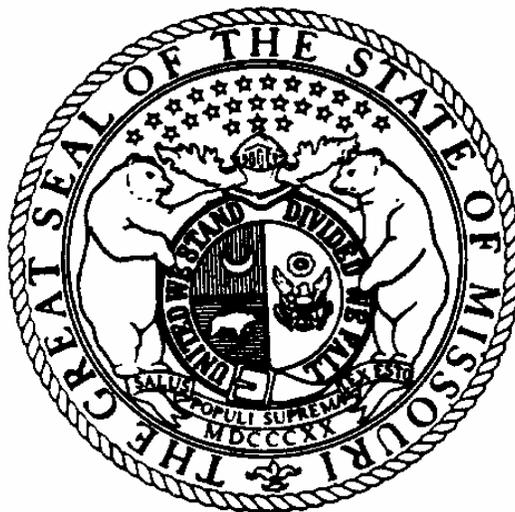


REPORT
OF
THE SENATE INTERIM COMMITTEE
ON CERTIFICATE OF NEED



January 17, 2007

Prepared by
Adriane Crouse, Senate Research Staff

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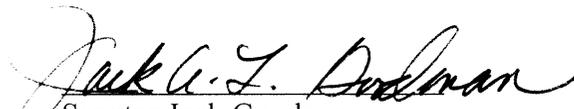
The Honorable Michael Gibbons, President Pro Tempore
State Capitol, Room 326
Jefferson City, Missouri 65101

Dear Mr. President:

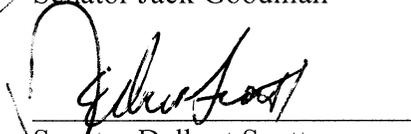
The Senate Interim Committee on Certificate of Need, acting pursuant to Rule 31 of the Missouri Senate, has met, taken testimony, deliberated, and concluded its study on the issue of Certificate of Need in Missouri, particularly in evaluating the potential consequences of limiting or repealing the application of certificate of need requirements for hospitals and other healthcare facilities, and has inquired into the nature and extent of the same. The committee now presents to the General Assembly a report of information and proposed recommendations of actions to address this issue.



Senator Bill Stouffer, Chair



Senator Jack Goodman



Senator Delbert Scott

Senator Frank Barnitz

Senator Harry Kennedy

Senate Interim Committee on Certificate of Need

I. OVERVIEW

As a result of continuing interest on the issue of the certificate of need program in Missouri and its effects on the quality of health care and the health care market, President Pro Tempore Senator Michael Gibbons established the Senate Interim Committee on Certificate of Need. The committee was charged primarily with the task of conducting hearings for the purpose of evaluating options that would limit or repeal application of certificate of need requirements for hospitals and other health care facilities and the potential consequences. The committee was also charged with examining the impact of physician ownership and self-referral in healthcare and with examining the current certificate of need law on consumer choice. The membership of the committee consisted of the following senate members: Senator Bill Stouffer, Chair, Senator Jack Goodman, Senator Delbert Scott, Senator Frank Barnitz, and Senator Harry Kennedy.

The committee held public hearings and solicited testimony regarding a wide range of issues related to the certificate of need program. Hearings were held on the following dates and locations:

August 1, 2006	Jefferson City, Missouri
August 30, 2006	St. Louis, Missouri
September 12, 2006	Jefferson City, Missouri

Oral and written testimony was provided by the Director of the Missouri Certificate of Need Program, representatives from the Missouri Hospital Association, Missouri State Medical Association, St. Louis Area Business Coalition, Signature Health Services, Metro Heart Group of St. Louis, Inc, Missouri Health Care Association; Associated Industries of Missouri; Monsanto and the Ford Motor Company. In addition, testimony was provided by citizens and experts in the field, including Robert Cimasi of Health Capitol Consultants, and Jean Mitchell, Ph.D. of Georgetown University Public Policy Institute. Based on testimony, the committee has compiled recommendations as to legislation that would provide for a phase-out of the certificate of need program while providing transparency for the consumer.

II. BACKGROUND

The origins of certificate of need (CON) programs throughout the country stem from a federal law that has since been repealed. In 1974, Congress passed the National Health Planning and Resources Development Act, Public Law 93-641. The law stated that in order to receive federal funding from certain federal programs such as Medicare and Medicaid, new health care facilities and new health care expenditures to existing facilities needed to be approved by a state agency issuing certificates of need.¹ The law mandated that all of the states have such certificate of need programs in place by 1980. By 1983, all states except Louisiana enacted CON programs. Louisiana later enacted a program in 1991.²

When the federal law was enacted, reimbursement rates for services were made on the basis of costs of services, including the costs of production (cost-basis or cost-plus method).³ The impetus for pushing the federal law was to curb the growing healthcare costs. It was believed that the cost-basis method of reimbursement encouraged inefficiency and unwise investment as there was no need to accurately research the demand for new facilities or expenditures because reimbursement would occur regardless of need. It was thought that facilities were being built and new unnecessary expenditures being made solely for the purpose of being reimbursed by the federal programs for the costs of production.⁴ Therefore, CON programs were originally intended to lower healthcare costs by avoiding duplication of costly services.

Congress repealed the CON mandate in 1986 after the federal government changed the cost-basis method of reimbursement to one where it paid a predetermined amount based on the kind of treatment and fee schedules that were the product of negotiation.⁵ This is also known as the prospective payment system (PPS or capitation method). This method of payment came about largely in the era of managed care.⁶ Since 1987, 14 states have repealed their CON programs, while 36 states, including Missouri, have retained their CON programs.⁷

State CON programs control market entry for regulated health care facilities, services and equipment. Among the entities generally falling under CON laws are hospitals, ambulatory surgical centers, and long-term care facilities. In Missouri, the CON law, sections 197.300 to 197.366, RSMo, is administered by the nine-member Missouri Health Facilities Review Committee.⁸ Five members are appointed by the governor, two by the president pro tem of the senate, and two by the speaker of the house, each serving two-year terms or until replaced. Generally, the Missouri CON program currently covers the following:⁹

- new hospitals costing one million dollars or more;
- major medical equipment costing one million dollars or more acquired for use in any location;
- any new long-term care facilities costing over \$600,000;
- additional long-term care beds in a residential care facility, nursing home, or acute care hospital costing \$600,000 or more up to 10 beds or 10% of that facility's existing capacity; and
- specialized long-term acute care beds or hospitals at any cost

III. SUMMARY OF INFORMATION AND TESTIMONY RECEIVED

In the course of the three public hearings, the committee gathered a large amount of information from witnesses who could assist the committee in making recommendations regarding the certificate of need program in Missouri. The following is a list of witnesses and a summary of the testimony provided.

August 1, 2006, Jefferson City, Missouri:

Tom Piper, Director of the Missouri Certificate of Need Program

Mr. Piper gave a brief background and history regarding CON programs. He noted that in 2006 there are fourteen states with no CON process, while others have reinstated or strengthened CON programs. Mr. Piper explained that Connecticut is known as having the broadest program, Louisiana the least restrictive one, while Missouri falls somewhere in the middle.

Mr. Piper noted at the hearing and in handouts provided to the committee that the Missouri CON program saves money, ensures accountability, protects the community and promotes planning. According to Mr. Piper, over \$145 in capital expenditures were precluded by CON actions for every \$1 invested to administer the program from 1990 to 2005.

Mr. Piper explained that in states where CON has been eliminated or greatly reduced, utilization rises along with a “capacity boom.” He gave an example of when Ohio eliminated its CON program in 1995. After the first four years, there was an increase of 19 new hospitals including 15 long-term care hospitals as well as a 137 % surge in outpatient dialysis stations as well as a 600 % increase in ambulatory surgical centers. He also noted how Indiana and Pennsylvania have made repeated efforts to reinstate their respective CON programs.

Mr. Piper presented slides from an independent study conducted by the big-three automakers, Ford Motor Company, General Motors Corporation and Daimler-Chrysler Corporation, comparing the adjusted healthcare costs per person, adjusted healthcare expenditures per employee, hospital inpatient, magnetic resonance imaging (MRI) and coronary bypass surgery relative costs. The slides illustrated how states with CON programs have lower healthcare costs than non-CON states.

Mr. Piper cautioned that there would be consequences for eliminating public oversight of healthcare expenditures. He argued that there would be fragmentation among the provider delivery network as well as a great threat to safety net facilities. In addition, without oversight and planning there would be a surge in high-profit niche markets. He argued that there needs to be a balance between regulation and competition in order to protect the public’s interest. Finally, Mr. Piper stated that he feels there are better outcomes in states with CON regulations.

Robert Cimasi, President of Health Capital Consultants

Mr. Cimasi is the president of a national healthcare economic and financial consulting firm and the author of The U.S. Healthcare Certificate of Need Sourcebook.¹⁰ In his testimony and handout presented to the committee, Mr. Cimasi concluded that the CON program is a failed public health policy that has created a negative impact on Missouri healthcare. He covered the following topics in advance of his conclusion:

- CON's history as a failed health planning policy
- The effects of CON repeal in several states (citing a study that found not all states have surges in healthcare expenditures and that if they do, the surges moderate after a period of time¹¹)
- The Federal Trade Commission's repeated denunciation of CON (noting a 2004 study stating that CON programs "pose serious anticompetitive risks that usually outweigh their purported economic benefits"¹²)
- CON programs failure to lower healthcare costs
- CON programs promoting anti-competitive atmosphere
- CON programs acting as barriers to healthcare innovation
- CON programs reducing access and patient choice; and
- CON programs not improving healthcare quality

Mr. Cimasi was asked to comment on the cost of applying for CON review. He gave an example of fees ranging from \$150,000 to \$250,000, which include not only the actual fee but the cost of hiring consultants, attorneys and lobbyists during the CON review process as well.

Mr. Cimasi further commented that there was no evidence that CON states achieve true cost-savings. He noted how in Illinois and Alabama a billion dollars in investment was driven away by the CON process. He calls this phenomenon of investment dollars being driven away as the "sentinel effect" wherein many investors believe in an investment idea at first but then are scared away by the onerous CON review process.

Mr. Cimasi was asked to comment on how a repeal of CON would have an impact on access to healthcare. He believes that CON does not help in that area and stated how at one point, Oregon had to ration services. He argues that other policies are needed to encourage access and that CON is not the answer because it discourages competition.

Mr. Cimasi was also asked to comment on the issue of physician self-referral. He stated that there is no evidence in the marketplace to conclude that physician self-referrals lead to over-utilization and that if there were such problems, CON would not be the solution for it. He believes that the issue of physician self-referral is not related to CON and that how physicians are reimbursed should be studied.

Daniel Landon, Vice-President of Government Relations- Missouri Hospital Association (MHA)

Mr. Landon expressed MHA's opposition to both the repeal of CON laws as to the construction of new hospitals and to the proliferation of physician-owned specialty hospitals. He argues that both issues are necessarily intertwined.

Mr. Landon explained that specialty hospitals limit their services to few medical services, serving primarily cardiac or orthopedic patients and are usually owned by specialist physicians. He noted that currently there are no physician-owned specialty hospitals in Missouri. He believes the issue of physician-owned specialty hospitals are of concern because of the potential for such hospitals focusing on the "most lucrative procedures and patients" leading to cherry-picking. The concern is that the cherry-picking would compete for profitable services that community hospitals provide. If the community hospitals are not able to profit from these services, then the hospitals would find it hard to maintain the unprofitable but essential services provided to the low-income or uninsured.

Mr. Landon also believes that physician-owned specialty hospitals could also increase patient steering, cost, and utilization because of the financial incentive to refer the more well-off patients to their own facilities and the unprofitable patients, such as those on public assistance programs and the uninsured, to community hospitals.

In support of his arguments, Mr. Landon cited various research findings about specialty hospitals, including findings from the Council of State Governments, Medicare Payment Advisory Commission (MedPAC), Center for Studying Health System Change, and a recent General Accounting Office (GAO) study.

Mr. Landon also argued that the CON process does not stifle innovation and cites the recent approval by the Missouri Health Facilities Review Committee of cutting-edge MRI technology and the opening of a heart hospital on the St. John's Mercy Medical Center Creve Coeur campus.

Finally, Mr. Landon noted that the CON process is also a means to monitor the healthcare market, especially for areas of the market that are not currently licensed by the state, such as imaging, endoscopy and dialysis centers.

August 30, 2006, St. Louis, Missouri:

Jan Vest, CEO, Signature Health Services, Inc

Mr. Vest testified in opposition of the CON program. He raised many of the same arguments raised previously by Mr. Cimasi, adding that "CON is a cartel enforcement device that protects incumbent providers from new entrants and competition." Mr. Vest further opposes CON because it causes the market to be run by government rather than "entrepreneurial insight"

and patient choices. Mr. Vest also cited the Federal Trade Commission study and a study by Duke University professors in support of his arguments.

Patrick Devereux, Citizen

Mr. Devereux is the president of Group 21, Inc., a healthcare consulting firm. He also raised many of the same arguments in opposition to CON laws. Mr. Devereux argued that more competition between providers will promote lower prices because providers will seek to attract patients by cutting prices as they do for managed care payers.

As to the specialty hospital debate, Mr. Devereux argues that the public merely wants a system that provides them with the best access to services at the lowest cost regardless of where or by whom the services are provided. He cites the example of taking his car to a transmission shop to have the transmission rebuilt. He notes that in a place where the technicians are specially trained for transmission work using the latest tools, he is certain he received better service and at a lower cost than if he had taken his car to a general car repair shop.

Mr. Devereux also raised the issue of helping patients and consumers navigate the market place by developing thorough, reliable data as to healthcare quality and costs. He notes that consumers are becoming better informed and will be able to drive healthcare forces.

Rock Erikson, Executive Director, Metro Heart Group of St. Louis, Inc

Mr. Erikson's group provides both in-patient and out-patient cardiology services to major hospitals in the area. He argues that the hospital control of the out-patient services are akin to an oligarchy and notes that hospitals are paid 160 percent more for a procedure than his group. He notes that while Metro Heart controls the quality of services, it does not control the process.

He notes that his group and others like it welcome high deductible health plans because it would promote transparency in the market place. He agrees with members of the committee that there needs to be a means to measure quality to avoid out-patient groups that merely "churn-out" patients.

Bruce Hillis, Missouri First

Mr. Hillis offered testimony in opposition to CON laws. He offered copies of a book for the committee members entitled, *What States Can Do to Reform Health Care: A Free-Market Primer*. He noted how CON laws interfere with free markets. Mr. Hillis explained that he does not call for legislation that would "level the playing field" but rather asks for the government to take no action on the "rules of play that prevent fair and open competition." Finally, Mr. Hillis argues three conditions must occur for free markets to exist: (1) customer defined expectations of care; (2) a freely-functioning price system; and (3) open competition.

Mr. Hillis was asked to comment on how to educate the consumer. He noted that customers need to be able to compare facilities and that the state needs to gather more data on the various healthcare entities currently operating. It was suggested that the National Committee for Quality Assurance (NCQA) standards be used as objective measures for comparison.

Louise Probst, Executive Director, St. Louis Area Business Health Coalition

The St. Louis Area Business Health Coalition represents business members who provide coverage for more than 400,000 persons in the region. Ms. Probst stated that the key message for the committee was to keep the certificate of need program in Missouri until “there is transparency in the healthcare market and financial incentives are appropriately aligned.”

Echoing some of the concerns brought up by the Missouri Hospital Association, Ms Probst made a link between the CON program and the ability to ensure safety and standards of care through oversight. She argues that without CON, there is no other method to provide oversight of certain healthcare facilities and services. As an example, she noted that there is no single registry of outpatient treatment and diagnostic facilities that exist in Missouri and the department of health and senior services is not able to make public the list of registered radiation-producing equipment and facilities.

Ms. Probst also argued that Missouri lags behind in data disclosure. She explained that although recent legislation requires disclosure of hospital-acquired infection rates, the following data disclosures are not mandated in Missouri:

- hospital discharge dataset
- adverse events reporting
- risk-adjusted outcomes of inpatient care
- common satisfaction survey results
- poor showing results

She also explained that if there is more public reporting in the healthcare area, performance improvements would arrive sooner than later.

Ultimately, Ms. Probst argued that CON is needed until there are more adequate safety standards and transparency is achieved for consumers. She recommended that the dollar amount triggering CON review for major medical equipment be lowered from one million dollars to \$500,000.

Robert Knowles, Monsanto

Mr. Knowles’ testimony regarding the need for transparency in the healthcare market place reiterated many of the themes raised earlier. He believes there is not sufficient comparative information available to the public and the providers. He argued that the state needs to determine

how to achieve transparency and data communication.

September 12, 2006, Jefferson City

Jean Mitchell, Ph.D, health economist with Georgetown University Public Policy Institute

Dr. Mitchell's testimony was sponsored by the Missouri Hospital Association and the Missouri Physical Therapy Association. Dr. Mitchell testified about the effects of physician self-referral and limited service providers. She noted that her research was one of the drivers of the current federal prohibitions on physician self-referrals.

Dr. Mitchell raised many of the previous arguments against physician ownership of free standing health care facilities, including conflicts of interest due to financial incentives, cherry-picking of patients with good insurance, and the fact that the arrangements are anti-competitive.

Dr. Mitchell also outlined some of the results of her latest research, which compares Medicare utilization rates for selected procedures in states with a large amount of specialty hospitals and those states without specialty hospitals. She stated that her studies indicate increased utilization of procedures and costs to consumers in those states where there has been a development of physician-owned specialty hospitals. She noted that when those specialty hospitals are excluded, the utilization rates in those states are very similar to those of the states without such hospitals.

Dr. Mitchell also explained that her findings on utilization increases in workers' compensation programs in Oklahoma correlated with orthopedic specialty hospitals. She noted that spinal surgeries increased in the specialty hospitals. She also argued that physician investors' practice patterns are affected by the financial incentives posed by self-referral arrangements.

Tony Reinhart, Ford Motor Company

Mr. Reinhart stated that he was testifying in response to previous testimony regarding the study conducted by the "Big-Three Automakers." He noted that there was a 60 percent increase in costs since 2000 and that \$1,200 cost per vehicle is devoted to health care costs, whereas for Toyota the cost is \$450 dollars per vehicle.

Mr. Reinhart discussed some of the results of the auto industry study. He noted that the costs in states without CON were higher. After Indiana reinstated its CON program, the study showed that the increase in healthcare costs was a one-time increase. The study has not revealed a decrease in competitive forces after allowing for the market to settle.

Mr. Reinhart argues for a strong CON program because he believes healthcare does not operate as a normal economic good and without CON, the rural and inner-city areas would be

affected by a lack of access to care. Mr. Reinhart also argues for a market place that would move to more transparency.

Jim Kistler, Associated Industries of Missouri

Mr. Kistler testified in support of retention of CON laws. He argued that the healthcare market place does not operate in a truly free marketplace. He cites as examples of factors beyond state control as Medicaid, Medicare and federal emergency medical treatment (EMTALA) laws.

Jon Dolan, Missouri Health Care Association

Mr. Dolan argued for the continuation of the CON program until such time as certain areas are addressed such as issues with long-term beds and the current regulatory and reimbursement environment in long-term care. He understands that some day CON will be gone but respects the fact that government has a stake in protecting the public good and health of its citizens.

Mr. Dolan suggested that the current long-term care facilities should be allowed to maximize reimbursement rates if the facilities remodel and add updates. There should be incentives for facilities that are already in place rather than opening new facilities.

Robert Boeger, citizen

Mr. Boeger testified in opposition to CON. He believes competition needs to be promoted in Missouri and that there are too many barriers in the market place.

Written Testimony, Missouri Health Facilities Review Committee (MHFRC)

The Missouri Health Facilities Review Committee provided testimony seeking to refute many of the arguments made in opposition of the CON program. The MHFRC noted, among other things, that the CON process is efficient and effective, encourages innovation, encourages public discourse and combined expertise on health planning issues, bases CON decisions on a foundation of clinical, educational and experience-based knowledge, balances choice with reasonable access, quality and cost, does not interfere with entry to market, and is not abused by hospitals. In addition, the MHFRC noted that there is evidence of problems with physician self-referral.

Finally, the MHRC argued that CON is “part of a publicly-accountable objectively-administered effort to cooperatively influence health care to motivate better outcomes for Missourians at a reasonable cost.”

Written Testimony, Missouri State Medical Association (MSMA)

MSMA issued its support for the repeal of the CON program. It argued that the CON program has outlived its usefulness, stifles competition and innovation, lowers quality of care, drives up the cost of health care, and is detrimental to Missouri's economy. MSMA also notes that there is no demonstrable adverse impact as a result of the repeal of CON in other states.

IV. FINDINGS AND RECOMMENDATIONS

After review of all information received by the committee during its three public hearings, the committee determined that the following findings and recommendations should be made to the General Assembly:

1. Although CON programs were initially mandated by the federal government in 1974 in an effort to lower healthcare costs due to the cost-basis/cost-plus method of reimbursement, testimony in this committee indicated that it is now questionable as to the necessity for state government to continue to intervene in all planned health care investments and growth due to the cost basis/cost plus method. The federal government repealed the mandate in 1986 after redesigning the method of reimbursement in the era of managed care. The federal repeal was designed to allow individual states to determine what was necessary for their respective state.
2. CON acts as an artificial barrier to entry reducing competition and innovation in the healthcare market. The onerous cost and process of undergoing CON review has a distinct chilling effect on those seeking to undertake modernization, specialization and efficiency in healthcare. Also, when there is no price competition, there is no incentive to reduce costs for the existing facilities nor is there incentive to improve the quality of care. Not only does this lead to higher healthcare costs but it also limits patient choice.
3. In determining need in the health care market, profitability should not be the only consideration, but rather access and delivery of service to all patients while providing ethical and appropriate care must be also be considered. Despite the CON program's goal of determining the true need for growth in the healthcare market, the CON program has focused primarily on the supply-side aspect in the healthcare arena by looking at what is currently in existence rather than what is needed in the community. However, if left to the free market, exhaustive studies on demand would be made by investors seeking to undertake a new healthcare venture. As a result, it stands to follow that market forces will accurately determine the need for certain facilities or services or the investors would not pursue such ventures.
4. CON hinders growth in the long-term care market and creates a disincentive to update and expand long-term care facilities because such updates do not garner

higher reimbursement rates from the government. The state should reduce such disincentives by providing for higher reimbursement rates for upgrading existing facilities.

5. The CON program is useful in helping the state maintain an inventory of facilities and services and in keeping track of the supply of health services and market. Without CON, there would be no ability to adequately track unlicensed facilities such as imaging, endoscopy and dialysis centers. There needs to be an implementation of minimum standards of safety and reporting by all types of facilities not currently mandated by law. Many of these minimum standards are already in place and used by certain types of facilities such as the objective measures for comparison from the National Committee for Quality Assurance (NCQA).
6. If the free market is to be left to dictate the true needs and demands in the healthcare community, consumers need to be adequately informed of the available choices. Not only do consumers need to compare the various facilities and services, but providers need to see how they compare with other facilities as well. Appropriate comparisons need to be made in terms of safety, quality, costs, and outcomes in care.
7. In order to achieve a responsible phase-out of the CON program in Missouri, any repeal of such program must coincide with transparency in the healthcare marketplace. For the long-term care market, a phase-out should be tied to major reform in reimbursement rates and capital improvement incentives.
8. As part of the goal of achieving transparency in the marketplace, the Department of Health and Senior Services should implement a long-range plan for making available cost, quality and safety outcome data on its Internet website that will allow consumers to compare healthcare services. The data should, at a minimum, include information on licensed physicians, hospitals and ambulatory surgical centers.

¹Roy Cordato, Ph.D, "Certificate of Need Laws: It's time for repeal," November 2005, p. 9

²Id. See also, Thomas R. Piper, "Certificate of Need: Protecting Public Interests," Director, Missouri Certificate of Need Program, August 2006

³Roy Cordato, supra at p. 10

⁴Id. See also Library of Congress, Bill Summary-S.2994, Public Law 93-641, <http://thomas.loc.gov/cgi-bin/bdquery/z?d093:SN02994:@@L%7CTOM:/bss/d093query.html%7C>. One of the stated goals of the act was to address the problem of infusion of federal funds into the health care system contributing to inflationary health care costs.

⁵Joshua M. Wiener, David G. Stevenson, and Susan M. Goldenson, "Controlling the Supply of Long-Term Care Providers at the State Level," Urban Institute, 1999; see also Cordato, supra at p. 10

⁶Wiener, Stevenson, and Goldenson, supra

⁷Missouri Health Facilities Review Committee, "Certificate of Need: Effective, Efficient, Accountable," February 2006; see also Louise Probst, "Senate Interim Committee on Certificate of Need" handout of St. Louis Area Business Health Coalition, August 2006

⁸The Missouri CON Rulebook: Missouri CON Review after 2002, www.dhss.mo.gov/CON/rulebook.pdf

⁹Id.

¹⁰, Robert Cimasi, 2005, *The U.S. Healthcare Certificate of Need Sourcebook*, Washington D.C., BeardBooks

¹¹Robert Cimasi, "Missouri Senate Interim Committee on Certificate of Need," August 2006, Written Testimony (citing "Effects of Certificate of Need and its Possible Repeal," 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, Jan. 8, 1999, pp 11, 13)

¹²Robert Cimasi, 2005, *The U.S. Healthcare Certificate of Need Sourcebook*, p. 19, Washington D.C., BeardBooks (citing "Improving Health Care: A Dose of Competition," a report by the Federal Trade Commission and the Department of Justice, July 2004)