark law exception for employment or personal services arrangements, however, the physicians could refer patients to the IDS and its affiliated physicians.

The policy that underlies the self-referral laws, therefore, sanctions and encourages IDS development because the IDS can enter into employment arrangements with physicians provided the IDS does not provide the physicians financial incentives to overutilize services. This policy is directly in conflict, however, with the corporate practice of medicine ban which hinders IDS development by preventing the IDS from employing physicians. The ban has been strongly criticized as inappropriate in today's health care environment which is focused on cost containment rather than merely increasing profits through maximizing referrals.

b. Reconciling the Conflict

One approach to reconciling this apparent conflict is for the IDS to establish effective control over an affiliated physician organization which has been formed as an entity not subject to the corporate practice of medicine ban (e.g., a professional corporation, a foundation in California, a nonprofit health corporation in Texas). The controlled entity then employs the physicians.

107 42 C.F.R. § 1001.952(i) (employee safe harbor) and 42 C.F.R. § 1001.952(d) (personal service safe harbor).

108 42 C.F.R. § 411.357(c) (employee exception) and 42 C.F.R. § 411.357(d) (employee exception).

109 These regulations generally require a bona fide arrangement exists whereby the physician receives fair market value for the services, and the compensation arrangements are not based on the volume or value of referrals.

110 In the context of managed care, this policy is observed; however, physicians are now being regulated to discourage underutilization which may occur under managed care physician compensation methodologies.

111 See supra text accompanying notes 77-80 for a discussion of various statutory exceptions to the doctrine.

112 President Clinton's original Health Security Act recognized this problem and contained a provision which would have preempted corporate practice of medicine for certain managed care organizations. Unfortunately, this provision was not enacted in the final version of the bill. Hitchner et al., supra note 4, at 274; H.R. 3600, 103d Cong., 1st Sess. § 1407(b) "Any state law related to the corporate practice of medicine . . . shall not apply to arrangements between health plans that are not fee-for-service plans and their participating providers.

The physician owner of the separate entity is subject to a trust or share control agreement which gives the IDS authority to approve certain shareholder actions such as the appointment of new directors to the controlled entity's board. The IDS can exert more control over the physician organization if it contracts to manage the organization's day-to-day operations. By effectively controlling board appointments to the organization and controlling day-to-day management of the organization, the IDS maintains governance and operational control over the organization.

Under the physician trust model, the IDS creates a trust, appoints a physician as trustee, and then delivers funds to the trustee to develop the affiliated physician group. The IDS is designated the beneficial owner of the trust. A professional corporation is formed, and the trustee uses the trust's funds to purchase the professional corporation's shares. The professional corporation then employs physicians to deliver services on behalf of the IDS. Through the trust documents, the IDS can maintain substantial control over the professional corporation's actions by requiring the physician shareholder to obtain IDS consent before voting on important strategic matters, such as the sale of substantially all of the organization's assets or the dissolution of the organization.

The share control agreement model is similar to the trust model. Under this approach, the physician organization is also organized as a sole shareholder professional corporation. A trust is not created; however, the IDS controls the professional corporation through a share control agreement whereby the physician shareholder agrees to obtain the IDS's consent before voting on certain matters.

Another model which has been used to avoid the corporate practice prohibition is the MSO in which the IDS owns the affiliated physicians' practice assets through the MSO. The physicians continue to practice medicine in

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114 Not only will these models help to alleviate the corporate practice of medicine concerns, as discussed herein, these models will also help the IDS to avoid private benefit/private inurement problems under the tax exemption laws and help any contract physicians to the physician organization maintain separate employee benefits plans.

115 The Ohio Attorney General has approved the transfer of a beneficial interest in stock of a professional corporation to a person who is not duly licensed to render professional services. For example, in 85 Ohio Att’y Gen. Op. 065, the Ohio Attorney General opined that a trustee can hold shares in an Ohio professional corporation for the benefit of non-licensed beneficiaries, so long as the trustee is duly licensed. Further, in 90 Ohio Att’y Gen. Op. 072, the Ohio Attorney General opined that a trust can be used to provide financial benefit to unlicensed individuals from licensed professional activities.

116 See I.R.S. determination letter to Marietta Health Care Physicians, Inc., dated October 3, 1995 on file with the authors, in which the I.R.S. granted tax-exempt status to a physician organization controlled by a hospital using the share control model. The applicant relied on the reasoning in the O.A.G. opinions cited supra in note 115 to convince the I.R.S. that the hospital's control was not a violation of the corporate practice ban.
compliance with the corporate practice doctrine because they maintain separate practices and bill directly for services provided. The MSO leases the assets to the physicians and provides administrative services through the MSO.

Under any of these models, the IDS minimizes the legal risks associated with the corporate practice doctrine. The IDS can argue that it is not directly employing physicians and, therefore, is not violating the prohibition. Provided the employment or independent contractor arrangements between physicians and the controlled entity comply with the self-referral laws, the apparent conflict should be reconciled.

B. Physician/Hospital Ventures: Tax v. Self Referral

1. The Conflict

As market forces encourage providers to organize collectively, tax-exempt hospitals and for profit physician organizations, like those in the hypothetical IDS, may pool their resources to develop IDSs as some form of joint venture. Hospitals and physicians use joint ventures to develop working alliances, minimize conflicting economic incentives, promote shared loyalties, enhance capital access, and generate additional revenues. The tax laws and the self-referral prohibitions, however, affect the tax-exempt hospital's and the physicians' ability to invest freely in the venture. Physician participants in the IDS may also become subject to intermediate sanctions if they receive an excess benefit from the transaction.

Under IRS policy regarding joint ventures, the private inurement and private benefit prohibitions are implicated. The primary concerns when a tax-exempt organization enters into a transaction with a for profit entity are (i) whether the financial or nonfinancial arrangements allow the inurement of the nonprofit hospital participant's net earnings to any private shareholder or individual (the physician investors in the hypothetical IDS); and (ii) whether the joint venture will confer a benefit to private interests substantial enough to demonstrate that the tax-exempt hospital is operating for private benefit rather than for public purposes. The IRS's position regarding hospital-physician joint ventures is discussed in General Counsel Memorandum 39862.

The IRS established that tax-exempt hospitals can jeopardize their tax-exempt status if the hospital shares its net profits from ancillary services

117Woodhall, supra note 3, at 223.
118Additionally, physician participants who are considered "disqualified persons" under the intermediate sanctions laws may be subject to intermediate sanctions as discussed in Part III. See supra text accompanying notes 52-53 for a discussion of the new intermediate sanctions laws.
119See supra text accompanying notes 46-53 for a discussion of the laws affecting tax-exempt organizations.
120DOUGLAS M. MANCINO, TAXATION OF HOSPITALS AND HEALTH CARE ORGANIZATIONS, 11-2 (1996)
with the hospital's staff physicians. More importantly, the IRS stated that violations of the anti-kickback statute are inconsistent with continued tax-exempt status and suggested that private letter rulings will be contingent upon compliance with the self-referral laws. \footnote{General Counsel Memorandum 39862, at 29.} A conflict could arise, therefore, if a joint venture passes muster under IRS analysis but fails to satisfy a safe harbor or exception under the self-referral laws, especially given that self-referral laws appear to be less tolerant of physician-hospital joint ventures.

Although the anti-kickback statute has recently been amended to encourage capitation and other managed care reimbursement arrangements, \footnote{Section 216 of the Health Insurance and Portability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) includes a managed care exception for risk-sharing arrangements. The exception allows remuneration between a Medicare-qualified HMO and an individual or entity providing items or services pursuant to a written agreement between the parties. The amendment also allows remuneration between an individual and an organization or entity if a written agreement places the individual at substantial financial risk for the cost or utilization of the items or services the individual is obligated to provide. This exception is broader than existing safe harbors and recognizes that managed care arrangements reverse traditional physician incentives to overutilize services.} only limited safe harbors exist to protect a physician's investment interest in an IDS. \footnote{Counsel should determine the applicability of the safe harbors for (i) personal service and management contracts, 42 C.F.R. § 1001.952(d); leases, 42 C.F.R. § 1001.952(b) & (c); small entity investments, 42 C.F.R. § 1001.952(a)(2); and large entity investment interests, 42 C.F.R. § 1001.952(a)(1). Proposed safe harbors include: investment interests in rural areas, ambulatory surgical centers and group practices composed of active investors. 58 Fed. Reg. 49008 (9/21/93).} The Office of the Inspector General (the "OIG") issued a special fraud alert in 1989 \footnote{See Medicare and Medicaid Guide 38,448 (CCH 1990).} in which the OIG expressed its concern with joint ventures formed by tax-exempt hospitals primarily to lock up referral streams from physician investors, rather than to engage in legitimate activities. Particularly suspect are arrangements where the amount of capital invested is disproportionate to the return on the physician investor's capital. \footnote{Another provision in the Health Insurance Portability and Accountability Act of 1996, Section 205, allows the public to request advisory opinions from the department of Health and Human Services regarding whether a particular arrangement constitutes grounds for penalty under the anti-kickback, civil money penalty and exclusion statutes. The opinion is binding only on the requesting party, similar to IRS's private letter rulings, and undoubtedly will help provide guidance to practitioners in this murky area.} The Stark self-referral prohibitions are even more restrictive because, unlike the anti-kickback statutes, physicians may violate the Stark laws regardless of their motive. \footnote{See supra text accompanying note 55 for a discussion of the significance of the intent requirement.}
physician and hospitals completely integrate, it is unlikely that the any of the exceptions to the Stark laws will apply.  

2. Reconciling the Conflict

In this example, there are three competing bodies of law which must be reconciled. Although the IRS has taken a more flexible approach than the OIG or the Department of Health and Human Services in analyzing hospital-physician joint ventures, these areas appear to be reconcilable if the policies underlying the laws are satisfied. In a sense, these policies can be satisfied if the IDS venture is engaged in a legitimate activity, the physician investors profit from the venture is proportional to their investment, and the IDS operates to discourage overutilization. An IDS structured and operated with these principals in mind minimizes the possibility that physicians will benefit at the expense of the tax-exempt participant and that physicians will have a financial incentive to refer to the joint venture.

IRS policy should not inhibit a tax-exempt organization’s participation in legitimate joint ventures designed to benefit the community because G.C.M. 39862 only applies if a tax-exempt hospital sells its revenue streams to the venture. Ventures that are structured to avoid this limitation, further charitable purposes, and benefit the community appear to be encouraged under current IRS policy.

Such ventures include ones that (i) establish a new health care provider, service, or resource in the community; (ii) raise capital for a bona fide project or purpose (iii) own or lease a separate provider facility or service; (iv) involve substantial risk sharing or pooling of expertise; and (v) measurably improve quality of service in an area.  

To the extent the venture does not meet any safe-harbor or exception under the self-referral laws, the IDS must be structured so that (i) the physician’s investment interest in the IDS is not considered remuneration intended to induce a referral; and (ii) the IDS is not considered an entity to which a physician can refer for the provision of Medicare or Medicaid services.

Under the anti-kickback statute, an argument can be made that distributions to the physician investors are not intended to induce referrals provided any distributions to the physician are proportional to their investment. A way to satisfy this policy is suggested by the structure of the hypothetical IDS in which preferred stock is provided to the hospital. The hospital member would receive preferred distributions (both profit and liquidating) as well as preferred voting rights (the right to break deadlocks among the board on strategic issues) because the hospital will make a larger initial capital contribution.

Another way to minimize anti-kickback concerns is to avoid making any profit distributions to the physician investors. Physicians could still participate

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127 See infra notes 148 and 150 discussing the rural investment interest and hospital investment exceptions respectively.

128 Mancino, supra note 120, at 11-16.
in governance as voting members in the IDS and participate financially through their compensation arrangements. Compensation arrangements can be structured under the self-referral laws to avoid providing incentives for physicians to overutilize services and to replicate equity type distributions based on overall IDS performance. By implementing these protections, the IDS structure helps to minimize private inurement and private benefit concerns as well as Stark concerns.

Under the Stark laws, an argument can be made that the physician investors cannot engage in a prohibited referral because the IDS is not a provider of services as defined under Medicare or Medicaid laws; therefore, it is impossible for the physicians to make referrals to the IDS for the provision of Medicare or Medicaid services. The IDS can also argue it complies with the policies that underlie the Stark law if its utilization review program discourages physicians from overutilization. Overutilization may also be discouraged if the physicians do not participate in profit distributions and physician compensation is tied to managed care utilization goals.

Other options for the IDS to minimize any Stark concerns are to provide designated health services through the affiliated physician organization, completely integrate physician and hospital operations, or not to offer physicians equity in the IDS. The physician organization may also be structured to meet the requirements of the in-office ancillary services exception.

C. Accepting Risk: Anti-Trust, Insurance and Tax

1. The Conflict

Under federal antitrust enforcement policy, an IDS can avoid antitrust challenges if the providers in the IDS integrate economically by sharing substantial financial risk. This can occur if the IDS and its providers agree to enter capitation, withhold or other at-risk reimbursement arrangements with payers. If the IDS itself enters into risk-sharing arrangements with payers to

129 Compensation arrangement are more flexible under the self-referral laws because safe harbors and exceptions exist for remuneration paid to employees and independent contract physicians.

130 See supra text accompanying notes 55-59 for a discussion of the Stark laws.

131 See supra note 122, discussing the definition of remuneration under the anti-kickback statute which excludes payment made to an individual pursuant to an arrangement that places the individual at substantial financial risk for the provision of services. This provision would protect participants in a fully integrated IDS and recognizes that participants in such an IDS have no incentive to overutilize services. Unfortunately, the Health Insurance and Portability Act of 1996 does not include similar revisions to the Stark prohibitions.


133 See supra text accompanying notes 60-72 for an overview of antitrust enforcement policy issues.
avoid antitrust scrutiny, however, the IDS risks engaging in the business of insurance and could become subject to additional state mandated financial requirements and restrictions applicable to insurance companies such as solvency requirements, deposits and financial reserves.

These two bodies of law often create a conflict because many IDSs, to avoid the additional financial requirements for insurers under state law, may avoid activity which could result in the IDS being classified as an insurer. If the IDS participants share financial risk to avoid scrutiny under the antitrust laws, the IDS risks being designated a state law insurer. Federal tax law can also create tax liability problems for an IDS that does not hold an insurance license.

In determining taxable income, federal tax law allows life insurance companies to deduct reserve items such as insurance reserves, unearned premiums and unpaid losses, certain dividend accumulations, and

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134 See supra note 90 (discussing financial solvency and reserve requirements in Ohio's new managed care legislation).

135 See OHIO REV. CODE ANN. § 3925.19 (Baldwin Supp. 1997) (which provides that insurance companies may provide for the accumulation of a permanent fund to pay losses and expenses when the liabilities of the company exceed the available cash funds of the company); see also OHIO ADMIN. CODE § 3901-3-13 (Baldwin 1997) (discussing the minimum reserve standards for group health insurance contracts). Whether an IDS is a health insurer will undoubtedly involve the consideration of two important questions: i) does the IDS merely arrange for another to provide services or is the IDS the provider of services; and ii) whether the IDS is receiving capitation payments for the services provided by the IDS or by the IDS's contract providers directly from a payer. Demetriou & Dutton supra note 3, at 1300:704; see also Jordan, supra note 4, at 2300:202 (citing The Health Plan Accountability Working Group, National Ass'n of Ins. Comm'rs, Suggested Bulletin Regarding Certain Types of Compensation and Reimbursement Arrangements Between Health Care Providers and Individuals, Employers and Other Groups (Aug. 10, 1995) (The Health Plan Accountability Working Group of the National Association of Insurance Commissioners concluded that any group of providers is engaged in the business of insurance whenever it contracts directly with an employer to provide future health care services on a fixed prepaid basis. The working group cautioned, however, against taking a cookie cutter approach to determining which organizations are accepting insurance risk and stated that the facts and circumstance of each situation must be evaluated.)).

136 To a certain extent, the policies and rationale that underlie the antitrust laws and the insurance laws are in harmony. Both encourage and allow providers to integrate through the sharing of financial risk among the providers in the IDS as well as with external payers, even though the IDS could become subject to the solvency, deposit or reserve requirements.

137 "Life insurance" companies include companies that issue noncancellable contracts of health and accident insurance provided certain requirements are met. See I.R.C. § 816(b) (1996) (life insurance defined).

138 I.R.C. § 807(c)(1)(1996) (reference to § 816(b)).

139 I.R.C. § 807(c)(2) (reference to § 816(c)(2)).

140 See I.R.C. § 807(c)(4).
certain reasonable contingency reserves.\textsuperscript{141} For insurers other than life insurance companies, these items are generally included in gross income and not deductible.\textsuperscript{142}

Under the federal tax law definition, any reserves maintained for future claims or unearned premiums may be taxable at the IDS level. Any amounts from these reserves or unearned premiums that are later distributed to the IDS's owners could also become subject to a second level of taxation. This creates a problem for equity participants in the IDS who are trying to minimize their tax liability.

2. Reconciling the Conflicts

If the IDS has sufficient available capital to meet the financial requirements for insurance companies and the IDS intends to become licensed as an insurer as well as enter a risk relationship with payers, these conflicts become moot. Exposure under the anti-trust laws would be minimized because the IDS could be considered integrated for purposes of anti-trust analysis. The IDS might also avoid the double taxation problem for reserve items because such items are deductible in computing taxable income.

These conflicting issues become especially troublesome, however, for the IDS that is transitioning from the fee-for-service regime to the managed care environment and has not yet embraced the concept of completely integrating payer and provider functions or assuming financial risk on all payer contracts. One way for the transitional IDS to avoid the double taxation issue is to form the IDS as a limited liability company as suggested by the hypothetical IDS. By receiving pass through taxation, the equity participants can avoid taxation on reserve items at the entity level. This approach will help to eliminate the double taxation problem.

A recent change in federal antitrust enforcement policy may allow the transitional IDS to not only avoid insurer classification but also avoid antitrust challenges. In a revision from the previous Policy Statements,\textsuperscript{143} some multiprovider networks may now qualify for rule of reason analysis even if the network members do not share substantial financial risk. For example, networks that do not share substantial financial risk may be able to demonstrate \textit{clinical integration} substantial enough to produce efficiency benefits for consumers and justify joint pricing among the members.

Examples of substantial clinical integration given in the Policy Statements include: (1) establishing mechanisms to monitor and control utilization, control costs and assure quality of care; (2) selectively choosing providers that are likely to further efficiency objectives; and (3) investing significant capital, both monetary and human, to build the infrastructure and capability to realize the

\textsuperscript{141}See I.R.C. § 807(c)(6).

\textsuperscript{142}See I.R.C. § 832(c)(establishing general deductions for insurance companies other than life insurance companies).

\textsuperscript{143}See \textit{supra} note 60.
claimed efficiencies. By clinically integrating rather than financially integrating, the IDS may be considered integrated for purposes of avoiding antitrust scrutiny. The IDS might also not be considered engaged in the business of insurance because the IDS participants are not assuming insurance risk.

D. IDS Reimbursement: Medicare Provider Status v. Self-referral

1. The Conflict

If the IDS is to provide services to Medicare and Medicaid beneficiaries, it would be advantageous for the IDS to become a Medicare and Medicaid provider with a unique identification number so that the IDS could receive reimbursement directly from Medicare. IDSs, like the hypothetical IDS, may qualify for a Medicare provider number as a health care delivery system. Health care delivery systems are organizations that provide and administer health care to individuals or groups through an organized system, such as a clinic.

Considering the hypothetical IDS as an example, if the IDS becomes a Medicare provider, however, the IDS may have effectively created a problem for its physician investors under the self-referral laws. Under the Stark laws, physician investors may not refer a Medicare or Medicaid patient to an entity in which they have an ownership or investment interest for the provision of designated health services, unless one of the Stark exceptions applies.

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144 Demetriou & Dutton *supra* note 3, at 1300-901 n.9 (Demetriou and Dutton argue that "health care delivery systems" can be considered suppliers in their own right. 42 C.F.R. § 424.80(c) provides that a health care delivery system, facility or employer receiving Medicare assignment will be considered the supplier of the services for purposes of subparts C, D, and E. 42 C.F.R. § 424.55 provides that a supplier accepting assignment can receive payment directly from Medicare, but the supplier will be bound by all the conditions of having accepted assignment).

145 Medicare Carrier's Manual Section 3060.3 (The Carrier's Manual describes four types of health care delivery systems: i) medical group clinics; ii) carrier dealing prepayment organizations; iii) direct-dealing health care prepayment plans; and iv) direct-dealing HMOs and competitive medical plans).

146 *Id.* at 3060.3.C (It is debatable whether the IDS would meet the requirements for being a clinic which is defined as freestanding entity such as a physician, medical group or imaging center. An IDS may not meet this definition depending on the Medicare carrier's policy.).

147 See *supra* text accompanying notes 55-59 for a discussion of the self-referral laws.

148 One exception that is worth reviewing in this situation is the exception to the referral prohibition related to ownership or investment interests in facilities located in rural areas. 42 U.S.C. § 1395nn(d)(2); see 42 C.F.R. § 411.356(C)(1). It is unlikely that the IDS would qualify for the in-office ancillary services exception, because it most likely would not qualify as a group practice as defined in 42 U.S.C. § 1395nn(h)(4).
2. Reconciling the Conflict

If the IDS is not considered a Medicare or Medicaid provider of services and is merely arranging for others to provide the services, some commentators argue that a physician could not make a referral to it. Therefore, the Stark prohibitions arguably would not prevent the physicians from holding an ownership interest in the IDS. The conflict in this situation for the IDS is apparent because on the one hand, the IDS would want to participate in Medicare and Medicaid as a provider for reimbursement purposes, but on the other, the IDS would want to avoid becoming a Medicare provider due to the Stark implications.

Given the importance of offering physician's equity in the IDS, unfortunately, many IDS's will avoid becoming a Medicare or Medicaid provider. This situation is an example of a conflict where the specific goal of the IDS, to become a Medicare provider for reimbursement purposes, may be outweighed by the broader goal of providing physicians incentives to participate in the IDS. Of course, if the IDS is not a Medicare provider, the IDS will not be authorized to accept assignment for physician's services including ancillary services. This result can be mitigated somewhat if the IDS becomes the billing agent for the independent physicians in the IDS as well as the affiliated physician group. If the IDS fully integrates physician and hospital services, the IDS could also seek a Medicare provider number without negative implications under the Stark laws. Physicians could be equity participants consistent with the Stark regulations concerning prepaid plans or investment interests in hospitals.

VI. CONCLUSION

The health care industry is changing at a rapid pace due to the spiraling costs of delivering care. Integrated delivery systems are being developed to improve the quality of care while simultaneously reducing costs. Because integrated systems were not contemplated when many of the existing health laws were adopted, these regulations often conflict in ways that dissuade system formation and operation.

Traditional methods for conflicts resolution are often inadequate, but traditional theory provides insights for developing a methodology to reconcile competing legislative and administrative laws and policies. This article suggests a systematic, client-objective oriented approach to conflicts resolution which can be summarized as follows:

149 Demetriou & Dutton, supra note 3, at 1300:613.

150 42 U.S.C. § 1395nn(b)(3) & § 1395nn(d)(3) (Physician ownership or investment interest in prepaid plans and hospitals are excepted from the referral ban. Prepaid plans include federally qualified HMOs, demonstration projects and plans that have entered into Medicare risk contracts.).
(i) Analyze the structure and the client’s goals in developing the IDS or engaging in the particular transaction and identify the apparent conflicts in law or policy;

(ii) Reconsider and prioritize the client’s objectives in developing the IDS in light of the conflict and any legal barriers created by the conflict;

(iii) Promote the more important law or policy after considering the relative importance of the conflicting laws and their underlying policies; and

(iv) Reconfigure the IDS’s business arrangement after considering exceptions to the law or regulation, agency interpretations regarding the conflict or any alternative organizational structures and operational arrangements that both accomplish the client’s goals and meet the legal requirements of each of the conflicting laws or policies.

If the conflict cannot be reconciled by following this approach, counsel for the IDS can urge compliance with the laws that satisfy the client’s most important objectives or consider tabling the transaction until there is a change in the conflicting laws or policies.

As the health care industry adjusts to meet changing market demands, legislative and administrative bodies will continue to promulgate conflicting laws and regulations and thereby create obstacles to the legitimate business objectives of the organizers of the IDS. Legal counsel must facilitate the process of complying with these laws and policies while meeting the client’s objectives. The methodology discussed in this article should provide counsel to the IDS with a valuable tool in this endeavor.