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SFA BILL ANALYSIS

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Senate Bill 1436 (as introduced 9-19-02)
Sponsor: Senator John J. H. Schwarz, M.D.
Committee: Health Policy

Date Completed: 9-24-02

CONTENT

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

-- Transfer the regulation of the certificate of need (CON) program from the Department of Community Health (DCH) 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.

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

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" that is issued in accordance with Part 122. To obtain an approved CON, an applicant must demonstrate to the satisfaction of the DCH that a proposed project will meet an unmet need in the area proposed to be served.

Currently, 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".

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 DCIS, before approving a CON application, to consider the applicant's participation in Title 19 of the Social Security Act (Medicaid) as a significant factor in granting the application. 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 rather than being subject to revocation.)

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 a final decision could be

appealed by the applicant, or any other person with a direct interest in the application.

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 that a concise summary of the expected impact of a proposed final action be submitted. 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 compliance by an applicant 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 licenses of lithotripters, including a schedule of fees for the renewal of licenses.

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 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 air transport operation.

MCL 333.22201 et al.

Legislative Analyst: George Towne

FISCAL IMPACT

The bill would transfer the regulation of the CON program from the DCH to the DCIS. For FY 2001-02, this program's GF/GP appropriation is $220,000 ($938,000 Gross). The bill would require the DCIS to perform some additional duties relating to the administration of the CON program; however, it appears that there are sufficient dollars available within the current appropriation to cover any additional costs.

The bill would remove CON requirements from MRI services and certain psychiatric program services. In addition, CON requirements for shock wave lithotripsy and air ambulance services would remain only until lithotripsy services became licensed and air ambulance licensure was updated (as proposed in the bill).

The CON process is a mechanism to control costs and improve the quality of health care by regulating the supply of health care services. Without the regulatory constraint of the CON on the amount of these types of services, each health care provider would have the option of offering these services as it saw fit, as long as the provider met other licensing requirements. While access to these services could improve for some, removing the CON requirements would not ensure that the services would be provided in an efficient or effective manner. The likely result would be duplication and unnecessary use of these expensive, high-technology health care services.

Fiscal Analyst: Dana Patterson

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