THE APPLICATION OF ANTITRUST AND FRAUD-AND-ABUSE LAW TO SPECIALTY HOSPITALS

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I. INTRODUCTION

The recent growth of specialty hospitals in the health care industry represents a significant departure from the way in which most hospital care is currently provided. While medical practice is highly fragmented, hospital care has traditionally been an integrated service—typically a large facility handles most medical treatments and provides a wide array of services for patients. Single specialty hospitals present a different form of hospital care that channels certain medical specialties and treatments into distinct

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hospitals, each devoted to particular sets of patients. The laws regulating health care must adapt to such changes in the provision of health care. Under current standards, fraud-and-abuse laws fail to address adequately the new challenges that specialty hospitals present to self-referral enforcement. The traditional application of antitrust laws may overlook the procompetitive effects of new types of transactions and agreements involving specialty hospitals, and, simultaneously, these laws may fail to protect the public effectively against some of the anticompetitive advantages that each type of hospital has over another. The rapid proliferation of specialty hospitals in the health care market demands evaluation of these issues now.

This Note argues that the existence of specialty hospitals raises issues that are not covered by current antitrust and antifraud legislation, yet must be addressed in the interests of the health care industry. Part II presents the current status of fraud-and-abuse laws regulating health care, with particular attention to self-referral regulations. Part III similarly seeks to outline the status quo of antitrust policy and enforcement in the health care industry. Part IV explains what single specialty hospitals are, and what advantages and disadvantages they present to the health care industry, focusing primarily on fraud and antitrust issues. Part V addresses particular instances and ways in which antitrust and fraud-and-abuse laws interact in the context of specialty hospitals. Part V first focuses on general conflicts between regulation and competition by providing three specific examples of such interaction: payment-for-performance theories, industry reactions to specialty hospital competition, and certificate of need ("CON") laws as a direct regulation of hospital care. Part V then examines specialty hospitals in terms of general health policy goals and nonprice features of competition. Finally, Part VI proposes possible solutions to some of the problems presented in earlier parts, including specific changes to the self-referral amendments and strict enforcement of antitrust laws in the specialty hospital subsector of the health care industry.

II. FRAUD-AND-ABUSE LAWS

Due to the unique nature of the industry, health care is regulated extensively by state and federal governments. An important component of this regulation includes fraud-and-abuse laws, which aim to minimize the fraudulent and wasteful claims of health care providers seeking payment from governments. It is estimated that as much as 10% of health care spending is lost to fraud, waste, and abuse,[1] which translates into losses of approximately $170 billion per year as of 2003.[2] Health care antifraud laws developed from a minor provision in the original Medicare and Medicaid legislation that prohibited false statements made to obtain benefits.[3] Today, health care antifraud laws include "a complicated interlocking array of state and federal civil, criminal, and administrative antifraud laws."[4] Many of these laws were implemented with the goal of controlling fraud, waste, and abuse in health care.[5] However, practical and theoretical problems in implementing antifraud policies help to explain the difficulty of actually controlling fraud and abuse. These problems show how the policies may lead to "underdeterring undesirable conduct and overdeterring desirable conduct" with corresponding negative impacts on the health care industry.[6]

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[1] David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen,"* 30 J. LEGAL STUD. 531, 532 (2001).

[2] NATIONAL HEALTH STATISTICS GROUP, CENTERS FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES AGGREGATE AND PER CAPITA AMOUNTS, PERCENT DISTRIBUTION, AND AVERAGE ANNUAL PERCENT GROWTH, BY SOURCE OF FUNDS, *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhetables.pdf (listing 2003 aggregate national health expenditures at approximately $1.68 trillion).

[3] William M. Sage, *Fraud and Abuse Law*, 282 J. AM. MED. ASS'N 1179, 1179 (1999).

[4] Hyman, *supra* note 1, at 534.

[5] *See, e.g.*, *id.* (discussing the "three most significant health care specific fraud control provisions" and listing several recent developments in attacking fraud in the health care industry).

[6] *Id.* at 533.

Historically, physicians dominated the health care system, controlling both the supply of, and demand for, health care services.[7] Physicians had professional expertise, while patients both lacked sufficient information to question physician decisions and trusted physicians on an almost "mythical" level.[8] The combination of this relationship between physicians and patients and the advent of third party payers taking cost concerns away from patients makes it easy to understand why health care spending rose dramatically after the introductions of Medicare, Medicaid, and employer-provided health insurance.[9] "Both private insurers and government programs effectively insulate patients and providers from the true cost of treatment decisions and so reduce the incentive to weigh costs carefully against benefits."[10] Several proposals for new types of health plans were made in the 1970s to deal with "escalating health care spending, unavailability of or inadequate access to health care services in inner cities and rural areas, fragmented services to the medically indigent, and insufficient use of preventive measures to reduce the incidence and severity of illness."[11] Ultimately, the plans divided along the lines of either market reform or regulatory reform. By the late 1970s, the general trend toward deregulation and reaction against big government influenced the health care industry to follow suit. In 1979, for example, Congress rejected President Carter's effort to put regulatory price controls on hospitals.[12] Despite this move toward deregulation in the health care market, there remains, even today, an "underlying tension . . . between a medical care system geared toward expansion and a society and state requiring some means of control over medical

[7] Gail B. Agrawal & Howard R. Veit, *Back to the Future: The Managed Care Revolution*, 65 LAW & CONTEMP. PROBS. 11, 14 (2002).

[8] *Id.*

[9] *Id.* at 16.

[10] PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 380 (1982).

[11] Agrawal & Veit, *supra* note 7, at 16.

[12] *Id.* at 20.

expenditures."[13] The government thus continues to work to control health care expenditures through antifraud laws.

The anti-kickback, civil false claims, and self-referral provisions are the most significant statutory antifraud provisions aimed at controlling health care spending.[14] They protect only the government and do so by criminalizing certain acts that result in overpayments to providers under the Medicare and Medicaid programs. Private insurers get minimal direct protection from health care antifraud laws and must either rely on general antifraud protections or monitor fraudulent practices themselves. For example, the Anti-Kickback Statute criminalizes the solicitation or receipt of remuneration in connection with items or services "for which payment may be made in whole or in part under a Federal health care program."[15] The Civil False Claims Act creates liability for any person who knowingly presents to the government a false claim for payment.[16]

The Self-Referral Amendments prohibit physicians from referring Medicare and Medicaid patients to providers in which they (or an immediate family member) hold a financial interest, and also prohibit service providers from billing for services performed as a result of such referrals.[17] The amendments include various exceptions. Among these exceptions is one for a financial interest in what may be termed "whole hospitals." This exception allows self-referral if the physician is authorized to perform services at a hospital and his ownership or investment is in the hospital itself (and not merely a subdivision thereof).[18] This exception for whole hospitals was created on the theory that a single physician's stake in an entire hospital is unlikely to be large enough for self-referrals to produce significant personal

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[13] STARR, *supra* note 10, at 380.

[14] 42 U.S.C. § 1320a-7b(b) (2000); 31 U.S.C. § 3729(a) (2000); 42 U.S.C. § 1395nn(a)(1) (2000).

[15] 42 U.S.C. § 1320a-7b(b) (2000).

[16] 31 U.S.C. § 3729(a) (2000).

[17] 42 U.S.C. § 1395nn(a)(1) (2000).

[18] *Id.* § 1395nn(d)(3).

financial gain.[19] From December 8, 2003, until June 8, 2005, an 18-month moratorium excluded investment in specialty hospitals from the "whole hospital" exception.[20] Pending legislation introduced in May 2005 would extend the moratorium permanently,[21] and in the meantime, the Deficit Reduction Act of 2005, which passed in December 2005, has added an additional eight months to the moratorium in order to allow further review by the Centers for Medicare & Medicaid Services.[22] This special treatment for specialty hospital investments is based on the fact that specialty hospitals are usually small enough in size and scope that physicians' referrals could affect the financial gains of the hospital and, consequently, a physician's financial interest therein.[23]

Fraud concerns generally arise because fragmentation in the health care industry and the fee-for-service government payment system provide doctors and hospitals with incentives to maximize service volume. Medicare and other health care payers pay a predetermined lump sum rate for

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[19] U.S. GEN. ACCOUNTING OFFICE, SPECIALTY HOSPITALS: INFORMATION ON NATIONAL MARKET SHARE, PHYSICIAN OWNERSHIP, AND PATIENTS SERVED, GAO-03-683R 2 (April 18, 2003), *available at* http://www.gao.gov/new.items/d03683r.pdf [hereinafter GAO LETTER].

[20] 42 U.S.C. § 1395nn(d)(3)(B) (2000) (as established through Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507 (2003)). The Act also requested reports from the General Accounting Office (GAO), the Medicare Payment Advisory Commission (MedPAC), and Centers for Medicare and Medicaid Services (CMS) on physician-owned specialty hospitals. The reports were delivered in the spring of 2005 and are available at http://www.gao.gov/new.items/d05647r.pdf, http://www.medpac.gov/publications/congressional_reports/Mar05_SpecHospitals.pdf, and http://www.cms.hhs.gov/media/press/files/052005/RTCStudyofPhysOwnedSpecHosp.pdf.

[21] Hospital Fair Competition Act of 2005, S. 1002, 109th Cong. § 3 (2005).

[22] Deficit Reduction Act of 2005, S. 1932, 109th Cong. § 5006 (2005). *See also* Terence Hyland, *Budget Deal Includes Extension of Present Limitations on Specialty Hospitals,* 10 BNA Health Care Daily Report 243 (Dec. 20, 2005), *available at* http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-6K8VDP?OpenDocument.

[23] GAO LETTER, *supra* note 19, at 2.

each hospital discharge, which is based on a patient's diagnosis, regardless of the particular patient's actual costs. The payment rate is based on an "average bundle of services" expected for a particular diagnosis—so the payment rate is the expected cost of a typical case within each patient's diagnosis related group ("DRG"), and the rate is "not adjusted for within-DRG differences in severity of illness."[24] This system leads to "self-referral" concerns that physician investors will over-refer less sick patients within a given DRG to hospitals in which they have investments. Although antifraud laws were established precisely to prevent such self-referrals, due to the "whole hospital" exception, investment in and referral to specialty hospitals allowed physicians to gain economic advantage through their dual role. With the benefit of abusive self-referrals, specialty hospitals could generate lower costs by treating less sick patients, and thus, achieve higher profits overall. The effect of the first moratorium was to halt temporarily further development of physician-owned specialty hospitals.[25] On May 11, 2005, with the end of the original 18-month moratorium on self-referral to physician-owned specialty hospitals looming, Senators Chuck Grassley and Max Baucus introduced the Hospital Fair Competition Act of 2005.[26] This act would extend the moratorium permanently by "prohibit[ing] physicians from referring Medicare and Medicaid patients to new specialty hospitals in which they have an ownership interest."[27] The bill's effective date was set at June 8, 2005, regardless of the date of enactment. At present, there has been no vote on the bipartisan bill, but

[24] *Id.* at 5.

[25] U.S. GOV'T ACCOUNTABILITY OFFICE, SPECIALTY HOSPITALS: INFORMATION ON POTENTIAL NEW FACILITIES, GAO-05-647R 5 (May 19, 2005), *available at* http://www.gao.gov/new.items/d05647r.pdf.

[26] Hospital Fair Competition Act of 2005, S. 1002, 109th Cong. (2005).

[27] Press Release, Senator Chuck Grassley, Grassley, Baucus Urge Colleagues to Support Bill Reining in Doctor-Owned Specialty Hospitals (June 8, 2005), *available at* http://finance.senate.gov/press/Gpress/2005/prg060805a.pdf.

twenty-two senators have signed on as co-sponsors.[28] In December 2005, Congress approved the Deficit Reduction Act of 2005, which includes a continued suspension on enrollment of new specialty hospitals for up to eight months, during which time the Secretary of Health and Human Services is to develop a strategic plan to address issues regarding physician investment in specialty hospitals.[29] Due to the uncertainty regarding future legislation and the extension of the moratorium on new specialty hospital approval, the growth and development of specialty hospitals remain slow.

The antifraud statutes were developed at a time when fee-for-service payment systems were the norm in the health care industry. Thus, the statutes were constructed to act against contractual commitments and cooperative agreements that contrast with fee-for-service transactions. With the introduction of an entirely different health care payment scheme by managed care providers, "fraud and abuse law continues to penalize the health care industry for entering into cooperative transactions that would be natural and desirable in other sectors of the economy."[30] Antifraud laws have not kept up with the changes in health care payment systems, and their enforcement may not always have meaningful and positive effects on the industry.

III. ANTITRUST LAWS

Antitrust laws regulate competition by encouraging competitive markets and restricting anticompetitive actions. Competition tends to maximize the economic performance of a market by promoting efficiency and consumer welfare. The foundation of antitrust law, the Sherman Act, generally prohibits contracts, combinations, and conspiracies in restraint of trade, as well as monopolization or attempts to

[28] Cosponsor count as of January 1, 2006. *See* Cosponsor List, S. 1002, The Hospital Fair Competition Act of 2005, http://thomas.loc.gov/cgi-bin/bdquery/z?d109:SN01002:@@@P.

[29] Deficit Reduction Act of 2005, S. 1932, 109th Cong. § 5006 (2005).

[30] Sage, *supra* note 3, at 1180.

monopolize by any person.[31] Common antitrust allegations in the health care industry include unreasonable restraint of trade, monopolization, and boycott.[32] Under the antitrust laws, there are both public causes of action, brought by the Department of Justice ("DOJ") and Federal Trade Commission ("FTC"), and private causes of action. Private cases are civil actions that may result in treble damages,[33] and therefore, private persons have an extra incentive to pursue cases against antitrust violators.

Health care is unique from most other industries, and thus, antitrust in health care must be conceived of differently than in traditional markets. Health care is highly regulated and often considered a "special" good to which traditional economic theories may not apply.[34] The extent of regulation and fragmentation in the health care industry prevent it from being a fully competitive market. Despite these differences, the Supreme Court has made it clear that antitrust laws fully apply to the health care market.[35] While both price and nonprice competition can yield significant benefits for the health care market by lowering prices, increasing access, raising quality, and encouraging innovation, competition leaves a number of other problems unsolved.[36] Significant information and incentive problems exist among consumers, providers, and payers. As a general matter, providers have vastly more information than consumers and payers about the services they provide, as well as strong incentives to prioritize cost over quality.[37] Yet, the extensive regulations on health care

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[31] 15 U.S.C. §§ 1-2 (2000).

[32] Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 578 (2002).

[33] 15 U.S.C. § 15(a) (2000).

[34] DOJ & FTC, IMPROVING HEALTH CARE: A DOSE OF COMPETITION ES-1 (July 2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf [hereinafter IMPROVING HEALTH CARE].

[35] *See* Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332 (1982); Goldfarb v. Va. State Bar, 421 U.S. 773 (1975).

[36] IMPROVING HEALTH CARE, *supra* note 34, at ES-4.

[37] *Id.* at ES-6.

developed "haphazardly," not all the pieces fit together, and the regulations often "exacerbate anticompetitive tendencies of the overall structure."[38] Due to the skyrocketing costs of health care, many in the industry are making attempts at cost containment. The result is a variety of new forms of payment by government and private payers, attempts by physicians and hospitals at consolidation and joint ventures, and more attention to the quality of health care services.[39] While these results may be competitively advantageous and in line with antitrust goals, they may only appear to be so when quality is factored into payment schemes. By changing the financial incentives of providers through these alternative payment systems and including quality as a factor in payment, competition may be increased.

Aside from particular areas like Medicare and Medicaid, the role of the federal government in health care has generally diminished since the early 1980s, when market reform dominated regulatory reform and the private sector "assumed the dominant role in reshaping the health care marketplace."[40] At the beginning of President Reagan's first term, the administration set the clear goals of increased reliance on competition and incentives in health care and a reduction of the government's role in health care markets.[41] These attempts at deregulation increased the role of antitrust law in monitoring the industry, which has expanded antitrust litigation in the health care field over the past few decades.[42] While antitrust laws apply fully to the health care market, enforcement efforts have largely avoided examining Medicare and Medicaid and their competitive impact. Antitrust law, like fraud law, is concerned primarily with physician domination, but takes aim at agreements and

[38] *Id.* at ES-4.

[39] *Id.* at ES-7.

[40] Agrawal & Veit, *supra* note 7, at 34.

[41] STARR, *supra* note 10, at 419.

[42] *Id.* at 418. The Federal Trade Commission entered the health care field in 1975 and has played a dominant role ever since.

cartels that stifle competition rather than specific transactions that unlawfully benefit physicians.[43]

In the health care industry, private antitrust causes of action often involve physician privileges and credentialing.[44] This type of action makes up 35% of private antitrust claims in health care; the next highest, at 28%, are exclusive contracting claims in which a hospital contracts with only one physician or group for services.[45] These cases are generally held to a rule-of-reason standard of review rather than a per se rule. Under a rule-of-reason standard, the plaintiff must prove that the defendant has market power.[46] Historically, defendants are significantly more likely to win than plaintiffs.[47] Physicians have such wide leeway in making staff decisions that the likelihood of successfully challenging these decisions is quite low.[48] Defendant hospitals and medical staff have a wide range of reasonable defenses to such charges. Common defenses include the absence of antitrust injury, legitimate business purposes, procompetitive effects, efficiencies, state action immunity, peer review immunity under HCQIA, and political action immunity.[49] Physician privileging suits are likely to become even more common in the context of specialty hospitals as

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[43] *See generally* DOJ & FTC, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), *available at* http://www.ftc.gov/reports/hlth3s.pdf (outlining various types of agreements, joint ventures, and arrangements that the agencies pursue in enforcing antitrust laws).

[44] These actions involve doctors suing medical staffs for anticompetitive behaviors such as exclusion from their staffs.

[45] Hammer & Sage, *supra* note 32, at 568.

[46] Tim A. Thomas, Annotation, *Denial by Hospital of Staff Privileges or Referrals to Physician or Other Health Care Practitioner as Violation of Sherman Act*, 89 A.L.R. FED. 419 (1994).

[47] In a survey of private health care antitrust decisions, plaintiffs in staff privileges cases prevailed in only seven percent of cases. Hammer & Sage, *supra* note 32, at 575.

[48] The Health Care Quality Improvement Act of 1986 (HCQIA) granted qualified immunity to physicians during the peer review process. 42 U.S.C. § 11101 (2000).

[49] Hammer & Sage, *supra* note 32, at 582.

general hospitals react to the increased competition by limiting staff privileges.

IV. SINGLE SPECIALTY HOSPITALS

Fraud laws and antitrust laws intersect within the health care arena in a variety of ways. One vivid example of such interaction is in single specialty hospitals ("SSHs"). SSHs provide care for a specific specialty or type of patient.[50] They tend to be for-profit hospitals whose physicians often have ownership interests in the facility.[51] Nationally, specialty hospitals have a relatively small presence,[52] but because they treat large shares of the patients with a specific medical condition, their presence can have a significant impact on the community health care markets in which they are

[50] Specialty hospitals are defined by GAO as hospitals in which "the diagnosis-related group (DRG) classification for two-thirds of its Medicare patients (or two-thirds of all of its patients where such data were available) fell into no more than two major diagnosis categories, or if at least two-thirds of its patients were classified in surgical DRGs." U.S. GEN. ACCOUNTING OFFICE, SPECIALTY HOSPITALS: GEOGRAPHIC LOCATION, SERVICES PROVIDED, AND FINANCIAL PERFORMANCE, GAO-04-167 2 (Oct. 2003), *available at* http://www.gao.gov/new.items/d04167.pdf [hereinafter GAO REPORT]. Specialty hospitals are defined in the self-referral laws as hospitals primarily or exclusively providing care and treatment for patients with cardiac conditions, orthopedic conditions, surgical procedures, or any other category designated by the Secretary. 42 U.S.C. § 1395nn(h)(7) (2000).

[51] Seventy-four percent of specialty hospitals overall are for-profit, as compared to about 20% of all general hospitals. Almost 93% of specialty hospitals opened between 1990 and 2003 are for-profit. In 2003, more than 70% of specialty hospitals had some degree of physician ownership. Of these hospitals, the average combined physician ownership was 50% of the hospital. Individual physician ownership varied by hospital but tended to be low. GAO REPORT, *supra* note 50, at 8-9.

[52] As of 2003, ninety-two specialty hospitals represented about 2% of short-term, acute care hospitals nationwide. GAO LETTER, *supra* note 19, at 5. In 2001, eighty specialty hospitals represented about 1% of Medicare spending for inpatient services. *Id.* at 5.

located.[53] Within its niche, the specialty hospital can be a significant competitor to a community's general hospital. Nationally, the number of specialty hospitals is rapidly growing.[54]

Interest in specialty hospitals has increased recently in response to both regulatory and market conditions that yield advantages for this type of hospital. Regulatory advantages include the "whole hospital" loophole in the self-referral laws, which allows physicians to realize financial gain by investing in and referring patients to specialty hospitals. Physicians hold a market advantage in their ability to send patients with good insurance or lower-cost treatment needs to their hospitals. Additionally, there are genuine economic advantages for specialty hospitals because they are small, concentrated facilities focusing on a narrow medical field. These include economies of scale, efficiencies, and returns to specialization based on volume. Specialty hospitals offer a particular lens through which to view the interaction of antitrust and fraud law from both regulatory and competitive approaches.

Many argue that the advantages of SSHs are improved efficiency and effectiveness, higher patient satisfaction, increased volume and access, better disease management and clinical standards, and lower costs due to shorter stays, efficient use of nursing, and the frequency of direct home discharges.[55] On the other hand, many believe that SSHs may have negative impacts on the health care market. While the potential that patients with multiple conditions may receive less comprehensive care at specialty hospitals exists, most of the concerns about SSHs involve their comparison to, and competition with, general community hospitals. For instance, SSHs are able to avoid significant costs by not providing emergency services, thus giving them

[53] Specialty hospitals in the GAO study often treated more patients than the median general hospital's practice in the specialty hospitals' market areas. GAO REPORT, *supra* note 50, at 24.

[54] The total number of specialty hospitals tripled between 1990 and March 2003. GAO LETTER, *supra* note 19, at 6.

[55] IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 19.

a competitive advantage in relation to general hospitals and making them less comparable to general hospitals.[56] Under the Emergency Medical Treatment and Labor Act ("EMTALA"), hospitals that receive Medicare funding and have an emergency department must give a medical screening exam and provide stabilizing treatment in emergency situations to any individual who comes into the emergency department, regardless of their ability to pay or eligibility for benefits.[57] Under this regulation, specialty hospitals that do not provide emergency services avoid the costs involved with EMTALA compliance.

Another general concern is that physicians will invest in specialty hospitals and take advantage of the "whole hospital" loophole in the self-referral laws by over-referring particular types of patients to their hospitals. Thus, healthier, lower risk patients will be referred to specialty hospitals while sicker, higher risk patients will be referred to general hospitals. As a result of the government's practice of paying a fixed amount for a given diagnosis, SSHs and general hospitals will be paid the same amount despite potentially having different costs based on their particular patients. The concern is that SSHs will receive the most profitable procedures and patients, while general hospitals will end up with less money to cross-subsidize less profitable care that serves community needs, such as charity care and emergency services.[58] For these reasons, the specialty hospital exception to the "whole hospital" loophole was put into the statute for the original 18-month term and then extended for eight months in December 2005.[59] The

[56] Overall, about 45% of specialty hospitals have emergency care facilities as compared to 92% of general hospitals. Emergency departments in specialty hospitals treat significantly fewer patients than those in general hospitals. GAO REPORT, *supra* note 50, at 17-18.

[57] 42 U.S.C. § 1395dd (2000).

[58] IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 20-21.

[59] 42 U.S.C. § 1395nn(d)(3) (2000) (as established through Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507 (2003)); Deficit Reduction Act of 2005, S. 1932, 109th Cong. § 5006 (2005).

moratorium on specialty hospital investment and referral contains various exceptions, including the caveat that it only applies to new specialty hospitals, not those hospitals already in operation or under development at the start of the moratorium.[60] The proposed bill to extend the moratorium permanently, if enacted, would contain similar exceptions.[61]

V. THE INTERSECTION OF ANTITRUST AND ANTIFRAUD LAW IN SPECIALTY HOSPITALS

Specialty hospitals provide a clear example of the way in which antifraud laws and antitrust laws meet, interact, and often conflict with one another in the health care industry. Specialty hospitals trigger antitrust and competition concerns by presenting alternative health care options for many patients while maintaining several competitive advantages over general hospitals. General hospitals, in turn, may violate antitrust laws by raising barriers to entry for SSHs and constraining their ability to compete in the shared market.[62] SSHs also raise regulatory concerns under fraud-and-abuse law. Most notably, the "whole hospital" exception to the self-referral fraud restrictions allowed physician-investors to profit by referring patients to their own specialty hospitals. While the temporary moratorium and the proposed Hospital Fair Competition Act of 2005 demonstrate legislators' initial acknowledgment of the

[60] Specifically, the moratorium does not apply to specialty hospitals in operation or under development as of November 18, 2003, to hospitals for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of that date, to hospitals for which the type of categories of treatment does not change relative to that date, to hospitals whose number of beds does not increase in size by more than 50%, or to any other facility that meets other requirements specified by the Secretary. 42 U.S.C. § 1395nn(h)(7)(B) (2000).

[61] *See* Hospital Fair Competition Act of 2005, S. 1002, 109th Cong. § 3(b) (2005).

[62] *See* IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 22 (describing the market reaction to SSH entry and possible anticompetitive reactions by general hospitals).

problem, additional steps must be taken in the specialty hospital context to ensure enforcement of the antifraud laws and to prevent physician-investors from realizing personal economic gain from government payment to hospitals. As regulation and competition both work to create efficient markets, their conflicting means to this goal are clearly framed in a discussion of specialty hospitals and their future prospects in the health care market.

More generally, specialty hospitals illustrate the fragmentation of hospital practice, which contributes to the highly fragmented nature of medical practice generally. Whereas general hospitals are often fully integrated facilities offering a wide range of services in one place, conversely, specialty hospitals offer highly specialized services treating only one particular group of ailments. This fragmentation raises concern about achieving the health policy goals of quality, access, and cost. SSH development provides additional competition, which is generally thought to improve both price and nonprice aspects of hospital care for consumers. Problems arise when antitrust and antifraud regimes as currently enforced fail to recognize the nonprice benefits (e.g., improved quality) provided by specialty hospitals and instead view them as violations, either being anticompetitive or violating self-referral fraud laws. At the same time, while specialty hospitals may claim to improve nonprice aspects of health care, these claims may be difficult to prove—specialty hospital arrangements may actually violate antitrust and antifraud laws so as to override any claimed benefits. Examining the development of specialty hospitals helps to identify how these regulatory regimes may impede or further health policy goals overall and to determine the best way to address unique specialty hospital issues through both antitrust and antifraud laws.

A. Regulation Versus Competition in the Health Care Market

The broad impact of antitrust and antifraud laws in the health care market can be explored through the benefits of competition as compared to and contrasted with the benefits

of regulation. When these two regimes are combined, there exist numerous points at which they push in different directions and address issues with the hopes of reaching opposite results. Generally, the goals of antitrust laws are to encourage competition through open markets that allow procompetitive coordination and contractual behavior, while limiting agreements that restrain trade. Antifraud regimes lean heavily against contractual behavior in order to effectively address fraud in fee-for-service government payment systems. Antifraud laws aim to eliminate overpayment by the government, so agreements or transfers outside of the traditional, transparent payment-for-service arrangement may raise issues for antifraud enforcement agencies. This has led to problems as traditional fee-for-service plans have evolved into managed care plans over the past two decades.

There are many examples of areas in which specialty hospitals have influenced competition and regulation in the health care market. Three examples are examined here: how the existence of specialty hospitals supports the argument for payment-for-performance plans; how general hospitals and antitrust enforcement agencies have reacted to SSH market entry; and the influence of certificate of need laws, an example of direct regulation, on the entry of SSHs into the health care market.

1. Specialty Hospitals in Payment-for-Performance Theories

Tying payment for health care services to the quality of the services provided, i.e., the performance of providers, may offer significant advantages for the health care industry generally and may help to clarify the role of specialty hospitals by dispelling some of the surrounding competitive and regulatory concerns. Because the quality of health care services is not easily measurable or tied to payment, transactions that could be procompetitive, if financial incentives were aligned "with the implementation of care

processes based on best practices and the achievement of better patient outcomes," cannot be measured as such.[63] Antitrust analyses by courts consistently fail to address quality concerns adequately and instead focus on price, a traditional parameter that is much easier to define and to assess than quality.[64] Similarly, antifraud laws may consider specialty hospitals that improve quality and efficiency to violate self-referral laws under theories that alignments of physicians and/or patients in specialty hospitals result in the enhanced ability of physicians to defraud the government.

Many commentators are currently arguing for payment-for-performance systems in which the provision of higher quality care is rewarded with payment incentives.[65] The ability to tie payments to measurable outcomes would allow for the formation of procompetitive alliances and transactions that, without qualitative measures, may otherwise appear to breach antitrust laws. This option may be especially relevant in the specialty hospital setting where physicians are organized and aligned in an untraditional manner that normally raises both antitrust and antifraud concerns; such issues would be addressed differently if health care quality were measurable as tied to price. Generally, tying price to quality would allow regulations promulgated under antifraud laws to be more easily applied to transactions made transparent by the price-quality factor, and pro- and anticompetitive measures by health care providers would be more easily recognizable in antitrust enforcement investigations when price and quality are linked.

The feasibility of such a payment system is difficult to determine. A variety of experimental programs continue to make strides in tying payment to quality. Among those possibilities currently being explored are the use of performance indicators by health plans, the development of a

[63] IMPROVING HEALTH CARE, *supra* note 34, ch. 1, at 8.

[64] Hammer & Sage, *supra* note 32, at 609.

[65] IMPROVING HEALTH CARE, *supra* note 34, ch. 1, at 8.

consensus on performance measures and best practices, the development of evidence-based treatment standards, and the use of disease management models to tie payment to performance.[66] A determined effort in this arena is necessary for any sort of significant change to be made and for a widespread payment-for-performance system to be effective.

2. Hospital and Agency Reaction to Specialty Hospital Competition

General hospitals have reacted to competition from specialty hospitals by using a variety of measures. One measure is economic credentialing, by which a hospital uses "economic criteria unrelated to quality of care or professional competency to determine an individual's qualifications for initial or continuing hospital medical staff membership or privileges."[67] In such cases, hospitals remove the admitting privileges of physicians involved with specialty hospitals. This action aims to minimize competition for the general hospital, as physicians react by distancing themselves from specialty hospitals in order to maintain their privileges at large general hospitals. Some hospitals have not removed privileges for physician-investors altogether but have taken some measures, such as limiting on-call rotations, making the scheduling of surgeries more difficult, limiting access to operating rooms, limiting extra assignments, and using CON laws[68] to limit SSH entry into the market. Other hospitals have reacted by creating single specialty wings within their general hospital or by partnering with physicians to open a SSH. Another method used by general hospitals to reduce competition from SSHs is to contract with health plans that either preclude members from using SSHs entirely or

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[66] Donald M. Berwick et al., Open Letter, *Paying for Performance: Medicare Should Lead*, HEALTH AFF., Nov.-Dec. 2003, at 8, *available at* http://content.healthaffairs.org/cgi/content/full/22/6/8.

[67] IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 22 n.111.

[68] CON laws require state approval for any new hospital facilities. *See, e.g.*, IMPROVING HEALTH CARE, *supra* note 34, ch. 8, at 1.

remove physician-investors from the insurance company's preferred provider list.[69] All of these actions may be deemed anticompetitive by physician-investors and lead to claims of antitrust violations, but empirical evidence shows that physicians will rarely win such challenges.[70] Others claim that these actions by hospitals do not harm competition.[71]

Antitrust enforcement agencies generally favor the elimination of anticompetitive barriers to entry on the grounds that competitive markets, where entry and exit occur as determined by market forces, maximize consumer welfare. But, hospital responses to SSH competition that alter admission privileges or address governments in CON proceedings are not the sort of per se antitrust violations that elicit agency reaction. Under some circumstances, a unilateral response will violate the Sherman Act, and with specific evidence of anticompetitive conduct by hospitals against SSHs, "the Agencies will aggressively pursue those activities."[72]

3. Certificate of Need Laws: An Example of Regulation Restricting Competition

Certificate of need ("CON") laws are an example of direct regulation in the health care market, and thus stand in contrast to the freely competitive markets endorsed by antitrust theory. CON laws require state approval for any increase in health care capacity (e.g., beds in a hospital, new hospital facilities, etc.). Federal legislation introduced in 1975 conditioned state funding on the implementation of CON requirements. Though this legislation was repealed in 1986 in HCQIA, many states still maintain CON

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[69] *Id.* ch. 3, at 22-23.

[70] *See* Hammer & Sage, *supra* note 32.

[71] Some panelists at the FTC hearings stated that these strategies protected the viability of general hospitals and suggested that a hospital need not "sacrifice the interests of [its] charitable institution in favor of the physician's self-interest." IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 22.

[72] IMPROVING HEALTH CARE, *supra* note 34, ch. 3, at 27.

requirements.[73] Under CON laws, a petitioner must demonstrate an unmet need for particular services to state authorities in order to get approval for new facilities.[74] The goals are both to prevent unnecessary capacity and to control health care costs. Because supply often generates demand in the health care industry, CON laws seek to curb excess demand by limiting supply. However, concerns exist that CON requirements raise anticompetitive problems that outweigh any economic benefits that they may provide.[75]

The FTC and DOJ have expressed several concerns regarding the continued use of CON laws. One concern is that, despite controlling capital expenditures, the regulations may actually increase costs by implementing barriers to entry.[76] Such regulations protect incumbent providers from competition, and thus, may result in supply being below competitive levels and increased costs. Another concern is that CON requirements restrict innovation and improvement by delaying the introduction of new treatments and helping to maintain the status quo.[77] Additionally, empirical studies have shown that CON programs often fail to control costs and may actually lead to higher prices.[78] Unnecessary expenditures are not avoided by the programs, but rather are moved to other areas. Generally, the antitrust enforcement agencies believe that CON requirements are not an effective means of controlling health care costs and that states should reconsider their use.[79] It is unclear to what degree CON laws will remain a powerful force in the health care industry. While there are clear and substantial arguments against their overall market benefit, as suggested by the FTC and DOJ, many hospitals, fearing

[73] As of 2002, 37 states maintained some degree of CON requirements. GAO REPORT, *supra* note 50, at 15.

[74] IMPROVING HEALTH CARE, *supra* note 34, ch. 8, at 1.

[75] *Id.* ch. 8, at 2.

[76] *Id.* ch. 8, at 3-4.

[77] *Id.* ch. 8, at 4.

[78] *Id.* ch. 8, at 5.

[79] IMPROVING HEALTH CARE, *supra* note 34, ch. 8, at 6.

competition, may continue to push their legislators to uphold these policies.

The location of specialty hospitals is highly correlated to the existence of CON laws. Eighty-three percent of specialty hospitals are located in states without CON laws, and ninety-six percent of specialty hospitals that opened between 1990 and June 2003 are located in states without CON laws.[80] Overall, CON laws have effectively restricted entry by specialty hospitals, and therefore, may represent an anticompetitive barrier to market entry. CON laws exemplify a situation in which direct regulation of the health care market has failed to provide the competitive environment desired and, in fact, may thwart many of the goals of a successful competitive market. At the same time, it is important to recognize some of the benefits that CON laws confer on the health care market. While restricting the positive competitive effects of specialty hospitals, they also help to address the self-referral concerns presented by specialty hospitals by preventing "cherry picking," in which well-insured or low-cost patients are diverted from general hospitals to specialty hospitals.[81]

B. Specialty Hospitals and Health Policy Goals

As SSHs begin to play a more significant role in health care markets around the country and the possibility of fragmented hospital practice becomes a reality, health policy goals such as quality, access, cost, and innovation must be kept in mind. Throughout the analysis of specialty hospitals under both antitrust and antifraud regimes, policy goals play an underlying and influential role. Specialty hospitals possess features that both promote and impede health policy goals; these elements must factor into decisions about whether, and if so, how, antitrust and fraud-and-abuse laws

[80] GAO REPORT, *supra* note 50, at 15. In 2002, approximately seventy-three percent of states (thirty-seven states, including the District of Columbia) maintained some type of CON requirements.

[81] IMPROVING HEALTH CARE, *supra* note 34, ch. 8, at 3.

should accommodate specialty hospitals in the health care market.

When specialty physicians concentrate in hospitals focused on a few specific DRGs, patients may benefit as quality may be easier to measure, and therefore easier to improve. This should provide a significant advantage over the current standard in which "vigorous price competition involving physicians, hospitals, health insurers, and other medical suppliers" threatens health care quality and where "the health care regulatory process shows limited ability to address quality concerns without significantly restricting the benefits of competition."[82] A highly competitive market in most industries generally leads to efficient prices and output. Health care is different, however, because nonprice factors are more critical than in many other industries. Quality, innovation, and access are important elements of the delivery of health care services that would matter to consumers if they had more options. Specialty hospitals provide an alternative through which nonprice advantages may be more easily identified by consumers than they would in general hospitals. In a smaller setting offering a smaller set of services, like an SSH, quality may be easier to measure and to report. Specialty hospitals may also have advantages in innovation, an area to which they have an increased ability to devote resources due to their superior financial positions relative to general hospitals.[83]

While antitrust law currently does not easily accommodate nonprice factors in quantitative analyses, "antitrust law espouses the belief that vigorous competition will enhance quality as well as price, and therefore, purports to safeguard a wide range of nonprice concerns through oversight of price competition."[84] Though this contention is

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[82] Hammer & Sage, *supra* note 32, at 549.

[83] When costs from all lines of businesses and revenues from all payers were considered, specialty hospitals tended to outperform general hospitals financially. Total facility margins for specialty hospitals averaged 6.4%, surpassing the 3.1% average margin for general hospitals. GAO REPORT, *supra* note 50, at 26.

[84] Hammer & Sage, *supra* note 32, at 547.

questionable and possibly wrong,[85] it is a starting point for assessing some of the advantages resulting from competition between general hospitals and specialty hospitals.

Alternatively, the fragmentation of hospital care into specialty hospitals may be detrimental to various health policy goals. For one thing, it eliminates the benefits of one-stop shopping at general hospitals. While the quality of individual treatments may be more easily assessed at SSHs, patients with multiple medical conditions may not be treated appropriately or comprehensively in such hospitals. Cost may also become an issue as patients must seek treatment at multiple facilities. Issues of access to multiple specialty facilities may be problematic for patients with limited time or financial resources. A negative view of the effects of specialty hospitals on the health care market emerges when these concerns about health policy are added to the potential fraud problems that specialty hospitals present under the self-referral amendments.

Another problem arising under antitrust law is that specialty hospitals engage in seemingly anticompetitive conduct with the presumable goal of improving quality. Providers often justify such anticompetitive conduct in this manner.[86] Such quality-of-care arguments have been used to support a wide array of anticompetitive conduct in the health care industry, from broad restraints on price competition to refusals to deal with competing providers and organizations.[87] According to an FTC and DOJ report on health care competition, "[t]here are almost always more narrowly tailored means of achieving the same quality improvements without employing the anticompetitive means selected by self-interested providers."[88] The report also found that "anticompetitive conduct that raises prices, even if it is done in the name of improving 'quality,' is likely to have a

[85] *See id.* The authors question the validity of this statement and address quality concerns under antitrust law.

[86] IMPROVING HEALTH CARE, *supra* note 34, ch. 1, at 28.

[87] *Id.*

[88] *Id.*

systemic adverse effect on the quality of care actually provided to the population as a whole."[89] Specialty hospitals must tread carefully when claiming an exception to antitrust laws due to resulting quality improvements.

VI. SOLUTIONS

Finding an effective resolution to the conflicts raised by the growth of specialty hospitals in the health care market under current standards will remain an ongoing challenge for legislators. The range of problems is great, and any changes will likely affect other aspects of the health care market. Consequently, each issue must be considered thoroughly before enacting any changes. One way to begin is to focus narrowly on a few specific problems arising under the antitrust and fraud-and-abuse regimes.

It is imperative that the general goals of fraud-and-abuse laws (i.e., eliminating overpayment by governments) be maintained. Specialty hospitals should not continue to benefit from the "whole hospital" investment exception. Additionally, the moratorium on new specialty hospitals, in combination with the proposed bill's permanent extension, insufficiently minimizes the risk of financially motivated and excessive referrals to specialty hospitals. Because it applies only to new specialty hospitals, the moratorium fails to address ongoing problems of self-referral at established and developing facilities. Completely eliminating self-referral in all currently operational specialty hospitals raises fairness issues for physician-investors who legitimately refer patients to these facilities. It is possible that some of these physician-investors would not have chosen to invest if that prevented them from referring patients based on genuine treatment needs. Ultimately, eliminating self-referral is a more critical concern. Though a seemingly severe solution, a complete ban on physician-investor self-referral to specialty hospitals may be the most appropriate and effective means of addressing the problem. Some of the fairness concerns of

[89] *Id.* ch. 1, at 30.

current investors may be addressed by modifying the definition of specialty hospitals in this context, such as by limiting the prohibition to hospitals below a certain size, to hospitals where physician-investors make up a minimum percentage of the ownership, and to physicians owning a minimum percentage of the hospital. These standards would substantially alleviate the current fraud concerns presented by specialty hospitals.

The increased competition that specialty hospitals bring to the health care market appears to align with antitrust policy. However, problems arise because general hospitals, or more specifically their medical staffs, have wide latitude in making staffing decisions, and therefore can use those decisions to restrict physicians who regularly send patients to, or invest in, a competing specialty hospital. At the same time, specialty hospitals compete with general hospitals on an unequal playing field. By eschewing emergency departments, SSHs eliminate a significant high-cost group of patients. Because referring physicians decide which patients go where, specialty hospitals might continually receive the most profitable patients while a general hospital must serve its community's needs and accept any and all patients who come to its emergency department,[90] including the most costly of those patients. General hospitals may claim a right to take actions to protect their viability in the face of specialty hospital competition. The ability of antitrust law to address these tensions is questionable. If fraud-and-abuse laws effectively eliminate any advantages based on fraud, and antitrust enforcement agencies hold true to their plans to "aggressively pursue" acts by hospitals or staffs in violation of the Sherman Act, general and specialty hospitals may be able to compete effectively. The ability of general hospitals to use staffing privileges to their advantage may be offset by the ability of specialty hospitals to reduce costs by not providing emergency services. An attempt to promote competition by changing the structure of hospitals in terms

[90] Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd (2003).

of these two features is not a viable option because each feature also has purposes and effects that extend beyond these competitive issues.

Payment-for-performance theories offer a way to promote health policy goals while minimizing the concerns of unfair competition and fraud raised by specialty hospitals. Much of the push behind linking payment to performance is keyed to making quality and outcomes measurable and thus easier to compare and improve.[91] With a link between quality and payment, classic antitrust analysis based on price, cost, and quantity may be able to address adequately quality concerns that are currently only an aside in antitrust theory as applied to health care. As specialty hospitals engage in transactions that yield significant qualitative gains, they will be more easily identified as procompetitive under antitrust theories. Additionally, fraud-and-abuse concerns may be alleviated by more transparent transactions that positively affect health care quality. A payment-for-performance system would also help to alleviate the controversy surrounding improved quality justifications and alleged underlying anticompetitive conduct. When quality is actually measurable in price, claims of improved quality will be easier to confirm; when quality is unaccounted for, conduct that is facially anticompetitive in fact may generate sufficient qualitative effects to overcome antitrust concerns.

VII. CONCLUSION

Antitrust laws and fraud-and-abuse laws have important regulatory functions in the health care industry. Antitrust laws help to ensure that competitive markets best serve consumers by providing low prices and by forbidding collusive, anticompetitive activity. Antitrust laws also help producers by encouraging market entry and fair competition among market players. In the context of health care and hospital services, this means that patients should have reasonable prices and options from which to choose. Health

[91] IMPROVING HEALTH CARE, *supra* note 34, ch. 1, at 8.

care providers should have free access to the market and patients without exclusion for purely anticompetitive reasons. Fraud-and-abuse laws serve everyone by ensuring the efficient use of government (i.e., taxpayer) money. While the goals of fraud-and-abuse law are generally lauded by the public, the way that the laws are set up may not adequately address fraud concerns related to new and different arrangements for health care service. There are a wide variety of instances in the provision of health care where this can be problematic. One strong example lies in specialty hospitals. As specialty hospitals become more common, new issues emerge under both the antitrust and antifraud regimes that must be addressed and resolved. Strong enforcement is critical on all fronts. Specifically, fraud laws must be adjusted to address self-referral concerns in specialty hospitals. Steps are being taken in this direction as Congress extended the moratorium on new specialty hospitals to allow for further review of the issues. Antitrust laws must reflect the competitive advantages and disadvantages that exist among specialty hospitals and general hospitals and must ensure that violations are dealt with appropriately. While the goals of both antitrust and antifraud regimes are still relevant and important, these regimes must adjust to the changing health care market to remain viable regulatory mechanisms.