

Michigan's Certificate of Need Program— Under Duress?

The Certificate of Need program is a state-administered regulatory program, governed by the Public Health Code (Part 222 of PA 368 of the Public Acts of 1978), as amended. Health care providers are required to obtain state approval prior to initiating, expanding, or moving specific health care services or beginning significant capital projects (construction or renovation) to ensure that only useful and needed health care services are developed. This regulatory program is intended to positively impact Michigan's health care system, by balancing the cost, quality, and access to health care services.

Background

In 1974, the U.S. Congress passed the "Health Planning Resources Development Act" which required states to establish a planning and approval agency and process for major capital projects or acquisition of new high-tech devices. The Act resulted from concern that the Medicare and Medicaid programs were facilitating unrestrained opportunities for expensive, unneeded, and perhaps duplicative capacity expansions, as well as concern about dramatically increasing health care inflation. The initial focus, intended to constrain health care cost increases, was regulation of hospital and nursing home beds and expensive equipment to avoid the over-capacity and duplication that drive up health care costs. Projects would be approved based on an objective analysis of community need. With this requirement came federal funds for developing Certificate of Need (CON) programs.

In 1987, Congress repealed the federal mandate and eliminated funding for the program. Over the next 10 years, 14 states discontinued their CON programs, while 36 states continued to maintain some form of a review program. Michigan is one of the states that maintained a CON program.

Michigan's Early Certificate of Need Program

Michigan's initial Certificate of Need Program was enacted in 1972, prior to the federal program, to contain health care costs and applied only to

hospitals, the spending area which represented the largest share of health care costs. Capital projects could only be initiated after documented need was provided and state approval given. The program was administered by the Department of Public Health and overseen by a newly established State Health Coordinating Council. Subsequent legislation in 1978, 1988, and 2002 significantly amended each of its predecessors. The 1978 amendments added nursing homes and some clinical services to those requiring CON approval. Subsequent amendments modified the services to be reviewed, the monetary threshold for approval of capital expenditures, and the review process. From the initial hospital review, the number of services requiring a Certificate of Need approval for change or expansion has grown to the current 16 services listed below, with some intermediate additions and deletions over time.

- ▶ Air Ambulance (Helicopter)
- ▶ Bone Marrow Transplants
- ▶ Cardiac Catheterization
- ▶ Computed Tomography (CT) Scanners
- ▶ Heart, Lung, Liver Transplants
- ▶ Hospital Beds
- ▶ Magnetic Resonance Imaging (MRI)
- ▶ Megavoltage Radiation Therapy (MRT)
- ▶ Neonatal Intensive Care Unit (NICU)
- ▶ Nursing Home/Hospital Long-Term Care Unit Beds (NH/HLTC)
- ▶ Open Heart Surgery

- ▶ Pancreas Transplantation Services
- ▶ Positron Emission Tomography (PET) Scanners
- ▶ Psychiatric Beds: Acute Inpatient Surgical Services
- ▶ Urinary Lithotripters

Source: Michigan Department of Community Health website, http://www.michigan.gov/mdch/0,1607,7-132-2945_5106-25558--,00.html.

In addition, health facility capital expenditure projects (new construction or renovations) must also receive Certificate of Need approval for projects that exceed \$2.9 million in 2008. The capital expenditure threshold is updated annually based on the Consumer Price Index.

The 1988 legislation established a 5 member commission to be appointed by the Governor and approved by the Senate. The 2002 amendments altered the roles and responsibilities of the Commission, the membership of the Commission, and increased the membership from 5 to 11. Amendments in the 2002 legislation also changed the operational policies and the categories of services that required approval to proceed.

Current Commission Charge and Membership

The current eleven-member Commission has the responsibility to develop, approve, disapprove, or revise CON Review Standards. The Review Standards are used by the CON Program Section of the Department of Community Health to issue initial decisions on CON applications. While the Commission establishes the Review Standards, the Commission is not involved in the review or decision making process for CON applications. The Commission evaluates the Review Standards for modification on a three-year rotating schedule. The Commission follows specific protocols to establish or revise standards. The two guiding principles used by the Commission in establishing standards include:

the promotion and assurance of the availability and accessibility of quality health care services at a reasonable cost and within a reasonable geographic proximity for all people of the state, and

the promotion and assurance of appropriate differential consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents.

Source: CON Program brochure, available at <http://www.Michigan.gov/con>

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Once new/revised standards have been agreed upon by the Commission members, they are presented to the Governor and Legislature who have 45 days to review and veto; no changes can be made. Standards not vetoed by the Governor or Legislature become effective following the review period. The Commission also has the authority to make recommendations to revise the list of covered clinical services subject to CON review. All CON Commission meetings are open to the public, and provide a public forum for consideration of cost, quality, and access as well as an opportunity for consumer participation.

The eleven member Commission must consist of the following representatives:

- Two individuals representing hospitals.
- An individual representing medical doctors (MD's).
- An individual representing osteopathic physicians.
- A physician representing a school of medicine or osteopathic medicine.
- An individual representing nursing homes.
- An individual representing nurses.
- An individual representing a company that is self-insured for health coverage.
- An individual representing a company that is not self-insured for health coverage.
- An individual representing Blue Cross Blue Shield.
- An individual representing organized labor unions in this state.

Source: Michigan Department of Community Health website, http://www.michigan.gov/mdch/0,1607,7-132-2945_5106-35111--,00.html.

Certificate of Need Review Process

While the Department follows a rigorous protocol for reviewing CON applications, it is the establishment of the Review Standards that is key in meeting the Certificate of Need objectives. Depending on the size and complexity of the project, initial decisions are rendered in a period ranging from 45 days to 150 days (most complex). If an application is denied, the applicant can request a hearing which must begin within 90 days of the request. The Department of Community Health Director issues the final decision on an application after the initial decision or a hearing, if one is requested.

Certificate of Need application fees are based on the cost of the project and fall into 3 categories:

- \$1,500 (projects under \$500,000),
- \$5,500 (projects over \$.5 million and less than \$4.0 million),
- \$8,500 (projects over \$4.0 million).

The annual activity report for the Certificate of Need Program can be viewed at: http://www.michigan.gov/documents/mdch/2007_Annual_Report_222906_7.pdf.

This report provides a brief history of the program as well as the review process and types of reviews conducted during FY2007. Comparisons of prior year application types, time frames for determinations and costs are among the data included. Commission activities for the year are also highlighted.

Current and Emerging Issue

In June 2008, for the first time, the Governor vetoed a proposed standard that required hospitals to form a consortium to build a costly cancer treatment facility. The specific treatment, proton beam therapy, is considered effective for limited types of cancer, mostly rare pediatric tumors, but is also used to treat prostate cancer, although it has not been clearly proven to be superior to other forms of treatment.

In July, the applicant, Beaumont Hospital was given approval by the Department of Community Health to proceed and begin construction on the estimated \$159 million proton facility in Royal Oak.

From the consumers' perspective...

Thirty years ago I heard a health economist from Massachusetts speak at a forum sponsored by the Catholic Archdiocese of Detroit on the future of health care in the United States.

He said the future looks like the health care delivery system will be “doing more and more for fewer and fewer people until we are doing everything for almost nobody.”

This concern gave life to the Certificate of Need review system in Michigan: How necessary are the changes we make in health care delivery, and how many health care consumers will actually benefit from the costly expansions, innovations and technologies reviewed in the Certificate of Need process.

The recent veto by the governor of a CON recommendation is most discouraging—the first in the thirty-year history of the state’s review process.

After months long, careful consideration by a work group, the CON Commission had recommended that the erection of a multi-million dollar proton beam center which promises to serve a very limited number of people be done by a consortium of health systems.

The fact that Beaumont Hospital received the go ahead on its own—in collaboration only with a private for profit entity that builds such systems—seriously undermines the CON process of public input.

The prophetic voices of the early seventies have pretty much gone unheeded as hi-tech costs continue to overwhelm us and deny millions access to basic health care services.

And the sad thing about the CON reversal is that—in this case—it wouldn’t have mattered if a consumer had been given a seat on the CON Commission.

Beverley McDonald, Chair

Michigan Consumer Health Care Coalition

Requests for approval for carbon ion therapy, another new but yet unproven treatment, may also soon be on the Commission’s agenda as hospitals continue to compete to offer the most high-tech services. In the end, these new services may benefit some, but will likely increase costs for all as facilities scramble to find ways to cover the cost of their new technologies.

Another emerging issue is the proposed movement of hospital beds from core city hospitals to more affluent suburbs to reduce the number of Medicare, Medicaid and uncompensated care patients

the hospital system serves, and increase the number of privately insured patients in their facilities. Approval of these types of proposals will result in further-diminished access, already limited in many areas, for low-income persons.

Opportunities for Input

The public has several opportunities to provide input and become involved in this process. Consumers can participate in work groups, be appointed to the Standards Advisory Committee, attend relevant meetings (all of which are open to the public), provide public comment on specific issues to CON staff, communicate with state legislators, draft letters to the editor to local newspapers, or share information with other consumer groups. For more information on participating in a work group, contact the CON Policy office at 517-335-6708.

Meetings of the Commission and committees are posted at http://www.michigan.gov/mdch/0,1607,7-132-2945_5106-169648--,00.html.

Consumers would be well-advised to become informed on the emerging issues and monitor the activities and recommendations of the Commission and subsequent responses of the Governor and Legislature.

We want to hear from you—
suggestions for improvements and
topics, questions, even encouragement!

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Consumer at-Large Member...

I have served as a consumer representative on many CON ad hoc committees charged with presenting recommendations to the CON Commission on a wide variety of services. I know how carefully the responsibility to try to balance costs with availability and quality has been discharged. It is a tribute to that process that never before have proposed standards accepted by the Commission been vetoed. In June, however, Governor Granholm exercised that veto power for the first time ever, when she rejected the Commission's recommendation that required hospitals to form a consortium to build a proton beam therapy facility for treatment of cancer. The cost is enormous.

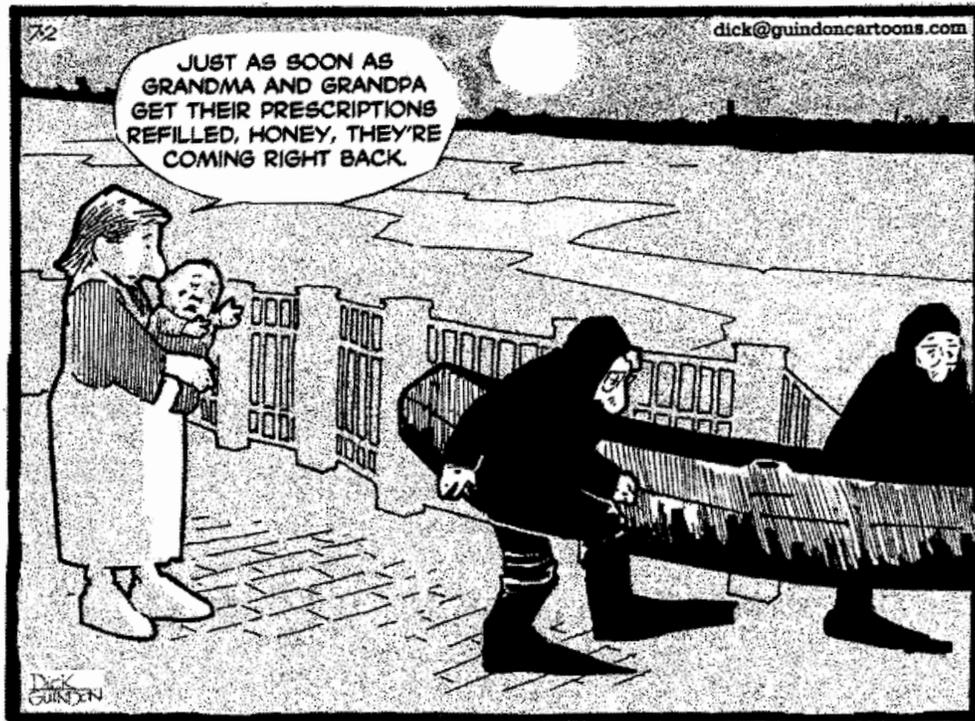
I am concerned that this veto threatens the very core of the CON process and its responsibility to Michigan residents, especially consumers.

It essentially opens the door for the probability that political pressures will replace the professional review process established by the CON legislation. The open review of new or expanded services by ad hoc committees of professional providers, medical experts on the issues, and consumer representatives to assure that they meet the goals of the CON legislation is now at risk as a result of this precedent.

The threat of gubernatorial or legislative veto has always existed, but the process in place had assured a credibility that mostly precluded a political end-around being successful at evading the CON process. Now the question is whether the CON process will remain relevant and credible. Will any of us, but consumers especially, have any voice at all in the expansion, approval process and funding of health care services in the future? Does this signify the potential end of state willingness, and ability, to exercise any control over costs, access, quantity, and quality of health services provided? What alternative controls will be made available? And, what should we as consumers be doing to develop and implement them?

We know that health services are very different from most other services consumers purchase. Options are fewer, and our needs and choices are mostly dictated by our health status and by our primary providers of health services. Is it mere coincidence that health care consumes the largest single share of our economy, and that those cost continue to grow? I fear that we will miss the CON process more than we can now know. If you share these concerns, talk with your legislators. Let them know you care how health services are approved.

Don VeCasey, Consumer-at-Large Member
Michigan Consumer Health Care Coalition



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The Health Care Happenings...

Nationally in FY2007, an estimated 3.4 million Medicare beneficiaries reached the “donut hole”—the Medicare Part D coverage gap when beneficiaries had to pay the full cost of their prescriptions.

Source: Kaiser Family Foundation’s The Medicare Part D Coverage Gap: Costs and Consequences in 2007, August 2008, available at <http://www.kff.org/medicare/upload/7811.pdf>.

The percentage of working age Americans facing high medical bills and medical debt continues to climb. In a new issue brief, *Seeing Red: The Growing Burden of Medical Bills and Debt Faced by U.S. Families*, the Commonwealth Fund reports that from 2005–2007, the percentage of working age Americans struggling to pay high medical bills or accumulated medical debt increased from 34 percent to 41 percent, or 72 million people. In addition, 7 million individuals aged 65 or older also struggled to pay medical debt or bills. High medical debt was not primarily the

result of being uninsured; 61 percent of those with high medical bills or debt were insured at the time the services were provided.

Source: *Seeing Red: The Growing Burden of Medical Bills and Debt Faced by U.S. Families*, The Commonwealth Fund, August 20, 2008, available at <http://www.commonwealthfund.org>.

HEALTH CARE BY THE NUMBERS

Certificate of Need applications submitted in FY2007	320
Application fees paid	\$1.67 Million
Final decisions issued	319
Total project costs for approved applications	\$1.9 Billion

Source: Certificate of Need Annual Report FY2007. Web site: http://www.michigan.gov/documents/mdch/2007_Annual_Report_222906_7.pdf.

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MPRO's QUALITY EXPO SET FOR OCTOBER 30TH EVENT FOCUSES ON QUALITY AND SAFETY ACROSS SETTINGS

MPRO is hosting the 2008 Quality EXPO on October 30th at the Radisson Plaza Hotel at the Kalamazoo Center, Kalamazoo, Michigan. The quality and patient safety conference will feature a variety of informative presentations that promote quality across the continuum. The keynote will be delivered by Barry Straube, MD, Director and Chief Clinical Officer, Centers for Medicare & Medicaid Services, on Bridging the Care Continuum - Improving Quality and Safety.

A special participant and vendor reception also will be held from 4 p.m. to 6 p.m. on October 29th prior to the Governor's Award of Excellence Dinner and Awards Ceremony.

Early registration until September 30 is \$130; the cost increases to \$180 on October 1. Registration includes welcome reception the evening prior to the conference. Event day features a continental breakfast, snack breaks, lunch, and access to vendors. Continuing education credits are available. For more information and to register, visit www.mpro.org/qualityexpo. Registration is available online only.

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