

DUPED BY CRIES OF DUPLICATION

The Failure of Certificate of Need Regulations

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I INTRODUCTION

I.A History of Certificate Of Need

Government involvement in enforced planning for health facilities has an extensive and well-documented history. As far back as 1946, with the Hill-Burton Act, the federal government has provided the means for developing health planning agencies.¹ Certificate Of Need regulations, or "CON laws", were the pinnacle of federal and state legislation advocating government mandated health planning efforts. Federal regulations provided enabling legislation and enforcement provisions, while program development and implementation generally took place on the state or local level.

I.A.1 Development of Federal Regulations

On the national level, certificate of need regulations developed gradually out of concerns for rapidly increasing healthcare costs. Two pieces of federal legislation were essential to the growth of CON programs. Section 1122 of the 1972 Social Security Act Amendments and the National Health Planning and Resources Development Act (NHPDA) of 1974 formed the framework for future CON programs.

Similar to CON in many ways, Section 1122 forced states to review all capital expenditures when they exceeded \$100,000, when bed capacity changed, or when a "substantial" change in services takes place.² States that failed to comply could be denied Medicare and Medicaid cost reimbursement.³ Hospitals could proceed with construction of new facilities without review, however, if another source of funding could be found.⁴ Professional Standards Review Organizations (PSROs) were also established by the 1972 Social Security Amendments to control utilization of services and to review procedures according to professional standards.⁵

Then, in 1974, the National Health Planning and Resources Development Act pushed CON regulations to the forefront of government healthcare cost containment efforts. This legislation encouraged states to enact CON regulatory programs. By guaranteeing federal funding for those states enacting CON review programs and tying certain healthcare funds to the enactment of those programs.⁶ State CON programs were required to meet federal guidelines in order to

¹ McGinley, P. J. (Summer, 1995). Beyond health care reform: reconsidering certificate of need laws in a "managed competition" system. Florida State University Law Review. 23 Fla. St. U. L. Rev. 141.

² Mendelson, D. N. and Arnold, J. (Winter, 1993). Certificate of need revisited. Spectrum: The Journal of State Government 66(1), 36-45.

³ Antel, J. J., Ohsfeldt, R. L., Becker, E. R. (Aug., 1995). State regulation and hospital costs. The Review of Economics and Statistics 77(3), 416-422.

⁴ Sloan, F. A. (May, 1982). Government and the regulation of hospital care. The American Economic Review 72(2), 196-201.

⁵ Ashby, J. L. (Spring, 1984). The impact of hospital regulatory programs on per capita costs, utilization and capital investment. Inquiry 21(1), 45-59.

⁶ McGinley, P. J. (Summer, 1995). Beyond health care reform: reconsidering certificate of need laws in a "managed competition" system. Florida State University Law Review. 23 Fla. St. U. L. Rev. 141.

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receive federal money.⁷ Federal legislation had firmly established public sanctions for states that failed to comply with mandates for CON review programs. Correspondingly, most states dropped their Section 1122 review provisions and replaced them with a CON regulatory apparatus.⁸ By 1980 almost every state developed some form of CON review program under these guidelines.⁹

In 1979, the National Health Planning and Resource Development Act was amended to clarify Congress's intent on the matter. Congress alleged the healthcare industry had been suffering from a phenomenon described as "*supply creating demand*" and purported to address this concern through government intervention in the market.¹⁰ These comments explicitly expressed a lack of faith in market forces as a primary means of cost control.

Although some states developed CON programs prior to national legislation, it is clear that these federal laws were the key stimulus for most state CON programs. States who later questioned the wisdom of CON still followed federal guidelines. Some states even reverted back to the voluntary review provisions in Section 1122 when their CON programs were allowed to expire.

The status of federal legislation advocating CON regulations changed dramatically in 1986 when the National Health Planning and Resources Development Act of 1974 was repealed.¹¹ States would no longer receive federal funding for their CON programs.¹² The free market argument had begun to garner support among legislators.

I.A.1.a Intent of Federal CON Laws

Congress had initially intended CON laws to restrain what were viewed as "*skyrocketing*" healthcare costs, to prevent the unnecessary "*duplication*" of healthcare resources and to achieve equal access to quality healthcare at a reasonable cost.¹³ "Four years after the enactment of CON, Congress repealed it's mandate. Two interrelated concerns spurred the decision—the law failed to reduce the nation's aggregate health care costs, and it was beginning to produce a detrimental effect in local communities."¹⁴

⁷ Madden, C. W. (Feb., 1999). Excess Capacity: markets, regulation, and values. HSR: Health Services Research 33(6), 1650-1668.

⁸ Sloan, F. A. (May, 1982). Government and the regulation of hospital care. The American Economic Review 72(2), 196-201.

⁹ Sloan, F. A. (May, 1982). Government and the regulation of hospital care. The American Economic Review 72(2), 196-201.

¹⁰ Wolfson, L. H. (Winter/Spring, 2001). State regulation of health facility planning: the economic theory and political realities of certificates of need. DePaul Journal of Health Care Law 4(4), 261-

¹¹ Madden, C. W. (Feb, 1999). Excess Capacity: markets, regulation, and values. HSR: Health Services Research 33(6), 1650-1668.

¹² Wolfson, L. H. (Winter/Spring, 2001). State regulation of health facility planning: the economic theory and political realities of certificates of need. DePaul Journal of Health Care Law 4(4), 261-

¹³ Patrick John McGinley, Beyond Health Care Reform: Reconsidering Certificate Of Need Laws In A "Managed Competition" System. 23 Fla. St. U.L. Rev. at 141, 168.

¹⁴ Patrick John McGinley, Beyond Health Care Reform: Reconsidering Certificate Of Need Laws In A "Managed Competition" System. 23 Fla. St. U.L. Rev. at 141, 157.

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I.A.1.b Context For Change

The primary driving force for CON programs developed out of the perception of and growing concerns for rapidly increasing healthcare costs. In the 1980s, however, deregulation caught on and set the tone for the elimination of CON provisions on a federal level.

I.A.2 Development of State Regulations

Over a period of years, the various states either repealed and abandoned CON or modified the scope and extent of its application. In some instances this was a “start and stop” process. A table which shows the status of the different states CON laws from 1979 to 2001, is set forth in Appendix B, attached.

I.B Government Mistrust of Physicians’ Medical Decisions

As healthcare costs continued to rise, increasing pressure has been brought to bear on limiting expenditures. One approach to achieving cost savings has been to fight fraud and abuse, which some believe costs the government a significant percentage of their overall health budget. Also, the government, as the largest single payor of health services, has implemented many of the generally used reimbursement and cost containment and payment methods. These include prospective pricing for both inpatient and outpatient facility and technical services as well as the Resource Based Relative Value Systems or RBRVS based Medicare fee schedule for professional services, and others. A further attempt to control costs included the government undertaking risk sharing systems including facets of managed care to encourage competitive pricing and provider initiatives at lowering costs. One manifestation of these cost containment and anti-fraud enforcement activities is a perceived loss of trust of physicians’ ability and motivation to make correct and appropriate medical decisions.

I.B.1 Stark Laws

The Ethics in Patient Referrals Act of 1989, the so-called Stark bill, prohibited physicians from making referrals for clinical laboratory services that are reimbursable under Medicare to an entity with which the physician or an immediate family member has a financial relationship or compensation arrangement. Nor can the entity present a claim to Medicare or bill any individual or other entity for such clinical laboratory services. The reason for these prohibitions was to prohibit physicians from profiting from the ordering of unnecessary lab tests.

Sanctions for violating this law include denial of Medicare reimbursement, refund of any amounts collected in violation of the law, and civil monetary penalties of up to \$15,000 for each item or service provided pursuant to a prohibited referral plus twice the amount billed for the item or service.

In August 1993, the federal self-referral prohibition was expanded as a part of the Omnibus Budget Reconciliation Act of 1993 (“OBRA 1993”). OBRA 1993, often called “Stark II”,

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changed the self-referral prohibition in several ways. Self-referral was banned for additional “designated health services” including:

- physical therapy
- occupational therapy
- radiology or other diagnostic services
- radiation therapy
- durable medical equipment
- parenteral and enteral nutrients, equipment and supplies
- prosthetics, orthotics and prosthetic devices
- home health services
- outpatient prescription drugs
- inpatient and outpatient hospital services

The self-referral ban prohibits physicians who have a “financial relationship” with an entity from referring their patients to the entity for “designated health services” which are covered by either the Medicare or Medicaid programs. Significantly, the Medicare self-referral prohibition was not broadened to all payors, but only to Medicaid services.

I.B.2 Certificate of Need

CON is simply another manifestation of this almost endemic manifestation of governmental mistrust of healthcare providers. If this distrust is unfounded, then CON would most likely be perceived as simply obstructing the construction of healthcare facilities and investments in equipment and services which may be, in fact, greatly needed and desirable from both a patient access and choice perspective as well as from the viewpoint of cost-effectiveness. The imposition of CON represented a form of government rationing of healthcare, not based on ability to pay, or age, or any other established reasonable and empirical data based criteria, but based solely on the asserted proximity to what was perceived to be over-utilized alternative services. There has been no significant or empirical data that establishes that healthcare facilities, or items of medical equipment actually, in and of themselves, raise either utilization or overall healthcare costs. Physicians and other healthcare providers must prescribe, order, or provide these services which CON seeks to prevent as unnecessary. This illustrates that medical decisions regarding diagnosis and treatment modalities are, in fact, being made by government or business payors instead of by physicians.

Furthermore, CON laws are essentially discriminatory to those areas where patient populations fall between the specific need thresholds which satisfy the “*health service to population*” ratios required by CON to establish their definition of “need” for additional facilities, equipment, or services. For instance, if a state requires a population of 100,000 to justify the need for one (1) MRI unit they are, in effect, limiting access to these patient populations that don’t quite meet that threshold. From the perspective of patient access to services there is a significant difference and impact between a 100,000 to 1 ratio for MRI when applied to an urban, geographically proximate, patient population of 3,000,000 resulting in an indicated “need” for thirty (30) MRI units, and a rural geographically dispersed population of 100,00 that would suggest a need of only one (1) MRI unit. The almost total reliance on population and utilization ratios derived

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from data obtained from national statistics or that of other states with varying epidemiological and public health needs belies the validity and efficacy of this method.

The fact that this flawed analytical process costs public tax dollars to deny access is an issue of which the public has not yet become aware as they have, e.g., with the failure of gatekeeper HMOs.

II CON RESEARCH CONSENSUS

The beneficial aspects of market competition in healthcare are significantly obstructed from controlling costs, providing patient access and choice, and improving quality, by a number of systemic barriers including the continued imposition of CON laws. These barriers to competition limit the types of innovation and technological advancements that create efficiencies in other industries, ultimately resulting in higher costs and lower quality care. Specific aspects of the challenges related to CON are examined below in greater detail.

II.A Theoretical Rationale for Eliminating CON

CON regulations, by reducing competition and consumer choice, inhibit market mechanisms that are vital components of the current healthcare system. Furthermore, a review of the literature clearly establishes that CON regulations have not achieved the forecasted reduction of overall healthcare costs, nor have they improved the quality of healthcare.

II.A.1 The Certificate of Need Paradox

CON proponents claim that this regulatory mechanism is able to “do a lot with a little”. This claim is based on CON’s simplistic and low budget review of capital expenditures of those entities applying under the CON process and a comparison of existing and forecasted population, utilization, and occupancy rates based upon arbitrary, capricious, and unfounded comparative criteria that do not at all consider “down-stream costs”, patient access, beneficial outcomes, or quality of care. CON laws seek to limit capital expenditures based on the flawed, unsupported, and refuted assumption that limiting infrastructure investment achieves lower overall healthcare costs. CON has been implemented as a clumsy, heavy-handed, “meat-ax” attempt by legislators to control the costs of healthcare by reducing duplication of services, without first determining what constitutes “duplication” or whether duplication raises costs. Many hospitals and other healthcare service providers encourage CON laws because they perpetuate a more predictable competitive environment by limiting competition in favor of the established oligopoly provider. The motives underlying the continued support for CON laws have pronounced implications for public policy, and invite a detailed investigation of the goals, processes, and requirements inherent in CON laws. By deconstructing the CON concept, the paradoxes of its development and continued implementation become apparent.

II.A.2 Market Failure

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II.A.2.a Justification for Governmental Intervention

An essential element in attempting to justify government intervention in the economic, competitive mechanisms of the private market, is the claimed need for correction of perceived market failures. Regardless of the prior state of healthcare markets, CON reduces competition and thereby creates or exacerbates market failures, by adding further barriers to market entry for innovative new market entrant competitors. In essence, government regulation thwarts innovation, and, lacking innovation, both U.S. healthcare costs, efficiencies, and quality will not improve.

II.A.3 Managed Care Cost Controls

Free markets allow purchasers of healthcare services to negotiate for lower costs in the face of the strength and leverage of established, large health system providers. CON laws shelter these established, large healthcare providers from the demands and needs of purchasers and payors regarding cost, quality, access, and patient choice. These desirable aspects of the healthcare market mechanisms may, however, be substantially thwarted by hospital oligopolies under color of CON laws.¹⁵

II.A.4 Integrated Delivery Systems

CON regulations promote the construction of vertically integrated systems, by disfavoring horizontal consolidation.¹⁶ “Attempts by providers to reduce costs, gain efficiencies of size, and position themselves aggressively in the marketplace have resulted in the formation of integrated delivery systems of such providers. However, the CON laws still in existence in 37 states and the District of Columbia actually increase the costs of forming these associations, while at the same time slowing the rate at which the providers are able to react appropriately to changing market circumstances.”¹⁷ However, at the same time, CON adds unnecessary costs to the development of these systems. To the extent that horizontal consolidation may allow, in a given market and / or geographic circumstance, for achieving the significant benefits of cost, quality, access, and patient choice, then CON defeats its own stated desired outcome and purpose.

II.B Impracticality of CON Legislation

Even, in the hypothetical, it were to be determined that CON regulations were able to control healthcare costs, major revisions would be necessary in order for them to be an effective and valid tool for this type of drastic government intervention into the complex competitive mechanisms of the healthcare market. The process would need to provide a more sophisticated, science-based methodology with objective analysis of valid and pertinent empirical data that reasonably considers the appropriate wider range of public health factors, that are considered

¹⁵ Patrick John McGinley, Beyond Health Care Reform: Reconsidering Certificate Of Need Laws In A “Managed Competition” System. 23 Fla. St. U.L. Rev. at 141, 168.

¹⁶ McKinlay, J. B. and Stoeckle, J. D. (1988). Corporatization and the social transformation of doctoring. *International Journal of Health Services* 18, 191-205.

¹⁷ Brulino Montesino, Anatomy of a Roadblock, *Health Systems Review* at 30 (1996).

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within the context of a larger public health vision. A comprehensive health planning policy, setting forth and based upon a consensus related to desired objectives is needed in order for any successful design or implementation of CON regulations. Lacking that, CON acts as the subjective enforcer of selective oligopoly interests – the “rule-of-men” not the “rule-of-law”.

II.B.1 Eliminates Patient Choice

There is ample evidence in the economic and business literature that, in a market economy, competition can create choices for consumers and raises quality standards as providers compete for patient loyalty. By eliminating competition, whether through the acquisition of physician practices, or by utilizing CON to block new, competitive providers, hospitals undermine the primary system of checks and balances in healthcare – patient choice. When patient choice is constrained or vanishes, control shifts from patients to committees of business executives, hospital administrators, and private organizations that loudly claim to have community health as their primary interest while, at the same time, often demonstrating a contempt for the competition that provides the fundamental aspects and incentives of patient access and choice to allow the public health objectives to be achieved.

When patient choice is diminished, decisions about access, quality, and beneficial outcomes become the sole purview of these elite groups. In the absence of healthy competition, they are free to ignore patient needs and demands.

Under CON laws, patients are *de facto* limited to accept the services that existing providers wish to offer them when making major healthcare decisions for themselves and their families because their community may be determined to lack a sufficient utilization ratio to allow alternative market entrants. Without ample consideration of access to healthcare services, a patient’s right to choose for himself and his family, the methodology utilized by CON laws does not meet the needs of the healthcare community or reflect the interest of the public. Instead CON serves to promote the oligopoly interests of existing, established provider organizations who find competition inconvenient.

Closely correlated to CON laws' dangerous denial of access and patient choice is the barrier to entry posed by these rules. New medical provider entrants, no matter how efficiently and creatively they might contribute to higher healthcare quality, more beneficial patient outcomes, greater patient access and convenience, and lower *overall* healthcare costs, face substantial opposition by these established interests, who would utilize CON laws to actively strive to limit competition and thereby deny patient choice.

II.B.2 Overall Healthcare Costs Not Considered

Current CON regulations do not consider the overall costs or the totality of healthcare costs for the state. By focusing on the capital costs, the operational costs are overlooked. Capital investment may, in fact, reduce the overall costs of healthcare provision.

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No consideration was given to a comparison of an overall cost of the continued utilization of older technology to the investment in newer technology. For example, a certain piece of medical equipment may be deemed cost-appropriate simply because it falls slightly below the expenditure threshold. At the same time, a different piece of equipment with improved technology which significantly enhances the quality of care; provides a lower operating cost per procedure; and prevents further exacerbation of the patient's medical condition, thereby saving enormous downstream patient treatment costs, is not considered cost-appropriate because the initial investment to attain it is slightly over the application of the artificial, arbitrary and capricious expenditure threshold promulgated by CON laws. In this manner, these laws irrationally defy any semblance of rational economic administration of public health and safety, while at the same time doing absolutely nothing to lower the overall costs of healthcare.

II.B.3 Prevention, Wellness, and Other New Cost Containment Mechanisms

CON regulations are being replaced by new, more effective cost containment strategies such as Medicare's Prospective Payment Systems (PPS), wellness/prevention programs and education, and, in theory, the growth of managed care. The re-evaluation of CON laws leads to the question, "does removing certificate-of-need regulations lead to a surge in health care spending?"¹⁸ In December 1996, Pennsylvania's CON program expired due to an unexpected legislative oversight. Although many people feared that this would cause serious problems for healthcare providers in the state, they did not materialize according to local regulators and providers. Market forces and local planning apparently took over.¹⁹ New Jersey has also been cited as a state which did not experience a significant increase in health facilities after relaxing CON standards.²⁰ Ohio, however, saw growth in the number of non-hospital facilities, particularly ASCs, after eliminating CON.²¹

II.C Lack of Data and Inappropriate Methodology

II.C.1 Insufficient Data

Policy makers often do not have sufficient relevant or accurate data to guide CON decisions.

II.C.2 Reliability of CON Application Data

Kottle v. Northwest Kidney Centers is a case where information to the CON board was falsified in order to have a new dialysis center turned down. The information helped to stifle competition

¹⁸ Christopher Conover and Frank Sloan, Does removing certificate-of-need regulations lead to a surge in health care spending?, *Journal of Health Politics, Policy and Law*, Vol. 23 Issue 3 at 455.

¹⁹ "Pennsylvania: Unplanned demise of CON program has not caused upheaval in industry." *BNA's Health Law Reporter*, Vol. 6, no. 33 (Aug. 14, 1997).

²⁰ "Opportunity at 'Sunset': Missouri relaxes its certificate of need requirements for ambulatory surgery centers" *Missouri Medicine*, Vol. 99, no. 2 (Feb. 2002), p. 71.

²¹ "Opportunity at 'Sunset': Missouri relaxes its certificate of need requirements for ambulatory surgery centers" *Missouri Medicine*, Vol. 99, no. 2 (Feb. 2002), p. 71.

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and allow the current operator to maintain a monopoly although there was a clear need for the facility.²²

II.C.3 CON Methodology Doesn't Consider All Variables

Often the methodologies employed do not include demographic analyses, epidemiological analyses, market analyses, and forecasting analyses that account for all the relevant covariables involved. Instead, variables that are dependent are often considered independent for analytical purposes. Utilization for one type of medical equipment often varies depending upon the utilization of other medical equipment devices.

For example, CT scanning equipment and PET scanners are both expensive enough to require CON approval in most states with CON laws. For many types of conditions these different imaging tools are used for the same diagnostic purposes. Therefore greater PET utilization may lower the utilization of CT or MRI and vice versa.

II.C.4 Utilization Measures Don't Consider Population Variations

Utilization methods do not account for disease incidence across populations nor do they account for the variation of population subgroups. These spatial patterns of disease are often not included in CON utilization thresholds or units per population "need" methodologies. A wider vision is needed in order to make CON regulations work.

III CON OLIGOPOLIES

CON laws create market failures by ensuring an oligopoly of established service providers. Market competition and consumer and payor choice are limited for consumers.

III.A Mergers of Competitors

Hospital mergers can result in the loss of competition for specific service lines for which the merging hospitals were the only competitors. There may be both direct and indirect effects on pricing due to a merger between direct competitors. Merging hospitals may then raise their own prices. In addition, because the level of competition for all remaining participants in the market is reduced, non-merging hospitals may be able to raise their prices. The extent of the potential price increases is heavily dependent on the final combined market share of the merged hospitals.²³

III.B Other Unregulated and Unnecessary Healthcare Costs

²² Young M. Park, Antitrust: Monopoly of Kidney Dialysis Service—Kottle v. Northwest Kidney Centers, 24 Am. J. L. and Med. at 503, 504 (1998).

²³ Glenn, Melnick, Emmett Keeler, Jack Zwanziger, Market Power and Hospital Pricing: Are Nonprofits Different?, Health Affairs, Vol. 18 Num. 3 at 167, 170 (1999).

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While the debate on the cost of new facilities and equipment receives legislators' attention, other healthcare costs have apparently been entirely overlooked. For example, changes in healthcare economics fueled by technology have decreased utilization of traditional hospital core services, such as inpatient services, in favor of services provided on an outpatient basis. Many large hospital systems have reacted to their diminished historical service mission by aggressively pursuing a new mission based on the strategy that the "winner" in healthcare will be the entity that coordinates and controls the delivery of healthcare services in the community. Many hospitals apparently believed that by controlling the market for physician services, their system would capture referrals for core (inpatient) services.

This quest led them to develop new services of privately held physician practices in the community. They have attempted to achieve this through the acquisition and new development of physician practices, often using tax-exempt dollars. Physician practices are not cheap; e.g., the average price of a physician practice in 1997 was over \$170,000 per physician.²⁴ At this rate, the price of a five-doctor group practice could be equal to more than 200,000 meals for the poor²⁵ or flu shots for more than 100,000 people^{26,27}, both of which would unquestionably increase the health of the community.

Unchecked by independent providers, a monopoly could form, and those hospitals could, if they choose, have inordinate influence in setting the price of all healthcare services. In this scenario because patient choice is diminished and cost grows. CON laws do not address these practice acquisition expenditures. They also do not address the compensation/severance, (a/k/a "golden parachutes" of healthcare executives) which commonly exceed the expenditure limits of CON review.

III.B.1 Duplication of Services and Excess Capacity

In healthcare markets nationwide, articles in the news media periodically report that proposed new facilities and healthcare services and equipment expansions have raised fears of duplication among local payors and existing facilities and service providers. These fears of duplication stem from either the fear of competition or the misguided and misinformed assertion that societal costs increase when there are "too many" providers of the same health services – a situation paradoxically labeled as "excess capacity." Excess capacity is a value-laden term, not an absolute standard. In a February 1999 article published in *Health Services Research*, Professor Carolyn Madden summarized a number of studies of excess capacity saying, "Without a clear statement of this standard [e.g., the correct number of hospital beds], we cannot determine what

²⁴ Cleverly W, Knott J, Dye C. *The 1997-98 Physician Practice Acquisition Resource Book*. Center for Hospital Industry Performance Studies, 1997, p. 152.

²⁵ Estimate based on \$4 per meal. This estimate is conservative as it is much higher than actual costs of operation at Paul's Pantry, a community outreach program that provides groceries to Green Bay families.

²⁶ Mullooly, JP, Bennett MD, Hornbrook, MC, Barker WH, Williams WW, Patriarca PA, Rhodes PH. Influenza vaccination programs for elderly persons: cost-effectiveness in a health maintenance organization. *Annals of Internal Medicine*, 1994; 121(12): 947-952. (Average cost of a flu vaccine is \$7.11)

²⁷ Estimate provided by Vaccination Services of America (Omaha, NE) was in the \$5 - \$6 range per flu shot for 20,000 flu shots.

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constitutes too many. The research literature provides no clear statement.”²⁸ That’s the trouble with duplication – everyone seems to be against it, but nobody knows what it means.

New market entrants are often been called “cherry-pickers.” The implication is that these new competitors are greedy, and their project is inconsistent with maximizing community health. This view dismisses the importance of patient choice and is founded in a one-dimensional focus on market monopoly. The ideal healthcare delivery system seeks **value** by considering all important components: access, quality, beneficial outcomes, appropriate cost and patient choice. Monopoly is not one of these components.

For patient choice to exist, there **must** be more than one service provider because choice, by definition, involves alternatives. Duplication, by definition, is the existence of more than one service provider. Since patient choice cannot exist without duplication, arguments against duplication are, in essence, arguments against patient choice. Healthcare decisions are deeply personal and based upon individual and family experiences. The right of every person to make these decisions merits preserving and encouraging choice.

Few would dispute that medicine is a business, and like any other business, it needs competition to keep it working efficiently and cost effectively. CON programs, under which the government determines where, when and how capital expenditures will be made for healthcare facilities and major equipment, thwarts competition. The fundamental, yet flawed, idea of a CON law is simple: lower costs by reducing duplication. From a market economy perspective, CON laws have been a miserable failure. In an article reviewing the CON law and its application to modern markets, Patrick J. McGinley wrote, *“In searching the scholarly journals, one cannot find a single article that asserts that CON laws succeed in lowering healthcare costs.”*²⁹

The research of Professor Michael Morrissey (University of Alabama-Birmingham Center for Health Policy) argues that established providers will fight to influence public policy to shelter themselves from competition, and maintain market leverage with both patients and payers. Morrissey suggests that CON laws are resurfacing in some states to protect existing hospitals from competition, and, in turn, decreasing pressure to reduce capacity and prices.³⁰ When that happens, incentives to improve quality decrease as well.

Remember that, as stated by Professor Madden, “there is ... agreement across all perspectives of [health economics theory] on one issue: the negative consequences of too much concentration of economic power.”³¹ Hospitals in more competitive markets have average costs below those of less competitive markets.³² Healthy competition gives economic power to patients and payers by creating choices for consumers and raising quality standards as providers compete for patient

²⁸ Madden CW. “Excess capacity: markets, regulation, and values.” *Health Services Research*. February, 1999.

²⁹ McGinley, PJ. “Beyond health care reform: reconsidering certificate of need laws in a managed care competition system.” *Florida State University Law Review*, 1995.

³⁰ Morrissey, M. “State Healthcare Reform: Protecting the Provider” Lister Hill Center for Health Policy, University of Alabama at Birmingham, 1995.

³¹ Madden CW. “Excess capacity: markets, regulation, and values.” *Health Services Research*. February, 1999.

³² Zwanziger J, Melnick G, Bamezai A. “California providers adjust to increasing price controls.” In *Health Policy Reform: Competition and Controls*. Edited by R. Helms, pp. 241-58. Washington, DC: AEI Press, 1993.

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loyalty. When patient choice is diminished, decisions about access, quality, and beneficial outcomes become the sole purview of elite groups of decision makers who, in the absence of healthy competition, are free to ignore patient demands and needs.

Our thriving economy has shown that in other industries, specialized providers of goods and services are increasingly able to offer customers a fuller range of services and choices through innovation of packaging and delivery.

III.C Barriers to Competition

These arguments, described above, that CON laws provide unnecessary barriers to market competition, hinder market forces and reduce consumer choice have been employed by States that have repealed CON regulations.

IV CERTIFICATE OF NEED REGULATIONS DO NOT REDUCE COSTS OR IMPROVE THE QUALITY OF HEALTHCARE

To arrive at an understanding of what CON might provide in terms of cost savings, (if any), some semblance of valid data and a scientific methodology are required. The most common methodology appears to be based on comparison of dollar amounts of disapproved applications to total dollar amounts of applications as submitted for review. Noted healthcare economist, Frank A. Sloan Ph.D., identifies three (3) flaws in this type of the current calculation of CON savings:

1. There is a built in bias toward showing savings. Agencies can reasonably be expected to deny some applicants and some claimed savings will be shown as a result.
2. Litigation and administrative costs incurred by hospitals as a result of the CON application process and the agency costs of administering the program are not considered as offsets to savings.
3. Finally, there are “compensatory effects” inherent in the expectation of regulation. Existing hospitals may undergo construction in order to prevent competitors from establishing a need for facilities or equipment. Hospitals may also accelerate construction in anticipation of CON as described earlier or make false CON applications to bog down the review process.³³

These are not the only flaws.

IV.A Oligopolies are inherently inefficient

Oligopoly is defined as “*a market situation in which each of a few producers affects but does not control the market.*”³⁴

³³ “Containing Health Expenditures: Lessons Learned from Certificate-of-Need Programs” by Frank A. Sloan excerpted from “Cost, Quality, and Access in Health Care”, Jossey-Bass, 1988, p.48-49.

³⁴ “Merriam-Webster’s Collegiate Dictionary” 10th ed. Merriam-Webster, Inc., 1999, p. 810.

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The American economy is based on the incentives for the control of prices and production of quality that stem from free market competition. When monopolies or monopsonies are allowed to control markets, these incentives disappear and individual purchasers and producers suffer.

*“A monopoly granted either to an individual or to a trading company has the same effect as a secret in trade or manufactures. The monopolists, by keeping the market constantly understocked, by never fully supplying the effectual demand, sell their commodities much above the natural price, and raise their emoluments, whether they consist in wages or profit, greatly above their natural rate.”*³⁵ – Adam Smith, *Wealth of Nations*, 1776.

American law recognizes that monopolies and oligopolies, or cartels, are inherently inefficient as they have market power to control prices and thereby profit based on their market leverage rather than the quality of their products or efficiency of their production. The Sherman Antitrust Act *“prohibits any unreasonable interference, by contract, or combination, or conspiracy, with the ordinary, usual and freely-competitive pricing or distribution system of the open market in interstate trade.”*³⁶ Further, *“the ‘monopoly power’ which must exist in order to establish a violation of Sherman Antitrust Act may be defined as the power to fix prices, to exclude competitors, or to control the market in the relevant geographic area in question.”*³⁷

These quotes acknowledge that excessive market power allows for abuse. Thus CON attempts to “fight fire with fire” by imposing potential monopolies or oligopolies on the markets to attempt to control what is felt to be a form of insurance fraud. Here, two wrongs, if they in fact exist, do not make a right.

IV.A.1 Market Entry Barriers

... “Barriers to entry are costs imposed on potential entrants by government or by existing firms that increase the difficulty for new firms to enter the market.”³⁸ In the government’s case against the Marshfield Clinic in Wisconsin it was asserted that the clinic operated a monopoly and continued to keep competitors out by not allowing new physicians staff privileges and that they were using state CON guidelines to maintain the monopoly. The court in this case, held there was a violation of Sherman Anti-Trust Act and so ordered a remedy.³⁹

IV.A.2 Competition and Antitrust

³⁵ “Wealth of Nations” Vol. I, book I, Ch. 7. By Adam Smith, 1776. - Quoted from “Familiar Quotations” 15th ed., By John Bartlett. Little, Brown & Co., 1980, p. 366.

³⁶ “Black’s Law Dictionary” 5th ed. By Henry Campbell Black. West Publishing, 1979, p. 1234.

³⁷ “Black’s Law Dictionary” 5th ed. By Henry Campbell Black. West Publishing, 1979, p. 908.

³⁸ Warren Greenberg, Marshfield Clinic, physician networks, and the exercise of monopoly power, Health Services Research, Vol. 33 Issue 5 at 1461.

³⁹ Warren Greenberg, Marshfield Clinic, physician networks, and the exercise of monopoly power, Health Services Research, Vol. 33 Issue 5 at 1461.

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Antitrust laws are designed to protect competition. Free and open competition benefits consumers by fostering lower prices and new and better products. In a freely competitive market, each competing business generally will try to attract consumers by cutting prices or increasing the quality of their product or services or both. Competition and the profit opportunities it brings also stimulate businesses to find new, innovative and more efficient methods of production.⁴⁰

When competitors agree to fix prices, rig bids, allocate customers, or otherwise circumvent competition consumers suffer. The prices that result when competitors agree in these ways are artificially high; such prices do not accurately reflect cost and therefore distort the allocation of society's resources. The result is a loss not only to consumers and taxpayers, but also the economy.

IV.B Washington State Study of Healthcare Costs and CON

The Joint Legislative and Audit Review Committee and the Health Policy Analysis Program of the University of Washington's School of Public Health and Community Medicine conducted a study of the certificate-of-need program in the state of Washington. The results of this study are published as "Effects of Certificate of Need and Its Possible Repeal", State of Washington Joint Legislative and Audit Review Committee, January 8, 1999. This meta-study, one of the most comprehensive recently conducted, "examined the effects of CON and its possible repeal on the cost, quality, and availability of five health services – hospitals, ambulatory surgery, kidney treatment, home health, and hospice – as well as on charity care and health services in rural areas." Results were based on a literature review, interviews and information from healthcare providers and healthcare economic experts in the State, and also the analyses of states that completely or partially repealed their CON laws. The study found that CON "has not controlled overall healthcare spending or hospital costs." It also found "conflicting or limited evidence about the effects of CON on the quality and availability of other healthcare services or about the effects of repealing CON." The study then used this information to identify strengths and weaknesses of Washington's CON program.

According to the study, the purposes of Washington's certificate-of-need program are to "(1) restrain health care costs by regulating the supply of services and facilities; (2) to guide the development of health services to avoid undue duplication or fragmentation; (3) to promote quality of care and access; and (4) to provide for adequate information about the health care system." The program "controls the creation or expansion of certain health care facilities and services, including nursing homes, hospitals, home health, hospice, kidney dialysis, ambulatory surgery centers, and hospital-based tertiary services, such as transplants and open heart surgery." Washington's certificate-of-need program began in 1971 in response to quickly rising healthcare costs as an attempt to control these costs by regulating the development of new healthcare facilities and services. In 1979, the program was broadened to require review of all new health care services." Health Maintenance Organizations (HMOs) were exempted from review in 1980. However, home health was made subject to CON review. Washington raised its capital

⁴⁰ Joel I. Klein, Antitrust Enforcement and the Consumer, United States Department of Justice Antitrust Division.

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expenditures thresholds in 1982 and 1983, exempting many projects from review. However, at the same time hospices were added to the scope of program review. In 1989, the state made further reductions to its CON review including hospital purchase of major medical equipment and new, non-specialized services.

The Washington State study included a literature review including “an extensive search of the trade, professional, and research literature, examining 150 articles, ranging from research papers to opinion articles. Four major state studies and several smaller state-specific studies were also examined.”

The study also examined the experience of six other states (Indiana, Ohio, Pennsylvania, Tennessee, Utah, and Wisconsin) that had repealed all or parts of their CON laws. Information was gathered through interviews with key people in government and interest groups in the six states examined. Articles and other information about these states’ experiences were examined.

Five focus groups of Washington State healthcare providers were conducted in the areas of hospitals, Ambulatory Surgery Centers (ASCs), kidney treatment, home health, and hospices. The focus groups were interviewed on how the CON program affected each service area. Arguments and evidence for retaining or repealing the program were identified.

Key Informants “HPAP conducted interviews with ten experts chosen for their knowledge of the state’s CON program and the overall health policy environment in Washington State. Informants were chosen to represent consumer, business, labor, academic, and government perspectives.”

Advisory Group “An advisory group, consisting of representatives of stakeholder organizations, provided suggestions and feedback over the course of the study.”

Peer Review “Two national expert peer reviewers with divergent views of health sector regulation provided suggestions regarding relevant literature, and provided feedback on draft reports. These independent reviewers were under contract with JLARC.”

The studies finding in each area studies are summarized as follows:

- Cost “The study found strong evidence that CON is not an effective mechanism for controlling overall health care spending. While CON laws can be effective in slowing the expansion of some services, other factors affect health care costs that CON laws do not control. In addition, CON has not been very effective in controlling hospital costs. Not all hospital services are covered by CON, and the program is not always effective in controlling supply. The study also found that CON has restricted the supply of some specific services and that the repeal of CON has been associated with supply surges in some states.” The study found no convincing evidence that CON “limits the number of hospitals and other providers” for managed care and “potentially reduces the ability of managed care organizations to bargain for reduced rates.”
- Quality “Evidence about the effect of CON on quality is inconclusive. The evidence is weak regarding the ability of CON to improve quality by concentrating volume of

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- specialized services. Indirect evidence suggests that CON may protect quality in home health and hospice by keeping out unprepared or unqualified providers. Weak, conflicting evidence exists regarding the effect of CON on the market share of for-profit providers and any resulting impacts on quality. CON does not provide an ongoing mechanism to monitor quality.”
- Access “Conflicting evidence was found regarding the effect of CON or its repeal on access to health services. In some instances, CON has been used to protect existing facilities in inner city areas or to prompt providers to locate in those areas. In other instances, CON appears to restrict access by preventing the development of new facilities. Evidence from other states shows that the relationship between CON and access varies state by state as well as service by service. CON does not provide an ongoing mechanism to monitor access.”
 - Charity Care “CON provides some initial screening regarding a facility’s likelihood of providing charity care, but the program in Washington and most other states does not include monitoring for compliance. Some states are more likely to grant a CON to facilities offering more charity care, and CON can improve the operating margins of existing providers. These factors *may* increase the likelihood that the providers will offer more charity care, but no studies have been conducted to measure the effect of CON in increasing levels of charity care. Also, financial and market pressures make it increasingly difficult for all types of providers to offer charity care.”
 - Rural Care “Weak and conflicting evidence was found regarding the effect of CON on access to services in rural areas. One analysis showed that CON did not affect the development of rural networks. Repeal of CON appears to have had no effect in some states, while at least one state has experienced some disruption of rural health care after repeal.”

The study didn’t make a recommendation about whether Washington’s CON program should be repealed or retained since the available evidence didn’t support a recommendation of this sort. However, the study provided specific options for policymakers depending on whether they decide to repeal or retain the CON program.

- Reform the program
 - Reassess legislative and regulatory goals in relation to new conditions and needs in healthcare system
 - Establish mechanism to make CON more responsive to changes in the healthcare system (ex. Create policy oversight or advisory board)
 - Improve data collection to allow for ongoing monitoring and oversight of quality, general and rural access, and community benefits (including levels of charity care)
- Repeal the program
 - Identify policy goals for cost, quality, access, and accountability along with alternative methods of attaining these goals (strengthened licensing rules, additional charity care requirements)
 - Strengthen data collection and reporting to monitor the effects of repeal on quality, general and rural access, and community benefits.
- Conduct Economic Analyses to Guide Policy Changes

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- Estimate the effects of deregulation in Washington State on the supply and price of services and by simulating the effects of deregulation on the operating margins of service providers in Washington State.
- Study could be limited or comprehensive, depending on available resources. Estimated costs for proposed studies range from \$200,000 to \$300,000

IV.B.1 Health Expenditures After Repeal of CON

An 1998 empirical study, which examined health spending between the late 1970's and 1993 looked at spending prior to and directly after state CON laws were repealed, stated, "The major findings about CON can be summarized as follows: first, we found no surge in expenditures after CON was lifted; second, despite a statistically significant reduction by mature programs on acute spending per capita, there was no corresponding reduction in total per capita spending (apparently due to offsetting expenditures on non-hospital services)".⁴¹ "We found that mature CON reduced hospital bed supply per capita population, but could detect no increase in bed supply following the removal of CON."⁴² Furthermore, the study authors found that established CON programs increased cost per adjusted patient day and also cost per admission.⁴³

IV.B.2 Research Into CON Effectiveness

Another report on the effectiveness of CON states, "Extensive research, however, suggests strongly that CON programs have not worked as originally intended. It appears, in fact, that they may have boosted the very costs they were supposed to control for these reasons: 1) they restrict competition among hospitals, and 2) by curtailing efficient capital investments they actually raise operating costs."⁴⁴

IV.C Effect on Quality of Care

Often, the barriers to the market created by CON laws also have negative effects on the quality of care offered in the states where these laws are in effect. These negative effects stem from a reduction in access to health services and also in investments in new technologies.

IV.D Investments in the Expectation of CON Law Implementation

Providers have been shown to accelerate investments in facilities and equipment in anticipation of the implementation of CON laws.⁴⁵ Such behavior demonstrates the willingness of providers to "play the system". Existing providers support CON laws to prevent competition

⁴¹ Christopher Conover and Frank Sloan, Does removing certificate-of-need regulations lead to a surge in health care spending?, *Journal of Health Politics, Policy and Law*, Vol. 23 Issue 3 at 455.

⁴² Christopher Conover and Frank Sloan, Does removing certificate-of-need regulations lead to a surge in health care spending?, *Journal of Health Politics, Policy and Law*, Vol. 23 Issue 3 at 455.

⁴³ Christopher Conover and Frank Sloan, Does removing certificate-of-need regulations lead to a surge in health care spending?, *Journal of Health Politics, Policy and Law*, Vol. 23 Issue 3 at 455.

⁴⁴ Terree Wasley, *Certificates of Need: Poor Health Care Policy* (1993).

⁴⁵ "Containing Health Expenditures: Lessons Learned from Certificate-of-Need Programs" by Frank A. Sloan excerpted from "Cost, Quality, and Access in Health Care", Jossey-Bass, 1988, p.48-49.

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A study conducted by Frank A. Sloan and Bruce Steinwald found a 1.4 percent additional increase in bed supply in the year prior to CON implementation and attributed to the anticipatory effects of CON implementation.⁴⁶ After CON implementation, providers shifted investment to those areas not covered by CON, such as hospital equipment. This continued investment contributes to the increase of expenditures per bed.

IV.E CON Doesn't Affect Hospital Prices

CON attempts to control a very complex healthcare economic equation by controlling a small number of variables which amount to only a small portion of hospitals' and other providers' overall budgets and which do not affect the prices providers can charge. This type of myopic approach to the management of a complex economic system which is not fully understood to begin with is misguided and unproductive.

IV.F Hospital Expenditures Unrelated to Bed Supply

There is a widespread perception in healthcare that "Where there's a bed, there's a patient day", a cornerstone rallying cry for those who seek to restrict competition through legislation and regulatory control. Cited in the establishment of many CON laws restricting the construction and expansion of healthcare facilities was the "Roemer Effect." In their 1959 study, Roemer and Shain argued that hospital beds can be intentionally filled by providers who induce ill-informed patients into hospital stays.⁴⁷

However, an example of the ineffectuality of this type of limited control is early attempts to limit costs by controlling the number of hospital beds. In the 1970's, CON had little effect in controlling hospital costs even when bed supply was controlled because hospitals often simply increased their expenditures per patient.

V CERTIFICATE OF NEED REGULATIONS DO NOT CONSIDER OVERALL COSTS

V.A Capital Costs

Healthcare capital costs often are only the tip of the iceberg in terms of overall costs. Investment in capital also requires other costs such as installation, licensing, training, maintenance, support contracts, repairs, and routine operation costs which often exceed the original acquisition costs. This may skew how equipment thresholds are established and applied requiring review for some services with overall costs below others that do not qualify as over the review thresholds.

⁴⁶ "Insurance, Regulation, and Hospital Costs" By Frank A. Sloan and Bruce Steinwald. Lexington Books, 1980, p. 169.

⁴⁷ Madden, C. "Excess Capacity: Markets, Regulation, and Values." Health Services Research, Feb. 1999.

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In addition, limits and thresholds for equipment are usually based on acquisition costs and units rather than the procedural capacities of the specific equipment. New equipment which has slightly higher costs may be able to perform many more procedures per day and thus serve a larger population base more cost effectively. More advanced technology may provide higher quality service which may preclude further healthcare utilization. Such important factors are not considered in the needs analyses used by most states.

V.B Capital Investment May Decrease Costs

However, investment in new capital may actually decrease overall costs in the long run. Capital upgrades are essential improvements that lead to greater efficiency. CON regulations simply decrease industry investment, shifting the supply curve to the left.

V.B.1 Capital Outlays and Operating Costs

Many previous studies have found that hospital capital investments significantly raise operating costs. However, a 1987 assessment of prior studies found that although current capital expenditures increased future operating expenditures, it estimated that the overall effect was much less than previously reported.⁴⁸ The study further advised, “As Congress debates whether to incorporate capital into the Medicare Prospective Payment System, our results suggest that controlling the rate of increase in operating expenses may only negligibly deter capital expansion by hospital administrators.”⁴⁹

V.C Administrative Costs of CON

CON laws also create administrative costs. Approval processes and administrative costs are not part of the CON regulatory process, but are a significant expenditure. These costs for providers often include application fees, internal paperwork preparation costs, legal costs, research and data expenses, and potentially many more.

For example, the Missouri Health Facilities Review Committee (MHFRC) oversees the Missouri CON program and had funding for 2002 of \$322,726 including personnel services, expenses, and equipment.⁵⁰ The MHFRC summarized the fiscal impact of Missouri’s Certificate of Need Program regulations on private health care facilities as \$7,000 per application. They estimated that 50 applications would be submitted for the year for a total, with miscellaneous costs, of \$353,600.⁵¹ Thus for Missouri, the total direct costs to the state and private health care facilities was estimated to be \$676,326. Using these figures as a floor and Missouri’s costs as a proxy for CON states nationally, CON laws are a significant healthcare expense in and of themselves. Any

⁴⁸ Gerard Anderson, Jane Erickson, Susan Feigenbaum, Examining the Relationship between Capital Investment and Hospital Operating Expenditures, *The Review of Economics and Statistics*, Vol. 69, Issue 4 709, 712 (1992).

⁴⁹ Gerard Anderson, Jane Erickson, Susan Feigenbaum, Examining the Relationship between Capital Investment and Hospital Operating Expenditures, *The Review of Economics and Statistics*, Vol. 69, Issue 4 709, 712-713 (1992).

⁵⁰ Source: Missouri Health Facilities Review Committee, James Carlson, 2/20/02

⁵¹ Missouri Register – January 16, 2002, Vol.27, No.2; 19CSR 60-50.430; Certificate of Need Program.

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cost savings obtained must first be applied to this deficit before any benefits may accrue to taxpayers.

V.D Litigation and Other Costs

Litigation costs are not part of the CON regulatory process, but are inevitably involved. Further, attorneys' and consultants' fees are almost inevitably involved in the preparation of CON applications. Lobbying on both sides of the CON debate is certainly a large expense for healthcare providers and is noteworthy as one of many indirect costs of CON laws.

VI ARBITRARY AND CAPRICIOUS STANDARDS

Arbitrary and capricious, as defined by Black's Law Dictionary, is the "*characterization of a decision or action taken by an administrative agency or inferior court meaning willful and unreasonable action without consideration or in disregard of facts or without determining principle.*"⁵²

VIA CON Regulations Violate State Administrative Guidelines

Under the generally accepted administrative law practices, statutes delegating power to agencies or committees must attach some measure of meaningful and reasonable administrative standards.⁵³ Statutes and rules that fail to provide meaningful standards are subject to strict judicial scrutiny.⁵⁴ This is commonly referred to as the "delegation doctrine".

The regulatory standards set forth by CON regulations, because they are not based on empirical data and sound analysis, violate reasonableness criteria and are arbitrary and capricious.

State courts are, understandably, often reluctant to uphold broad delegation of rule-making authority, when the rules promulgated are "*in excess of any express or reasonably implied delegated legislative authority*".⁵⁵

VI.B CON Regulatory Thresholds Don't Consider Market Differences

Not only are the need thresholds arbitrary and capricious, but the definition and uniform treatment of different healthcare markets does not consider important local market differences. Regulations set uniform limits in terms of equipment, new facility, and new hospital costs that do not consider the differentiation of the market. It is not reasonable to hold all service areas to the same standard when the market environment and capital expenditures involved may have significantly dissimilar characteristics. For example, specifying a geographic area says nothing

⁵²Black's Law Dictionary with Pronunciations" 5th ed., Henry Campbell Black, West Publishing, 1979, p. 96.

⁵³ "Administrative Law in the Political System." Kenneth F. Warren, Ph.D. (1996). (3rd Ed.) Upper Saddle River, NJ: Prentice Hall, p.95.

⁵⁴ "Administrative Law in the Political System." Kenneth F. Warren, Ph.D. (1996). (3rd Ed.) Upper Saddle River, NJ: Prentice Hall.

⁵⁵ *State Department of Environmental Regulation v. Puckett Oil*, 577 So. 2d 988 (Fla. App. 1 Dist. 1991).

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about its economics, demographics, political divisions, or health status, all of which heavily influence its level of need for health services.

VI.B.1 Findings of the Community Snapshots Study

The Robert Wood Johnson Foundation's 1996 Community Snapshots "study underscores the fact that not all communities are alike, and hence not all health care markets are at the same point in their development or even on the same development continuum. By recognizing the importance of local community context to the process of change, we enhance our ability to understand the consequences of private business decision and public policy initiatives. The economics of a health care market interact with individual community characteristics, such as the presence of cultural or ethnic groups with particular needs or traditions, or the existence of an influential business sector, to influence the magnitude, direction, and sustainability of change."⁵⁶

VII CONCLUSIONS

If the market is not effective in controlling healthcare costs then other means may need to be employed. These may range from socialized national healthcare, as is widely found in Europe and other industrialized nations, to a completely fee-for-service system. On the other hand, managed care was touted by the government as the answer to healthcare cost inflation beginning with the HMO Act of 1973.⁵⁷ The term *health maintenance organization* was first coined during this period, referring to a prepaid organization that provided healthcare to voluntarily enrolled members in return for a preset amount of money on a PMPM basis. The HMO Act provided grants and loans for new HMOs and aided the expansion of existing HMOs.⁵⁸ It also required employers (with at least 25 employees) to offer two federally qualified HMO plans to their existing healthcare coverage mix.⁵⁹

Managed care did temporarily slow the growth of health insurance premiums. However, controlling costs by limiting utilization, as CON laws also do, has not stopped cost inflation and has lowered healthcare quality. In order to best balance quality and cost, utilization must be controlled to prevent unnecessary care and reimbursement must be structured to provide incentive to providers and facilities to provide adequate level of care including preventative treatments.

VII.A Methodology Suggestions

VII.A.1 Local Market Utilization Analysis

Any utilization analysis must also consider the context of the neighborhoods serviced by healthcare facilities and equipment. Service area demographic analysis must be considered in

⁵⁶ Chevy Chase et. al, Context and Catalysts for Change in Health Care Markets, Health Affairs, Vol. 15 Issue 2, at 121 (1996).

⁵⁷ The Managed Health Care Handbook, 3rd edition, Aspen Publishers, 1996, p. 6.

⁵⁸ The Managed Health Care Handbook, 3rd edition, Aspen Publishers, 1996, p. 6.

⁵⁹ The Managed Health Care Handbook, 3rd edition, Aspen Publishers, 1996, p. 6.

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order to provide meaning to utilization data. Markets are unique and require different standards dependent on population characteristics. Population projections and demographic analysis of characteristics would enhance the use of utilization data.

VII.A.2 The Influence of Market Power

Any appropriate methodology would also investigate market power. Market share can be used to measure the potential monopolistic tendencies of hospitals in a given service area.⁶⁰ Healthy competition gives economic power to patients. In 1990, hospitals in more competitive markets had average costs below those of less competitive markets.⁶¹

VII.A.3 Consideration of Unit Costs

Per capita costs, per day costs, per admissions, and per procedure cost should be used as a more accurate measure of total hospital utilization costs.⁶² Cost per Relative Value Unit (RVU) may also provide a more accurate representation of costs.

VII.A.4 Costs of Empty Hospital Beds

The costs of empty hospital beds should be linked to the market environment in which the hospital operates.⁶³ By doing so, variations in cost can be accounted for without resorting to uniform standards that may be inequitable in certain service areas.

VII.A.5 Fluctuations in Hospital Occupancy Rates

Simple uses of target occupancy levels are not sufficient in utilization analysis. Any analysis must include aspects of fluctuation in hospital bed utilization over the long term and short term to account for emergency demand.⁶⁴

VII.B Data Recommendations

VII.B.1 National Discharge Statistics

Utilization statistics used as an overall demand benchmark should be national. While discharge statistics may be an appropriate source of hospital utilization, the challenge is to utilize this data in a way that is not skewed. For example, local statistics, where available, may be based on

⁶⁰ Greenberg, W. (Dec. 1998). Marshfield Clinic, Physician Networks, and the Exercise of Monopoly Power. *Health Services Research* 33(5) 1461-1476

⁶¹ Zwanziger J, Melnick G, Bamezai A. "California providers adjust to increasing price controls." In *Health Policy Reform: Competition and Controls*. Edited by R. Helms, pp. 241-58. Washington, DC: AEI Press, 1993.

⁶² Antel, J. J., Ohsfeldt, R. L. and Becker, E. R. (Aug. 1995). State Regulation and Hospital Costs. *The Review of Economics and Statistics* 77(3) 416-422

⁶³ Magnussen, J. and Mobley, L. R. (Nov. 1999). The Impact of Market Environment on Excess Capacity and the Cost of an Empty Hospital Bed. *International Journal of the Economics of Business* 6(3) 383

⁶⁴ Green, L. V. and Nguyen, G. V. (June, 2001). Strategies for Cutting Hospital Beds: The Impact on Patient Service. *Health Services Research* 36(2) 421

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localized under-utilization possibly even due to a lack of available facilities, which would not accurately reflect need.

VII.B.2 Population and Demographics Data

Population and demographics data utilized in CON analyses also needs careful scrutiny. For example, U.S. Census data for specific census tracts will vary from data at the block group level, which data is often taken from samples and is therefore less reliable. The specific Census geopolitical designated regions for which data is available may not appropriately match the provider catchment or patient service area for which need is being determined.

VII.C Areas for Further Study

Scrutiny of the very limited information from studies which indicate that CON lowers costs is advisable to identify the underlying reasons for these results. It is noteworthy that CON may be effective in lowering costs simply by dangerously reducing access to healthcare facilities and services.

VII.D Alternate Approaches for Governmental Influence on Healthcare Costs

Free market competition independently establishes need for new health facilities, equipment, and services. In an unregulated market, investors in new healthcare infrastructure must conduct their own market research into the local demand for and availability of the proposed health service; the sources or payment and their sufficiency for local patients and payors; the existence and capacity of competing and substitute providers and services; as well as, all of the other competitive factors influencing the viability of a new health service business investment.

Competition compels providers to control costs and provide quality service. This competitive system is the basis for cost control in the U.S. economy. CON is an artificial, government imposed barrier to competition rarely seen in the U.S. outside of the healthcare industry. To switch to a regulated system of cost control in healthcare would require an enormous level of control and coordination far beyond the current small scope of the information gathering and analysis capacity of existing CON programs. Such an effort to switch to a regulated market would be one to which Americans have historically appeared to oppose.

Michael Porter (et al.) wrote in the Harvard Business Review that,

“In industry after industry, the underlying dynamic is the same: competition compels companies to deliver increasing value to customers. The fundamental driver of this continuous quality improvement and cost reduction is innovation. Without incentives to sustain innovation in health care, short-term cost savings will soon be overwhelmed by the desire to widen access, the growing health needs of an aging population, and the unwillingness of Americans to settle for anything less than the best treatments available. Inevitably, the failure to promote innovation will lead

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to lower quality or more rationing of care – two equally undesirable results.”⁶⁵

If the healthcare industry is to achieve a reduction in cost in response to market pressures, then the healthcare market must first create incentives for innovation. The barriers to competition cannot include barriers to innovation as many do now. Healthcare purchasers, managers, and legislators must ensure innovation takes the forefront of any reform, if it is to be effective. If we are to achieve **value** in healthcare delivery there must be concern about how innovation and competition can achieve the really important considerations - access, quality, beneficial outcomes, appropriate cost and patient choice. Don't be duped by cries of duplication!

⁶⁵ “Making competition in health care work.” By Michael Porter, et al. Harvard Business Review, July/Aug. 1994, p. 131.

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APPENDIX A
About the Author

Robert James Cimasi, ASA, CBA, AVA, FCBI, President

Robert James Cimasi, ASA, CBA, AVA, FCBI is President of HCC with over nineteen years of experience serving clients with a professional focus on the financial and economic aspects of healthcare service sector entities. Prior to founding HCC in 1993, Mr. Cimasi was Vice President—VALUATION & PRACTICE EXCHANGE ® Services for Physician International. Mr. Cimasi holds the Accredited Senior Appraiser (ASA) designation in Business Valuation, as well as, the Certified Business Appraiser (CBA), and Certified Business Intermediary (Fellow) (FCBI) designations. He is a member of the following healthcare associations: Academy for Health Services Research and Health Policy; Healthcare Financial Management Association; Medical Group Management Association; National Association of Health Care Consultants; and, St. Louis Society for Healthcare Planning and Marketing.

Mr. Cimasi is a nationally known speaker on healthcare industry topics, who has served as conference faculty or presenter for such organizations as the American College of Healthcare Executives (ACHE), National Association of Healthcare Consultants (NAHC), American Society of Appraisers (ASA), American Institute of Certified Public Accountants (AICPA), Institute of Business Appraisers (IBA), National CPA Health Care Advisors Association, International Business Brokers Association (IBBA), Institute of Certified Business Counselors (CBC), National Litigation Support Services Association (NLSSA), and many other national and state healthcare companies and organizations as well as industry associations and professional societies. He has been certified and has served as an expert witness on cases in several states.

He is the author of A Guide to Consulting Services for Emerging Healthcare Organizations (John Wiley & Sons, 1999), The Valuation of Healthcare Entities in a Changing Regulatory and Reimbursement Environment (IBA Course 1011 text - 1999), and Health Care Industry and Medical Practice Valuation (AICPA Advanced Business Valuation course text 1997, rev.2000.) He has written chapters on medical practice valuation in The Handbook of Business Valuation (John Wiley & Sons), Valuing Professional Practices and Licenses: A Guide for the Matrimonial Practitioner, 3rd ed., 1999 (Aspen Law & Business), and Valuing Specific Assets in Divorce (Aspen Law & Business) and has been a contributor to The Guide to Business Valuations (Practitioners Publishing Company) and Physician's Managed Care Success Manual: Strategic Options, Alliances, and Contracting Issues (Mosby). He has written numerous published articles, has presented several papers and case studies before national conferences, and is often quoted by healthcare industry trade publications and the general media.

Mr. Cimasi has recently developed *Appraisal MD Pro*, advanced medical practice valuation software, released by the ValuSource division of John Wiley & Sons in March, 2000.