House Legislative Analysis Section

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CERTIFICATE OF NEED REVISION

House Bill 5145 as enrolled
Sponsor: Rep. Michael J. Bennane

House Bill 5575 as enrolled
Sponsor: Rep. Wilbur V. Brotherton

House Committee: Public Health
Senate Committe: Health Policy

Senate Bill 64 as enrolled
Sponsor: Sen. Vern Ehlers
Senate Committee: Health Policy
House Committee: Public Health

Second Analysis (1-25-89)

THE APPARENT PROBLEM:

For several years, the state's certificate of need (CON) system has been under review by a group representing providers of health care, such as hospitals, nursing homes, and doctors, major purchasers of health care, such as business and labor, and state health planners. The CON system requires health care providers to obtain the approval of state health planners before making large expenditures for new facilities, equipment, and services. The program has as an underlying assumption that controlling the supply of health facilities and services is an effective way of controlling health care costs. (It also has quality assurance and a fair allocation of resources as goals.) Even its supporters, however, agree that the CON process too often ties up hospitals and other providers in unnecessary and burdensome red tape and denies Michigan residents the use of the latest advances in medical technology, while failing to effectively control the cost of health care. Many people, particularly those in the business and labor sectors who pay much of the health care bill, are concerned about the apparent dramatic recent increases in health care costs and believe that an effective certificate of need program is essential to protect the economic health of the state. After much effort, a compromise has been reached on reforms to the CON system.

THE CONTENT OF THE BILL:

The bills constitute a package aimed at revamping the state's certificate of need program, as well as other elements in the state health planning system. The existing CON law would be repealed and replaced with a new law, although many features of the existing system would be retained. As now, decisions to grant or deny an application for a certificate of need would be made by the director of the Department of Public Health. Following is a brief outline of major changes to the CON and health planning programs.

- The threshold that determines whether a proposed capital expenditure must go through the certificate of need review process would be increased, meaning fewer expenditures would be subject to review. The current $150,000 threshold would be replaced by three separate thresholds: $750,000 for a single project involving a clinical service area (i.e., related to diagnosis, treatment, and rehabilitation of patients), to increase to $850,000 as of October 1, 1991; $1.5 million for a single project involving a nonclinical service area (e.g., renovation of physical plant), to increase to $1.7 million as of October 1, 1991; and $1.5 million for a single project involving the acquisition or utilization of nonfixed, nonmedical equipment without physical plant renovation (e.g., computers, telephones, laundry), to increase to $1.7 million as of October 1, 1991. The thresholds are contained in Senate Bill 64.
- Some proposals would be subject to review no matter what their cost. There would be no threshold for the acquisition or operation of certain new health facilities, acquiring certain kinds of medical equipment, initiating new clinical services, or for changing bed capacity. However, the package of bills would modify somewhat which facilities, equipment, services, and changes in bed capacity would be subject to CON review and which would not. Furthermore, the initial lists of covered facilities, equipment, and services could be amended (items deleted or added) by a newly created CON commission, which would be created as part of the package. Among the services that would be reviewed are: cardiac services; organ transplant services; specialized psychiatric programs (including those for geriatric, pediatric, adolescent, and substance abuse patients); special diagnostic radiological procedure rooms used for invasive procedures; radiation therapy services; neonatal intensive care and newborn nursing services, and partial day hospitalization psychiatric programs. Among the equipment that would be reviewed are: lithotripters, magnetic resonance units, mobile computerized tomography (CT) scanners, fixed CT scanners, surgical facilities, air ambulances, and positron emission tomography (PET) scanners.
- The 54-member Statewide Health Coordinating Council (SHCC) would be abolished and replaced by two separate bodies: 1) the State Health Planning Council, whose primary responsibility would be the formulation of general health policy goals and recommendations, including approval of the state health plan at least every three years; and 2) the Certificate of Need Commission, whose main responsibility would be to approve, revise, and eliminate standards for use in the certificate of need process, such as standards for determining which clinical services and medical equipment would require

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certificates and standards to be used in assessing the need for services, equipment, facilities, capital expenditures, and changes in bed capacity. (Standards currently adopted by state health regulators would stay in effect until the new standards were approved.) Standards would also be developed for designating regional review agencies, for the acquisition of new technology, for procedural rules, and the reporting of information. In adopting or revising standards, the commission would act on proposals from health department staff. The standards would be adopted outside of the usual administrative rules process. The commission would also be required to make annual assessments of the effectiveness of the CON program and at least every five years make recommendations to the legislature. (The first set of recommendations, however, would be due in four years.) House Bill 5575 contains the provisions regarding the planning council; the CON commission is created in House Bill 5145.

- The CON commission would have five members appointed by the governor with the advice and consent of the Senate. Three appointees would be from one major political party and two appointees from the other major party. The commission would be within the Department of Public Health and would be staffed jointly by the Office of Health and Medical Affairs (OHMA) and the health department. In general, the commission would be duty-bound to promote the availability of quality health services at reasonable cost and the general health objectives in the state health plan. Before taking final action on various certificate of need standards, the commission would have to hold a public hearing and also submit the proposed final action for comment to the standing committees in the House and Senate with jurisdiction over public health matters. Before a final commission approval could take effect, the proposed action would have to be submitted to the governor and, again, to the appropriate legislative committees. The governor or legislature would have 45 days to disapprove. Legislative disapproval would have to be by concurrent resolution adopted by each house. If not disapproved, a commission action would take effect. The SHCC could carry out the commission's duties for the first five months or until all the commission members were appointed, whichever came first.
- Under House Bill 5575, the new State Health Planning Council "may be created" in the executive office of the governor. It would have 24 voting members appointed by the governor with the advice and consent of the Senate, eight each to represent consumers, providers, and purchasers of health care. They would serve three-year terms, initially staggered. Four legislators would serve as non-voting representatives to the council, two appointed by the Speaker of the House and two appointed by the Senate Majority Leader. The council's duties principally are those currently assigned to the SHCC, including: preparing and approving a state health plan every three years; reviewing activities and budgets of state departments for consistency with the plan and reporting its conclusions to the governor, legislature, and others; recommending changes in statutes, policies, and budgets; evaluating the collection and use of health-related statistics; cooperate with the legislature and advise in the development of state health policy. The health council would also provide a public forum for the discussion and identification of health issues and pursue the implementation of the recommendations in the state health plan, in part by producing an annual implementation plan.

As now, the state health plan would be submitted to the governor and legislative committees with jurisdiction over public health matters, and the governor and legislature would have 60 legislative session days to disapprove the plan. Legislative action would have to be by concurrent resolution stating specific objections. The council would revise the plan based on the objections. The state health plan would be required to: discuss ways of promoting adequate access to health care for all; outline initiatives for containing health care costs and improving efficiency; address how changes in individual behavior could help reduce health care costs; promote strategies for meeting future health care needs; encourage the rational development and distribution of health care services; recommend ways of improving the quality of health care by improving delivery systems; and promote cooperation on health care policy between the public and private sectors.

The Office of Health and Medical Affairs (OHMA) would serve as staff to the new council as it has to the SHCC and, among other things, would prepare the preliminary state health plan for the planning council. As is the case now, OHMA would be designated the state health planning and health policy development agency and would be charged with advising the governor and legislature on health policy and generally promoting more informed decision-making on issues related to health care. The act being amended (much of which is obsolete due to the elimination of federal health planning programs) would also have its name altered, with "health policy" substituted for "resources." This means the act would be known as the Michigan Health Planning and Health Policy Development Act. Obsolete provisions, including those involving the relationship between state health planners and now-defunct local health systems agencies (HSAs), would be repealed. The bill would require that the act be reviewed by January 1, 1994, by the standing committee of each house of the legislature with jurisdiction over public health matters. The bill's provisions would take effect October 1, 1988.

- Regional review agencies could be designated as participants in the certificate of need process. To be designated, a regional agency would have to be an independent nonprofit organization governed by a broadly representive board made up of a majority of consumers and purchasers of health care and have demonstrated a willingness and ability to conduct reviews of all proposed projects requiring a certificate in its area. (The regions to be served would be the old health systems areas served by the now defunct health systems agencies or else regions specially designated by the Department of Public Health and Office of Health and Medical Affairs.) Two existing local review agencies would be grandparented until one year after standards for designating review agencies have been approved by the CON commission. The department and OHMA would develop the standards; designations would be made by the department. (There is no requirement that regional review agencies be designated; interested local agencies would have to apply.) Senate Bill 64 contains the regional review agency provisions.
- The number of criteria applied in CON reviews would be clarified and reduced and comparative reviews (i.e., several projects evaluated at once) would sometimes be required. An applicant would first have to satisfy the Department of Public Health that the proposed project would meet an unmet need in the area to be served and that the completed project would be geographically

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accessible and efficiently and appropriately utilized. Only if those criteria were met would other criteria be applied: that the method of meeting the need was efficient and effective; that the project was the least costly way of implementing the method, in light of the alternatives; that the project would comply with quality assurance standards and other operating standards (taking into consideration the applicant's history, when appropriate); that the facility in which the services would be provided meets viability criteria (such as occupancy rates, share of patients, operating margin, etc.); and that the governing board of the institution or its advisory board is properly constituted, with a majority of consumer representatives (if a nonprofit institution). Generally speaking, comparative review would be called for when proposed projects in combination exceed the need of the planning area, and specifically in cases involving the establishment or expansion of open heart surgery, megavoltage radiation therapy, neonatal intensive care or special newborn nursery units, extracorporeal shock wave lithotripsy services, extrarenal organ transplant services, and air ambulance services. The standards commission could develop procedures to serve as alternatives to comparative review. In comparative review, willingness to participate in the federal Medicaid program would be weighted as very important.

- The CON review appeals process would be streamlined. The decision to grant or deny a certificate (or to approve with conditions or stipulations) would be the decision of the director of the Department of Public Health. (If the review was a comparative review, one decision would cover all the proposals under review.) A bureau within the department would issue a proposed decision addressing CON criteria to the director and the applicant. The applicant would have 60 days to file written exceptions, and the bureau would have to respond in writing, in turn, within 60 days. The director would consider the proposed decision, the exceptions, and the replies, and make a final decision within 60 days. The final decision could be appealed on the record directly to the circuit court for Ingham County. (Appeals already brought under the current CON provisions would continue under those provisions.)
- A New Medical Technology Advisory Committee would be created to assist the department in identifying new technology in the earliest possible stages and put in place a procedure to allow the early use of new technology under certain circumstances and subject to certain limitations.
- Penalties for violating the CON law would be expanded, including the imposition of civil fines up to the amount billed for services provided in violation of the CON law and the imposition of refunds. Other penalties would include injunctive actions, compliance orders, and certificate revocations and suspensions.
- CON application fees would be revised. The base fee would be $750 per application, and there would be an additional fee of $2,000 for projects of over $150,000 and under $1.5 million and an additional fee (over the base) of $3,500 for projects valued at $1.5 million or more. The current fees are $691 for projects up to $150,000, and $1621 for projects above that.

House Bill 5145 would amend the Public Health Code (MCL 333.20101 et al.) to repeal the current certificate of need provisions (Part 221) and create a new CON law (Part 222). The bill contains most of the changes to the CON process. Senate Bill 64 would amend the same part of the code (MCL 333.22203 et al.), specifically to put in place the thresholds for determining which capital expenditures are subject to review, and to establish the process for designating regional review agencies. The two bills contain interlocking definitions. House Bill 5575 would amend the Michigan Health Planning and Resources Development Act (MCL 325.2001 et al.) (much of which is obsolete due to the elimination of federal health planning programs) to create the new planning council and describe the requirements of the state health plan, which generally speaking would be a policy planning document and not a document containing CON criteria. The act's name would also be changed, with "health policy" substituted for "resources." Two other bills are part of the package, House Bill 4525, which provided for a short-term nursing care or "swing bed" program; and Senate Bill 948, which exempted CON standards from the usual administrative rules process. Those bills are explained in separate analyses.

FISCAL IMPLICATIONS:

The following information was provided by the Senate Fiscal Agency:

House Bill 5145 and Senate Bill 64 together would have an indeterminate impact on state expenditures. The impact would depend on the number of CON applications filed with the DPH; the extent to which existing resources could be used; the number of CON commission meetings held; and the number of exceptions to or violations of DPH CON decisions. The DPH estimates that the bills would require an additional 9.5 FTE positions and approximately $300,000. (The current CON program budget is approximately 25.0 FTEs and $1.3 million.) Based on current CON applications and decisions, the bills would have no appreciable impact on state Medicaid Program expenditures. The bills would also increase CON application fee revenues by between $200,000 and $350,000 annually. (Currently CON application fee revenues are approximately $400,000 annually).

House Bill 5575 would result in an indeterminate reduction in expenditures related to the activities of the Statewide Health Coordinating Council (SHCC) due to the decrease in membership from 54 to 24 of the proposed State Health Planning Council. The bill would have no impact on Office of Health and Medical Affairs (OHMA) expenditures. The FY 1987-88 appropriation for OHMA, including the SHCC, is approximately $1.5 million of which more than $1.1 million is appropriated from the state general fund.

ARGUMENTS:

For:

The package of bills would revise the certificate of need process and has been developed over the past several years by representatives of health care facilities, state health agencies, business, and labor. It has been characterized as making the CON process timely, consistent, enforceable, and predictable. Even friends of the current system would not apply those adjectives to it. The package would exempt many small projects from the process entirely, would clarify standards, promote flexibility, streamline appeals, reduce litigation, close loopholes, strengthen penalties, and break down barriers to medical research. Designed and administered properly, the CON process can play an important role in restraining health care costs, guaranteeing quality services, and assuring equitable distribution of and access to health care. The package attempts to strike a balance that will allow for the meaningful regulation of new capital

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expenditures (at a time when there is an oversupply or underutilization of many health facilities) and at the same time not discourage innovation or deny Michigan residents the benefits of new advances in medical technology. The package also recognizes the demise of the old federal health planning system, with its subsidized local reviews, and provides for local review of major health facility proposals where there is strong local support (including financial support). It would create a new, smaller, health planning body, as well as a new commission to develop and regularly modify the standards used in the CON process.

Against:

In a Federal Trade Commission (FTC) study of Michigan's CON program, issued in March 1988, the FTC found that: CON programs do not result in health care cost savings, but may actually increase costs; continued CON regulation is unlikely to benefit health care consumers in the state; and, CON laws, in effect, pose a "hidden tax" on all health services in the form of higher prices and lower quality. Continued CON regulation, the FTC concluded, would be contrary to the interests of Michigan's health care consumers. Ongoing changes in the health care financing system are eliminating the principal grounds that prompted CON regulation — namely, that unregulated competition would result in the construction of unnecessary facilities, unnecessary expansion of existing facilities, or unnecessary capital expenditures by health facilities. The FTC also concluded that the CON regulatory process does not appear to serve its intended purpose of controlling health care costs and actually may defeat that purpose by interfering with competitive market forces that otherwise would help contain costs. Thus, reform of the CON process may not be enough. If the process only is to be revised and not eliminated, however, then steps should be taken to reduce the negative effects of the CON system.

Response: One could argue that the FTC report actually supports the bills, which would address the very problems that may have invoked the FTC's criticism: the cumbersome and time consuming nature of the CON process and its costs to providers and consumers. Everyone will benefit, for example, from the proposed deadlines within the approval process, and consumers as well as the health care industry would benefit from the introduction to the state of new medical technology. Also, a 24-member health planning council should operate more effectively and efficiently than the 54-member health coordinating council.