

STATE OF MICHIGAN

MIKE COX, ATTORNEY GENERAL

CERTIFICATE OF NEED: Certificate of need for heart transplant services

DEPARTMENT OF COMMUNITY HEALTH:

PUBLIC HEALTH CODE:

Currently there are only two approved heart, heart/lung or lung transplantation services existing in Michigan, and thus there is one available certificate of need for these services under section 4(1) of the Certificate of Need Review Standards for Heart/Lung and Liver Transplantation Services.

Opinion No. 7243

February 11, 2010

Honorable Bill Hardiman
State Senator
The Capitol
Lansing, MI

Honorable Roger Kahn, M.D.
State Senator
The Capitol
Lansing, MI

You have asked whether a certificate of need application to initiate a new heart transplant service in Michigan must be denied on the basis that approving such application would result in more than three heart transplant services in the State, which is the maximum number allowed under section 4(1) of the Certificate of Need Review Standards for Heart/Lung and Liver Transplantation Services.

The Michigan Department of Community Health (Department) reviews certificate of need requests for certain health facilities and clinical services described in Part 222 of the Public Health Code (Code), 1978 PA 368, MCL 333.22201 *et seq.*¹ Section 22209 (1)(c) of the Code

¹ Part 222 was added to the Public Health Code by 1988 PA 332, and replaced Part 221 as the chapter governing the certificate of need process.

lists activities for which certificates of need are necessary, and provides that a person shall not initiate a covered clinical service without first obtaining a certificate from the Department. MCL 333.22209(1)(c). A covered clinical service is defined to include extrarenal organ transplantation services, such as heart or heart/lung transplants. MCL 333.22203(10)(iii).²

For purposes of administering the Code, the Certificate of Need Commission (Commission) develops and approves standards for the initiation of covered clinical services. MCL 333.22215(b). The Commission has issued Certificate of Need Review Standards for Heart/Lung and Liver Transplantation Services (Review Standards), the most recent of which became effective in June 2004. Section 4(1) of the standards governing heart transplant services states that "not . . . more than three (3) heart or heart/lung or lung transplantation services" shall be approved "in the planning area," which is defined as the entire State of Michigan. See Review Standards, section 2(1)(m). This cap of three heart transplant services has existed, in some form, since the 1980s.

Information included with your request reveals that on December 26, 1986, the Department approved four applicants to provide heart transplant services – William Beaumont Hospital, Henry Ford Hospital, Detroit Medical Center,³ and the University of Michigan Hospital. The Department's approval, however, required one of the four entities to refrain from implementing its project to stay within the cap of three services. (December 26, 1986, letter

² Under the applicable review standards, "heart, heart/lung or lung transplantation" is regulated as a single service. Information included with your request indicates that the common term used for this related or combined activity is "heart transplant," which term will be used for purposes of this opinion.

³ The Detroit Medical Center's application was for the provision of services at two sites – Harper Hospital for adult transplant services, and Children's Hospital for pediatric services.

from Gloria R. Smith, Department of Public Health). Based on the materials you provided, the Detroit Medical Center did not implement its project, which allowed William Beaumont Hospital, University of Michigan Hospital, and Henry Ford Hospital to proceed with their projects.

In 1993, the Commission revised the Review Standards to provide for the approval of joint sharing arrangements between licensed sites that were not part of a single legal entity for the provision of heart transplant services.⁴ Section 4(5) was added to the standards and provided that:

(5) An application which proposes a joint sharing arrangement for a heart or heart/lung or lung transplantation service which involves more than one licensed site, where the licensed sites in the joint sharing arrangement are not part of a single legal entity authorized to do business in Michigan, *shall not be required to meet Section 4(1) of these standards*, if an applicant can demonstrate all of the following:

(i) each licensed site in the joint sharing arrangement is party to a written joint venture agreement and each licensed site has jointly filed as the applicant for the Certificate of Need;

(ii) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;

(iii) the application contains a formal plan for the sharing of services, staff and administrative functions related to the transplantation service including but not limited to: patient review, patient selection, donor organ retrieval and patient care management;

(iv) an applicant has designated a single licensed site where all of the adult transplantation procedures will be performed and a single licensed site where all of the pediatric transplantation procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;

(v) the licensed site at which the pediatric transplantation service will be provided shall have admitted or discharged at least 7,000 pediatric patients during

⁴ The standards previously provided for joint sharing arrangements only between licensed sites that were part of a single legal entity. See Standards for Heart/Lung and Liver Transplantation Services, section 3(3).

the most recent 12 month period for which verifiable data are available to the Department;

(vi) *the licensed site that is designated as the site at which adult procedures will be performed is authorized under former Part 221 or Part 222, at the time the application is submitted to the Department, to perform adult heart or heart/lung or lung transplantation services;*

(vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification; and

(viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung transplantation procedures in the second 12 months of operation following the date on which the first heart or heart/lung or lung transplant procedure is performed, and annually thereafter. [1993 Review Standards; emphasis added.]

In light of this new joint sharing arrangement provision for unrelated legal entities, section 4(1) of the standards was revised to state:

Approval of an application proposing to provide heart or heart/lung or lung transplantation services shall not result in more than three (3) heart or heart/lung or lung transplantation services in the planning area. *In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 4(5) of these standards shall be considered as a single service.* [1993 Review Standards; emphasis added.]

Accordingly, after the 1993 amendments, two separately licensed and unrelated entities could enter into a joint sharing arrangement for the provision of adult and pediatric transplant services, and receive a certificate of need to operate in such a fashion, as long as the site offering the adult services was already or would be operating under a previously issued certificate of need at the time the joint application was filed. In addition, such a joint sharing arrangement would only count as a single service for purposes of the cap, although services were to be provided at two licensed sites.

In 1996, Henry Ford Hospital, a holder of one of the original certificates approved by the Department in 1986 for the provision of adult transplant services, filed a joint application with Children's Hospital of Detroit to provide adult and pediatric transplant services through a joint sharing agreement under section 4(5) of the standards. The Department approved this arrangement, and granted a certificate of need in a letter dated October 24, 1996. The letter observes that Henry Ford was previously granted a certificate in 1986, and that subsequently the standards were revised in 1993 to allow for joint sharing arrangements. It goes on to state:

Section 4(5), specifically subsection 4(5)(vi), requires that the licensed site designated to perform adult heart transplant procedures be authorized to do so under former Part 221 or Part 222 at the time the joint sharing application is submitted to the Department. As discussed . . . above, Henry Ford Hospital presently operates an adult heart transplant program and is identified as the licensed site that will perform adult heart transplant procedures under the joint sharing agreement.

Also under the revised standards, specifically Section 4(1), only three heart, heart/lung or lung transplantation programs are allowed in the planning area (state). In the decision issued for Comparative Review No. 86-0021 on December 26, 1986, four applicants were approved to provide heart, heart/lung or lung transplantation services. Only three of those services, however, are active (William Beaumont, Henry Ford, and University of Michigan). The program at Harper Hospital has not provided services over the last 12 months and, thus, is no longer considered an approved provider for . . . services.

Approval of this application (No. 96-0010) will not result in an increase in the number of providers for heart, heart/lung or lung transplantation services in the state, and the number of providers will remain at three. [October 24, 1996, letter from James K. Haveman, Jr., Director, Department of Community Health.]

The letter further provided that, "[i]n the event the joint sharing arrangement is terminated for any reason . . . Henry Ford Hospital will continue to be authorized to perform . . . transplantation services under the provisions of its *original* Certificate of Need" *Id.* (Emphasis added.)

Thus, after the Department's approval of the joint sharing arrangement between Henry Ford and Detroit Children's Hospital in 1996, there continued to be three services in the State – William Beaumont Hospital, University of Michigan Hospital, and the new Henry Ford/Detroit Children's Hospital arrangement.

In September 2008, the Department administratively closed William Beaumont Hospital's heart transplant certificate of need because the hospital had not performed the service for a number of years.⁵ In light of this development and the circumstances described above, your question may be restated as whether, under the current Review Standards for Heart/Lung and Liver Transplantation Services, there are only two approved heart transplant services active in the State.

MCL 333.22215(1)(b) authorizes the Commission to adopt review standards by which the Department determines whether to grant a certificate of need.⁶ These standards are proposed by the Commission; reviewed by a joint legislative committee; and then submitted to the Governor and the Legislature for disapproval within 45 days of submission. MCL 333.22215(1), (3)-(4). If not disapproved, the standards become "effective and binding on all persons affected." MCL 333.22215(4). Under subsection 7(1) of the Administrative Procedures Act (APA), MCL

⁵ Section 2(f) of the review standards, in effect, provides for a certificate of need to lapse if "the service did not perform a transplant procedure during any consecutive 12-month period." In October 2009, Spectrum Health Hospital of Grand Rapids filed an application (CON ID No. 09-0228) for a certificate of need to initiate heart, heart/lung or lung transplant services.

⁶ "(1) The commission shall do all of the following: . . . (b) "Develop, approve, disapprove, or revise certificate of need review standards that establish for purposes of section 22225 the need, if any, for the initiation, replacement, or expansion of covered clinical services, . . . including conditions, standards, assurances, or information that must be met, demonstrated, or provided by a person who applies for a certificate of need." MCL 333.22215(1)(b).

24.201 *et seq*, certificate of need review standards are not considered to be rules⁷ and, therefore, need not be promulgated under the APA procedures to become "effective and binding."

Given that the review standards have the general effect of rules, in that they provide binding standards governing the issuance of certificates of need under section 22225 of the Public Health Code, MCL 333.22225, it is appropriate to apply the principles of statutory construction when seeking to determine the meaning and effect of the review standards.⁸ The first step is to review the language employed. If the language is unambiguous, it is accorded the meaning expressed. *Brown v Detroit Mayor*, 478 Mich 589, 593; 734 NW2d 514 (2007). Where the language employed is plain and unambiguous the provision must be enforced as written. *Lash v Traverse City*, 479 Mich 180, 187; 735 NW2d 628 (2007).

Since 1993, the standards governing heart transplants have been revised, most recently in 2004, but no significant changes were made to sections 4(1) and 4(5). More specifically, section 4(1) continues to impose a cap of three transplant services statewide, and provides that applications or certificates approved under section 4(5) only count as a single service for purposes of the cap:

In evaluating compliance with this subsection [relating to the cap of three] an application submitted or a certificate approved pursuant to Section 4(5) of these standards shall be considered as a single service. [2004 Review Standards.]

Similarly, section 4(5) still provides, in part, that:

⁷ Section 7(m)(ii) of the Administrative Procedures Act, MCL 24.207(m)(ii), provides that: "Rule does not include any of the following: . . . Certificate of need review standards."

⁸ "In construing administrative rules, courts apply principles of statutory construction." *Detroit Base Coalition for Human Rights of Handicapped v Dep't of Social Services*, 431 Mich 172, 185; 428 NW2d 335 (1988).

An application which proposes a joint sharing arrangement for a heart or heart/lung or lung transplantation service which involves more than one licensed site . . . shall not be required to meet Section 4(1) of these standards. [2004 Review Standards.]

These standards are clear. Section 4(5) expressly states that an application is not subject to the cap of three set forth in section 4(1) if: (1) it proposes a joint sharing arrangement for a heart transplant service; (2) it involves more than one licensed site; (3) the licensed sites are not part of a single legal entity authorized to do business in Michigan; and (4) the joint applicants meet the remaining criteria in the section. Section 4(1) makes clear that an application submitted or a certificate approved for a joint sharing arrangement under section 4(5) "shall be considered as a single service," even though the participants in the joint venture provide services at two separate locations.

In 1996, the Department granted a certificate of need to Henry Ford/Children's Hospital under section 4(5). In its letter granting the application, the Department expressly recognized that an application approved under that section counts as a single service for purposes of assessing compliance with the three-service cap set forth in section 4(1). The Department concluded that, at the time of the application by Henry Ford/Children's Hospital, there were only three active services, which included Henry Ford. The Department further determined that in granting the new certificate of need under the joint sharing agreement, the number of services remained at three. In essence, the new Henry Ford/Children's Hospital service assumed the place of the Henry Ford Hospital service.

The Department's interpretation and application of the standards in its 1996 letter is consistent with the plain language of both the 1993 and 2004 standards. The Department confirmed that since 1996, no new certificates of need for heart transplant services have been granted. The only significant change in circumstances occurred in 2008, when William Beaumont Hospital's certificate of need was closed by the Department. Because William Beaumont Hospital was one of the three holders of a certificate of need for heart transplant services, the closing of its certificate means that there is one certificate of need available for heart, heart/lung or lung transplant services.

It is my opinion, therefore, that currently there are only two approved heart, heart/lung or lung transplantation services existing in Michigan, and thus there is one available certificate of need for these services under section 4(1) of the Certificate of Need Review Standards for Heart/Lung and Liver Transplantation Services.

MIKE COX
Attorney General