House
Legislative
Analysis
Section

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# CERTIFICATE OF NEED REVISIONS

**Senate Bill 396 with House committee amendment**
**First Analysis (6-30-93)**

**Sponsor: Sen. John Pridnia**
**Senate Committee: Health Policy**
**House Committee: Public Health**

## *THE APPARENT PROBLEM:*

Michigan's first certificate of need (CON) program was enacted in 1972 to give the state regulatory control over the construction, conversion, and modernization of health facilities, and subsequently was expanded to cover equipment and services. Essentially, the program requires a health facility or person to obtain a CON from the state before making large capital expenditures (to acquire a facility, for example, or to purchase certain equipment, such as a CAT scanner), or before providing particular services (such as organ transplantation). The program is premised on the notion that controlling the supply of health facilities and services is an effective way of controlling health care costs, as well as assuring quality health care and the fair allocation of resources.

In recent years, the CON system underwent considerable review by a group representing health care providers, major purchasers of health care, and state health planners. This group worked to address complaints that the CON process too often tied up hospitals and other providers in unnecessary and burdensome red tape, and denied Michigan residents the use of the latest advances in medical technology, while failing to control health care costs effectively. The group's efforts culminated in the enactment in 1988 of legislation aimed at revamping the CON program, as well as other elements in the state health planning system.

Despite these changes, many people continue to believe that state regulations pose substantial barriers to the health care industry's ability to adjust rapidly to the health needs of local communities, and that the CON program has failed to distribute scarce resources and ensure geographic access to them.

## *THE CONTENT OF THE BILL:*

The bill would amend Part 222 of the Public Health Code, which governs the certificate of need process, to do the following:

* Increase from $850,000 to $2 million the capital expenditure threshold at which a health facility must obtain a CON before improving, constructing, or replacing a clinical service area; increase the threshold from $1.7 million to $3 million for a nonclinical service area; and require those figures to be adjusted according to the consumer price index.

* Require the Department of Public Health (DPH), in applying a review standard for magnetic resonance imaging (MRI) services, to apply an adjustment factor of 1.4 or 2.0 for a mobile MRI service for a hospital in a rural county.

* Require the development of review standards for psychiatric programs.

* Allow the Certificate of Need Commission to revise CON review standards for the initiation of new services and facilities, and to revise the designation of covered clinical services, without prior submissions by the DPH and the Office of Health and Medical Affairs (OHMA); and alter the timetable for commission action on these revisions.

* Revise the criteria for the approval of a CON, concerning the costliness of a project.

* Revise provisions concerning the comparative review of projects, including nursing home replacement beds.

* Set new deadlines for the final decision on CON applications.

* Set a threshold of $1 million on the capital costs of a project requiring a construction permit, and require an applicant for a construction permit not requiring a CON to submit certain information.

CON projects and thresholds. The health code defines "certificate of need" as a certificate issued under Part 222 of the code authorizing a new health facility, a change in bed capacity, the initiation of a new service, the acquisition of covered medical equipment, or a covered capital expenditure. The bill, instead, would refer to a certificate authorizing a new health facility, a change in bed capacity, the initiation, replacement, or expansion of a covered clinical service, or a covered capital expenditure. (The revised definition of "covered clinical service", described below, would include both services and equipment.)

The current definition of "covered capital expenditure" refers to a capital expenditure made by a health facility for a single project, in an amount that varies according to whether the project involves a clinical service area (an area in which individuals receive diagnosis, treatment, or rehabilitation), a nonclinical service area, or nonmedical equipment, excluding the cost of nonfixed medical equipment. For a single project that involves the acquisition, improvement, expansion, addition, conversion, modernization, new construction, or replacement of a clinical service area, the threshold is $750,000 for applications submitted before October 1, 1991, or $850,000 for applications submitted on or after that date. The bill would replace these figures with a threshold of $2 million. The bill also would increase to $3 million the threshold for a single project that involved nonclinical service areas only. (The current threshold is $1.5 million for applications submitted before October 1, 1991, or $1.7 million for applications submitted on or after that date.) In addition, the bill would require that the DPH, beginning January 1, 1995, adjust the $2 million and $3 million thresholds by an amount determined by the state treasurer to reflect the annual percentage change in the consumer price index.

In addition, the bill would delete the reporting requirement (for capital expenditures and single projects that were subject to CON provisions in former Part 221 of the code, which was replaced by Part 222 under Public Act 332 of 1988).

Covered clinical services and health facilities. The health code requires a CON before the initiation of a covered clinical service if that service has not been offered on a regular basis at the location where it is to be offered within the 12-month period preceding the date the service will be offered. The bill also would require a CON before a person replaced or expanded a covered clinical service.

The bill would replace the current definitions of "covered clinical service" and "covered medical equipment" with a new definition of "covered clinical service". After the bill's effective date, that term would mean, except as otherwise modified by the CON commission, any of the following:

* Initiation or expansion of neonatal intensive care services or special newborn nursing services; open heart surgery; or extrarenal organ transplantation.

* Initiation, replacement, or expansion of extracorporeal shock wave lithotripsy; megavoltage radiation therapy; positron emission tomography; surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center, or a surgical department of a hospital offering inpatient or outpatient surgical services; cardiac catheterization; fixed and mobile magnetic resonance imaging services; fixed and mobile computerized tomography (CAT) scanner services; or air ambulance services.

* Initiation, replacement, or expansion of a partial hospitalization psychiatric program service.

* Initiation or expansion of a specialized psychiatric program for children and adolescent patients using licensed psychiatric beds.

Like the current definition, the bill also would include the initiation, replacement, or expansion of a service not listed above but designated as a covered clinical service by the commission.

The health code's definition of "covered clinical service", which the bill would delete, is any of the following:

* Initiation or replacement of cardiac services or extrarenal organ transplantation.

* Initiation of a specialized psychiatric program using existing licensed psychiatric beds.

* Initiation, replacement, or expansion of one or more of the following: a) special radiological procedure rooms used for invasive procedures such as angiography, arteriography, venography, catheterizations, and electro physiology; b) specialized radiation therapy services; or c) a partial day hospitalization psychiatric program.

* Initiation or increase in the number of licensed hospital beds dedicated to neonatal intensive care services or special newborn nursing services.

The current definition of "covered medical equipment", which the bill would delete, is any of the following: an extracorporeal shock wave lithotripter; a magnetic resonance unit; a mobile or fixed CAT scanner; surgical facilities; or an air ambulance.

The code requires a CON before acquisition or begins operation of a new health facility. The bill, instead, would require a CON before acquisition of an existing health facility or beginning operation of a health facility at a site that was not currently licensed for that type of health facility.

Under the bill, an applicant seeking a CON for the acquisition of an existing health facility could file a single, consolidated application for the CON if the project did not result in an increase or relocation of licensed beds or the initiation, expansion, or replacement of a covered clinical service. Acquisition of an existing health facility would be subject to the applicable CON review standards in effect on the date of the transfer for the covered clinical services provided by the acquired facility. The DPH could exempt one or more of certain covered clinical services (shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, cardiac catheterization, MRI services, CAT scanner services, or air ambulance services) from the minimum volume requirements due to the technological incapacity of the equipment. A covered clinical service excepted by the DPH would be subject to all of the other provisions in the applicable CON review standards in effect on the date of the transfer.

Health maintenance organizations. A health maintenance organization (HMO) must obtain a CON for the acquisition, purchase, new construction, modernization, or replacement of, or addition to, a hospital or other health facility providing inpatient services, if a covered capital expenditure is required; or for the acquisition of covered medical equipment. The bill would delete reference to covered medical equipment, but would require an HMO to obtain a CON for the initiation, replacement, or expansion of a covered clinical service.

Review standards and covered services. Currently, upon submission by the DPH and OHMA, the CON commission is authorized to approve, disapprove, or revise CON review standards that establish the need, if any, for initiating new services, acquiring covered medical equipment, acquiring or initiating new health facilities, changing bed capacity, or making covered capital expenditures. Also, upon submission by the DPH and OHMA, the commission may approve, disapprove, or revise the designation of covered clinical services and covered medical equipment. Before the commission can take final action under either of these provisions, it must seek the advice and counsel of the DPH and OHMA.

The bill would eliminate the requirements of submission by, and advice and counsel of, the DPH and OHMA. The bill also would refer to the replacement or expansion, as well as the initiation, of covered clinical services, and would delete references to covered medical equipment and the acquisition of new facilities. If it proposed to add to the list of covered clinical services (described above), the commission would have to develop proposed review standards and make them available to the public at least 30 days before conducting a public hearing.

The DPH still would be responsible for developing proposed CON review standards for submission to the commission. Currently, the department is required to appoint an ad hoc advisory committee to assist in developing standards and to comment on the proposals submitted to the commission. The bill instead would require the commission to appoint ad hoc advisory committees, which would have to complete their duties and submit their recommendations to the commission within the time specified by the commission.

Currently, before the commission takes final action to revise standards or covered services, it must conduct a public hearing and, at least 30 days before taking final action, submit the proposed final action for comment to the standing committees of the Senate and House with jurisdiction over public

health matters. Further, before final commission approval is effective, the commission must submit the proposed action to the governor and the public health committees. The bill would require the commission to hold the public hearing at least 30 days before taking final action.

The governor and the legislature would still have 45 days in which they could disapprove proposed final action. Currently, if the legislature is not in session at the time the proposed action is submitted, or is in recess, the 45 days begin on the first day the legislature reconvenes. The bill provides, instead, that if the proposed final action were not submitted on a legislative session day, the 45 days would begin on the first legislative session day after the proposed final action was submitted.

The health code currently requires the CON commission to exercise its duties to promote both the availability of quality health care at reasonable cost, and the general health objectives in the state health plan. The bill would require, instead, that the commission exercise its duties to promote a) the availability and accessibility of quality health services at reasonable cost and within reasonable geographic proximity for all people in the state; and b) appropriate differential consideration of the health care needs of residents in rural counties in ways that did not compromise the quality and affordability of health care services for those residents.

Magnetic resonance imaging (MRI) services. In applying a review standard that established the minimum number of magnetic resonance imaging procedures necessary for a CON for a mobile MRI service, servicing only hospitals located in rural counties, the DPH would have to use an adjustment factor of 2.0. For an MRI service servicing hospitals located in both rural and nonrural counties, the department would have to use an adjustment factor of 1.4 for a hospital located in a rural county. ("Rural county" would mean a county not located in a metropolitan area as that term is defined under the "revised standards for defining metropolitan areas in the 1990's" by the statistical policy office of the Office of Information and Regulatory Affairs of the U.S. Office of Management and Budget.)

Psychiatric Services. Within two years after the bill's effective date, the ad hoc advisory committee for psychiatric services appointed by the DPH or by the CON commission would have to develop and submit CON review standards pertaining to psychiatric programs. The review standards would have to include a specific methodology for the determination of need. If the ad hoc advisory committee did not develop and submit review standards within the two-year limit, the commission would have to delete those services pursuant to the provisions described above for deleting covered clinical services.

CON Commission Recommendations. The health code requires the CON commission, every five years, to make recommendations to the legislative public health committees regarding statutory changes to improve the CON program. After considering these recommendations, the committees are required to make findings and recommendations. The bill would delete the requirement that the committees make findings and recommendations, but would require the commission to recommend statutory changes to improve or eliminate the program.

CON Application Criteria. To be approved, an applicant for a CON must demonstrate to the DPH's satisfaction that the proposed project will meet a need in the area proposed to be served, and must demonstrate the need for a proposed project by credible documentation of compliance with the applicable CON review standards or, if there are no standards, by credible documentation that the project will be geographically accessible and efficiently and appropriately used in light of the type of project and the existing health care systems. The bill would delete reference to the credible documentation of geographic accessibility and efficient use. Under the bill, if no CON review standards applied to the proposed project or to a portion of a proposed project that was otherwise governed by Part 222 of the health code, the applicant would have to demonstrate to the DPH's satisfaction that an unmet need for the proposed project or portion of a project existed. The demonstration would have to be by credible documentation that the project would be geographically accessible and efficiently and appropriately used, in light of the type of project and the existing health care system.

In addition, the applicant currently must show that the project meets other criteria in regard to the method proposed to meet the need and with respect to the financial aspects of the project. The bill

would delete requirements that an applicant show that a proposed new construction project is the most appropriate construction option; that a project, in terms of capital costs, is the least costly project, in light of available alternatives; that a project represents the least costly alternative of providing the health facility, service, or equipment; and that, in the case of a construction project, an alternative to competitive bidding will result in the least costly method for implementing the project. An applicant still would have to demonstrate that the capital costs of a project would result in the least costly total annual operating costs; that funds were available to meet the capital and operating needs of a project; that a project used the least costly method of financing, in light of available alternatives; and that, in the case of a construction project, the applicant would competitively bid capital expenditures or was proposing an alternative to competitive bidding that would achieve substantially the same results as competitive bidding. In regard to the method proposed to meet the need for a project, the applicant would have to demonstrate that it had considered alternatives and that, in light of the alternatives available for consideration, the chosen alternative was the most efficient and effective method of meeting that unmet need.

Comparative Review. Under the health code, proposed projects that, when combined, exceed the need of the planning area are subject to comparative review. The bill would delete this provision.

Currently, comparative review is not required for replacement beds in a hospital or nursing home that are proposed for construction on the original site, on a contiguous site, within a five- mile radius of the original site if the hospital or nursing home is located in a county with a population under 200,000, or within a two-mile radius of the original site if the facility is in a county with a population of 200,000 or more. The bill would delete nursing home beds from this provision. Under the bill, comparative review would not be required for replacement beds in a nursing home located in a nonrural county, that were proposed for construction on the original site, on a contiguous site, or within a two-mile radius of the original site. Comparative review would not be required, either, for replacement beds in a nursing home located in a rural county that were proposed for construction on the original site, on a contiguous site, or within the same planning area.

The health code provides that, until otherwise established in a CON review standard approved by the CON commission, the establishment or expansion of any of the following services is subject to comparative review if applications exceed the need for the service as stated in the standard: open heart surgery services, specialized radiation therapy services, neonatal intensive care unit or special newborn nursery unit services, extracorporeal shock wave lithotripsy services, extrarenal organ transplantation services, and air ambulance services. The bill would delete this provision.

Currently, CON review standards approved by the commission may establish comparative review or an alternative procedure based on the specific considerations of a particular applicant, verifiable applicant performance data, or other information considered relevant by the DPH. The bill provides, instead, that the commission could approve CON review standards that established comparative review or an alternative procedure for determining whether one or more of several qualified applicants could be approved if the level of need were not sufficient to justify approval of all qualified applicants.

The health code specifies that if an application under comparative review or appeal is not subject to comparative review, the application may be withdrawn and resubmitted as a new application. The bill would delete this provision.

CON Approval Process. The decision to grant or deny a CON application must be made by the DPH director after a decision has been proposed to the director by the responsible DPH bureau. The decision can approve or disapprove the application, approve it with conditions that must be met within one year, or approve it with stipulations agreed to by the applicant. The proposed decision must be submitted to the director on the day it is issued, if the decision is an approval without conditions or stipulations; otherwise, the proposed decision must be submitted to the director within 16 days after its receipt by the applicant. If the proposed decision is an approval, the director must issue a final decision within 20 days after the decision is submitted to him or her. If the proposed decision is other than an approval without conditions or stipulations, the director has 60 days to issue a final decision. If a proposed decision is an approval and if the director reverses it, the director immediately must notify the applicant of the reversal. Within 15 days after

receiving the notice, the applicant may request a hearing. After the hearing, the applicant may request the director to reconsider the reversal.

Under the bill, all proposed decisions would have to be submitted to the director on the day they were issued. If the proposed decision were other than an approval without conditions or stipulations, the director would have to issue a final decision within 60 days after a proposed decision was submitted to the director, unless the applicant had filed a request for a hearing on the proposed decision. If the proposed decision were an approval, the director would have to issue a final decision of approval within five days after the proposed decision was submitted to the director.

Construction Permit. The health code requires a construction permit from the DPH before contracting for and initiating a construction project involving new construction, additions, modernizations, or conversions of a health facility or agency for which a CON is required. Instead of requiring a permit for a project for which a CON is required, the bill would require a construction permit for a project with a capital expenditure of $1 million or more. The bill would retain the provision that a permit cannot be issued unless the applicant holds a valid CON.

To protect the public health, safety, and welfare, the code also permits the department to promulgate rules to require construction permits and the submission of plans for other construction projects to expand or change service areas and services provided. The bill specifies that this would apply to projects other than those described above.

Under the bill, if a construction project required a construction permit under either category (expenditure level or DPH rules), but did not require a CON, the department would have to require the applicant to submit information considered necessary by the DPH to assure that the capital expenditure for the project was not a covered capital expenditure as defined in the code.

If a construction project required a construction permit due to its capital expenditure amount, but did not require a CON, the department would have to require the applicant to submit information on a one-page sheet, along with the permit application, consisting of all of the following: a short description of the reason for the project and the funding source; a contact person for further information, including address and phone number; the estimated resulting increase or decrease in annual operating costs; the applicant's current governing board membership; and the entity, if any, that owned the applicant. The DPH would have to make this information publicly available by the same methods used to make information about CON applications publicly available.

Other Provisions. The health code provides that a CON ceases to be effective if its approval was based on a stipulation that the project would participate in Medicaid and the project has not done so for at least 12 consecutive months within the first two years of operation. Under the bill, this stipulation would apply to all health facility projects, not just to proposed hospital projects, as currently provided.

The code requires the DPH and the OHMA to appoint a standing new medical technology advisory committee to assist in the identification of new medical technology in the earliest possible stage of its development. The bill would require the CON commission, rather than the DPH and the OHMA, to appoint the committee, which would assist in the identification of new medical technology or new medical services that would be appropriate for inclusion as a covered clinical service. A majority, rather than all, of the committee would have to be representatives of health care provider organizations concerned with licensed facilities or health professionals and other persons knowledgeable in medical technology. The commission also would have to appoint representatives of health care consumer, purchaser, and third party payer organizations.

The health code requires the DPH to monitor compliance with CONs, including project costs and conditions and stipulations contained in a decision to approve an application, and permits the DPH to investigate allegations of noncompliance with a CON. The bill would permit the DPH to monitor compliance and would require the department to investigate allegations of noncompliance.

The health code requires the DPH to report to the CON commission at least three times each year on the department's performance under Part 222. The bill would require the DPH to report at least annually.

The bill would require the DPH to designate adequate staff or other resources to assist directly hospitals and nursing homes with fewer than 100 beds in preparing CON applications.

Repeal. The bill would repeal a section of the health code that provides for the continued effectiveness of a list of subareas having excess hospital beds and plans for the reduction of excess beds (MCL 333.22251).

MCL 333.20145 et al.

## *HOUSE COMMITTEE ACTION:*

The Senate-passed version of the bill (S-3) would have deleted the existing requirement that the CON commission recommend fee revisions if the revenue from CON applications fell short of paying for half of the costs to the Department of Public Health to implement the program. The House Committee on Public Health restored this deleted section.

## *FISCAL IMPLICATIONS:*

According to an analysis by the Department of Public Health dated March 29, 1993, the department would not be able to implement the section of the bill requiring the department to designate adequate staff or resources to help small health facilities in preparing CON applications until a funding source is identified. The analysis also notes that the bill would also reduce revenues by an indeterminate amount as a result of the fact that some projects no longer would require a CON, and says that some adjustment of existing fees might be required.

## *ARGUMENTS:*

### *For:*

The CON program, as presently constituted, serves as a deterrent to the efficient and effective operation of the health care delivery system in Michigan. By virtue of this program, access to service is limited and quality of care can be compromised. While there is a recognized need for the CON program and its role in controlling costly experimentation in the marketplace, it is now important to strike a balance between access to health care and the program's extraordinary emphasis on cost containment.

Specifically, by raising the CON thresholds for capital expenditures, the bill would restructure the CON program so that it did not micro-manage hospital decision-making. Raising the thresholds also would allow the DPH to focus on projects that represented potential expensive additions to health care services by eliminating the paperwork and staff time now directed at less important projects. According to the department, between November 1988 and August 1992, it received 64 applications for projects costing under $2 million; of these, only three actually were disapproved.

Also, the bill would refocus the CON program on the distribution of scarce services and resources. Under the present process, rural areas are limited in their access to certain equipment, such as MRI machines, because the availability of this technology is presently based in large part upon CON analysis of projected use. A low population density is unable to generate a total head count of sufficient size to justify local access to the equipment. According to the Michigan Hospital Association, there are only two or three fixed MRIs, and no mobile MRIs, north of Clare. In addition to making it easier for rural counties to qualify for MRI services, the bill specifically would require the CON commission to exercise its duties to promote the availability and accessibility of quality health services within reasonable geographic proximity for all areas of the state, and to promote appropriate differential consideration of the needs of residents in rural counties. The bill also would make an accommodation for rural counties in regard to nursing home replacement beds.

Further, the bill would streamline the application and appeal process and shorten the time frame for CON decisions. In the quickly changing world of health care, it is imperative that health facilities not be mired in departmental red tape and lengthy litigation. In particular, the bill would streamline the process for acquiring an existing health facility, by allowing a single, consolidated application. Currently, it may be necessary to file seven or eight applications to acquire a facility. Also, the CON commission would have greater independence to assure more timely determination of review standards and availability of new technology. At present, the DPH must initiate action, at two points, before the commission can act on a new or a revised standard. First, the department must appoint an advisory committee to review the issue and make recommendations to the DPH, and then

the commission can act only after it receives the department's recommendations. Under the bill, the commission itself would appoint the advisory committee, and could exercise its responsibilities without prior DPH submission.

Taken together, these changes would offer health facilities maximum flexibility to adapt to a changing environment. This in turn would promote access to quality health care across the state.

***Against:***

The bill should not be passed until certain funding issues have also been addressed. One provision of the bill would require the Department of Public Health (DPH) to help small hospitals in their certificate of need (CON) applications, but the department reportedly has indicated that without additional funding it will have difficulty in meeting this proposed new requirement. Also, under current law, Michigan hospitals are supposed to pay for half of the CON program through application fees, but reportedly the revenue from these fees in the recent past have amounted to only about 41 percent of the cost to the department of implementing the program. The bill should not be advanced until these funding issues are addressed.

***Response:***

Reportedly, the Senate has promised to take the funding issues up separately in a fee bill to be proposed at a later date. The Michigan Hospital Association also reportedly has indicated that it would be willing to provide a low-cost alternative to the proposed new DPH requirement regarding helping small hospitals with their CON applications, namely, by sponsoring seminars for these small facilities and inviting DPH staff to serve as speakers.

***Against:***

Retroactive application of new, more restrictive standards would be unfair to those hospitals that already have applied for open heart surgery programs, having taken the time and expense of writing their application under the existing standards. Hospitals that already have submitted CON applications under the current requirements should be "grandfathered" in under the bill.

***Against:***

The bill addresses the problem of long-term care in rural areas (by moving and/or converting beds in hospitals and nursing homes), but urban areas have equally serious, comparable problems. The bill should address this problem in urban as well as rural areas.

***Against:***

The capital expenditure thresholds should not be adjusted according to the consumer price index (CPI). Proponents of the bill argue that it will have little, if any, effect on cost containment while yet helping streamline the process and thereby making appropriate medical care more readily accessible to more people. But indexing the CON thresholds to increases in the CPI obviously will have an effect on health care costs by increasing them as the CPI increases. Furthermore, indexing is inconsistent with the need for legislative review and oversight by providing for an automatic increase in the threshold amount absent the involvement of the legislature and/or the CON commission and without the opportunity for input from patients and purchasers of health insurance.

***Against:***

The bill would delete the reporting requirement for capital expenditures and single projects that were subject to Part 221; this provision both enables the state to assess the impact of changes in the law, and deters applicants from "unbundling" (separating a proposed project into components that individually do not trigger CON review).

## *POSITIONS:*

The Department of Public Health supports the bill. (6-29-93)

The Michigan Hospital Association supports the bill. (6-29-93)

The Economic Alliance for Michigan supports the bill. (6-29-93)