Barriers to Hospital Diversification: The Regulatory Environment

Reed Hamilton
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The hospital industry, now as never before, is challenged by an increasingly competitive but nevertheless highly regulated marketplace. Due to federally initiated regulatory and reimbursement programs designed to achieve health care cost containment and efficient delivery of health services, the marketplace has been forced to respond to the rapid rise in health care costs. These federal initiatives most notably include the Certificate of Need (CON) health planning program\(^1\) and the Medicare and Medicaid health benefits payment system.\(^2\) As a result of changes in the administration of these programs, hospitals have reevaluated their existing corporate structures in order to become more competitive with other providers and to more effectively navigate within the regulatory environment. Typically, hospital responses include the establishment of cost control mechanisms, the development of new streams of revenue, and the adoption of new methods of health care delivery, particularly outpatient care. A common corporate experience in the hospital industry to achieve these results has been consolidation and diversification. For many of these efforts, however, Certificate of Need and Medicare and Medicaid fraud and abuse restrictions present formidable barriers. Those barriers are the subject of this article.

I. BACKGROUND TO THE CURRENT HEALTH CARE MARKETPLACE

In recent decades, the health care industry has experienced an overwhelming rise in health care costs. Skyrocketing expenditures


for health care cause concern to government payors, businesses, labor, consumers and providers. As a result, cost control has become the driving force behind recent developments in the health care delivery system. Efforts to contain rising costs have included extensive regulation and restrictive reimbursement. The emphasis in delivery has now shifted from expensive inpatient services to less costly outpatient services. To accommodate this shift, many new and alternative delivery and financing systems are developing. The regulatory environment is also changing, but not always in directions compatible with new and existing reimbursement incentives. A brief history of the payment and regulatory systems will help explain how the industry arrived at its current position.

A. Health Planning and Reimbursement: The Delivery System Grows

Major health planning efforts began at the federal level with adoption of the Hill-Burton Act. Adopted in 1946, the Act represented a congressional directive to expand inpatient capacity in order to provide citizens throughout the country with greater access to health care services. The Hill-Burton Act provided low interest loans, loan guarantees, and outright grants for the development of new public and voluntary non-profit hospitals and nursing homes. As a condition for receipt of Hill-Burton funds, hospitals had to make free and low cost health care available to indigents who otherwise could not afford to obtain care. As intended, inpatient capacity grew rapidly during the 1950's and 1960's.

Even with this expanded availability of health facilities, however, the federal government wanted further assurances that the indigent and elderly would have access to health care services. With a focus on the indigent and elderly, Congress then passed Social Security Act amendments in 1965, thus establishing the Medicare and Medicaid reimbursement programs. Medicare and

4. 42 U.S.C. § 291-291o-1 (1982). The Hill-Burton Act was adopted to address the shortage of hospital beds after World War II. Id. The Act established a federal-state partnership and provided grants to states for surveying state needs and developing state plans for the construction of voluntary non-profit and public hospitals. Id. The grants were also used to help construct and equip such facilities. Id.
5. Id.
Medicaid provided the mechanism by which health care facilities would be reimbursed for the reasonable costs incurred in caring for eligible individuals. The "cost based" payment methodology adopted by these programs provided reimbursement for both operating and capital costs, with capital costs being reimbursed virtually on a dollar for dollar pass-through. As such, the capital pass-through provided still another stimulus to the growth of inpatient capacity.

The cost-based payment methodology, however, provided no incentives for facilities to control costs. As a result, the Medicare and Medicaid budgets expanded rapidly. Labor and other operating costs increased generally, and capital expenditures supported by long-term debt spiralled. Medicare and Medicaid and the growth of other third party private insurance programs provided no reason for the recipients or patients to become cost-conscious health care consumers. The recipients of the Medicare and Medicaid programs were, in effect, insulated from bearing the financial burden of medical costs. That, of course, was the intended purpose of these programs. Rarely did recipients have more than a token economic incentive to make cost-conscious purchasing decisions. The absence of cost sensitivity among purchasers contributed to the inflation of health care costs.

Another factor contributing to the rise in health care costs was the patient's psychological and physical dependence on his physi-

7. 42 U.S.C. §§ 1395-1395zz (1982 & Supp. I 1983). Medicare is an exclusively federal program providing two types of health insurance for eligible elderly and other individuals under which physicians, hospitals and other providers are reimbursed for covered services provided to the Medicare beneficiaries. Id. Reimbursement is provided for inpatient hospitals, skilled nursing, home health and related care under Part A of the program. 42 C.F.R. §§ 405.100-405.196 (1984). Physicians' services and other medical services are provided under Part B of the program. Id.


8. Under both the Medicare and Medicaid programs as originally enacted, providers were reimbursed the lesser of their customary charges or their reasonable costs incurred in providing covered services. 42 C.F.R. § 405.451 (1984). Although facilities were restricted in their reimbursement to those costs necessary and reasonable to treatment, there were no real incentives to decreasing costs or limiting spending. Id. The regulations did not tag a particular service with a specific dollar amount. Id. Therefore, while one facility recovered one amount for a particular service, another may have been reimbursed for an entirely different sum depending on the hospital's costs. Id.
This dependence normally precluded the patient from identifying and using cost-efficient alternative methods of treatment. The physician, therefore, was able to dictate not only treatment methods, but he could also demand that a medical facility provide equipment and services that he considered vital for the patient's care without consideration as to the cost or other resources involved.

In sum, Medicare, Medicaid, and other third party insurance created a market force for uninhibited growth and utilization of medical facilities, equipment and services with little or no cost sensitivity. Under such conditions, the health care marketplace, unlike most marketplaces, lacked forces promoting natural competition. As a result, there were no internal mechanisms working to control costs. An outside effort would be required to promote cost containment.

B. Early Cost Containment: Capital Expenditure Controls

The first major effort at cost containment was the federally initiated health planning and capital expenditure review program established by amendments to the Social Security Act in 1972, commonly referred to as section 1122. Section 1122 was enacted to assure that federal Medicare and Medicaid funds were not used to support unnecessary capital expenditures which previously had been reimbursable in the cost-based system on a pass-through basis. Section 1122 introduced a capital expenditure review program requiring advance notice from facilities prior to any capital expenditures in excess of $100,000, or prior to other capital expenditures which would result in changes to bed capacity or health services offered by institutions. Notice would be given to state and regional planning agencies which would then recommend to the U.S. Department of Health Education and Welfare (HEW) whether to approve reimbursement for that portion of depreciation and interest expenses incurred in the treatment of recipients of the Medicare and Medicaid programs.


10. 42 U.S.C. § 1320 (1982 & Supp. I 1983). Under the section 1122 program, health care facilities were not reimbursed by Medicare or Medicaid for depreciation, interest or return in equity capital relating to capital expenditures which regional health planning agencies found to be inconsistent with the health needs of the community. Id. With the advent of the section 1122 program, expenditures under Medicare and Medicaid for the first time were related to state health planning. Id.
The section 1122 program, however, was voluntary among the states. States were not required to enter into an agreement with HEW to review the proposed expenditures and make such recommendations. In non-participating states, facilities were not obligated to give advance notice and did not have to receive approval of HEW to be eligible for reimbursement of capital expenditures under the Medicare and Medicaid programs. In states that did participate, regional comprehensive health planning agencies conducted reviews of proposed expenditures to see whether they were needed by the community and were financially feasible. Those planning agencies then made a recommendation to a designated state health planning agency which in turn made a recommendation to HEW as to whether capital reimbursement should be withheld or allowed.

In those states which participated in the program, if a health care facility was not reviewed under section 1122, the facility was unable to receive reimbursement for that portion of the depreciation and interest expenses associated with the care of Medicare and Medicaid recipients. A health care facility that failed to obtain a section 1122 review, or which obtained a review but failed to receive a recommendation of approval from the designated state planning agency, was not prohibited from incurring the expenditure. Rather, the facility was merely prohibited from obtaining Medicare and Medicaid reimbursement. Many facilities were willing to suffer this penalty and proceed without the approvals. Thus, the section 1122 review program was often ineffective. A more rigorous cost control program was needed. Certificate of Need was thought to be the answer.11

The Certificate of Need program was established by the National Health Planning and Resources Development Act in 1974 (National Health Planning Act).12 Patterned after the section 1122 program, the Certificate of Need (CON) program required review and approval of capital expenditures in excess of $150,000, the offering of new clinical health services, and the acquisition of major medical equipment used to serve inpatients.13 Unlike section 1122, however, CON programs were not voluntary among the states. States were compelled to establish a CON review program or face the loss of millions of dollars in federal public health allocations.

12. Id.
13. Id.
The National Health Planning Act established State Health Planning and Development Agencies (SHPDAs) and Health Systems Agencies (HSAs) to administer the programs. Those agencies were obligated to undertake a comprehensive assessment of community health needs, to develop long-range State Health Plans and regional Health Systems Plans which established goals and standards for health care services, and to review and approve only those proposed health facility expenditures and services which were consistent with those standards. In most instances, these functions were similar to those performed during the section 1122 program by the state and regional comprehensive health planning agencies. Unlike section 1122, however, the CON program absolutely prohibited health care facilities from obligating any expenditures or offering a new service without first obtaining the required CON approval. Persons or facilities who did proceed without CON approval could be fined, enjoined from further activity, and could suffer loss of their license to operate. This, in contrast, was a far more serious penalty than the inability to obtain reimbursement for depreciation and interest expenses for the treatment of Medicare and Medicaid recipients, the penalty imposed under section 1122. CON, as intended, clearly imposed a major barrier to the development of the health care delivery system, a perceived goal of cost containment initiatives. In the 1950's and 1960's, growth was stimulated. In the 1970's, growth was deterred.

C. CON in Detail

The new CON program requires that the offering or establishment of a “new institutional health service” first receive CON approval. New institutional health services are defined by federal regulations as follows: (1) the obligation of a capital expenditure “by or on behalf of” a health care facility in excess of the capital expenditure threshold periodically adjusted by the federal government; (2) the offering of a new clinical health service not previously offered within the previous twelve months, if it is associated with any capital expenditure or with an annual operating expense in excess of the operating expenditure threshold which is also peri-

odically adjusted by the federal government;18 (3) the termination of a health service associated with any capital expenditure;19 (4) a change in bed capacity, a relocation of beds, or a redistribution of beds from one category to another, except those changes that constitute less than 10 beds or 10 percent of total capacity, whichever is less;20 and (5) the acquisition of major medical equipment if it will be owned by or located within a health care facility, or is not owned by a health facility, if it will be used to serve inpatients.21

As administered by the various SHPDAs and HSAs, these “new institutional health services” can be further defined or interpreted in a highly restrictive manner. Such restrictive definitions can seriously impede management flexibility and institutional development. “Clinical health services,” for example, can be defined variously to require CON review for the extension of a service into different diagnostic or treatment modalities, even where a pre-existing department or service within the hospital had been established to treat patients for those conditions in the past. To illustrate, there are in Pennsylvania at least ten separate radiology services for which a separate CON review as a new clinical health service is required.

The CON review process is extremely cumbersome and often political. It may involve a substantial degree of bargaining with HSA and SHPDA staff members on institutional services and activities which may or may not be related to the specific project under consideration. The CON reviews themselves routinely take from six to nine months. Moreover, when all application fees, consulting fees, and other associated costs are totalled, the reviews can be extremely expensive. Finally, even those facilities which receive CON approval may face challenges from competitors who can appeal the approval for additional administrative and judicial review, thus frustrating the CON holder from proceeding with development. A project can be held up for years in litigation, a condition which often makes it impossible to obtain financing for the project.

In the end, the powerful institutions with greater political clout tend to receive approval, albeit with considerable bargaining of costs and services during the process. Smaller, less influential institutions, and projects with a lesser impact on overall health care

18. 42 U.S.C. § 300m-6 (1982). The threshold, originally set at $75,000, is now $297,500. Id.
19. Id.
20. Id.
21. Id.
costs, tend to receive a disproportionate share of the disapprovals. Nursing homes, for example, are more likely to suffer disapprovals than the more powerful hospitals. Thus, notwithstanding the substantial barrier CON poses to new development, there is a widespread belief that the CON program, as with the section 1122 program before it, failed to control escalating health care costs. Those costs continued to increase in spite of regulatory review pursuant to section 1122 and CON. Moreover, the burden of high health care cost continued, of course, to fall heavily upon the Medicare and Medicaid programs, and ultimately, upon the taxpayers. New approaches to cost containment would be needed.

II. THE PROSPECTIVE PAYMENT SYSTEM: DELIVERY INCENTIVES CHANGE

The cost-based payment methodology for reimbursing health care facilities was perceived to be the fundamental obstacle to effective cost containment. Its adverse incentives contributed to increased spending, notwithstanding section 1122 and CON. While this problem had been recognized for years, a major overhaul of that system had not been contemplated. Instead, savings were achieved through piecemeal changes to the reimbursement system. The Pennsylvania Department of Public Welfare (PaDPW), for example, placed a $22,000 per bed ceiling on capital reimbursement for new nursing home beds. PaDPW also began to interpret existing regulations more restrictively. More fundamental changes in reimbursement policy, however, would be necessary to bring about more meaningful cost containment.

The revolutionary breakthrough in reimbursement policy occurred in 1983 with the establishment of the Prospective Payment System (PPS) for inpatient hospital care. Medicare discarded the

22. 55 Pa. Admin. Code § 1181.259(s) (Shepard's 1983). The pertinent code section reads, "After July 1, 1977, allowable depreciation costs for existing new, renovated repurchased facilities shall be limited to a maximum construction cost per bed of $22,000." Id.

23. In one situation, PaDPW completely revised its audit policy with respect to the interpretation of a regulation mandating the recapture of depreciation of a facility when sold for a profit. The regulation provided that gains were an allowable cost up to 10% of the depreciation, an ambiguous provision at best. For years, PaDPW had used this provision to recover 10% of the depreciation that had been paid to the facility during its last year of operation by the seller. In what appeared to be an effort to save money, PaDPW simply revised its audit policy without amending the regulation to recover 90% of the depreciation paid to the facility in that last year prior to the sale.

24. 42 U.S.C. § 1320b-5 (1982); 42 C.F.R. §§ 405.470-405.477 (1983). The fundamental purpose of PPS is to change the incentives facing hospitals in order to increase the efficiency with which they produce care for patients and with which they use other elements of
cost-based reimbursement system and substituted a system which permits hospitals to recover a fixed amount per inpatient admission, depending on the principal diagnosis of the case, not on the costs incurred in providing care. This changed the entire system of financial incentives by which hospitals would deliver services to Medicare recipients.

Pursuant to the PPS legislation, each patient admitted to a hospital would be classified in one of 467 Diagnosis Related Groups (DRG) that were established. Each was assigned a relative value or weighing factor used to determine the final dollar amounts to be paid for each of the possible 467 DRG cases. The length of stay or actual cost for treating a patient did not affect the payment amount, except in rare instances where the length of stay was extremely long or the cost extremely high. In those so-called outlier cases, an additional payment amount is allowed. Many states have followed the Medicare lead by adopting a DRG-based payment system for their Medicaid programs.

This radical change in the payment system now provides hospitals with incentives to cut costs by reducing length of stay and by reducing unnecessary ancillary services. The incentives encourage hospitals to discharge patients as early as medically possible, to identify and eliminate the use of unnecessary tests and procedures, and to utilize lower cost outpatient services and freestanding facilities to the maximum extent possible. As a result, hospitals will be discharging patients to hospices, nursing homes, and home health care as promptly as possible.

To assure the availability of other such providers for their patients, hospitals can either acquire a facility, establish a facility of

the health care delivery system. Id. Under the PPS system, hospitals are to be paid a fixed price for a Medicare case, defined by Diagnosis Related Groups (DRGs). Id. Therefore, if hospitals are able to provide care for less than the associated DRG fixed price, they will retain more net income. Id.

Under PPS, the Health Care Financing Administration (HCFA), the agency which administers the Medicare program, uses the principal diagnosis to assign patients to DRGs. Id. The principal diagnosis is defined as the condition most responsible for the admission of the patient. Id. Therefore, if a Medicare patient has a number of diagnoses and the one defined as most responsible for admission is less expensive than one identified later, the hospital may be underpaid significantly. Id. Thus arises the critical issue of managing physicians so that they appropriately identify the principal diagnosis.

25. Under PPS, hospitals attempt to reduce the number of hospital inpatient days per patient because the hospital is receiving a fixed sum for a predetermined number of inpatient days per case. Therefore, if the hospital is able to discharge a patient a day earlier than that associated with the appropriate DRG, the hospital will still recover the same amount from HCFA. Reduction in lengths of stay has become a major cause of reduced costs and therefore increased net income under PPS.
their own, or contract with existing facilities. Hospitals will also want to increase admissions to help fill the empty beds resulting from the earlier discharge of patients. Some hospitals may want to reduce bed capacity or discontinue unnecessary and non-profitable services. Others will want to add new services or develop new facilities such as nursing homes and home health agencies to accomplish these objectives. The competition among hospitals for more patients and for more efficient delivery systems will be keen. As can be seen, PPS holds the possibility of restoring traditional market forces to control costs.

Unfortunately, these market forces and the industry response to them, all of which may be appropriate and desirable, may be subject to barriers posed by CON. CON will make many of the new arrangements desired by hospitals considerably more difficult and time-consuming to implement. Moreover, the competitive response by one facility may be met by challenges, during the CON process, from the community of other competitors who do not understand or consider the financial implications facing the institution.  

In response to PPS, hospitals will also seek to broaden their referral base by strengthening ties with admitting physicians. To do so, they will enter into joint ventures with physicians to establish outpatient clinics or home health agencies and similar organizations in targeted service areas where additional referrals might be generated. CON, licensure, and reimbursement regulations will all impact on these activities. As will be discussed more fully later in this article, regulatory restrictions against referrals must also be examined carefully to avoid criminal fraud and abuse violations under the Medicare and Medicaid programs. Moreover, those programs impose strict ownership reporting requirements or limitations. These limitations are in many respects, incompatible with other aspects of the reimbursement system which foster these developments.

III. MANAGEMENT AND STRATEGIC PLANNING

In order to maintain or increase their patient market share, hos-

26. See infra notes 47-61 and accompanying text.
27. For a description of the joint ventures that hospitals and physicians may be entering, see infra notes 33-50 and accompanying text.
28. Id.
29. For a detailed analysis of the fraud and abuse issues, see infra notes 62-93 and accompanying text.
pitals are being forced by PPS to examine their competitive position in the health care marketplace. A strong hospital management team with strategic planning goals will be necessary. The management response of many hospitals has included major corporate reorganization. Reorganization has been achieved by having hospitals participate in the establishment of new health care providers which serve as part of a multi-institutional system. Among other functions, the system provides facilities and services to patients after discharge from a hospital. This type of arrangement not only enlarges the patient referral base, but it also enhances the revenue generating potential of the multi-institutional system. These multi-institutional systems often include outpatient providers and hospital/physician joint ventures. Once again, however, the barriers of CON may be raised to frustrate management.

A. Efficiency and Diversification

Although not all payors have discontinued cost-based reimbursement, the impact of the Medicare PPS program has forced hospitals into more businesslike practices. Unlike the cost-based payment system, the DRG payment system no longer rewards management inefficiencies. Physicians must also be educated regarding the effect of their practice on hospital costs. The physician’s role in cost containment is critical. It is the physician who admits patients, orders tests, prescribes medications, orders surgery and discharges the patient. These activities will drive up or cut down on costs. An effective management relationship between the hospital and medical staff will be vital to cost control and survival in the marketplace.

An effective hospital/physician relationship must include privately imposed regulatory mechanisms within a hospital to control utilization of hospital facilities. Utilization review committees will scrutinize physician activity to determine whether routine tests and procedures ordered by physicians are medically necessary and are cost effective. Physicians will also be asked to complete medical records more accurately and in a more timely fashion. Hospital management will have to work jointly and cooperatively with their medical staffs to implement these controls while at the same time maintaining the quality of care provided.

While hospitals must enhance their relationships with the medical staff, they must also work with the medical staff on strategic planning to develop new methods of health care delivery and new revenue streams. PPS with fixed, often limited, reimbursement for
inpatient health care services compels hospitals to develop new product lines. Slowly, the traditional community hospital is being replaced by multihospital systems. This move toward consolidation brings together economies of scale and provides a stronger base for diversification and reorganization.

Diversification of hospital services often includes both the development of new types of health care providers and also participation in alternate delivery systems. New service providers include Home Health Agencies, Urgicenters, Ambulatory Surgical Centers, Birth Centers, and Dialysis Centers. Alternate delivery systems generally refer to Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Exclusive Provider Organizations (EPOs), and Health Insuring Organizations.

31. For a description of the prospective payment system, see supra notes 24-30 and accompanying text.

32. See ERNST & WHINNEY, CORPORATE REORGANIZATION (1983). Of the 155 hospital respondents who had reorganized their corporate structure, the single most important reason for the initial decision to reorganize was reimbursement problems. Id. at 14-15. A significant number of respondents also cited economic needs and avoidance of government regulation as primary reasons for reorganization. Id. But surprisingly, the survey indicated that reimbursement maximization and CON avoidance were not the most significant benefits realized from reorganizations. Id. at 16-17.

33. 42 U.S.C. § 1395x(o) (1982). A home health agency is one which provides nursing and other therapeutic services to disabled or injured persons in their place of residence.

34. The term "urgicenter" refers to a variety of freestanding medical offices that provide physician services.

35. The term "ambulatory surgical center" refers to a facility which provides selective surgical care on an outpatient basis.

36. The term "birth center" refers to a distinct facility which provides services to pregnant women.

37. The term "dialysis center" refers to a facility separate and apart from any other facility which provides renal dialysis to persons with kidney disease.

38. Health Maintenance Organizations (HMOs) enroll subscribers for a premium much like a traditional insurance company, but services are provided by a closed group of providers and referrals to hospitals and specialists are carefully controlled by a primary care physician. The subscriber patient loses freedom to choose a physician outside the HMO group. Payment to the primary care physician is based on a fixed amount or capital fee for each subscriber, not on a fee-for-service billing basis.

39. Preferred Provider Organizations (PPOs) are a series of contractual relationships between payors and providers with an intermediary often serving as a third party broker and administrator. At a minimum, the essential contractual characteristics will include the subscriber freedom of choice, the subscriber incentives to choose a preferred lower cost provider, and discounts by the preferred provider from normal fee-for-service payment basis.

40. Exclusive Provider Organizations (EPOs) are more similar to PPOs than HMOs in their structural characteristics. However, under an EPO, the patient/subscriber is required to use the exclusive provider and loses any freedom of choice. The patient/subscriber pays on a discounted fee-for-service basis, thereby avoiding HMO characteristics.

41. A Health Insuring Organization (HIO) is a health delivery system authorized by
Participation in alternate delivery systems will help strengthen the patient referral base and may itself generate a new source of revenue. HMOs are generally regulated by state health and insurance departments. PPOs, a new financing system in the marketplace, are generally not subject to well-defined regulatory controls. This does not, however, ease the burden for the hospital planner or lawyer developing a PPO. Those organizing a PPO must be sensitive to regulations governing both insurance companies and HMOs to avoid regulatory provisions applicable to those financing systems. The lawyer organizing a PPO must also be alert to antitrust and CON issues. The structural characteristics of an EPO are similar to that of a PPO. With an EPO, however, the subscriber patient is required to use the exclusive provider and loses freedom of choice.

B. The Regulatory Environment for New Providers

The development of new types of health care providers and alternate delivery systems has generated new regulatory concerns which the existing regulatory structure does not adequately address. For one, the agencies charged with administering the existing regulatory programs may not adequately coordinate regulatory policy with the new hospital management activities taking place in the industry. It was, after all, the adoption of PPS and other cost containment legislation which encouraged hospitals to offer a diversity of care in alternate settings.

The CON program remains a barrier to many of these developments. For example, the establishment of a new health care facility generally requires a CON. The types of health care facilities covered by this requirement vary from state to state, but most include hospitals, skilled or intermediate care nursing homes, ambulatory surgical centers, kidney disease treatment centers or freestanding hemodialysis units.

In many instances, statutory provisions as to whether a facility requires a CON may be ambiguous, thus complicating both the attorney to provide care to Medicaid recipients on a capitation payment basis.

42. The legal problems that must be addressed in organizing a PPO are numerous. The organization might consider the need for possible governmental approvals like CON and the necessity of meeting certain securities requirements. Tax and malpractice issues may also be a key concern to a PPO. The organization may have difficulty defining the extent of physician liability.

torney's and management's role. Not always clearly subject to review are projects involving the establishment of home health agencies, drug and alcohol treatment facilities, birth centers, hospices, urgicenters or primary care diagnostic facilities, and laboratories or other medical testing facilities. In Pennsylvania, for example, the establishment of a freestanding home health agency does not require a CON. In Florida it does. Moreover, in Florida, the expansion of services by a home health agency into a new county not previously served requires a CON.

Another example is instructive. The Pennsylvania Department of Health has placed hospitals and freestanding facilities on a level of parity, pursuant to a policy which does not characterize the establishment of hospital based home health services as the addition of a new clinical health service requiring a CON. In this instance, the regulatory agency has adapted to the incentives of PPS and has removed regulatory barriers so that hospitals may respond accordingly. Conversely, the establishment of a freestanding birth center does not require a CON in Pennsylvania, but the establishment of a hospital based birth center is treated as the addition of a new service which does require a CON. As can be seen from this, not all policies will be consistent, and not all facilities will be treated with parity.

Although thought by many to be cost effective, the development of hospital based ambulatory surgical programs may also face regulatory barriers. CONs are generally required for both freestanding ambulatory surgical centers and the establishment of hospital based ambulatory surgical services. Until just recently, again using Pennsylvania as the example, the Pennsylvania Department of Health considered the need for ambulatory surgical suites on the same basis as the need for hospital inpatient operating rooms. This was done due to the fact that there were no provisions in either the Health Systems Plans or the State Health Plan for separate consideration of ambulatory surgical capacity. Thus, because of excess hospital inpatient operating room capacity, it appeared likely that CON approval for ambulatory operating room capacity would be difficult to obtain. Once again, the potential regulatory problems facing prudent hospital diversification are apparent.

44. 28 PA. ADMIN. CODE § 401.2 (Shepard's 1984).
While hospitals will nevertheless be exploring the possibility of providing a wide range of new services in response to PPS, rehabilitation and psychiatric services deserve special attention. These latter services are not included in PPS when they are provided in "discrete" rehabilitation or psychiatric units. Rehabilitation and psychiatric care provided in discrete units will remain subject to cost-based reimbursement by the Medicare and Medicaid programs in most states. Hospitals currently providing those services have consequently sought to qualify as discrete units to obtain the more favorable cost-based reimbursement.

SHPDAs, however, may take the position that the establishment of a discrete unit requires a CON, even where those services have been provided by the hospital in the past in nondesignated beds. This creates a serious burden to hospitals providing comprehensive rehabilitation or psychiatric care and is entirely inconsistent with the incentives of PPS. Where hospitals might have been providing rehabilitation and psychiatric care in medical/surgical beds, they now must establish a discrete segregated unit or otherwise forgo favorable reimbursement. The inability to obtain a CON could force hospitals to discontinue those services.

Moreover, CON approvals for those discrete units may be difficult to obtain. Rigorous opposition by competitors can be expected, and often, as in the ambulatory surgical area, standards of need by which to evaluate the CON applications may not have been incorporated into the Health Systems Plans or the State Health Plan.

In addition, hospitals should not hesitate to challenge a finding that they must obtain a CON in such instances. Until a recent decision of the administration hearing board in Pennsylvania, hospitals were required to appeal the determination that the establishment of a discrete unit required a CON within thirty days of that determination.\(^\text{47}\) Often, such challenges had to be made before the actual CON application was reviewed. Failure to timely appeal forfeited the right to challenge the issue of reviewability.\(^\text{48}\) In the recent decision of In re: College Hill Medical Center,\(^\text{49}\) however, the

\(^{47}\) See In re: Wesley Manor Health Care, Inc., 1 STATE HEALTH FACILITY HEARING BOARD 8 (1981). Under the Wesley Manor decision, if a facility in Pennsylvania did not appeal a PaDOH Determination of Reviewability within 30 days of its issuance, it forfeited any future right to appeal the initial determination of whether the project was subject to CON review. Id.

\(^{48}\) Id.

\(^{49}\) CN 84-017, 84-018, decided by the Pennsylvania State Health Facility Hearing
board ruled that the failure to appeal a determination of reviewability within thirty days of its issuance does not prohibit a facility from raising that issue on any subsequent appeal from a decision on the merits of the CON application. 60

C. CON and Corporate Reorganization

Thus far we have emphasized that PPS encourages hospital diversification. Corporate restructuring has often been necessary to accommodate the multiple facilities services that result from diversification. As with those specific instances discussed above, however, corporate restructuring in the hospital industry faces significant CON barriers. Although many health care consultants have suggested that CON restrictions can be avoided through a reorganization, this is not always so. In most states, CON statutes have a provision consistent with federal regulations that requires a CON for "[t]he obligation by or on behalf of a health care facility of any capital expenditure" that exceeds the threshold amount. 51 The Department of Health and Human Services' (HHS) analysis of this regulation, as published in the Federal Register, suggests that expenditures by parent holding companies should not be considered as undertaken "on behalf of" a health care subsidiary unless either inpatient revenues are used to finance the capital expenditure or health care services will be provided to inpatients. 52 This narrow construction does not discourage corporate restructuring and nonpatient care activities can be developed by sister subsidiaries of hospitals without having to obtain a CON. Unfortunately, the states have not been as narrow in their interpretation.

The Pennsylvania SHPDA was among the first to develop a formal policy with respect to corporate restructuring and the interpretation of the "by or on behalf of" clause. 53 It was determined

Board on May 15, 1985.

50. Id.


53. Health care facilities are advised to examine regulatory agencies' internal memo and criteria in depth. Not all policies regarding CON review will be set forth in formal regulations. The Pennsylvania Department of Health has published various policy guidelines for a number of topics, not all of which are codified in official publications. See e.g., Certificate of Need Memorandum CON-82-06, "Reviewability of Corporate Restructuring," January 8, 1982, reprinted in Pennsylvania Bar Institute, No. 1985-305, Joint Ventures in Health Care 154-55 (1985).
that the presence of certain factors would likely lead to the conclusion that an activity was being undertaken "on behalf of" a health care facility and that a CON would, therefore, be required. These factors include the following:

1. The health care facility controls the new corporation, control being defined as the power to influence directly or indirectly the actions of the new corporation;
2. A one-third overlap of the boards of directors, and the presence of common officers;
3. The utilization of common employees;
4. The use of patient revenues to support the development or operation of the activity in question;
5. A contribution by the health care facility of one-third or more of the assets or acquisition costs of the new corporation or activity;
6. The health care facility guarantees financing in excess of the capital expenditure threshold; and
7. The activity in question benefits the health care facility.

Many of these factors will be difficult to avoid in a normal hospital reorganization where a parent holding company is created and new subsidiaries are formed for each new product line or service. Corporate reorganization does provide some advantage with respect to CON review of capital expenditures in excess of the current threshold of $736,200. As noted previously, expenditures in excess of that amount incurred by the hospital directly would generally require CON approval. Pursuant to a reorganization, however, a subsidiary of a parent holding company could incur the expenditure and possibly avoid CON review as an activity being undertaken "by or on behalf of" the hospital subsidiary, especially if the new activity is one not geared to providing health services. Beware, however, of activities in which any services will be provided to patients.

In Pennsylvania, health care facilities have been put on notice that they should not look to corporate reorganization as a means to avoid CON review. The only sure way to avoid CON review is to create a truly independent corporation over which the hospital will have no direct or indirect control. The establishment of such a cor-

55. Id.
56. 42 U.S.C. § 330m-6 (1982). The federal CON laws and regulations set forth the threshold amount that will trigger CON review. These numbers are indexed according to inflammatory rates and the cost of providing services.
poration, however, may not be possible with the typical hospital where its board is unwilling to relinquish that control. Even where control is relinquished, a risk remains that CON review could be premised on any benefit derived by the hospital from an activity of the independent corporation. Such is the basis for the CON review of hospital services provided pursuant to contract. A contractual relationship with the independent corporation for the provision of services to the hospital might be subject to review as the introduction of a new clinical health service by the hospital. Clearly, interpretation of the phrase "by or on behalf of" a health care facility leaves much discretion to the SHPDAs, many of which remain aggressive administrators of CON review as a cost containment method.

One type of reorganization which often can reduce the potential for CON review is one in which a parent holding company is created, with a Board of Directors only partially overlapping that of the hospital. New subsidiaries are then created as needed to conduct otherwise non-reviewable activities. The Board of the subsidiary will overlap with that of the parent, but not that of the hospital. Thus, the parent, not the hospital, controls the subsidiary. Similarly, major medical equipment, such as magnetic resonance imaging equipment, could be acquired through a subsidiary corporation without acquiring a CON if it is not used to treat inpatients and does not meet the "on behalf of" test.\(^{57}\) It is best for hospitals to address the factors that might trigger a CON review before contemplating reorganization, not afterwards. Thus, reorganization can be structured to minimize the possibility of CON review of future projects.

Once a CON has been issued, the SHPDA is responsible for periodically reviewing the progress of the CON applicant in implementing the project.\(^{58}\) Failure to implement the project as proposed could result in withdrawal of the CON. Here too, management may be confronting unpleasant barriers which restrict its progress. Most states, however, do not have the capacity to monitor CON projects. Rather, they have placed the burden on the CON applicant to inform the state as to progress in meeting the timetable for implementation and for conformity with the project description as approved in the CON.

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\(^{57}\) 35 Pa. Cons. Stat. Ann. § 448.701(5) (Purdon Supp. 1985). This section provides for the review of major medical equipment not owned by or located in a health care facility which will serve hospital inpatients. \(\text{Id.}\)

\(^{58}\) 42 C.F.R. § 123.410(18) (1985).
Major changes made to a project during implementation could result in development of a project different from that as originally approved. The federal regulations require review of such changes and, consequently, many states have developed separate mechanisms to conduct such reviews. With most projects, however, some changes will occur throughout implementation. These may result from unanticipated design problems during construction, or from a host of factors over which management should have some decision-making flexibility without having to receive further approvals. Unfortunately, some SHPDAs have adopted all-encompassing regulations for the review of changes, thereby severely restricting management flexibility. Again, using Pennsylvania for the example, approval is required for all changes, even those which may have only "relatively insignificant consequences." The types of changes most often encountered relate to the cost and financing of the project, the scope of the project, and changes in the bed complement of a facility.

Many states recognize that cost increases are to be expected due to inflation, work stoppages, and other factors. Those states may not require a review of minor cost increases, which are usually defined as some percentage of total approved costs. Other states, however, wanting to guard against cost increases resulting from poor planning and underestimated construction cost estimates, require a review of all cost increases. Regulators will argue that significant cost increases might bring into question the feasibility of the project and could jeopardize the facility's ability to complete it.

In order to avoid CON review of cost increases, some facilities reallocate or reduce the cost of individual project components, thereby holding total costs within the total approved amounts. This practice, while often not carefully monitored by the SHPDAs, can significantly alter the nature of an approved project. Some states have sought to prohibit such cost reallocations and will subject such changes to further CON review. Careful planning in preparing the CON application is, therefore, essential.

Other changes to a project may also require additional CON review. Most states require some review if there is a change in the construction square footage or design, a change in the bed capac-

59. 42 C.F.R. § 404(d) (1985). The Pennsylvania Department of Health requires applicants to notify the Department of any proposed project changes. 28 Pa. Admin. Code § 401.5(l) (Shepard's 1984). The Department must approve the changes before the applicant can proceed with the project. Id.

ity, a change in movable or fixed equipment, a change in the scope of services, or a change in the mode of financing. A CON is required for refinancing where the capital costs associated with the refinancing exceed the applicable capital expenditure threshold. Refinancing may be necessary prior to a reorganization in order to overcome restrictive covenants that would prohibit the transfer of assets and other aspects of the reorganization. Changes in location may also be reviewable. The nature of the review is likely to vary from an administrative review to a full review depending on the degree to which changes affect the nature of the project.

The review of changes in bed capacity can be particularly troublesome. Changes of more than 10 beds or 10% of total bed capacity are subject to CON review. Consistent with the incentives of the Medicare and Medicaid payment policy described above, many hospitals are seeking to realign their bed complement and adjust it to the changing services of the facility. Hospitals so acting may find unduly restrictive CON barriers. Federal regulations authorize capital expenditures associated with increases or decreases of up to 10 beds or 10% of bed capacity during a two year period without obtaining a CON. Similarly, capital expenditures associated with a relocation of beds or a redistribution among various categories of beds by up to 10 beds or 10%, whichever is less, are also authorized without acquiring a CON. It is not clear, however, whether a facility having exercised the right to increase capacity will then be able to relocate or redistribute up to 10 beds in the same two year period without first obtaining a CON. There may be a wide variation in policy among the states on this issue. A careful review of state requirements is thus necessary because this provision also leaves much to the discretion of the SHPDAs for interpretation.

D. Remaining Competitive in a Regulatory Environment

The extensive coverage of CON programs illustrates the difficulty facing hospital management in its effort to respond to the changing incentives of the Medicare and Medicaid programs. CON regulations create a barrier to achieving the diversification in facilities and services necessary to remain competitive.

To overcome these problems, a vigorous lobbying effort to review and restructure CON policy and priorities is necessary. The present regulations are too often inconsistent with the incentives of the reimbursement system. Regulation of activities such as

refinancings and incidental project changes promotes neither cost containment nor the efficient delivery of services.

Absent legislative reform, there is no reason to believe that SHPDAs and HSAs will not continue to apply CON laws broadly with a restrictive effect on hospital development. Administration of CON programs should not, however, be allowed to impair the ability of hospitals to offer necessary facilities and services. They should be given greater opportunity to compete freely in the marketplace which, because of the Medicare and Medicaid programs, will behave in a more traditional, competitive manner.

IV. Fraud and Abuse

Hospitals which have employed a variety of methods to increase admissions and develop new revenue streams are also confronted with possible violations of the highly restrictive prohibitions of the Medicare and Medicaid programs against fraud and abuse. In an effort to generate referrals and other business, many hospitals and other health-related enterprises have established more formalized links to physicians, physician groups, and other suppliers of goods and services. Hospitals, for example, will establish business relationships, such as joint ventures, with groups of physicians in the hope of increasing admissions by those physicians. While such joint venture arrangements are common in the business world, the regulatory restrictions of the fraud and abuse laws applicable to the health care industry lead to peculiar difficulties in structuring and operating a health care joint venture.

Government pressure to reduce the overall cost of health care services brought about the cost-saving measures, including PPS, that have been discussed above. Most of those cost containment efforts focus on ways to slow or limit unnecessary development. Similarly, vigorous review of the billing practices and business relationships between physicians and other providers, and even prosecution where appropriate, is also perceived by Congress and government officials as providing substantial cost savings to the taxpayer.

The Medicare and Medicaid Fraud and Abuse Amendments, first enacted by Congress in 1972, provide the specific statutory

63. For a discussion of the prospective payment reimbursement system, see supra notes 24-30 and accompanying text.
64. 42 U.S.C. §§ 1395nn, 1396h(n) (1982).
authority for defining "fraud" and "abuse" and for prosecuting physicians and other health care providers. Activities specifically proscribed by the amendments constitute criminal "fraud." Activities of a practitioner that do not rise to the level of criminality, but which nevertheless result in unnecessary expenditures by the Medicare or Medicaid Programs, constitute "abuse."

The amendments prohibit: (1) making false statements in connection with an application for benefits or payments; (2) failure to disclose any event affecting the rights to benefits or payments where there is an intent to defraud the Medicare or Medicaid programs; (3) conversion of any benefit or payment other than for the use of the beneficiary; and (4) receipt, payment, or solicitation of any remuneration such as a kickback, bribe, or rebate in exchange for the referral of a patient covered by the Medicare or Medicaid programs.

Criminal prosecutions of physicians for Medicare and Medicaid fraud, and suspension of physicians from participation in the Medicare and Medicaid programs, have increased dramatically in recent years. The increase in fraud and abuse prosecutions is directly related to the soaring cost of health care. Jail sentences are imposed more and more frequently. No one would question the importance of eliminating outright fraud and abuse. Numerous examples can be cited. A Kentucky physician received a one-year jail sentence for billing Medicare and Medicaid for sonograms, x-rays, blood and other tests that were never performed. An audacious Texas physician, already in jail for Medicare fraud, continued to use his provider number to bill Medicare for treatments of fictitious ailments using names of cellmates as patients.

The prohibition against remuneration in exchange for a referral, however, raises criminal implications for what otherwise appear to be normal business transactions. When applied to specific situations where participants in a joint venture may be generating increased Medicare and Medicaid referrals and receiving some form of financial benefit from an otherwise legitimate joint venture activity, the prohibitions of this provision are highly ambiguous. A more careful analysis of this provision is thus necessary.

65. Id.
66. Id.
69. Id. at 24.
Known as the "anti-kickback" or "illegal remuneration" provision, this section of the fraud and abuse amendments could provide a basis for prosecution of hospitals and other participants in joint venture arrangements. It reads as follows:

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or
(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or
(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.70

There are two exceptions:

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under this title if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this title; and
(B) any amount paid by an employer to any employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.71

How do these provisions impact on the joint venture or diversified business activities of hospitals and other health care entities? The most common method by which hospitals hope to increase admissions is to strengthen relationships with potential admitting

physicians. They want to encourage new admissions and they hope to do so by giving physicians an opportunity to share in the business that is generated. Hospitals, therefore, have entered into joint venture arrangements with physicians and together they have organized and operated diagnostic centers, home health agencies, ambulatory surgical centers, and even parking garages. They are also becoming partners in developing PPOs, HMOs, and insurance companies.

Similarly, other health-related enterprises are entering joint ventures with hospitals and physicians to increase their business. Durable Medical Equipment (DME) suppliers, for example, have established home health agencies in joint ventures with both hospitals and physicians in hopes of thereby providing an outlet for the sale of additional DME commonly used by patients served by those agencies.

These arrangements have the hidden potential to violate the illegal remuneration provision. For example, does the receipt of profits from a joint venture home health agency to whom a hospital refers patients constitute a kickback or illegal remuneration? Many lawyers think not, but there is no definite answer.

Addressing some of these issues, the Health Care Financing Administration (HCFA), in a letter to the fiscal intermediaries which administer the processing of claims for the Medicare program, advised of potential illegal "fee generating opportunities." In the example used by HCFA, DME companies paid "finder" or "referral fees" to health professionals such as discharge planners, social workers, or respiratory therapists, who were in a position to direct patients needing DME to a particular supplier. Payment of such fees specifically designed to induce referrals is clearly illegal.

The letter then suggests that more subtle arrangements might also be illegal. It cites instances where therapists refer patients to a DME supplier, and pursuant to an arrangement, receive payments from the supplier for setting up the DME equipment, performing monthly maintenance on the equipment, and instructing the patient in the use of the equipment. Some suppliers and ther-

73. Id.
74. Id.
75. Id.
apists have argued that such arrangements amount to no more than a bona fide employer-employee relationship and are therefore legal pursuant to the exception. Others have argued that payments under such arrangements are made only for legitimate services rendered and are not made in return for referrals. HCFA, on the other hand, stated that although the fee paid for the services actually rendered might not have been illegal, the opportunity to generate that fee is or very likely could be illegal because it is offered to induce a referral. This would constitute an illegal fee-generating opportunity. According to HCFA, payment or receipt of any remuneration, overt or covert, in kind or in cash intended to induce a referral is illegal. Thus, the supplier who induces patient referrals by offering therapists fee-generating opportunities is offering illegal remuneration. The opportunity becomes a form of remuneration.

The implications of HCFA's position should frighten any hospital or physician contemplating a joint venture in which either or both parties might anticipate increased business and profits. On a similar note, do arrangements by hospitals to provide physicians with clinic space, lab facilities and other opportunities which enhance the hospital/physician relationship, constitute illegal remuneration if referrals are made to the hospital by those physicians? In a common example, the hospital will construct a medical office building to attract physicians in hopes of strengthening the hospital's patient referral base. Is this an offer of illegal remuneration? In its strictest application, this indeed could be a technical violation of the illegal remuneration provision. Suppose the hospital leases the space to physicians for less than fair market rental value? What is the result if there is no obligation by the physicians to make referrals? What happens to a hospital which recruits physicians by offering a salary guarantee and other benefits? In rural areas, this latter practice has been accepted by HCFA to assure that otherwise underserved communities have access to health care services. Does this imply a different result for urban areas?

76. Id.
77. Id.
78. Id.
79. Id. HCFA's position was that a supplier who induces patient referrals by offering therapists the fee-generating opportunity was offering an illegal remuneration, even if the therapist received no more than his or her usual fee. Id.
80. Id.
81. Id.
For the most part, the hospitals themselves have not been the target of fraud and abuse investigations. Nevertheless, the examples demonstrate the complexity of the illegal remuneration provision. Moreover, there is no reason to believe that hospital practices will not be given more careful scrutiny in the future.

HCFA’s position on illegal fee-generating opportunities has not been well received. In response, the position was recently modified so as to permit evaluation of these opportunities on a case by case basis. Factors taken into consideration to determine whether fee-generating opportunities are illegal include, for example, consideration as to whether the respiratory therapists provide services to all patients of the DME supplier or only those referred by the therapist; whether there are unusual geographic or medical reasons for using the therapists who make the referrals; and whether the practices for installation and maintenance of equipment by other suppliers in the area are consistent with the practices under question.

The modified position of HCFA, however, provides little comfort in the face of a decision by the United States Third Circuit Court of Appeals in United States v. Greber. Dr. Greber, a cardiologist, owned and operated a company which provided cardiac diagnostic services. The company paid consultation fees for interpretations provided by all physicians who referred patients for testing. Both the trial court and the Third Circuit Court of Appeals held that the consultation fees constituted illegal remuneration, a holding which appears consistent with the illegal fee-generating opportunity described by HCFA. The Third Circuit stated:

Defendant contends that the [trial judge’s] charge was erroneous. He insists that absent a showing that the only purpose behind the fee was to improperly induce future services, compensating a physician for services actually rendered could not be a violation of the statute.

The government argues that Congress intended to combat financial incentives to physicians for ordering particular services patients did not require. The language and purpose of the statute support the government’s view. Even if the physician performs some service for the money received, the

83. Id.
84. 760 F.2d 68 (3d Cir. 1985).
85. Id. at 69-70.
86. Id.
87. Id. at 72.
potential for unnecessary drain on the Medicare system remains. The statute is aimed at the inducement factor. 88

This is an ominous decision. However, prosecution for this violation may not have commenced if this had been the only violation at issue. This violation could have been treated as a harmless technical matter that otherwise would not have deserved notice but for the fact that numerous other more serious violations were also present in the Greber case. The defendant Greber had clearly made false statements in seeking reimbursement for services that were medically unnecessary.

We have all been taught that hard cases make bad law. The Greber case must have been a hard case indeed. It will now be even more difficult for lawyers to offer definitive advise on arrangements such as these which may arise routinely as health care clients increasingly undertake joint venture arrangements. It is incumbent upon lawyers to provide practical advice. It is equally incumbent upon those responsible for enforcing these criminal provisions to exempt reasonable business practices from prosecution as technical violations of the fraud and abuse laws. 89

Unfortunately, it is not clear that the Department of Justice will recognize reasonable practices. In October of 1985, it advised the Office of Inspector General that it could not inform the public that those engaged in certain practices that did not increase costs to the Medicare and Medicaid programs would not be prosecuted. 90 The two activities at issue were both the waiver of Part A co-payments by hospitals as a marketing tool to increase admissions, and the case of vendor-paid administrative fees by hospital group purchasing organizations. 91 In the view of the Department of Justice, those

88. Id. at 71.

89. 42 U.S.C. § 1396b(g) (1982). The Office of the Inspector General (OIG) is the federal agency charged with the task of enforcing the Medicaid and Medicare fraud and abuse amendments. Id. Each state has its own state Medicaid Fraud Control Unit which is responsible for the investigation and prosecution of all violations of applicable state laws pertaining to fraud in the administration of the state Medicaid plan. 42 C.F.R. § 455.300(f) (1984). These units are also responsible for prosecuting allegations of abuse or neglect of patients who reside in facilities which receive payments under the plan. Id.

90. Letter from Stephen S. Trott, Assistant Attorney General, Criminal Division, U.S. Department of Justice to Richard T. Kusserow, Inspector General, Department of Health and Human Services (October 30, 1985)(discussing current health care marketing practices dealing with the routine waiver of Medicare coinsurance and deductible amounts and the payment by a supplier to an agent of a group of hospitals of a percentage of gross receipts resulting from the referral of hospital business).

91. Id.
activities technically violate the illegal remuneration provision. The Justice Department does, however, suggest that it will examine reasonableness on a case by case basis. A determination to prosecute represents a policy judgment that the fundamental interests of society require that criminal laws be applied to a particular set of circumstances. Such a determination must recognize that serious violations of federal law must be prosecuted, but also that prosecution entails profound consequences for the accused whether or not a conviction ultimately results.

In general, an analysis of whether a given joint venture violates the anti-remuneration provisions should take into consideration the legislative purpose of the anti-fraud and abuse rules and whether the activities run counter to that purpose. The joint venture should have a well-defined and bona fide business purpose. Each participant should make a reasonable contribution to the venture with respect to capitalization, funding of operations, performance of legitimate services, and sharing of economic risks. Each participant’s share of the profits should be consistent with his respective contributions and risks. Profits should not be based upon the volume of business or referrals generated by either of the participants. Finally, the venture should not lead to increased costs to the Medicare or Medicaid programs. With these principles in mind, the cautious lawyer should be able to structure joint venture arrangements with a fair degree of confidence that they will not be deemed violations of the fraud and abuse laws.

Conclusion

The health care industry faces a rapidly changing marketplace. The new payment policies of the Medicare and Medicaid benefit

92. Id. Assistant Attorney General Trott wrote that waiver of coinsurance was technically an illegal activity for a number of reasons. First, the existence of coinsurance is necessary to deter patients from seeking unnecessary hospitalization under the new prospective payment system. Second, simply because other mechanisms act as disincentives to overutilization by health care consumers, the necessity of the coinsurance payment is not negated. Third, the Department of Justice does not have the authority to change rules Congress has mandated applicable to federal programs. Fourth, the Inspector General has no authority to immunize conduct from prosecution which is clearly a crime under the law. Finally, Trott wrote that the Department of Justice does not have the resources to prosecute every violation of the Criminal Code, and, therefore, many prosecutions represent a policy judgment. He did not believe, however, that it was within his discretion to legalize certain conduct. For the same reasons, Trott also wrote that the Department of Justice was unwilling to take the position that obtaining supply discounts was legal in all cases, as it would be tantamount to saying a crime is not a crime. Id.

93. Id.
programs have introduced new incentives by which cost control will hopefully be achieved. The results so far have been promising. Somewhere along the way, however, other pre-existing programs must also change. They must be adapted to the new payment policies to relieve hospitals and other industry participants from restrictive regulatory barriers and prohibitive laws that frustrate appropriate development.