

EVALUATION OF CERTIFICATE OF NEED IN MICHIGAN

Volume I: Final Report

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**A Report to the
Michigan Department of Community Health**

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PREFACE

The following report constitutes the final and complete report of the Center for Health Policy, Law and Management (Center) to the Michigan Department of Community Health (MDCH). This report is based on a five-month study conducted by the Center at the request of the Department through a subcontract administered by the Michigan Public Health Institute (MPHI).

In April 2002, the Michigan Auditor General completed a performance audit of the Certificate of Need (CON) Program administered by the Michigan Department of Community Health. The audit concluded that MDCH "in conjunction with the CON Commission, had not evaluated the CON program in order to determine whether the CON Program was achieving its goal of balancing cost, quality, and access issues and ensuring that only needed services are developed in Michigan." The MDCH concurred and agreed to contract with an independent outside contractor to conduct an evaluation of the CON Program.

The MDCH entered into a contract with the MPHI, a Michigan nonprofit corporation, to establish a contract with a contractor with a thorough and objective understanding of the issues involved.

Process and Overview

In July 2002, the Center for Health Policy, Law and Management at Duke University was selected by the Michigan Public Health Institute to undertake an evaluation of the CON program. Christopher J. Conover, Ph.D. served as principal investigator and Frank Sloan, Ph.D. served as a consultant. Dr. Sloan is a nationally recognized expert in this field, having contributed some of the seminal pieces of analysis to the published literature. In 1996, Professors Sloan and Conover assisted the Delaware Health Care Commission in assembling the most thorough and systematic examination of evidence on this issue ever available to state policy makers faced with the decision of what to do about CON. They subsequently published their key findings regarding CON for acute care services in a 1998 article for *Journal of Health Politics, Policy and Law*.

The Michigan evaluation focused on CON for acute care services, with particular attention given to CON for hospital beds, MRI services, and cardiac services (including cardiac catheterization laboratories and open heart surgery units). The evaluation consisted of two parts: an update of the 1998 study and three case studies focused on hospital inpatient beds, MRI services and open heart/cardiac catheterization (OH/CC) services. The quantitative part of the study was largely focused on updating the 1998 study using the latest

available data on health expenditures, hospital services availability (including selected technologies), hospital costs and profitability, for-profit share of hospital beds and HMO market share. In addition, data from various sources were assembled to better understand what happened in states that lifted CON and to compare these experiences to those in Michigan. Finally, the comprehensive literature synthesis completed for Delaware in 1996 was updated to ensure that all pertinent literature related to CON's impact on costs, quality and access had been taken into account.

Professors Conover and Sloan met in Lansing with officials of DCH and MPHI in early August 2002 to confirm the scope of work and arrangements to coordinate the collection of data and subsequent analysis. Over the course of the project, MDCH provided a graduate research assistant who was instrumental in compiling some of the raw data needed for analysis. In addition, Dr. Greg Cline from MPHI undertook some of the key informant interviews used for the qualitative analysis. After completing their analysis and sending a draft report to MDCH and MPHI, professors Conover and Sloan returned to Lansing in early December to provide a briefing to MCDH staff on findings and recommendations. Following a systematic review and comment of the draft report by MDCH and MPHI staff, the Center submitted its final report on May 30, 2003.

EXECUTIVE SUMMARY

BACKGROUND

In spring 2002, following a performance audit by the Michigan Auditor General, the Michigan Department of Community Health (MDCH) agreed to conduct an evaluation of Michigan's Certificate of Need (CON) program. The MDCH contracted with the Michigan Public Health Institute (MPHI) to subcontract with a suitable outside contractor to undertake this evaluation.

Originally, the principal rationale for CON was to control health costs, although in Michigan, both quality and access were important additional reasons that CON was adopted and continues today. However, since CON began in the early 1970's, and even compared to the early 1990's, Michigan has experienced monumental changes in its health care system. As in most other states, the rapid emergence of managed care and vertical integration in the health care market have combined to make the market considerably more competitive than in the past. With the recent return of double-digit rates of medical cost inflation, the combination of pressures for cost containment from both private and public payers, excess hospital beds and a surplus of specialty physicians in Michigan virtually assures that pressures to consolidate and squeeze out excess capacity will continue unabated.

This report presents the Center for Health Policy, Law and Management's (Center) findings and recommendations regarding Certificate of Need, and particularly in Michigan.

SCOPE OF PROJECT

The MPHI sought assistance from experts with a thorough and objective understanding of the issues involved. Because of their previous experience, Frank A. Sloan, Ph.D., and Christopher J. Conover, Ph.D., both at Duke University's Center for Health Policy, Law and Management (a part of the Terry Sanford Institute of Public Policy) were retained to assist in this project. Dr. Sloan has been a nationally recognized expert in this field for more than two decades, having contributed some of the seminal pieces of analysis to the published literature. In 1996, Professors Sloan and Conover assisted the Delaware Health Care Commission in assembling the most thorough and systematic examination of evidence on this issue ever available to state policy makers faced with the decision of what to do about CON. They subsequently published their key findings regarding CON for acute care services in a 1998 article *for Journal of Health Politics, Policy and Law*.

This evaluation focused on CON for acute care services, with particular attention given to CON for hospital beds, MRI services, and cardiac services (including cardiac catheterization laboratories and open heart surgery units). The Center conducted a systematic evaluation of a range of options regarding CON, examining a broad continuum of possibilities, ranging from strengthening CON regulation of acute care facilities, on the one hand, to elimination of CON regulation, on the other. The Center reviewed CON for acute care *facilities* (which include hospital facilities, freestanding birthing centers, freestanding surgical centers, freestanding emergency centers, prescribed pediatric extended care centers, medical detoxification centers, kidney disease treatment centers, and alcoholism rehabilitation facilities), *services* (which include any diagnostic, curative and rehabilitative services provided by such facilities) and *major medical equipment* (which includes technology, such as MRIs and lithotripters, both in facilities and elsewhere).

The Center systematically reviewed the evidence regarding the impact of CON on costs, quality and access. Because of some weaknesses and gaps in evidence, the Center relied on new data and analysis performed expressly for Michigan. Not surprisingly, there were instances where the evidence was mixed and in such instances, the Center's findings and recommendations are based on the weight of the available evidence.

FINDINGS

The Center recognizes the sweeping changes that continue to occur both in the evolution of medical technology as well as in health care delivery and financing. The consultants believe that the stronger market forces being ushered in by these changes offer considerable potential for curbing costs. With its roots in the rapidly disappearing cost-based, third party reimbursement mechanisms of the past, CON is becoming clearly less relevant as a cost containment mechanism. Primary justification for CON, therefore, must rest on its ability to improve or maintain quality and/or access to care.

General CON

Upon reviewing a large body of national and Michigan-specific material regarding acute care CON, including an analysis of what happened in states that dropped acute care CON, the Center found that:

- There is little evidence that CON results in a reduction in costs and some evidence to suggest the opposite;
- Removal of CON does not consistently lead to a "surge" in either acquisition of new facilities or medical expenditures;

- Because it is reasonably well-established that higher volume facilities generally achieve better health outcomes (e.g., lower mortality rates), the higher volumes that accompany specialization of facilities should improve health outcomes. While the general evidence that CON actually achieves such specialization is relatively weak, we did find evidence in Michigan that CON does constrain supply of MRI units, open heart programs and cardiac catheterization facilities;
- It is an open question whether any quality improvements achieved through CON might be as effectively or more efficiently be achieved using an alternative mechanism such as hospital outcomes reporting or quality standards enforced through a licensure process;
- CON may have a beneficial impact on access to care for the uninsured and underinsured, but the evidence is thin and even if true, such an impact is relatively modest in the context of the state's 1 million uninsured;
- CON appears to improve inner city access at the expense of access in suburban areas, hence elimination of CON could create financial difficulties absent some sort of alternative mechanism, such as a hospital pool, that would more equitably distribute the burden of uncompensated care.

All in all, justification for the current CON system in Michigan entails a trade-off in which the state must balance the costs of retaining CON (both in terms of the state's budget as well as the hidden costs imposed by the process on the health system) and lower access for a growing population living in suburban areas against modest potential gains in quality and/or access that conceivably be attained by other means. How much weight to attach to these effects ultimately is a political calculation well beyond the scope or purpose of this report. But in light of the state's fiscal crisis, a useful thought experiment might be to consider whether anyone would propose adopting CON in 2003 if the system were not already in place. In light of the evidence presented, reasonable people are likely to disagree on the answer to this question.

An examination of potential alternatives to CON, such as quality reporting mechanisms or hospital pooling mechanisms, were beyond the scope of this report. These would require further analysis if it were determined that elimination of selected components of CON were warranted. Conversely, if it is decided that acute care CON should be retained, some improvements suggested by Michigan key informants include:

- more staffing;
- enforcement of standards;
- improve/streamline the standard-setting process so that it is less cumbersome.

CON for Hospital Beds

Upon reviewing an extensive body of material regarding CON for hospital beds, the Center found that:

- The weight of the available evidence provides weak support for continuing CON for hospital beds. The empirical evidence regarding CON's impact on costs/availability of hospital beds provides little reason to believe that lifting restrictions on beds would result in a surge in building of new facilities;
- With respect to *quality*, neither the key informant interviews nor literature suggest that CON for beds per se affects quality. To the degree there are concerns about volume and quality, these could be addressed by continuing CON regulation of selected facilities (e.g., open heart units) rather than hospital facilities in general;
- The strongest case for continuing CON for hospital beds relates to access. As noted earlier, it is an open question whether removal of CON would produce the two-tiered system many fear, with hospitals fleeing the inner cities to relocate in the suburbs jeopardizing access to care for selected populations and/or financial health of hospitals that remain.

Thus, whether to continue CON for hospital beds also comes down to a trade-off: is it worth inconveniencing an uncertain number of residents living predominantly in suburbs in order to achieve relatively modest improvements (if any) in access? If CON for beds is continued, the following improvements were suggested for consideration by key informants: a) fix bed need methodology so that it is based on more current data; b) increase flexibility by permitting transfers of beds within hospital systems; and c) develop a mechanism to take excess capacity offline.

CON for MRI

Upon reviewing a smaller and less complete body of material regarding CON for MRI services, the Center found that the weight of the available evidence provides stronger support for continuing CON for MRI services than for hospital beds.

- The empirical evidence regarding CON's impact on costs/availability of MRI services is mixed: individual cases suggest that lifting CON does often lead to a surge in acquisition of new facilities or equipment and some subsequent retrenchment as unsuccessful facilities fail. However, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of MRI units and found that if anything, controlling for all these factors, lifting CON was associated with a *reduction* of MRI units in the short run, but not in the long run.

- Our analysis further showed that stringent CON was associated with a statistically significant reduction in MRI availability, consistent with the findings from other studies. Our own analyses are limited in that we only have information for hospital-based MRI units for a limited time period; moreover, we do not have detailed information regarding which states actually regulate MRI services through CON. Thus, some states that “dropped CON” may never have been regulating MRI in the first place, in which case any subsequent trends in MRI supply cannot be attributed to CON’s elimination.
- Likewise, the key informant interviews provide fairly good evidence that Michigan’s CON has inhibited growth in the supply of MRIs, but there are mixed views on whether this is good or bad for consumers.
- With respect to *quality*, neither the key informant interviews nor literature suggest that CON for MRI adversely affects quality. However, there also is not solid volume-quality evidence or standards to warrant CON review. So if CON improves quality, it would have to be through the imposition of project delivery standards, raising the question of whether the same result could be achieved through licensure rather than CON. In addition, one has to consider whether alternatives to CON (such as BCBSM’s Evidence of Necessity Program) would achieve the same purpose.
- Most key informants viewed CON as having a beneficial impact on access to MRI services for the uninsured and underinsured: we found no evidence to the contrary.
- On balance, CON appears to have improved access in rural areas relative to what would have been built and sustained in the absence of CON; conversely, however, access in suburban areas almost certainly is less than it would be in an unrestricted market.

Thus, whether to continue CON for MRI comes down to the a somewhat different trade-off than that posed by CON for hospital beds: is it worth inconveniencing an uncertain number of residents living predominantly in suburbs in order to achieve a reduction in MRI supply (which may or may not translate into parallel reductions in utilization or costs) or relatively modest improvements (if any) in quality and similarly modest improvements in access?

If CON for MRI is retained, key informants suggested the following improvements: a) improve the process for collecting physician signatures to make it less cumbersome and less

prone to abuse; and b) use professional certification standards to ensure high quality MRI services.

CON for Cardiac Services

Upon reviewing a smaller and less complete body of material regarding CON for cardiac services, the Center found that the weight of the available evidence provides stronger support for continuing CON for cardiac services than for hospital beds.

- The empirical evidence regarding CON's impact on costs/availability of cardiac services is mixed: individual cases suggest that lifting CON does typically lead to a surge in acquisition of new facilities or equipment (although some states have experienced this). Moreover, our multivariate analysis was able to control for many factors that might otherwise affect the proliferation of open heart/cardiac catheterization (OH/CC) services and found that if anything, controlling for all these factors, lifting CON was associated with a *reduction* of CC services in the short run, but not in the long run.
- Our analysis further showed that stringent CON had no significant effects (although other studies have found that states with stringent CON achieve significant reductions in the number of OH/CC services deployed). Our own analyses are limited in that we only have information for hospital-based CC services; moreover, we do not have detailed information regarding which states actually regulate cardiac services through CON. Thus, some states that “dropped CON” may never have been regulating cardiac services in the first place, in which case any subsequent trends in OH/CC services supply cannot be attributed to CON's elimination.
- Regardless of the “general case,” the key informant interviews provides fairly good evidence that Michigan's CON has inhibited growth in the supply of OH/CC services, but there are mixed views on whether this is good or bad for consumers.
- These subjective beliefs are only partially borne out by reality: Michigan's OH services supply is 13 percent below the national average, but its CC services supply is 3 percent above. Moreover, the Dartmouth Atlas data show that notwithstanding its holding supply of OH services so far below the national average, its CABG rate for Medicare patients is 10 percent higher than the U.S. average, suggesting the possibility of some “excess care” (or more positively, as an indication that CON has not constrained supply of OH services “too much”). But the same is true of Indiana, Ohio and Pennsylvania even though they have dropped CON suggesting CON may not have much impact overall on quantity of services provided even if it might constrain supply of facilities.

- With respect to *quality*, both the key informant interviews and literature suggest that there is a solid volume-quality relationship for both CCs and OH surgeries, with mortality rates for the latter being reduced by 20 percent or more in high-volume facilities. However, the literature on CON as it relates to CABG is mixed: one study found that states with CON had better surgical outcomes, whereas a case study in Pennsylvania found no evidence that lifting CON resulted in worse outcomes even though the supply of OHUs increased by 25 percent after CON was removed.
- Most key informants viewed CON as having no impact on access to cardiac services for the uninsured and underinsured. Conversely, CON appears to have improved access in rural areas in the opinion of most respondents and the impact on access in suburbs did not appear as severe as was described for MRI units.

Thus, whether to continue CON for cardiac services seems less of a trade-off than for MRIs: the supply of services seems distributed well enough that there are not the same concerns about access in suburbs. There's more evidence than in the case of MRIs that CON may improve quality because of the volume-quality effect and the evidence that CON improves access in rural areas is probably at least as good for cardiac services as it is for MRIs. If CON for cardiac services is continued, key informants recommend enforcement of quality standards. Potentially, this could be achieved by following a recent recommendation of the Maryland Health Care Commission in its recent comprehensive review of CON: "The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission." (MHCC 2001).

Concluding Observations

The Center is not in a position to weigh the various trade-offs identified in this report. Thus, it is not in a position to recommend whether acute care CON be ended entirely or instead "mended" in a variety of possible ways. However, it does seem reasonable to conclude from these findings that retaining the current CON program unchanged probably is undesirable. There are sufficient problems or limitations of the current program that portions either should be scrapped or at least modified. Moreover, if cost containment is no longer the central justification for CON, this may mean that strengthening certain aspects—e.g., monitoring and enforcement of project delivery standards—may merit consideration.

The Center recognizes there are legitimate concerns raised by reliance on markets to hold down spending, including what would happen to cost shifting now used to finance uncompensated care. Michigan cannot and should not ignore these looming threats; however, CON has only a very limited potential to offset forces of this magnitude. In the long run, the Center believes Michigan may be better served by explicitly considering how to

address these critical funding shortfalls directly rather than placing an unrealistic expectation on the CON program to overcome the funding reductions for these activities that will stem from increasing competition and federal budget changes. Likewise, it may make little sense to rely on CON to carry out functions such as quality assurance that can be better performed by other more direct or more cost-effective approaches. It was beyond the scope of this report to explore these alternatives and the mere existence of such alternatives is no guarantee they would be more cost-effective than CON. Only further study could determine this for certain.

In short, the evidence provided by this report does not provide unambiguous evidence that acute care CON in Michigan has failed and should be ended; nor does it provide incontestable proof that CON has succeeded in its objectives and unequivocally should be retained. What all sides might be able to agree upon is that the program can and should be improved so that it attains its objectives in the most efficient and equitable fashion.

ACKNOWLEDGEMENTS

The Center is grateful for the opportunity to provide advice to the Michigan Department of Community Health. The views expressed in this report are those of the consultants and do not necessarily reflect those of the Michigan Public Health Institute or MDCH.

The report has been prepared with the assistance of many individuals and organizations. We especially want to thank those who participated in the key informant surveys and others who provided information used for the analysis. Professors Sloan and Conover especially would like to thank:

- Larry Horvath, Planning Specialist, Community Assessment Division, DCH, who provided capable assistance in assembling the four lists of key informants used for our qualitative analysis and also served as an on-going liaison with DCH throughout the project (moreover, the accuracy and clarity of the report has improved from very helpful editorial comments by Mr. Horvath and others at DCH);
- Greg Cline, Ph.D., Director of the Center for Collaborative Research in Health Outcomes and Policy at MPHI, who conducted 8 of the key informant interviews and provided invaluable assistance and advice throughout the project;
- Yan Cheng, a Ph.D. graduate student in economics at Wayne State University, who as a student intern to MDCH provided very able assistance during the summer in assembling raw data needed for the multivariate analysis;
- John Ratliff, a Research Associate in the Center for Health Policy, Law and Management, who did extensive computer programming to both update the longitudinal dataset and carry out the multivariate analysis of the effects of lifting CON;
- John Siracusa, Erica Fritz and Monica Bestawros, undergraduate research assistants who spent many hours keeping track of key informant interviews, conducting literature searches and tracking down various pieces of information needed from a multitude of sources.
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I. INTRODUCTION

OVERVIEW

In April 2002, the Michigan Auditor General completed a performance audit of the Certificate of Need Program (CON) administered by the Michigan Department of Community Health (MDCH). The audit concluded that "DCH, in conjunction with the CON Commission, had not evaluated the CON program in order to determine whether the CON Program was achieving its goal of balancing cost, quality, and access issues and ensuring that only needed services are developed in Michigan." The MDCH concurred and agreed to contract with an independent outside contractor to conduct an evaluation of the CON Program. This report is the result of that evaluation.

SCOPE OF PROJECT

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With Christopher J. Conover serving as principal investigator and Frank Sloan as a consultant, the Center agreed to undertake a 3-month evaluation consisting of two parts: an update of the 1998 study and three case studies focused on hospital inpatient beds, MRI units and open heart/cardiac catheterization services. It was not possible within the time frame and resources available for this study to examine CON for long term care services. The quantitative part of the study was largely focused on updating the 1998 study using the latest available data on health expenditures, hospital services availability (including selected technologies), hospital costs and profitability, for-profit share of hospital beds and HMO market share. In addition, data from various sources was assembled to better understand what happened in states that lifted CON and to compare these experiences to those in Michigan. Finally, the comprehensive literature synthesis completed for Delaware in 1996 was updated to ensure that all pertinent literature related to CON's impact on costs, quality and access had been taken into account.

In recognition that the foregoing could not provide a complete picture, the qualitative part of the study consisted of more than 40 key informant interviews of knowledgeable individuals within the state of Michigan, including approximately ten apiece for each of the case studies and another ten who were broadly knowledgeable about CON. In both the quantitative and qualitative components of the study, the Center was assisted by the MPHI (see Acknowledgements for details).

REPORT OUTLINE

Section II provides an overview of CON in Michigan, briefly describing the evolution of the program and comparing Michigan's program to those in other states. Section III provides an overview of how CON was evaluated in this study, including a summary of the criteria used by the Center to evaluate CON, along with a brief description of the methods used to develop evidence on which to base findings and recommendations.

Section IV evaluates CON for acute care services, including hospital care, new technologies unrelated to those examined in the case studies, and other services unrelated to either nursing home or home health. This section provides an assessment of the impact of CON on costs, quality, access to care and equity.

Section V provides the results of the case study on hospital beds, including our key informant results, findings from our review of the literature, descriptive evidence, and multivariate analysis. Sections VI and VII represents our case study on Magnetic Resonance Imaging (MRI) services, open heart surgery/cardiac catheterization (OH/CC) services, using similar material.

Section VIII synthesizes the Center's key findings and conclusions.

II. CERTIFICATE OF NEED IN MICHIGAN

OVERVIEW

The state of Michigan has a long history of regulating health facilities. This section will describe the evolution of CON in Michigan and summarize the current status of the program in terms of how it compares to neighboring states and the rest of the nation.

RATIONALE FOR CON

Acute Care CON

Historically, the principal motivation behind CON generally was to offset incentives for excess capital investment in the market for institutional health services (Simpson 1986; Wolfson 2001), thereby restraining health spending. For hospital and other acute care services, because of widespread third party coverage—including private insurance, Medicare and Medicaid—many consumers have been price insensitive and therefore prone to utilize more services than if they had to pay the entire cost themselves. This so-called “moral hazard” meant that consumers could not be relied upon to exert much market discipline since suppliers could build new facilities and equipment knowing that third party payers would cover their costs. That is, even if facilities were not fully utilized, charges could be raised to recover costs without driving away too many patients since many had insurance to pay their bills and were therefore more interested in convenience and amenities than in the best price. Second, because consumers tended to be price insensitive, facilities were prone to the “medical arms race” in which facilities competed for the best physicians, who in turn could attract patients. As a result, unlike conventional markets—in which competition would have been expected to reduce costs through greater efficiency—hospital costs tended to be *higher* in areas with more competition (Robinson and Luft 1987) and lengths of stay tended to be longer (Robinson et al. 1988). An important goal of CON was to rationalize the industry by preventing excess capacity and unnecessary duplication of services.

Another major rationale for CON was to protect public health by preserving and improving quality of care (Simpson 1986). For example, by the late 1970's, evidence suggested that regionalization of facilities might lead to improved quality as well as higher efficiency since for many procedures, hospitals doing a larger annual number of procedures showed markedly lower mortality rates than those with a lower volume of such surgeries (Luft, Bunker and Enthoven 1979).

A third major rationale for CON was better geographic distribution of facilities and improved access to care, with the potential to improve access being one of the arguments that influenced federal policy makers to encourage states to adopt CON regulation (Havighurst 1973).

Rationale in Michigan

In Michigan, quality and access historically have played a somewhat greater role than in most other states in the decision to adopt CON and the nature of the decisions made under CON regulation. Concerns about costs, quality and access have been important factors in past decisions about whether to retain CON and how it should be modified. Therefore, all three factors should be used as criteria in determining whether the current CON program in Michigan should be continued, eliminated or modified.

EVOLUTION OF CON

Evolution of CON in the U.S.

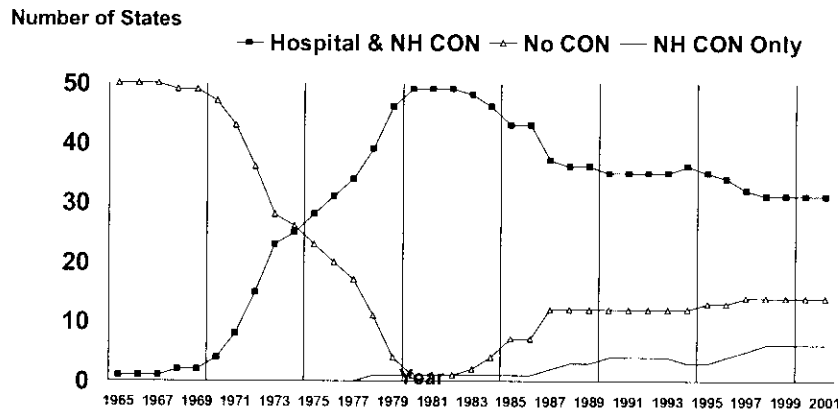
CON regulation first began in New York in 1964, followed by lobbying efforts beginning in 1968 by the American Hospital Association to enact such laws in every state (Wolfson 2001). A number of other states did so by the early 1970's, including Michigan, which enacted its first CON statute in 1972 (this law became effective in 1973). Capital review programs became more widespread with the passage of Section 1122 of the 1972 amendments to the Social Security Act, which required states to review all capital expenditures that exceeded \$100,000, changed bed capacity or involved a "substantial change" in services. States that elected not to do so were subject to loss of Medicare capital reimbursement, federal Medicaid payments and Maternal and Child Health payments (Mendelson and Arnold, 1993).

The Nixon administration's wage and price controls temporarily had held hospital spending in check from 1971-1974. But following the repeal of price controls in 1974, concerns about a crisis in health costs led Congress to pass the National Health Planning and Resources Development Act of 1974 (P.L. 93-641), which provided federal funds for state efforts to implement CON programs. By 1980, all states had adopted CON programs except for Louisiana (which has never adopted CON, but did rely on Section 1122 between 1973 to 1987) and New Hampshire, which finally adopted it in 1982 (Fig. 2.1).

However, by the early 1980's, a growing faith in competition in health care (see Enthoven 1978; Greenberg 1978; Olsen 1981; Langwell and Moore 1982; and CBO 1982), coupled with a growing literature that questioned the efficacy of CON (Salkever and Bice 1976; Hellinger 1976; PAI-US 1980; Sloan and Steinwald 1980; Joskow 1980; Coelen and Sullivan 1981; Eastaugh 1981; Sloan 1981; Joskow 1981; Sloan 1983; Ashby 1984; and Howell 1984)

culminated in the 1986 repeal of P.L. 93-641, making states solely responsible for continuing CON.

**Fig. 2.1
Evolution of CON Regulation, 1964-2001**



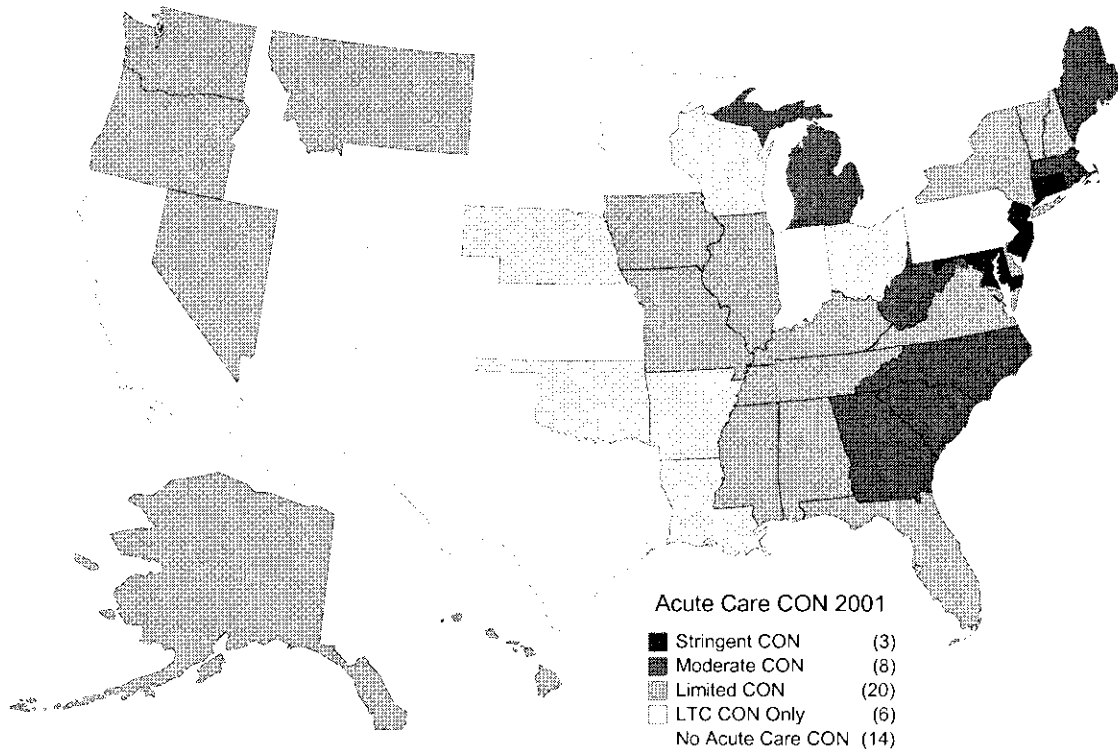
Source: Table B-1

Thus, the prevalence of CON peaked in the early 1980's, followed by three "waves" of states electing to drop CON for acute care services. This includes:

- 8 states that dropped CON prior to the ending of federal support for CON activities on October 1, 1986 (Arizona, Idaho, Indiana, Kansas, Minnesota, New Mexico, Texas, and Utah);
- 7 states that dropped CON immediately after federal support ended, but prior to 1990 (Arkansas, California, Colorado, Oklahoma, South Dakota, Wisconsin and Wyoming);
- 4 states that dropped CON in 1995 or later (Nebraska, North Dakota, Ohio, and Pennsylvania).

Virginia was scheduled to sunset its program in 2002, but then decided to retain it (Jackson 2002). Note that the only state to reverse CON repeal has been Wisconsin, which originally allowed its acute care CON program to sunset in 1987 (retaining CON for long term care services) resurrected its program in 1992 and then repealed it again after 2 years (again retaining CON for LTC). Proposals to resurrect CON have failed to date in other states such as Ohio (Jackson 2002) and Oklahoma (Nathan 1998). Other states such as Florida and New Jersey have explicitly considered whether to eliminate CON, ultimately deciding to "mend not end" their programs (McGinley 1995; State of New Jersey, CON Study Commission, 2000). Note also that five states opted to eliminate CON for hospital and other acute care services, while retaining it for long term care (Arkansas, Nebraska, Ohio, Oklahoma, and Wisconsin). Thus, inclusive of Louisiana (which never dropped acute care CON since it never had such a

Fig. 2.2 -- Acute Care CON Regulation in US, 2001



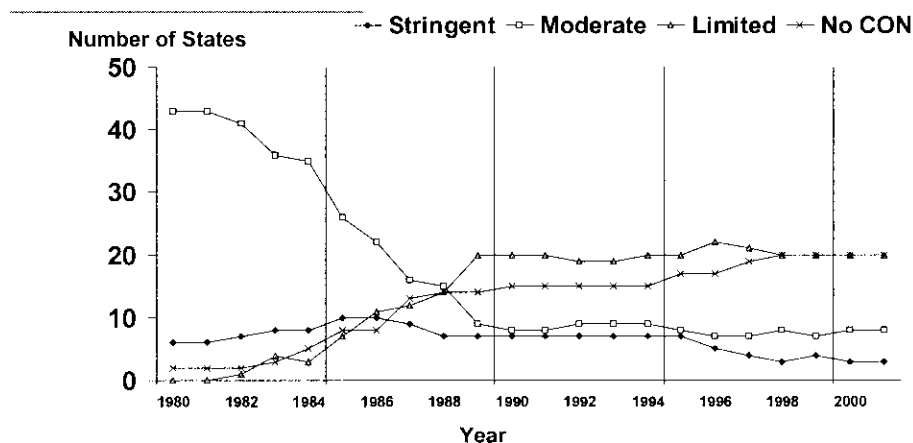
Source: American Health Planning Association. 2002 National Directory of Health Planning, Policy and Regulatory Agencies (12th ed.)

program, but currently retains CON for long term care services), there are today 20 states without CON for acute care services.

To date, most of the states that have dropped CON entirely have been in the West and Midwest, as have the states which have dropped acute care CON only (Fig. 2.2). Michigan is one of only 4 of the 12 states in the Midwest to retain CON for acute care, although how long this will remain true is unclear. For example, at the end of 2001, Missouri eliminated much but not all of its acute care CON regulation. In 1987, the Illinois Health Care Cost Containment Council recommended eliminating CON, but the state did not do so (State of Illinois, Office of the Auditor General 2001); however, in 2000, Illinois enacted CON reforms that will sunset the program effective July 1, 2003 unless interim action is taken (IHHA Blue Ribbon Panel on Certificate of Need, 2001). In 1997, an Iowa statute was enacted requiring a comprehensive review of CON by early 2000; a 30-member task force established in June 1999 studied the issue for more than a year, ultimately recommending that the program be retained unchanged (IDPH 2002).

During the 1980's, many states that retained CON loosened their regulations.¹ By 1980, with the exception of a half dozen states which chose more stringent CON standards than those set by the federal government, all the remaining states had what could be described as "moderate" thresholds for determining which projects to review (Fig. 2.3). In the early 1980's a few additional states opted to become more stringent in their CON regulations, but most states moved in the opposite direction by making their CON programs more limited. States opting for stringent CON "peaked" in 1986, followed by a gradual decline, with only 3 states in that category today (Connecticut, Maryland and New Jersey). Throughout this entire period, Michigan has maintained a *moderate* CON program.

**Fig. 2.3
Evolution of CON Stringency, 1980-2001**



Source: Table B-2

Brief Program History in Michigan

The genesis of CON in Michigan lay in health planning efforts originating in the 1960's. Because the history of CON has been documented elsewhere,² what follows is a brief synopsis of key events during the past 50 years:

¹For purposes of this discussion, we rely on definitions of CON stringency developed by Lewin-ICF (1992, 1995). These are based on taking into account the dollar thresholds used to determine whether a project is subject to CON review, as well as the scope of CON review in terms of specific categories of services subject to review.

²Some details of Michigan's early CON program are found in US DHHS (1986). Sources of the descriptions of federal statutes include Litman and Robins (1991), Simpson (1986) and Wolfson (2001).

- 1946:** *Hospital Survey and Construction Act of 1946 (Hill-Burton)* (PL 79-725). This law provided federal grants for construction and modernization of hospitals and other health facilities (eventually expanded to include nursing homes, diagnostic and treatment centers, home health agencies, etc.). A state Hill-Burton agency was required to prepare a medical facilities plan establishing the need for various facilities, and applicants could not receive grants without this agency's approval.
- 1966:** *Comprehensive Health Planning Act* (PL 89-749). This law was intended to promote comprehensive health planning for health services, personnel, and facilities in a federal-state-local partnership. In Michigan, the designated State Health Planning and Development Agency (SHPDA) was located in the Department of Management and Budget.
- 1972:** *Social Security Amendments of 1972* (Section 1122). This law provided for optional state review of health facilities capital expenditures, allowing for the withhold of Medicare and Medicaid payment for capital costs associated with any project not recommended by the state (these recommendations typically were based on state health plans adopted by comprehensive health planning and Hill-Burton agencies). Michigan entered into its Section 1122 agreement on December 14, 1973.
- 1972:** *Michigan CON Statute (Public Act 256)*. Michigan enacted its first CON statute in 1972; prior to that time, hospital investment had been informally regulated by Blue Cross of Michigan, with facilities requiring Blue Cross approval to qualify for reimbursement.
- 1974:** *National Health Planning and Resources Development Act* (PL 93-641). This law provided federal funding for State Health Planning and Development Agencies (SHPDAs) and local health planning agencies (Health Systems Agencies or HSAs) which largely replaced Hill-Burton and Comprehensive Health Planning programs. SHPDAs were to develop state health plans that reflected HSA plans, while HSAs had the authority to review and approve capital projects. States were not required to adopt federal CON standards, but faced large federal funding cutbacks under various health-related grants and contracts for failure to do so.
- 1978:** *Michigan CON Statute (Public Act 368)*. Michigan amended its CON statute effective September 30, 1978; this established the framework for CON decisions for the next decade.
- 1986:** *Repeal of National Health Planning and Resources Development Act*. Reagan administration opposition to health planning in the early 1980's had led to substantial cutbacks in federal funding for health planning and annual funding riders that prohibited the enforcement of federal funding penalties for states not in compliance with NHPRA. In late 1986, NHPRA was repealed entirely, effective January 1, 1987.

- 1987:** *Section 1122 Agreements Terminated.* The U.S. Department of Health and Human Services terminated all remaining Section 1122 agreements (including Michigan's) effective October 1, 1987.
- 1988:** *Michigan CON Reform Act of 1988.* Due to concerns about a lack of clarity regarding both process and standards in CON, resulting in the overturning of too many CON decisions by the courts, Michigan substantially revised its program. This statute, effective October 1, 1988, established a specific process for developing and approving standards used in making CON decisions. It further created a 5-member bipartisan CON Commission within the Department of Public Health (DPH). The Commission's members are appointed by the Governor and is responsible for approving review standards.
- 1993:** *CON Amendments.* This program was further revised requiring ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of review standards.
- 1996:** *Executive Order No. 1996-1.* Effective April 1, 1996, this order created the Department of Community Health (DCH) and transferred responsibilities for CON from DPH to DCH. The Health Facilities Section within DCH has the responsibility for day-to-day operations, including making decisions consistent with review standards.
- 2002:** *Auditor General Performance Audit.* As required by statute, the Office of the Auditor General completed an audit in April 2002 with 5 findings and 7 recommendations.

CURRENT ACUTE CARE CON PROGRAM IN MICHIGAN

CON Review Thresholds

As shown in Table 2.1, the capital thresholds used to determine whether a project needs to undergo CON scrutiny vary widely by state from a low of \$500,000 (Maine) to as high as \$9.8 million (Massachusetts). Michigan's threshold for capital expenditures (\$2,426,000) is higher than in 28 other states; moreover, it uses a figure that is 50 percent higher than this for any projects related to nonclinical services only. While this makes Michigan's less stringent than in most other states having acute care CON, the state's program is more stringent than in

Table 2.1
Summary of CON Review Thresholds, January 2002

Type of Service	Michigan		States Surrounding Michigan					Other States	
	Threshold	Rank	Illinois	IN/PA	New York	Ohio	Wisconsin	Strictest	Least Strict
ilities Regulated	Acute/LTC		Acute/LTC	None	Acute/LTC	LTC Only	LTC Only		
Capital	\$ 2,426,000	29	\$ 6,000,000	No CON	\$ 3,000,000	2 mil renov	\$ 1,000,000	\$500,000 (ME)	\$9,841,075 (MA)
Equipment	Any		6,000,000	No CON	1,000,000	NA	600,000	400,000 (CT, MI, NH)	6,000,000 (IL)
New Service	Any Clin.		Any	No CON	Any	NA	Any LTC	0 (CT)	1,000,000 (AK)

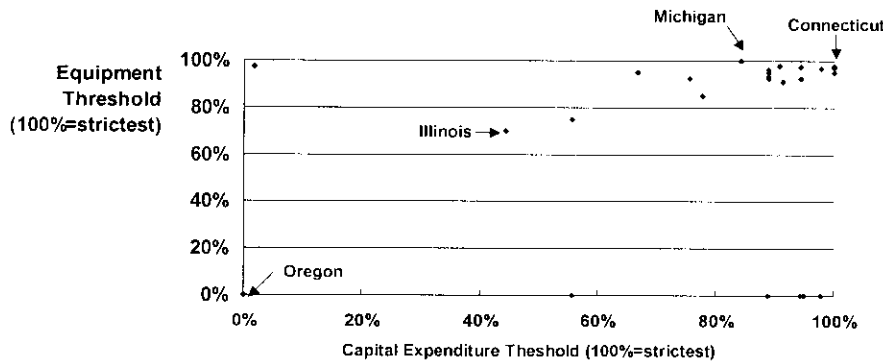
Note: \$0 denotes services for which CON review is required regardless of expenditure. NA denotes services for which no separate threshold is in effect.

surrounding states, most of which have either dropped CON entirely (Indiana and Pennsylvania) or restricted it to long term care (Ohio, Wisconsin). The threshold for capital expenditures in Illinois is \$6 million, while New York sets its threshold closer to Michigan's, at \$3 million.

Michigan differs from most states in not have a parallel review threshold for major medical equipment; instead, it automatically reviews any proposed addition of specific types of equipment, such as MRIs, CT scanners or PET scanners. In contrast, New York and Illinois use thresholds of \$1 million and \$6 million respectively.

In regulating services, states generally use annual operating costs as the basis for determining whether CON review is warranted. Of the 30 states with acute care regulation, only 9 use such dollar thresholds, with the remainder (including Illinois and New York) using an approach similar to Michigan's in which selected services are automatically reviewed regardless of project cost or operating expense.

**Fig. 2.4
CON Review Thresholds, 2001**



Source: Tables B-3 and B-4

On balance, Michigan maintains a relatively more stringent CON program than do surrounding states, based on current review thresholds for capital and equipment (Fig. 2.4). On the other hand, compared to all states, Michigan is in the middle tier of states in terms of stringency, because its relatively lenient threshold for capital expenses is offset by its far more stringent standard for review of major medical equipment, at least for the services it reviews.

Scope of Services Under CON

In terms of the *scope* of CON regulation, Michigan currently ranks 18th among the 30 states with acute care CON, regulating 17 of 30 different services for which comparative information on CON is available (no state regulates all 30: Alaska comes closest, with 27

Table 2.2
Summary of Services Regulated by CON, January 2002

	Michigan	States Surrounding Michigan				All States
		Illinois	New York	Ohio	Wisconsin	
Diagnostic Equipment	4	2	5	0	0	
Cardiac Catheterization	Y	Y	Y	N	N	32
CT Scanners	Y	N	Y	N	N	21
MRI Scanners	Y	N	Y	N	N	30
PET Scanners	Y	Y	Y	N	N	24
Ultra-Sound	N	N	Y	N	N	5
Surgical-Related	5	4	5	0	0	
Ambulatory Surgical Centers	Y	Y	Y	N	N	30
Gamma Knives	Y	Y	Y	N	N	25
Lithotripters	Y	N	Y	N	N	26
Open Heart Units	Y	Y	Y	N	N	34
Organ Transplant Units	Y	Y	Y	N	N	24
Other Acute Care	7	10	11	0	1	
Acute Care Services	Y	Y	Y	N	N	32
Air Ambulance	Y	N	N	N	N	12
Burn Care	N	Y	Y	N	N	14
Business Computers	N	N	N	N	N	4
Medical Office Buildings	N	N	N	N	N	3
Mobile High Tech	Y	N	Y	N	N	20
Neonatal ICU	Y	Y	Y	N	N	27
Obstetrical	N	Y	Y	N	N	10
Psychiatric Services	Y	Y	Y	N	N	29
Radiation Therapy	Y	Y	Y	N	N	30
Rehabilitation	N	Y	Y	N	N	30
Renal Dialysis	N	Y	Y	N	N	23
Subacute Care	N	Y	N	N	Y	12
Substance Abuse	N	N	Y	N	N	28
Swing Beds	Y	Y	Y	N	N	17
Long Term Care-Related	1	2	4	1	2	38
Home Health	N	N	Y	N	N	24
ICF/MR	N	Y	Y	N	Y	26
Long Term Care	Y	Y	Y	Y	Y	38
Residential Care Facilities	N	N	Y	N	N	6
GRAND TOTAL	17	18	25	1	3	

Source: American Health Planning Association (2002). Details in Table B-6 (including glossary of terms)

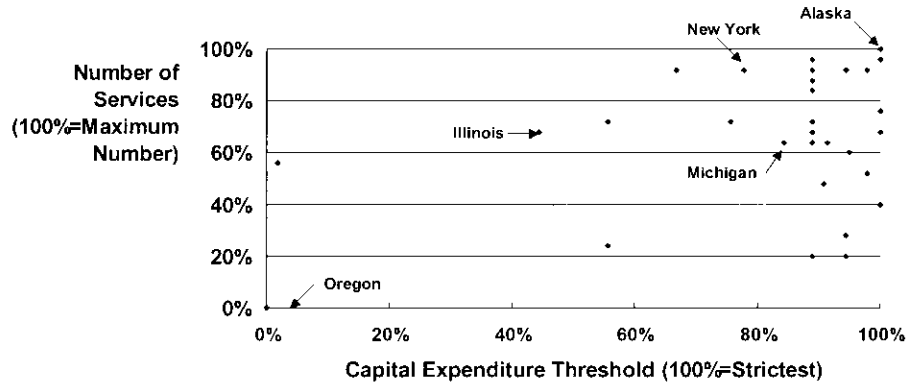
services). Illinois is very similar to Michigan in the scope of services it reviews, whereas New York's program covers considerably more services, 25 in all (Table 2.2).

In terms of *type* of service, Michigan has opted to review cardiac catheterization services, CT scanners, MRI and PET scanners (as has New York, which is also one of only 5 states to review ultra-sound; in contrast Illinois does not review either MRI or CT scanners). Michigan also reviews all of the surgical-related services, including ambulatory surgical centers, gamma knives, urinary lithotripters, open heart surgery and transplantation services (as has New York; Illinois reviews all of these except lithotripters). In terms of other acute care services, Michigan has opted to review only 7 of the 15 possible services, including acute care services generally, air ambulance, mobile high tech, neonatal intensive care units, psychiatric services,

radiation therapy and swing beds. In contrast, New York and Illinois review 11 and 10 such services respectively. In contrast to New York, which covers all long term care-related services, Michigan covers long term care services (e.g., nursing homes), but does not review home health, intermediate care facilities for the mentally retarded or residential care facilities (i.e., other than skilled nursing facilities).

Thus, if stringency of CON is measured in terms of number of services covered as well as the thresholds used for review, Michigan appears to be much more “in the middle of the pack” (Fig. 2.5). In contrast, Illinois appears somewhat less strict, while New York is somewhat more strict overall compared to Michigan.

Fig. 2.5
Stringency of CON Regulation, 2001



Source: Tables B-3 and B-6

SUMMARY

Nationally, the popularity of CON peaked in the early 1980's, with many states subsequently dropping CON altogether or making it less stringent. Michigan has had CON or a similar process for planning and or regulating health facilities construction for three decades. Today, Michigan's CON program reviews fewer services than in most other states sharing a border with Michigan, including Illinois and New York. However, Michigan generally uses more lenient capital thresholds than most other states (though stricter than those of all of the states on its borders) while at the same time electing to automatically review a selected list of services rather than use a dollar threshold to avoid reviewing smaller projects. For all these reasons, on average, Michigan's acute care CON program may be viewed as moderately stringent. A stringency measure used by the American Health Planning Association shows that Michigan's CON program ranks 18th overall in terms of stringency and ranks 10th among the 15 states that it includes in its middle category of stringency (AHPA 2002).

III. EVALUATING CERTIFICATE OF NEED

OVERVIEW

This section describes the four major criteria used in this report for in evaluating the effectiveness of CON, along with a description of the methods used by the Center to reach its findings and conclusions.

This report focused only on acute care CON, with the objective of assessing performance using the criteria of costs, quality, access and equity. Three methods were used to provide information relevant for each of this assessment. These include a conventional review of the literature where available, empirical analyses and a key informant survey. The empirical analyses included a descriptive analysis of what happened in states which dropped CON and a multivariate analysis which allows a more precise measurement of the impact of CON taking into account simultaneously the many differences in states and changes across time in both regulation and other critical factors. The key informant survey was conducted in Michigan to provide subjective impressions of how well CON had worked, what improvements might be considered, and advice about whether and how to transition away from CON regulation.

CRITERIA FOR EVALUATING CERTIFICATE OF NEED

There are four major criteria that the Center used to evaluate CON for acute care services: cost, quality, access and equity.

By far, most of the empirical literature on the effectiveness of CON focuses on its impact on costs, for several reasons: a) cost control was the major motivation behind CON at the federal level; b) costs and changes in costs over time are much easier to measure than either quality or access and c) comparative longitudinal cost data are readily available at both the level of states (e.g., hospital spending per capita) and institutions (e.g., hospital cost per day). Notwithstanding the importance of costs, the Center also recognized the importance of both quality and access in motivating Michigan's approach to CON. In addition, it was important to take into account whether or not the CON process was conducted fairly regardless of its impact on the other three dimensions. Therefore, our analysis was conducted by systematically reviewing all of the available evidence on costs, quality, access and equity rather than restricting the scope to areas where the most is known.

Note that the decision about which approach is "best" for Michigan is ultimately a political one, reflecting judgments about the relative importance to attach to costs, quality, access and equity. That is, even if there were no uncertainty about the exact impact of CON or alternatives to CON on costs, quality, access or equity in Michigan, different people will

disagree on what to do since some may attach relatively greater importance to one dimension compared to another.

In fact, however, there is uncertainty in the evidence itself, with some evidence pointing in the direction of a favorable impact of CON on a particular dimension while other evidence may show the opposite. Given this uncertainty, the Center has adopted a "reasonable person" test to evaluate instances of conflicting evidence: if the "weight of the evidence" points in a particular direction, the Center is comfortable with letting policy be determined on the basis of that predominance of evidence, recognizing that there is some chance that the resultant policy judgment was in error. The investigators believe that this approach is preferable to the alternatives of either waiting forever for perfect information (since that day will never arrive) or using an unduly strict "reasonable doubt" standard that is biased in favor of the status quo. That is, "reasonable doubt" is a useful standard in jury trials where society wants to minimize the risk of inadvertently convicting an innocent party. In making policy, however, such standard requires far more certainty of evidence regarding the potential impact of a potential alternative policy approach than is typically available.

The following summarizes the specific measures related to cost, quality, access and equity that were used by the Center in formulating its recommendations.

Costs

The principal motivation behind national efforts in the 1970's to establish CON in every state was to restrain the growth of health spending. Therefore, a central question regarding CON regulation or its alternatives is: *what is the impact on the total burden of medical care?* Although this is easy to understand conceptually, it is more difficult to measure empirically for several reasons.

One critical issue concerns *how to measure direct spending*. The most comprehensive measure is total health spending for all residents. However, even if regulation has *no* impact on overall spending for the *general* population, public policy makers may be interested in knowing the impact on spending for certain populations whose care is publicly financed, including Medicaid and Medicare. A second major issue concerns *cost offsets*: if regulation produces spending reductions in one sector (e.g., hospitals), are these partly or fully offset by spending increases elsewhere in the system? Third, does regulation affect the supply or utilization of services and/or alter the mix of inputs (e.g., labor vs. capital) used to provide a unit of service? A related issue concerns regulation's impact on the rate of technological innovation in health care and whether the net effect of this is cost-decreasing or cost-

increasing.¹ A longer term issue is whether regulation influences market structure, either in terms of the profitability of the hospital industry, the distribution of beds by ownership or the rate of development of alternative delivery systems (e.g., HMOs), and what impact these changes would have on medical costs in the long run.

Impact of CON on Health Spending. Several alternative sets of measures were considered in attempting to estimate the impact of CON on health spending per capita. As noted below, neither of these measures is perfect, but each provides a different snapshot of the system, so collectively, they provide a more complete picture than reliance on a single indicator of spending.

Health Spending per Resident. For two decades, the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) has provided state-level estimates of total per capita health spending and on components of spending from 1980-1998 (Levit et al. 1995; Martin, Whittle and Levit 2001). Four different measures were used to evaluate the impact of acute care CON, including a) total spending; b) acute spending (all spending except nursing home and home health); c) hospital spending; and d) physician spending. This allowed a direct examination of the offset issue to determine whether reductions in hospital spending were made up by spending elsewhere. Although the CMS data also include data on nursing home and home health, analyzing the impact of CON for long term care services was beyond the scope of this study.

The advantage of this dataset is that it provides a consistently measured, continuous annual time series, by state, of per capita spending from 1980-1998.² By 1980, all states except Louisiana and New Hampshire had acute care CON in place, so this time series allows a definitive test of whether states that dropped CON during the subsequent decade experienced any change in their health spending trends relative to those that did not. The disadvantage is that the data are not available beyond 1998 and therefore cannot reflect more recent changes in the market. In addition, per capita spending is measured in terms of

¹Although the Center was able to examine the impact of CON on diffusion of technology, a critical related issue that has not been addressed in the literature is whether, if regulation produces apparent reductions in *direct* medical costs by discouraging use of particular procedures (e.g., lithotripsy), are these partially or fully offset by increases in *indirect* costs such as productivity losses (e.g., longer recovery times due to surgery)? Note that this would be of importance only if it first could be demonstrated that regulation slows down the diffusion of technology.

²Previous HCFA state level spending data were sporadic and do not form a continuous annual time series: data for 1966, 1969, 1972, and 1976-1982 are reported in Levit et al. (1985). The estimating method has improved so that the 'old' figures for 1980-1982 differ from the more recently released figures. For this reason, and because the decomposition of spending into services is not reported for all years, we did not attempt to combine the earlier (pre-1980) figures with the more recent figures in order to extend the length of the time series used in this analysis.

spending by *location of service* (i.e., all care provided within a state's borders) divided by a state's resident population. In states with a large amount of importing or exporting of health care, the results therefore may be misleading.

Medicare data suggest that Michigan is a net importer of medical services, i.e., the net amount of Medicare expenditures on services provided by providers within Michigan's borders is about 2.4% lower than the amount of Medicare expenditures accounted for by Medicare beneficiaries living in Michigan.³ Illinois (-4.9%), Wisconsin (-2.0%) and Ohio (-0.8%) also are net importers, whereas Indiana (+1.7%) and New York (+0.4%) are net exporters of Medicare services. However, this should not bias conclusions drawn about the impact of CON on *growth* in spending over time unless there are substantial changes in the degree to which a state is a net importer or exporter during that period. Also, we have no good evidence about whether the patterns of border-crossing by Medicare patients in any way mirror the patterns for the general population.

Spending per Medicare Eligible. One way to overcome this limitation of the CMS data would have been to rely on another consistent time series that also is available by state: annual Medicare spending per eligible. Although separate figures were available for elderly (65 and over) and disabled eligibles, the Center, in an earlier study for the state of Delaware, had focused only on the former since the elderly account for nearly 40 percent of all health spending (Waldo et al. 1989) and because per capita spending estimates for the disabled population (which is much smaller than the elderly) may be more susceptible to fluctuations due to differences in health status across states (e.g., spending per disabled in New York may be artificially inflated due to a disproportionate concentration of AIDS patients in that state).

The advantage of using Medicare data is that they are for a more standardized population having access to standardized benefits (since Medicare eligibility rules and benefits are the same in all states). In addition, these data also allow an examination of cost offsets, to some extent, by separately assessing the impact of CON on Medicare Part A (which includes mostly hospital care) and Part B (covering mostly physician and other outpatient care). A disadvantage is that the figures are based on spending per eligible regardless of where care is received. Thus, for beneficiaries who receive care outside the state, their spending will not be a reliable indicator of relative spending within their own state's borders. On the other

³This means that the dollar value of services received by non-residents within Michigan's borders is lower than the dollar value of services received by Michigan residents in other states. That is, if all Medicare spending within Michigan borders is divided by total Medicare beneficiaries living in Michigan, the total is 2.4% lower than the per capita total obtained using Medicare expenditures on Michigan beneficiaries regardless of where in the U.S. they obtained their medical care.

hand, to the degree that regulation is so tight that it induces residents to cross borders to seek care, policy makers presumably would want to know about such cross-border spending.

As it turned out, the time series used for the Delaware study (which examined total, Part A and Part B spending by place of service per Medicare eligible) was not available beyond the dates used in the Delaware analysis. Instead, the investigators were forced to use over Medicare spending by place of residence per enrollee; this figure is more analogous to the total spending per capita figures in the sense that the spending is by place of residence rather than place of service, but does have the advantage of being for a more homogenous population. These data were available for 1980-1998.

Spending per Medicaid Eligible. Another consistent time series that was available by state for the period of interest is annual Medicaid spending per eligible. The problem is that Medicaid benefits, services and reimbursement standards vary by state, so these will produce some observed variations in spending that may be difficult to distinguish from variations due to differences in regulation. Moreover, Medicaid eligibility changed rapidly in the late 1980's and early 1990's as states took advantage of increasing flexibility given to them by federal policy makers. One way to control for this problem would be to adjust for differences in state eligibility policies, but this is both time-consuming and complicated. Due to the huge number of different Medicaid policy variables one might conceivably use as controls, a skeptic would always be in a position to argue that all findings are suspect because the analysis failed to control adequately for differences in Medicaid policies. Therefore, the Center opted *not* to use Medicaid spending figures in its analysis.

Spending per Employee. We also were able to obtain some more limited comparisons of expenditures per employee for health benefits in Michigan vs. selected other states with and without CON. These figures included data from GM, Ford and Daimler Chrysler. Unfortunately, we only had summary estimates without a full accounting of methodology and each used a somewhat different method to "standardize" the data to arrive at comparable comparisons across states: a) GM provided age-adjusted dollars-per-life (GM); b) the Ford figures are adjusted for age, gender and health status; and c) the DaimlerChrysler figures are adjusted for age, gender and geographic area. By comparing these estimates with the CMS and Medicare spending data, some qualitative insights were possible.

Impact of CON on Supply and Utilization of Facilities. The most direct impact of CON should be seen in the form of changes in the availability and/or use of institutional services. Acute care CON was evaluated by examining a) hospital supply/utilization; and b) hospital-based technology. Earlier work for Delaware had examined CON's impact on ambulatory surgical facilities inside and outside hospitals, but obtaining updated data to include this analysis in this study was not feasible in the time-frame permitted.

Hospital Supply/Utilization. Using data from the AHA Annual Survey, the impact of acute care CON on hospital supply and utilization in general was assessed by examining changes in short-stay community hospital beds per 1,000 population and short-stay hospital admissions per 1,000 through the year 2000.

Hospital-Based Technology. Because of concerns about growth in medical technology in the absence of CON, the Center examined the impact of CON on six major hospital-based technologies for which data were readily available from the AHA: a) certified trauma centers; b) organ transplant units; c) MRI units; d) CT scanners; e) open heart units; and f) cardiac catheterization labs. In all cases, supply was measured in terms of units per million population (although it would have been better to have measured the volume of supply more precisely--given variations in the capacity of these units--reported AHA figures include only the total number of units). Trauma units, open heart units and transplant units were included since they represent technologies for which the full universe of units was readily available on grounds that this would provide some insights regarding CON's impact on diffusion of technology more generally. MRI units, CT scanners and cardiac catheterization labs were included because of Michigan's interest in these technologies, but recognizing that all three represent procedures/technologies that can be provided outside of hospitals in freestanding facilities. Reliable time series data on outpatient facilities are available for some of these technologies, and in theory could have been merged with AHA data, but only at very great expense and not within the time-frame provided for this study.

Ambulatory Surgical Facilities. The same dilemma surrounded whether to examine CON's impact on the supply of ambulatory surgical facilities. As with many technologies, ambulatory surgery can be performed in freestanding facilities that are completely unrelated to the hospital. For the Delaware study, data on the freestanding centers was available at a reasonable cost, so these were combined with AHA data on hospital-based outpatient surgical units to provide a total count of such facilities. Although data on the total number of operating rooms in freestanding facilities was available, parallel information is not reported in the AHA data, so the analysis is based on facilities per million population (recognizing that this results in a less clear picture than if more refined data were available). Unfortunately these data also could not be updated within the time and cost constraints of this study, so we have elected to report some of the results for 1980-1993 to compare and contrast those findings with some of the other technologies.

Impact of CON on Hospital Input Use. Even if CON has no apparent impact on supply or spending, it may influence how care is delivered. The Center examined whether CON had a detectable effect on *hospital intensity* by analyzing: a) expense per adjusted patient day; and b) expense per adjusted admission for short-stay community hospitals.

A related issue is whether CON affects the mix of resources used to provide inpatient services. This was evaluated earlier for Delaware based on CON's impact on hospital labor costs and utilization, including: a) hospital labor expense per 1,000 population; b) full-time-equivalent personnel per adjusted patient day; and c) nurses per adjusted patient day. Because we had not found significant effects in the earlier study and given time and resource constraints, these analyses were not included in the present study.

Impact on Market Structure. To determine the potential longer term impact of CON, the Center had also assessed for Delaware whether CON had any influence on a) hospital profits; b) the share of hospital beds accounted for by for-profit facilities; c) HMO market share; and d) PPO market share. Unfortunately, no reliable figures were available to update the PPO analysis, but the remaining time series were analyzed for the latest year feasible.

Quality

Another rationale for CON has been to improve quality (although this was never a central purpose insofar as states typically rely on much more direct methods such as licensure and certification standards to monitor and regulate quality). On the acute care side, CON 's potential to improve quality lies principally in the regionalization of facilities to ensure an adequate volume of services to ensure high quality.

There are two important issues related to how regulation affects quality. The first is the net impact on *clinical quality* given that regulation has the potential both to *improve* quality (e.g., by regionalizing services to ensure a critical volume of procedures) and *reduce* quality (e.g., by limiting access to the newest, most advanced technology or limiting competition, thereby giving consumers less ability to shop based on quality). The second issue is the impact on *patient satisfaction*, but this is more relevant in long term care, where the treatment goal typically is more palliative in nature than to restore or improve functional status.

Impact of CON on Clinical Quality. To establish whether there was a reasonable basis for believing that better regionalization of facilities might improve quality, the Center first examined whether high-volume facilities have superior outcomes compared to those performing fewer procedures. But it was also necessary to evaluate whether CON has any impact on the diffusion of new technology (since if CON has *no* impact on diffusion, this implies that regionalization is not affected, in which case it is difficult to argue that CON has improved quality by concentrating procedures in high-volume facilities). On the other hand, if CON does achieve regionalization, it may also restrict availability "too much" in which case adverse effects on quality would result.

The Center was able to examine quality more directly based on very limited evidence regarding the impact of regulation on mortality as well as subjective impressions and indirect evidence. For example, all other things being equal, a tighter supply of beds will result in higher occupancy rates which could adversely affect quality in two ways. First, excessively high hospital occupancy rates raise the risk that a genuinely sick patient will need to be turned away due to lack of beds. Thus, if CON results in excessively high hospital occupancy rates, one could infer that this would have an adverse effect on quality even if it cannot be measured directly.

Impact of CON on Patient Satisfaction. As with clinical quality, inferences about patient satisfaction had to be made based on indirect evidence and subjective impressions. Again, all other things being equal, one would expect greater choice to be associated with greater patient satisfaction since this will allow the diversity of patient preferences for different types of beds/facilities to be accommodated more closely.

Access

Nationally, improved access to care was secondary to cost control as a rationale for adopting CON. As with quality, there are many other policy instruments available for achieving this objective more directly (e.g., Medicaid, Hill-Burton, community health centers, high risk pools etc.). Nevertheless, arguments in favor of CON have been based in part on the potential of CON to improve access (see Havighurst, 1973 for an early discussion of this issue and Campbell and Fournier, 1993 a more recent articulation of this argument).

There are three important issues related to access. The first is the net impact of CON and other types of regulation on *access to care for disadvantaged populations* (e.g., poor and or uninsured) given that CON has the potential both to improve access (e.g., shielding facilities from competition in order to improve their ability to “cost shift”) and reduce access (e.g., by favoring politically powerful interests, such as suburban hospitals, over less wealthy or politically powerful facilities, such as urban hospitals). The second is whether regulation affects *geographic access* to services, in terms of both time spent traveling to obtain care or waiting for services.

Impact of CON on Access to Care for the Disadvantaged. In addition to subjective estimates of CON's impact on access, the Center reviewed a handful of studies which have examined the extent to which hospital CON decisions are influenced by access considerations. The impact on access was further analyzed indirectly based on empirical evidence regarding the impact of CON on hospital revenues relative to expenses and on data from 1992 and 1999 showing the extent to which private payer payments to hospitals exceeded the cost of their care in states with and without CON.

Impact of CON on Geographic Access. This issue was addressed based on an examination of evidence regarding a) the general willingness of patients to travel to seek care; b) the circumstances under which patient travel times affect patient use of services and c) inferences that can be drawn from a small number of studies which specifically have examined the impact of regionalization on patient travel times.

Equity

A final criterion by which to judge CON concerns whether the process itself is fair. A process that tilts the playing field in one direction or another might be viewed as inequitable. This could occur either if the process itself is unfair (e.g., giving favored treatment to the politically connected), biased (e.g., against certain types or ownership of facilities, regardless of their objective merits) or if the burden of getting through the process is so cumbersome that it effectively gives favored treatment to those with greater means to overcome these hurdles.

The Center reviewed national evidence related to this issue to determine whether CON typically provides a fair process of decision making and/or results in a level playing field. In addition, the key informant interviews in Michigan provided insight on this issue.

METHODS USED TO EVALUATE CERTIFICATE OF NEED

Literature Review

The investigators have reviewed and synthesized all of the published literature that empirically assesses the impact of CON on costs, quality or access to care.⁴ This includes peer-reviewed literature such as books and journals, but we also searched so-called “gray” literature including a) CON studies conducted by other states; b) other pertinent reports by government agencies; c) unpublished reports or published reports from “think tanks” and academic centers that may not have gone through a formal peer review process; and d) unpublished dissertations. Because the empirical analysis was designed specifically to overcome some of the gaps and limitations in these previous studies, all of this material is integrated where appropriate into the discussions of the impact of CON on costs, quality and access. This will allow the interested reader to see the extent to which the Center has relied on previous work and which findings rely more heavily on new analysis.

⁴This search began with several extensive prior reviews of the literature, including Simpson (1986), Sloan (1988) and Lewin-ICF (1991). More recent relevant medical/health policy literature was identified using *Medline*; social science literature was identified using *EconLit* and the *ProQuest Social Science Index*; and relevant legal literature was identified using *LegalTrac*. Although the investigators deliberately ignored a large body of literature which discusses CON from a theoretical/normative point of view, they are satisfied that they have synthesized all of the important literature that empirically evaluates the impact of CON.

Empirical Analysis

There were two parts to the empirical analysis. The first was *descriptive evidence* that generally focused on an important concern: does dropping CON result in a “surge” of building that leads to higher health spending? This analysis allows one to visually see whether such a surge occurred in any or all of the states that dropped CON. But it is limited in the sense that there are other factors (e.g., improving economies as states came out of the 1982-83 recession, expansions in Medicaid, etc.) that might have accounted for a surge being observed (or not observed) in any particular state. What is needed is an analysis that controls for all these unique state characteristics and that can isolate the independent contribution of CON on trends in both supply and utilization of health services as well as health spending. Therefore, the second part was a *multivariate analysis* which examined whether either having CON or the stringency of CON regulation could explain differences among states in supply, utilization or spending.

Descriptive Evidence. The descriptive analysis focused on states that dropped CON sometime during the 1980's, using data for 1980 through 1998 or 2000 (depending on the availability of data for particular items of interest). To facilitate comparisons, all data were indexed relative to the U.S. average so it would be quickly apparent upon inspection whether the relative supply of services (or use of services or spending) rose or fell compared to the national average over the period examined. In addition, equivalent calculations were performed for the state of Michigan to determine whether the state performed any better than any of the states that dropped CON or better than the national average during this period.

The analysis of acute care CON examined whether dropping CON was followed by an apparent “surge” in hospital beds, outpatient surgical centers or expensive hospital-based technologies (open heart units, organ transplant units and certified trauma centers). States that repealed CON in various periods were compared to states with stringent, moderate and limited CON, as well as Michigan. Summary findings are provided in this report; full results and further description of data sources and methods are contained in Appendix D.

Multivariate Analysis. The multivariate analysis included all states except Alaska, Hawaii and Washington D.C.⁵ using data from the period 1980 through 1998 (due to limited availability of data for selected variables, all analyses were limited to these years). This analysis was a state-level analysis that took into account major characteristics of each state (e.g., per capita income, physician supply) to determine the net impact of CON regulation,

⁵Neither Alaska nor Hawaii was included in the original state-level time series that was updated for this analysis. Washington DC was excluded because its per capita health spending figures are heavily skewed by exporting health services to non-residents and because of wide swings in HMO penetration rates that also may have been skewed due to the District's small size and unique characteristics.

after accounting for changes in these various characteristics over time. The analysis also took into account other types of regulation, such as hospital rate-setting, as well as competition (e.g., HMO market share) to determine whether these had any significant effect on supply, utilization, costs or spending.

The analysis of acute care CON examined the impact of CON and other factors on a variety of different measures described earlier, including a) health spending per resident; b) spending per Medicare eligible; c) hospital supply and utilization; d) hospital-based technology; e) hospital intensity; and f) market structure. Some of the latter measures were included as a way of gauging indirectly the impact of CON on access and quality.

Key Informant Survey

Due to limitations on the availability of data, the updated empirical analysis of CON is restricted to all years through 1998. However, the health care market has continued to evolve in the interim, particularly in terms of the continued growth of vertical integration and a slow-down in the growth of managed care. To take into account these more recent trends, case studies (involving key informant interviews) were conducted to provide a more complete picture of the potential impact of changes in CON in the context of these market shifts.

Areas of Focus. Our desire was to obtain a general overview of CON for hospital facilities and services and then to focus attention on three important components of CON relating to a) hospital beds; b) MRI units; and c) cardiac catheterization and open heart units. These areas were selected both because they were of particular interest to the MDCH, but also in recognition that even if CON may have outlived its usefulness as a means of controlling bed supply, there might be good reasons to retain it for selected expensive technologies. Time constraints did not allow us to examine every technology now regulated by Michigan's CON program; hence the ones selected might be viewed as representative in some way of how CON works in regulating technology more generally.

Survey Respondents. Our goal was to obtain a wide variety of informed opinions about how CON worked, whether it needed to be fixed and/or whether it should be abandoned entirely. It was important to have the views of regulators, payers, providers and the general public as it was clear each group might have very different views on the merits of CON. On the other hand, CON is not necessarily well understood by even well-informed members of the public, so an effort was made to find individuals who at least had some familiarity with the process, either through personal experience or by talking with colleagues familiar with it. Time constraints imposed a natural limit on the numbers who could be interviewed, so it was decided to identify at least 12 individuals in each of the four groups, but to have additional names to substitute in the event that a prospective respondent was unwilling or unable to participate. The goal was interview at least 10 but no more than a dozen individuals within each group. Because the consultants for this study were from outside Michigan, a small

working group within DCH selected the list of names of individuals to interview. This working list was carefully vetted to ensure that it fairly represented a broad cross-section of views and was not obviously tilted in the direction of either supporting or opposing CON. Thus, the final sample was neither a purely random sample of Michigan residents nor a group whose opinion was invited by their predisposition to support or oppose either the continuation or reform of CON. Ultimately 11 individuals refused to participate and 2 others could not be reached or did not respond after a half dozen separate attempts. Substitutes were found for all but two of these.

Questionnaires. To minimize the burden on respondents and ensure cooperation in obtaining interviews, each questionnaire was designed to last no longer than 15-20 minutes. In addition, respondents were assured that their answers would be kept confidential. A total of 35 interviews were conducted by the Duke University consultants and the balance were conducted by Greg Cline, *Director*, Center for Collaborative Research in Health Outcomes and Policy, Michigan Public Health Institute.

Each questionnaire had four parts. The first section addressed perceptions about the impact of CON in actual practice. These questions asked for a subjective evaluation of CON in terms of *effectiveness* (e.g., did/does it really affect the size or nature of the industry or number/nature of beds, MRI units etc.?), *access* (for the uninsured and other disadvantaged populations), and *quality* (patient satisfaction and technical quality of care). Respondents also were asked to judge CON in terms of *equity*, that is, whether the process in Michigan--regardless of effectiveness--is currently conducted in a manner that produces a level playing field between different players (e.g., hospital versus non-hospital outpatient, teaching hospitals vs. non-teaching hospitals, or any other comparisons deemed relevant by the respondent).

The second section focused on potential improvements in CON, asking respondents to name the single most important improvement that might be considered and then to offer any additional major improvements in CON that related to the area about which they were being queried.

The next section included questions about the potential impact of dropping CON. Respondents for the general CON and inpatient beds questions were asked to evaluate whether dropping CON has influenced/would influence the nature or pace of Medicaid cost containment efforts. A second question examined whether lack of CON has/would have a positive or negative effect on the rate at which the delivery system would change over the next 5 or 10 years. Respondents also were asked whether the public would be better served by relying on CON or the market. Those given the technology questionnaire were asked a more focused set of questions would have any impact, positive or negative, on costs, access

or quality of that particular service (those who answered affirmatively were asked to briefly explain how removal of CON might make a difference).

The final section addressed the best way to make a transition away from CON, i.e., whether this should be done all at once or phased in over time and the risks associated with one approach rather than another. For those who thought CON should be phased out, further probing was done to determine the time-frame and manner in which they thought this might be done. Note that respondents were not asked to accept the premise that dropping CON was a desirable direction to take: they were instead asked to focus on the narrower “what if” question of how it might be best to take this step if for whatever reason Michigan elected to move in that direction.

SUMMARY

The effectiveness of CON can be evaluated in terms of cost, quality, access and equity. Previous literature on the impact of CON in these four areas is a useful starting point, but much of this literature is dated or methodologically flawed. Very little of the available literature has examined what happened in states which lifted CON. Therefore, the Center’s evaluation is based not only on their previous work for the state of Delaware, but also on evidence from new analyses conducted by the Duke consultants specifically for Michigan. These include a descriptive analysis of what happened in states that lifted CON, a multivariate analysis of longitudinal state-level data (updating previously published by Professors Conover and Sloan) and a key informant survey of Michigan.

The next section is devoted to a detailed analysis of the evidence regarding CON for acute care services.

