

OPINIONS OF THE SUPREME COURT OF OHIO

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In re Mansfield General Hospital.

[Cite as In re Mansfield Gen. Hosp. (1995), Ohio St.3d .]  
Hospitals -- Where hospital lacks on-site open-heart surgery capabilities, its certificate of need application will be denied, and it will not be allowed to perform high-risk cardiac catheterization procedures.

Where a hospital lacks on-site, open-heart surgery capabilities, as required by Ohio Adm.Code 3701-12-25(L), its certificate of need application will be denied and it will not be allowed to perform high-risk cardiac catheterization procedures.

(No. 93-2275 -- Submitted February 8, 1995 -- Decided May 24, 1995.)

Appeal from the Court of Appeals from Franklin County, No. 93AP-330.

In August 1987, appellee, Mansfield General Hospital filed an application for a certificate of need with the Ohio Department of Health, appellant, to establish a cardiac catheterization laboratory. At that time, a certificate of need was required for all new cardiac catheterization units. The criteria then used to determine whether to grant a certificate of need were based upon the volume of cardiac catheterizations done within the particular health service area. Former Ohio Adm.Code 3701-12-25, 1982-1983 Ohio Monthly Record 1028, effective March 19, 1983. Because Mansfield General Hospital did not meet these criteria, its application was denied. However, this decision was reversed by the Certificate of Need Review Board. Based upon this ruling, Mansfield General Hospital opened its cardiac catheterization laboratory in May 1989. The court of common pleas affirmed the granting of the application on January 4, 1990. Upon further appeal, the court of appeals reversed the trial court's decision. In re Mansfield Gen. Hosp. (Sept. 20, 1990), Franklin App. No. 90AP-219, unreported, 1990 WL 135883. We overruled a motion and cross-motion to certify the record on February 20, 1991, 57 Ohio St.3d 725, 568 N.E.2d 1229.

While the case had been pending before the court of common pleas, the criteria used to evaluate a certificate of need

application had been altered so that they were no longer based only upon the volume of procedures done. Ohio Adm.Code 3701-12-25, 1988-1989 Ohio Monthly Record 845, effective February 27, 1989. Instead, they focused on whether a procedure or a patient was considered high-risk and whether the hospital met certain requirements, including having on-site, open-heart surgery capabilities. No certificate of need was required for low-risk procedures if the hospital had a certain number of beds and admissions, as did Mansfield General Hospital. R.C. 3702.51(R)(3)(b), as amended by Am.Sub.H.B. No. 332, 143 Ohio Laws, Part III, 4384, 4416, effective August 5, 1989. Because of these changes, Mansfield General Hospital filed a second certificate of need application on December 5, 1990.

On April 26, 1991, the Director of the Ohio Department of Health rejected the hospital's application on the ground that it did not possess on-site, open-heart surgery capabilities. Mansfield General Hospital appealed this decision to the Certificate of Need Review Board. The board affirmed the director's ruling on the same basis. However, the court of appeals reversed, in a two-to-one decision, and remanded to the Certificate of Need Review Board for consideration of the application. In re Mansfield Gen. Hosp. (1993), 90 Ohio App.3d 135, 628 N.E.2d 93.

The cause is now before this court upon allowance of a motion to certify the record.

Bricker & Eckler, Gretchen A. McBeath, Scott W. Taebel and James F. Flynn, for appellee Mansfield General Hospital.

Betty D. Montgomery, Attorney General, and Steven P. Dlott, Assistant Attorney General, for appellant Ohio Department of Health.

Francis E. Sweeney, Sr., J. In this case, we are asked to determine whether, in filing a certificate of need application, Mansfield General Hospital, a facility with an existing cardiac catheterization laboratory, is subject to the special review criteria contained in Ohio Adm.Code 3701-12-25. For the reasons that follow, we find that the administrative rule applies to Mansfield General Hospital's request and bars the hospital from obtaining a certificate of need. Accordingly, we reverse the judgment of the court of appeals.

First, it is important to note that Mansfield General Hospital has been providing cardiac catheterization services since May 1989. It opened its cardiac catheterization laboratory after the Certificate of Need Review Board's order approved the hospital's first application. Even though the court of appeals reversed the granting of this certificate of need, and despite the fact that material changes were made in the law in 1989, Mansfield General Hospital continued to perform cardiac catheterizations, including procedures on high-risk patients.

The changes made by the General Assembly and the Public Health Council in 1989 have altered the entire way in which certificate of need applications are reviewed. These bodies promulgated a number of statutory and regulatory reforms specifying the exact prerequisites a hospital must possess

prior to performing either high-risk cardiac catheterizations, such as angioplasties, or cardiac catheterizations on high-risk patients--those who are most likely to sustain serious complications and who may potentially need immediate surgical intervention. Ohio Adm.Code 3701-12-25, as amended in 1988-1989 Ohio Monthly Record 845, effective February 27, 1989. Among these provisions is the requirement that any hospital intending to perform therapeutic or high-risk procedures or catheterizations on high-risk patients must possess on-site, open-heart surgery facilities. Ohio Adm.Code 3701-12-25(L) (1).

Thus, firm rules have been established. To be granted a certificate of need to perform high-risk procedures, a hospital must satisfy special review criteria. These changes came about in response to public health concerns that cardiac catheterizations pose serious health risks and that if a hospital intends to perform high-risk procedures, it must be able to handle and correct any complication. Rather than focus on the frequency of cardiac catheterization procedures done within a certain area, these reforms also differentiated between degrees of risk based on patient condition and type of procedure to be performed. Low-risk procedures are used for diagnostic purposes only, whereas high-risk procedures, such as angioplasties, are invasive, therapeutic procedures. These new laws and regulations were passed to protect the lives of cardiac catheterization patients by ensuring that any hospital intending to perform high-risk procedures or procedures on high-risk patients is properly equipped to handle emergency coronary care.

Turning to the applicable statutory and regulatory rules, we begin with former R.C. 3702.51(R) (3) (b), which defines when a cardiac catheterization service is a "reviewable activity" and hence subjected to certificate of need review by R.C. 3702.53(A). Under this section, a certificate of need is required when a hospital intends to provide a "cardiac catheterization service or the addition of another cardiac catheterization laboratory to an existing service, when the service treats or will treat high-risk patients." Am.Sub.H.B. No. 332, 143 Ohio Laws, Part III, 4384, 4416. No certificate of need is required for the treatment of low-risk patients unless the health-care facility has fewer than two hundred fifty beds and had fewer than eight thousand five hundred admissions in the preceding calendar year.

In addition, a hospital's application for a certificate of need is subject to the criteria set forth in Ohio Adm.Code 3701-12-25, including the requirement under 3710-12-25(L) of having on-site, open-heart surgery capabilities. These criteria come into play if the applicant proposes to establish a new cardiac catheterization service or if it seeks to add one or more cardiac catheterization laboratories to an existing service.<sup>1</sup> Ohio Adm.Code 3701-12-25(A) (1) and (2).

The term "cardiac catheterization service" is defined as one or more cardiac catheterization laboratories. Ohio Adm.Code 3701-12-25(B) (2). Ohio Adm.Code 3701-12-25(B) (4) further defines a "cardiac catheterization laboratory" as "a room or suite of rooms in a hospital \*\*\* which has the equipment, staff, and support services to function as an

integrated unit for the purposes of performing cardiac catheterization procedures \*\*\*."

Mansfield General Hospital successfully argued in the court of appeals that since it already had a cardiac catheterization laboratory in place and since it did not intend to create a new physical facility, its certificate of need application was not governed by Ohio Adm.Code 3701-12-25(A) (1) or (2). The court of appeals agreed. It interpreted the phrase "cardiac catheterization service" in terms of physical facilities; thus, since Mansfield General Hospital was not constructing a new facility, it held that Ohio Adm.Code 3701-12-25 was inapplicable to the hospital's certificate of need application.

We flatly reject the reasoning used by the court of appeals in this case and the conclusion it reached. The phrase "cardiac catheterization service" cannot be construed so narrowly. To do so would jeopardize the health and well-being of all Ohioans faced with the need to undergo serious heart catheterization procedures. We are unwilling to allow a hospital, such as Mansfield General Hospital, to skirt its responsibilities to those in need in the absence of having open-heart surgery backup. The safety of cardiac catheterization patients should be considered utmost in the minds of hospital administrators rather than the desire to expand the hospital's pre-existing cardiac services.

Although the Mansfield area may be in need of expanded services, high-risk cardiac catheterizations are invasive procedures that may be dangerous in and of themselves or dangerous when performed on high-risk patients. In the event a complication arises, the hospital must be able to rectify the situation. If a hospital lacks appropriate backup capabilities, it cannot possibly provide the emergency treatment a seriously ill cardiac care patient must receive. We do not believe it is in the public's best interest for a hospital to take unnecessary risks on a patient where to do so could very well endanger that life. Thus, without the proper facilities to deal with life-threatening complications, a hospital's certificate of need application will be denied.

Turning to the facts at hand, it is clear from the certificate of need application that Mansfield General Hospital proposed a form of cardiac catheterization service in which it would perform high-risk procedures. The hospital listed among its objectives the need to "continue to enhance the quality and complement the scope of diagnostic and therapeutic cardiology services" and to "continue to improve the availability \*\*\* of invasive cardiographic services." (Emphasis added.) Despite these objectives, Mansfield General Hospital argues that it would exercise the authority to perform high-risk cardiac catheterizations only when it was absolutely necessary to save the life of a patient.

A hospital's stated intent to abide by the spirit of the rules is not enough. The rules were passed to be followed. According to one expert who testified on behalf of the Ohio Department of Health before the Certificate of Need Review Board, of one hundred three selected cardiac catheterizations performed at Mansfield General Hospital in a fourteen-month period (from June 1, 1991 to July 29, 1992), eighteen of these

patients, or more than seventeen percent, were deemed high-risk. Although Mansfield General Hospital may have thought it was medically necessary to treat these high-risk patients, by doing so, the hospital could have imperiled the lives of the very people it intended to help. Since the hospital does not have the capability to perform immediate coronary artery surgery as mandated by Ohio Adm.Code 3701-12-25(L) (1), the rule does not give Mansfield General Hospital carte blanche to decide under what circumstances it is medically necessary to perform such high-risk procedures. For us to do so would be against the clear mandate of these laws and regulations, which we believe were enacted to protect the health of cardiac catheterization patients.

Thus, we hold that where a hospital lacks on-site, open-heart surgery capabilities, as required by Ohio Adm.Code 3701-12-25(L), its certificate of need application will be denied and it will not be allowed to perform high-risk cardiac catheterization procedures. Since Mansfield General Hospital intended to perform high-risk cardiac catheterizations without having on-site, open-heart capabilities, its certificate of need application was properly denied by the Certificate of Need Review Board. We find that the court of appeals erred in overturning the decision of the Certificate of Need Review Board.

In view of the foregoing, the judgment of the court of appeals is reversed.

Judgment reversed.

Moyer, C.J., Douglas, Wright, Resnick and Cook, JJ., concur.

Pfeifer, J., dissents.

Footnote:

1 This section also applies to establishment of freestanding or mobile cardiac catheterization laboratories, relocation of cardiac catheterization laboratories from one health-care facility to another, and renovation or replacement activities relative to existing laboratories.

In re Mansfield General Hosp.

Pfeifer, J., dissenting. The strict adherence to complex rules lies at the very heart of the Byzantine world of certificate of need review. In this case, the Department of Health deserves a taste of its own medicine. Mansfield General Hospital seeks only to expand the treatment opportunities provided by its current cardiac catheterization service, not to construct any additional facilities. Thus, strictly speaking, Ohio Adm.Code 3701-12-25 is inapplicable to the hospital's certificate of need application. I would therefore affirm the court of appeals.