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Rural Healthcare Pro

An Issue Brief

February 1996

Health care delivery is no longer a cottage industry, its providers—clinics, hospitals, doctors and other practitioners—are struggling to cope with important changes including the displacement of traditional fee-for-service and indemnity insurance by managed care and the creation of integrated delivery systems which directly employ or manage them. These changes have created new organizational forms and modified relationships between professionals, the institutions in which they work, and the organizations that pay them. The expansion of contracting under managed care, cost containment, mergers into integrated networks and the rise of insurance control of patient groups is creating uncertainty for professionals and providers. These changes are occurring within a legal structure that grew to cope with a "traditional" health care delivery system. At the time that this issue brief is being completed, February 1996, there are changes being contemplated to meet the demands of the new market for health care, but those changes are neither certain nor considered by a consensus to be necessary. This *Issue Brief* presents the outlines of the laws that are, at this point in time, most relevant to rural providers.

Navigating through a new health care marketplace that favors economies of scale and hard bargaining is hardest for the rural provider, the group that retains much of the cottage industry character. Rural providers are following market trends and forming networks and affiliations and contracting with new payers to survive and compete. As they do so, they urgently seek some fixed points in the law by which to chart their course. Yet regulatory law that governs antitrust, fraud and abuse, and provides safe harbors has been created for a different set of circumstances than those which face rural providers as they innovate to remain competitive.

This *Issue Brief* is designed to offer a current (through 1995) explanation and description of legal and regulatory provisions that affect rural providers and their ability to adapt. This should not be considered a legally authoritative source; instead, the *Brief* seeks to help rural providers understand when they might face a legal or regulatory situation where they should seek qualified counsel.

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Who are rural health care providers?

In general, the US Department of Health and Human Services (DHHS) defines as rural any geographic area not within a Metropolitan Statistical Area, as delineated by the Office of Management and Budget (OMB) and the Census Bureau (42 U.S. Code Sec. 1320ww(2)(D)). Antitrust law also defines a 'rural area' as any definite geographic area that is nonmetropolitan according to OMB (CCH Medicare/Medicaid Guide, paragraph 41677). However, for certain purposes DHHS will look at rural health facilities more narrowly. For example, Section 1102(b) of the Social Security Act requires the Secretary of DHHS to issue an impact statement for rural hospitals when altering reimbursement policies; for Section 1102(b) purposes, a rural hospital must not only be outside a Metropolitan Statistical Area (MSA), but must also have fewer than 50 beds.[1]

DHHS will designate a defined geographic area as a 'shortage area' when either personal health services or primary medical care manpower are inadequate. (1994 Medicare Explained, Commerce Clearing House, Inc., Chicago)

How do 'fraud and abuse' rules apply to rural providers?

FRAUD is the misrepresentation of material facts for gain. For example, submitting false claims in order to obtain payment under the Medicare or Medicaid systems is fraud in the traditional legal sense. Fraud is a felony and rural providers have no special defenses to such charges. In 1992, the Health Care Financing Administration (HCFA) claimed $45 million in allegedly fraudulent overcharges from some 180,000 physicians. Fraudulent claims against the government are subject to federal prosecution under the False Claims Act and are punishable by fines of up to $2,000 per claim and expulsion from Medicare for up to five years. Both individual practitioners and facilities can be prosecuted.

ABUSE, in the context of health care, involves the provision of inappropriate, excessive, harmful, or poor-quality healthcare. Medicare and Medicaid 'fraud and abuse' includes incidents or practices by providers, practitioners, or suppliers that are inconsistent with accepted medical or business practice and which result in unnecessary costs, improper payments, or otherwise fail to meet professional standards. Section 1128(b) of the Social Security Act declares Medicare/Medicaid fraud and abuse a felony, punishable by fines and imprisonment. Fraud and abuse includes kickbacks, bribes, and rebates, defined as the knowing and willful offer to pay, solicit, or receive remuneration to induce business that Medicare or state healthcare programs (Medicaid) will reimburse.

What are the most important Safe Harbors available to Rural Providers?

The US DHHS Office of the Inspector General has set out ten broad areas, generally known as 'safe harbors,' where providers are exempt from the anti-kickback statute. The ten protected areas are as follows: investment interests, space rental, equipment rental, personal services and management contracts, sale of a practice, referral services, warranties, discounts, employees, and group purchasing arrangements. (54 Fed. Reg. 3088, as required by 42 USC 1320, Medicare and Medicaid Patient and Program Protection Act of 1987)

Meanwhile, Congress continues to refine the definition of which practices are acceptable and which are abusive. The Ethics in Patient Referrals Act of 1989 (often called 'Stark I') prohibits physicians from making referrals for laboratory

services to an entity in which the physician has an ownership interest or other financial arrangement from which the physician might realize gain. Congress later expanded the limitations on self-referral in the Comprehensive Physician Ownership and Self Referral Act (called Stark II). New Stark I regulations, most of which took effect September 13, 1995, also apply to Stark II. Stark II final rules are expected in late 1995 or early 1996. Stark II proposes to limit physicians' interests in the following:

- clinical laboratory services (prohibited since Jan. 1, 1992)
- physical therapy
- occupational therapy
- radiology and diagnostics
- radiation therapy
- durable medical equipment
- parenteral/enteral nutrients and supplies
- prosthetics and orthotics
- home health care
- outpatient prescriptions
- inpatient or outpatient hospital services

Moreover, under Stark II, the Department of Justice (DOJ) or the Inspector General of the DHHS need not prove intent to induce referrals for gain on the part of the provider in question. Like fraud, claims for improper referrals are also subject to the penalties provided by the False Claims Act (see above). Settlement agreements with the DOJ or the Inspector General of the DHHS usually demand repayment of the claims in question plus a penalty of three to four times that amount.

Physician investment in medical services is not completely prohibited, however. *Safe Harbors* protect legitimate investments in large, publicly traded corporations, and in small entities, typically joint ventures, where safeguards minimize any financial influence on a physician's decisions about patient referral. Safe harbor requirements for small entities are commonly described as 60–40 rules. Investors in a position to generate business (i.e., physicians who could make referrals) may hold no more than 40% of each class of interest during the previous fiscal year or 12-month period. Furthermore, no more than 40% of the entity's gross revenue in the prior fiscal year or 12-month period can arise from interested investors. However, financial relationships which do not fit squarely within the safe harbors are prohibited.

What additional legal protections exist for rural providers?

The 1993 Omnibus Budget Reconciliation Act (OBRA) created an exception to the general rules concerning physicians' interests in ancillary health care services. The 60–40 ownership provisions will not apply to designated health services *in rural areas* (and Puerto Rico), provided that substantially all of those services are furnished to residents of the rural area.[2] (Social Security Act Section 1877(d)) DHHS has proposed eliminating the 60–40 investor and the 60–40 revenue rules for entities in rural areas, as defined by OMB and the Census Bureau. DHHS is now accepting comments on the definition of 'rural' and may adopt that of 42 CFR 412.62(f)(1)(ii).

The other six standards for safe harbors will *not* be modified (Secs. 1001.952(a)(2)(ii - v, vii, viii).

The proposed modification of the 60–40 rules will permit an entity to make a bona fide offer of the investment interest to any person or entity without regard to whether the prospective investor is in a position to make referrals, furnish goods or services, or otherwise generate business for the investment. In place of the 60–40 requirements, at least 85% of the dollar value of the business in the prior year must arise from services provided to rural residents. (58 Fed. Reg. 49008)

How does Antitrust law apply to rural providers?

The Antitrust Division of the DOJ and the Federal Trade Commission (FTC) have issued a Joint Statement of Enforcement Policy and Analytical Principles relating to antitrust in the health care industry. The Statement creates nine 'safety zones,' paralleling the fraud and abuse safe harbors, designed to provide antitrust guidance to the health care industry as providers contemplate mergers, joint ventures, and other affiliations, in anticipation of health care reform. The following is a brief summary of some of the key provisions in the Statement:[3]

1. *Mergers*. Most mergers between two general acute-care hospitals, where one hospital has fewer than 100 licensed beds and a three-year average daily inpatient census of fewer than 40 patients, will fall within this safety zone, unless the small hospital is less than five years old.
2. *Joint Ventures Involving High Technology or Other Expensive Health Care Equipment*. Generally, no challenge will be made if the joint venture includes only the number of hospitals whose participation is necessary to own or operate the equipment, or both.
3. *Joint Ventures Involving Specialized Clinical or Other Expensive Health Care Services*. The Agencies have never challenged an integrated joint venture among hospitals to provide a specialized clinical or other expensive health care service, and they did not create a safety zone for these types of ventures.
4. *Collective Provision of Non-Fee-Related Information*. The Agencies generally will not challenge provider efforts to supply purchasers with outcome data or to jointly develop practice parameters.
5. *Fee-Related Information*. To qualify for this safety zone, a non-competitor third party must be responsible for managing the collection of information that will be given to purchasers. If information is shared among or available to competing providers, it must be more than three months old. Furthermore, if information is available to the providers furnishing data, at least five providers must report these data, and no individual provider's data may represent more than 25% of any statistic. Recipients must not be able to identify prices charged by any individual provider.
6. *Provider Participation in Exchanges of Price and Cost Information*. This safety zone is identical to the one governing providers that supply fee-related information to third parties.
7. *Joint Purchasing Arrangements Among Health Care Providers*. The Agencies generally will not challenge joint purchase arrangements if: (1) the purchases account for less than 35% of the total sales of the product/service in the relevant market; and (2) the cost of the products/services being purchased accounts for less than 20% of each participant's total revenues.
8. *Physician Joint Ventures*. The Agencies will not generally challenge a non-exclusive physician network comprising 30% or fewer of the physicians in each physician specialty who practice in a relevant geographic market. The venture must create a 'substantial financial risk' for its participants.
9. *Multi-Provider Networks*. The Agencies do not have sufficient experience in evaluating multi-provider networks at this time to create a safety zone. In analyzing a multi-provider network for antitrust violations, the Agencies will consider the geographic and service markets in question, the competitive effects of the network upon health care providers in those markets, the impact of selective contracting by the network and any efficiencies created by the network.

Rural health care systems may face additional difficulties in expanding into previously unserved communities, since DOJ/FTC look at the percentage of physicians an entity controls as evidence of its market power. Antitrust law considers a 'relevant market' to be a group of products and producers to whom geographically similarly situated consumers would turn if one producer's product became significantly more expensive, scarce, or the quality declined.

On the other hand, rural hospitals enjoy some exemptions to help them attract physicians to their localities. A rural hospital may offer a physician benefits such as income guarantees provided that he/she is relocating to start a practice in a new geographic area, or must have just completed an internship or residency. Payments to obtain referrals from physicians already practicing at another hospital in the area are forbidden. Congress is considering establishing seven standards for physician recruiting safe harbors for rural hospitals, medical service shortage areas, and hospitals with a large medically underserved population. The proposed requirements are the following:

1. Agreements between the hospital and the practitioner must be in writing;
2. The new practice must be at least 100 miles from the old one, and at least 85% of the revenue from the new practice must arise from treatment of new patients;
3. Benefits may be awarded for no more than three years, unless the hospital is in a shortage area;
4. The entity providing the benefits cannot condition them on volume of referrals;
5. The physician cannot be restricted from being on staff at other facilities;
6. Adjustments of benefits based on volume of business generated are prohibited; and
7. The physician must treat Medicare and Medicaid patients.

A proposed IRS Revenue Ruling, which was available for comment by the healthcare industry until July 3, 1995, set forth five situations involving physician recruiting.[4] According to this proposal, there are three important criteria to follow when determining the appropriateness of a hospital's physician recruitment incentives. First, the hospital must demonstrate objective evidence of a need for the physician's services. Second, the recruiting activities must bear a reasonable relationship to promoting and protecting the health of the community. And finally, the agreement must meet certain standards of formality, such as being properly documented and negotiated at arm's length. These three criteria are set out more fully below.

(1) *Objective Evidence Demonstrating a Need for the Physician's Services*

Examples of the type of objective evidence demonstrating a need for the physician's services may include, but are not limited to, the following:

- The hospital is in an area designated by the US Public Health Service as a Health Professional Shortage Area (HPSA); or
- The hospital is in an economically depressed area and has conducted a community needs assessment that indicates a shortage of the type of physician service being recruited; or
- The hospital has determined that it needs additional physicians of the type being recruited to provide adequate coverage and to ensure a high quality of medical care.

(2) *Recruiting Activities Bearing a Reasonable Relationship to Promoting and Protecting the Health of the Community*

These activities may include, but are not limited to, the following:

- payment of a bonus;

- guarantee of a mortgage;
- reimbursement of malpractice insurance;
- provision of subsidized office space for a limited time;
- provision of start-up financial assistance;
- payment of moving expenses;
- reimbursement of malpractice "tail" coverage; or
- provision of a reasonable private practice income guarantee.

(3) *Other Factors to Be Included in a Proper Physician Recruitment Incentive Agreement*

The following factors should all be included in a proper agreement:

- proper documentation;
- commercially reasonable terms;
- negotiated at arm's length; and
- approval by hospital's board of directors or its designees.

Some states have attempted to shield health care providers from federal antitrust action for collaborative activities by enacting Health Care Cooperative Acts (HCAs).[6] These laws attempt to bring sharing arrangements among facilities and providers within the scope of state action immunity to antitrust law if the parties can show the public benefit of their joint activities.

Wyoming, for example, enacted on July 1, 1995 legislation titled "Health Care Cooperative Arrangements for Antitrust Exceptions," which exempts collaborative health care arrangements from antitrust law by imposing active state regulation and supervision over such arrangements. The Wyoming legislation requires certain background material and empowers the director of the Department of Health to accept applications only when it is determined that "the arrangement is more likely to result in a better overall promotion of the quality of health care, access to health care, a lower cost for health care and the increased availability of a comprehensive health care system." Any application that improves certain criteria at the expense of other criteria will be accepted only if it is clear that the improvements will outweigh the negative impacts.[7]

What are the malpractice standards for rural health care providers?

The type of physician most often sued for medical malpractice is aged 41-45, in full-time solo practice, board-certified and US-educated; these types of physicians are more likely to serve a rural community than an urban one. Physicians practicing Ob-Gyn, general internal medicine, general surgery, orthopedic surgery, and general and family practice are most commonly sued. Primary care gatekeepers are often responsible for many aspects of care which may lead to a suit, such as prescription of medication, consultations, diagnostic evaluations, and the administration of anesthesia. This also describes a physician who is more likely to serve a rural community than an urban one. Nevertheless, prevailing wisdom has been that rural physicians are less likely to be sued than their urban counterparts. However, two studies have found that geographic factors (urban vs. rural) do not seem to have an impact on physicians' malpractice claim experience.[8]

The proportions of Ob-Gyns and of surgeons who have had at least one claim filed against them are 57% and 53% respectively. Birth outcomes, breast cancer, displaced discs, acute myocardial infarction, lung cancer, femoral fracture,

appendicitis, and cataracts bring the highest numbers of claims. The highest damage awards tend to occur in cases involving neurology, pediatrics, colon and rectal surgery, Ob-Gyn, and pathology.

Traditionally, tort law afforded rural practitioners some additional protection from liability through the locality rule, which used a community-based standard of care to determine negligence. However, most courts have now abandoned the traditional doctrine in favor of national standards for medical decisionmaking, declaring the older rule irrelevant to contemporary practice, especially for physicians who are board-certified, e.g., Morrison v. Macnamara, 407 A.2d 555 at 565, D.C. Ct. App. 1979 (holding that the standard of care as to board-certified physicians, hospitals, medical laboratories, and other health care providers is to be measured by the national standard). In response to standardization of medical treatment, some states (e.g., Maine, Florida, Vermont, and Minnesota) are developing practice guidelines that physicians can use as evidence in their defense in malpractice cases.

In implementing the Medicare and Medicaid Patient and Program Protection Act of 1987 (Public Law 100-93), DHHS ruled that allegations of medical malpractice will continue to be evaluated by peer review organizations (PROs). (57 Fed. Reg. 3298) However, HCFA has defined PRO areas as states (49 Fed Reg. 7202), seemingly eliminating the community-based standard of care which might not demand the same things from rural as from urban practitioners. DHHS has commented that while *standards* will continue to be established on the state or national level, a *facility's* technical equipment and level of expertise will be considered in the review of malpractice claims. Whether or when the patient in question should have been transferred to a more specialized facility will be one of the factors PROs will take into account. Furthermore, in designated shortage areas, hospitals will be allowed to pay for malpractice insurance for obstetricians or certified nurse-midwives without being in violation of antitrust laws.

Endnotes

1. See 42 U.S. Code Sec. 1395ww(d)(5)(D)(iii) for the definition of 'sole community hospital,' and Sec. 1861(aa)(2) of the Social Security Act for the definition of 'rural health clinic.'
2. 'Substantially all' has been defined to mean that at least 75 percent of the individuals to whom services are furnished reside in a rural area. 60 Fed. Reg. 41914.
3. See Department of Justice press release, Sept. 27, 1994.
4. Source: "Tax Consequences of Physician Recruitment Incentives Provided by Hospitals Described in Section 501(c)(3) of the Internal Revenue Code," *Internal Revenue Bulletin*, April 3, 1995.
5. Size, Tim. "Antitrust and Certificates of Public Advantage," Rural Wisconsin Health Cooperative, June 1995.
6. Teevans, James W. and Daniel M. Campion. "State Action Immunity: Immunizing Health Care Cooperative Agreements." Washington, DC: Alpha Center, 1995.
7. "Rural Providers Risk Antitrust Scrutiny: State Legislation Sets Up Supervision of Cooperative Arrangements," *Integrated Health Care Delivery Systems*, Vol. 2, No. 12, August 1995.
8. Sloan et al., "Medical Malpractice Experiences of Physicians—Predictable or Haphazard?" *Journal of the American Medical Association*, December 15, 1989; Rolph et al., "Malpractice Claims Data as Quality Improvement Tool," *Journal of the American Medical Association*, October 16, 1991.

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