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SFA BILL ANALYSIS

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Senate Bill 1436 (Substitute S-1 as reported)
Sponsor: Senator John J. H. Schwarz, M.D.
Committee: Health Policy

Date Completed: 11-8-02

RATIONALE

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. The CON program is administered by the Department of Community Health (DCH) and by the CON Commission (which consists of five members appointed by the Governor). As provided under Part 222 of the Public Health Code, the CON program essentially requires a health facility or person to obtain a CON from the State before making large capital expenditures for 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 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.

Through the years, there have been complaints that the CON process too often tied up hospitals and other providers in unnecessary and burdensome red tape, and denied Michigan residents access to the latest advances in medical technology, while failing to control health care costs effectively. In response to these and other concerns, Part 222 has been amended numerous times. Despite these changes, many people continue to believe that the State regulations pose substantial barriers to the health care industry's ability to adjust rapidly to the health needs of the State's residents, and that Part 222 is in need of further revision.

CONTENT

The bill would amend the Public Health Code to do the following:

-- Transfer the regulation of the certificate of need program from the Department of Community Health to the Department of Consumer and Industry Services (DCIS).
-- Increase from $2 million to $2.5 million the capital expenditure threshold at which a health facility must obtain a CON before improving, constructing, or replacing a clinical service area; and increase the threshold from $3 million to $5 million for a nonclinical service area.
-- Remove from CON requirements magnetic resonance imager (MRI) services, and certain psychiatric program services.
-- Revise, and add, certain reporting requirements for the DCIS; and require the DCIS each year to review the CON application process.
-- Allow an applicant to file a single, consolidated CON application under certain conditions.
-- Require, and prescribe procedures for, the licensure of a lithotripter (a unit that uses shock waves to pulverize kidney stones).
-- Require the DCIS to review requirements for the licensure of aircraft transport vehicles.
-- Require the CON Commission, by January 1, 2004, to include in all CON review standards a requirement that each applicant participate in Title 19 of the Social Security Act (Medicaid).

Statement of Purpose

The bill states that the certificate of need program created under Part 222 of the Code "is to assure the availability and accessibility of quality health services at a reasonable cost and within a reasonable geographic proximity to all residents of this state".

CON Thresholds/Definitions

Currently, under Part 222, a "covered capital expenditure" is a capital expenditure of $2 million or more by a person for a health facility for a single project, excluding the cost of nonfixed medical equipment, that includes or involves the acquisition, improvement, expansion, addition, conversion, modernization, new construction, or replacement of a clinical service area; or a capital expenditure of $3 million or more for a nonclinical service area. The bill would increase the thresholds to $2.5 million and $5 million, respectively. The bill would retain a current requirement that the thresholds be adjusted each year for inflation.

Part 222 lists those services that are considered "covered clinical services" (and thus subject to a CON). The bill would remove from the list fixed and mobile MRI services, and partial hospitalization psychiatric program services. The bill also would remove requirements that the DCH follow specific procedures to review standards for MRI services.

Further, shock wave lithotripsy and air ambulance services currently are considered to be covered clinical services. Under the bill, shock wave lithotripsy would remain a covered clinical service until licensed under Part 132 (proposed by the bill); and air ambulance services would remain a covered clinical service until licensing requirements under Part 209 were reviewed and updated by the DCIS (as the bill would require).

The bill would remove a partial hospitalization psychiatric program from the definition of "health facility".

The bill would define "health planner" as an individual who was employed by a health facility or health system, had experience in quantitative and qualitative research and data analysis, and was responsible for long-range planning and implementation of policies, rules, and regulations mandated by State and Federal governmental agencies including, but not limited to, CON procedures.

DCIS Requirements

The bill would require the DCIS to conduct an annual review of the application process, including all forms, reports, and other materials required to be submitted with an application. If needed to promote administrative efficiency, the DCIS would have to revise the forms, reports, and materials.

Currently, the DCH is required to promulgate rules implementing its powers and duties under Part 222, and to develop proposed CON review standards for submission to the CON Commission. The bill provides that the rules would be subject to the approval of the Commission, and the standards would have to be based on recommendations submitted by an ad hoc advisory committee. (The CON Commission is required, under Part 222, to appoint ad hoc advisory committees to assist in the development of proposed CON review standards.)

The bill would require the CON Commission, by January 1, 2004, to include in all CON review standards a requirement that each applicant participate in Title 19 of the Social Security Act (Medicaid). The DCIS would have to monitor the participation in Title 19 of each CON applicant approved under Part 222. The DCIS could require each applicant to provide verification of participation in Title 19 with its application and annually thereafter. The DCIS would have to revoke a CON if its approval were based on a stipulation that the project would participate in Title 19 and the project had not participated for at least 12 consecutive months within the first two years of operation. (Currently, under these conditions, a CON ceases to be effective.) The bill also would require revocation if a project did not continue to participate annually after its first two years of operation, if CON approval were based on a stipulation that the project would participate.

Part 222 allows the DCH to monitor compliance with issued CONs. The bill instead would require the DCIS to monitor compliance with all CONs issued. Further, Part 222 contains a list of actions the DCH may take if it determines that a CON recipient is not in

compliance with the CON terms or is in violation of the provisions of Part 222 or rules; the actions may include revoking or suspending the CON, imposing fines, and taking any enforcement action authorized by the Code. The bill would require the DCIS to take one or more of the actions if it determined that the recipient of a CON was not in compliance with the terms of the CON, or was in violation of Part 222 or the rules. Further, the bill specifies that the DCIS could take any other action if determined appropriate.

Part 222 requires the DCH to prepare and publish annual reports of reviews conducted under Part 222, and prescribes the content of the reports. The bill would require the DCIS to prepare and publish the reports monthly.

The bill would require the DCIS, upon request, to provide copies of an application or part of an application, and would allow the DCIS to charge a reasonable fee for the copies.

Single Applications

The bill specifies that an applicant seeking a CON for the relocation or replacement of an existing health facility could file a single, consolidated application if the project did not result in an increase of licensed beds, or the initiation, expansion, or replacement of a covered clinical service. A person relocating or replacing an existing health facility would be subject to the applicable CON review standards in effect on the date of the relocation or replacement of the health facility. Within six months of the bill's effective date, the DCIS would have to create a consolidated application for a CON for the relocation or replacement of an existing health facility.

Final Decisions

Part 222 provides that the decision to grant or deny a CON application must be made by the DCH Director. The final decision may be appealed, only by the applicant, to the circuit court for the county where the applicant has its principal place of business, or to the Ingham County Circuit Court. The bill provides that within 30 days after the final decision of the DCIS Director, it could be appealed by the applicant, or any other person adversely affected or aggrieved by the final decision.

CON Commission

Part 222 provides for the creation, appointment, powers, and duties of the five-member CON Commission. In making appointments to the Commission, the Governor must, to the extent feasible, assure that its membership is broadly representative of the interests of all of the people of the State. The bill also would require the Governor, to the extent feasible, to assure that the membership was representative of the various geographic regions. The membership would have to include representatives of health care consumers, payers, providers, and purchasers.

Currently, the Commission, every five years, must make recommendations to the standing committees in the Senate and the House that have jurisdiction over matters pertaining to public health regarding statutory changes to improve or eliminate the CON program. The bill provides that after January 1, 2003, the Commission would have to make the recommendations every two years.

Under Part 222, the DCH must furnish administrative services to the Commission, has charge of the Commission's offices, records, and accounts, and must provide secretarial and other staff necessary to allow the proper exercise of the powers and duties of the Commission. The bill specifies that, in addition, the DCIS would have to provide at least two full-time administrative employees to the Commission. The bill also would require the DCIS to make available a brief summary of the actions taken by the Commission.

Part 222 requires the Commission to perform certain duties, including revising the covered clinical services list if necessary and revising the CON review standards. Before taking final action, the Commission must submit the proposed action to the standing committees of the Senate and the House with jurisdiction over public health matters, and to the Governor. (The Governor or the Legislature may disapprove a proposed final action.) The bill also would require the commission to submit a concise summary of the expected impact of a proposed action. The Commission would have to inform the Senate and House standing committees of the date, time, and location of the next meeting regarding the

proposed action.

In addition, the bill would require the Commission to make recommendations to the Governor and to each member of the Senate and House standing committees regarding the revision of CON application fees.

Part 222 allows the Commission to appoint a medical technology advisory committee to assist in the identification of new medical technology or new medical services that may be appropriate for inclusion as a covered clinical service. A majority of the committee must be representatives of health care provider organizations concerned with licensed health facilities or licensed health professions and other persons knowledgeable in medical technology. The Commission also must appoint representatives of health care consumer, purchaser, and third party payer organizations to the committee. The bill also would require the Commission to appoint faculty members from schools of medicine and osteopathy in the State.

Lithotripter Licensure

The bill would add Part 132 to the Code to provide for the licensure of a lithotripter, that is, a urinary extracorporeal shock wave lithotripter unit, the medical equipment that produces the shock waves for the lithotripsy procedure, including a mobile lithotripter unit. "Lithotripsy" would mean urinary extracorporeal shock wave lithotripsy, "a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract".

Beginning one year after the bill's effective date, a person or a governmental agency could not transfer, dispose of, acquire, own, possess, or operate a lithotripter to perform lithotripsy until the lithotripter was licensed with the DCIS under Part 132.

The DCIS could receive license applications for the operation of a lithotripter. Upon an applicant's compliance with the requirements of Part 132 and the rules and standards adopted under it, the DCIS could issue a license. The DCIS could not issue a license unless the applicant demonstrated a capability to provide complicated stone disease treatment on site; the applicant had a standing medical staff for the medical and administrative control of the ordering and use of the lithotripter at the hospital or health facility; and each individual who operated the lithotripter had completed a training program approved by the DCIS regarding the use of a lithotripter. Further, the operation of a lithotripter could be performed only within a hospital or health facility that provided on-call availability of an anesthesiologist and a surgeon, and provided all of the following on site:

-- Advanced cardiac life support certified personnel and nursing personnel.
-- Supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
-- General anesthesia, electrocardiogram, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.
-- Crash cart.
-- Cardiac intensive care unit or a written transfer agreement with a hospital or health facility that had a cardiac intensive care unit.
-- 23-hour holding unit.

A license would be valid for two years and could be renewed upon the timely submission of a completed application and payment of the license fee.

As determined reasonable and appropriate by the DCIS, it could promulgate rules to establish a schedule of fees to be paid by the applicants for lithotripter licenses, including a schedule of fees for the license renewal.

Within 180 days after the bill's effective date, the DCIS would have to promulgate rules to set standards for the licensure of lithotripters. The rules could provide for adoption of all or part of the standards of any professional organization the DCIS considered appropriately qualified. The DCIS could promulgate rules regarding standards for lithotripters, or could adopt standards established under Part 222.

Air Ambulance Services

Within 180 days after the bill's effective date, the DCIS would have to review the requirements of Part 209 and the rules promulgated under it for the licensure of an ambulance and an aircraft transport vehicle. (Part 209 of the Code provides for the regulation of emergency medical services in the State, including aircraft transport operations and vehicles). The bill would require the DCIS to incorporate the quality assurance standards adopted for air ambulance services under Part 222 into the requirements or rules promulgated under Part 209 for licensure of an ambulance and an air transport operation.

MCL 333.22201 et al.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The CON program regulates the health care industry in Michigan by attempting to ensure that only needed health care facilities and services are developed. To receive a certificate, an applicant must demonstrate a need for a facility, or regulated service, in a community. 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.

In the three decades that the State has had the CON program, periodically legislation has been enacted to make the program more efficient and responsive to the needs of the medical community. It is time to do so again. The CON program, as presently operated, is cumbersome and serves as a deterrent to the efficient and effective operation of the health care delivery system. 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 emphasis on cost containment.

Specifically, by raising the thresholds for capital expenditures, the bill would restructure the CON program so that it did not micro-manage hospital decision-making. A hospital's management is capable of making the medical care decisions for its own community, and should have the authority to do so. Raising the thresholds also would allow the State to focus on projects that represented potential expensive additions to health care services, by eliminating the paperwork and staff time now directed at less costly projects. Reviewing proposals to expand expensive surgical services or transplant programs, or other life-saving procedures, would be a better use of the State's resources than reviewing relatively inexpensive building renovations or utility improvements.

Supporting Argument

The bill contains several proposals to improve the efficiency of the CON program. Perhaps the most significant is the proposal to transfer administration of the program from the DCH to the DCIS. This needs to be done so that the department responsible for health occupations and facilities licensure (the DCIS) also would be responsible for CON oversight. Accomplishing this would facilitate the coordination of these activities.

Currently, the DCH must furnish administrative services to the CON Commission and provide secretarial and other staff adequate for the Commission to exercise its powers and duties. The bill would require the DCIS to provide at least two full-time administrative employees for the Commission, in addition to the other required staff. This should improve the Commission's ability to perform its duties in a timely and efficient manner.

The bill also would require the Commission to make recommendations to the Legislature every two years, rather than every five years, regarding statutory changes to improve or eliminate the CON program; and would require the Commission to review the CON application process every year. These changes would ensure that the program was subject to continual and timely review.

Currently, in appointing members to the CON Commission, the Governor must assure, to the extent feasible, that its membership is broadly representative of the interests of all the people of the State. The bill also would

require the Governor, to the extent feasible, to appoint members representing various geographic regions, and include representatives of health care consumers, payers, providers, and purchasers. These requirements would, in effect, assure geographic and occupational representation on the Commission and thus make the members more representative of the entire State and its residents.

Finally, the bill contains a statement that the CON program "is to assure the availability and accessibility of quality health services at a reasonable cost" and within a reasonable distance to all residents of Michigan. This would eliminate any ambiguity that exists or may have existed regarding the purpose of the program.

Response: Transferring the CON program from the DCH to the DCIS could be done by executive order, if it is necessary to do so at all. If the CON Commission is understaffed, this could be corrected by the Department rather than by statute.

Supporting Argument

The bill would eliminate some problems that the present CON program is causing in regard to the availability of certain care. For instance, the use of magnetic resonance imaging has become the standard of care as a diagnostic tool; that is, it is considered critical to the diagnosis of certain conditions (closed head injury, for one) in order for a physician to decide upon the proper course of treatment. If an attending doctor is unable to offer an MRI, the doctor might be at risk of a lawsuit if his or her treatment plan proves to be inadequate. Reportedly, many MRI machines run 24 hours per day, and some people have found it so difficult to obtain an MRI test in Michigan that they have traveled out of the State to get one. Many people feel that the CON process has been too restrictive in allowing providers to purchase MRI machines. Others have made the same claims regarding the availability of lithotripters, and air ambulance services. By removing MRIs, lithotripters, and air ambulances from the CON process, the bill would increase the likelihood that health care providers would purchase these tools and make them available for use.

Response: An MRI machine is expensive, and some practitioners are prone to overusing this equipment. Simply removing it from the list of covered clinical services, and thus from the purview of the CON program, could have the effect of greatly increasing the number of machines because virtually every health facility would want one in order to compete with those that have one. This could increase overall health care costs substantially. It is widely acknowledged that updating CON review standards for MRIs was delayed for too long, which probably contributed to a shortage of MRI machines; however, those standards were revised and put into place in July. It has been predicted that the new standards will allow for the addition of approximately 60 machines, bringing the total in Michigan to around 150. The impact of the new standards is not yet known, and should be measured before MRIs are removed from CON consideration.

Further, lithotripters and air ambulances should remain under the CON program. These devices serve a limited population and unchecked proliferation of either or both would increase health care costs, as a greater number of these devices would still be competing for the same small number of patients who need the services they provide. Lithotripters and air ambulances should remain on the list of covered clinical services, so that costs are contained and the quality of service is maintained.

In a broader sense, removing specific covered clinical services from the CON process, without the involvement of the CON Commission, is improper. The Commission has procedures for reviewing covered clinical services and sometimes removes a service from CON requirements. Issues involved in a CON review of a particular service are complex and technical. The public is better served by a deliberative process for reviewing services, rather than by the elimination of services through statute. If the services cited in the bill were removed from the CON process by statute, other health care specialists could be encouraged to seek individual exemptions from CON through legislation.

Opposing Argument

There is little evidence that the CON program saves money or improves access to health care. Many states that used to have CON programs have eliminated them. Health care has become a burdensome cost of doing business in Michigan. In order for the State to retain a competitive economic status, these

expenses must be brought under control. Despite 30 years of a CON program, costs for health care continue to increase at a frightening pace that far exceeds inflation. This threatens employment, wages, and benefits. Rather than once again revising the CON program, the bill should repeal the statute.

Response: Health care costs are rising all over the county, and this is precisely why the State should retain its CON program. The CON is an essential tool for the State to use in making health care affordable, accessible, and of high quality. The containment of health care costs can be seen when they are compared with the costs in states that do not have CON and thus have unregulated expansion of services. Further, unregulated expansion reduces the overall quality of health care. The more times a health professional uses certain equipment for performing a procedure or diagnosis, the better he or she becomes. Unregulated expansion of services diffuses the concentration of care; as a result each doctor performs fewer procedures. The bill would strike a proper balance by making needed changes to the current CON program while maintaining its position in the delivery of health care in the State.

Legislative Analyst: George Towne

FISCAL IMPACT

The fiscal impact is indeterminate. For FY 2002-03, the CON program is appropriated at $222,900 GF/GP ($944,000 Gross). Although the bill would require the DCIS to perform some additional duties relating to the administration of the program, it appears that sufficient dollars are available within the current appropriation to cover any additional costs.

Quantifying the impact of removing CON requirements on selected, currently covered clinical services, as proposed in this bill, is difficult. Arguments have been made in support of both sides of the issue (continuation of the CON process or removal/restructure of the CON process), all in the name of providing access to quality health care.

The CON program is a mechanism to control costs and improve the quality of health care by regulating the supply of health care services. The premise of the CON program is based on an extrapolation of Roemer's Law (a hospital bed built is a hospital bed filled -- and billed), which suggests that an increase in the supply of health care services will lead to an increase in the use of health care, independent of need.

It has been well established that the presence of third party insurance coverage has expanded the demand for health care services and made consumers insensitive to price. As a result, health care providers compete for patients on the basis of the types of services and amenities they offer, rather than their ability to provide the consumer with bargain health care. One concern raised about the removal of CON requirements for certain covered clinical services is that it would lead to excess capacity of expensive, high-technology services. An increase in capacity of these types of services, without a corresponding increase in need, could lead to a number of situations, all detrimental to health care costs and quality, such as: higher total and per-unit costs; an increase in the receipt of unnecessary health care services; decreased volume per facility/provider; and underused facilities.

On the other hand, in situations in which there are currently shortages in service capacity, removing CON requirements could result in improved access to care for some. However, this would not likely be a very efficient or effective mechanism for improving access to care. Without CON requirements, health care providers could offer services based on whether they believe a service will be profitable, not based on whether a community is in need of the particular service. Areas with a high concentration of insured individuals, such as suburban areas, could see an increase in the availability of high-technology services, potentially to the point of excess capacity. Access to care for other areas that have lower total population and/or a high proportion of publicly insured or uninsured individuals, such as rural and urban areas, would not likely be improved.

Complicating these issues is a provision in the bill that would require all CON applicants to participate in the Medicaid program. Currently, all hospitals in Michigan participate in Medicaid and would not be affected by this provision. However, a significant number of

other types of providers, such as ambulatory surgical centers (ASCs) and even a number of nursing homes, do not participate in Medicaid. Medicaid reimbursement rates are often substantially lower than private insurance reimbursement rates and once providers agree to accept Medicaid, they cannot deny care to Medicaid beneficiaries in favor of persons with private insurance. If providers believe that participating in Medicaid would not be a profitable business decision, this provision of the bill could lead to a reduction in service capacity and potentially to a lack of access to care. For example, if ASCs, which are predominately not Medicaid providers, found that in order to establish new sites or to undertake extensive capital expenditures on existing sites, they had to become Medicaid providers, there could be a reduction in the number of ASC facilities. The effect of this would be that services now provided in ASCs would have to be provided in a more costly setting (inpatient hospital) and/or service capacity would be reduced in areas where the ASCs had been located.

Fiscal Analyst: Dana Patterson

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