

LETTER OPINION
80-99

January 28, 1980 (OPINION)

Mr. Gene A. Christianson
Acting Administrator
North Dakota State Health Department
State Capitol
Bismarck, North Dakota 58505

RE: Department of Health v. Trinity Medical Center
Administrative No. 79-301

Dear Mr. Christianson:

This opinion is in response to your letter dated December 31, 1979, concerning the acquisition of a CT head scanner by Trinity Medical Center, Minot, North Dakota, along with the "Findings of Fact and Conclusions of Law and Order" signed by Dr. Beithon, chairman of the State Health Council and dated December 28, 1979. Your letter stated:

The State Health Council at its December 18, 1979, meeting passed a motion concerning the Trinity Medical Center case. This motion consisted of three (3) parts:

First, on the basis of the information available to the Health Council, the Council believes that there has been a violation of the certificate of need law by Trinity Medical Center in initiating CT head scanning services without submitting and having approved a certificate of need application for this service because it is our belief that: (a) CT head scanning is a health care service, (b) this service was not provided by Trinity Medical Center prior to February of 1979, (c) the cost was over \$100,000 in capital expenditures, and (d) the former whole body CT scanner application was denied by the Council on November 2, 1978.

Second, the Health Council requests that the Health Department seek appropriate action through civil court in order to determine whether or not a violation has occurred and if so, to establish the appropriate penalty, and

Third, that the Council establish findings of fact consistent with this motion.

With respect to the third part of the motion noted above, the Council subsequently passed a motion adopting seventeen (17) findings of fact to be signed by the chairman of the Council.

In accordance with the request by the Health Council, the Department herewith transmits to your office the adopted findings of fact of the Council along with evidence gathered through an administrative hearing process in order that we may proceed with appropriate action in civil court.

Should your office desire additional information or have some questions concerning the aforementioned transmittal, please feel free to contact me.

For the reasons stated below, and pursuant to chapter 54-12, N.D.C.C., litigation requested against the Trinity Medical Center on this matter is not authorized.

The basic certificate of need requirement is contained in section 23-17.2-04 of the North Dakota Century Code which provides, in part:

No hospital or related medical facility shall be constructed or expanded and no new medical care service shall be instituted after the effective date of this chapter except upon application for and receipt of a certificate of need as provided by this chapter.

This statute clearly requires a certificate of need for two, and only two, activities: (1) construction or expansion of a medical facility and (2) institution of a "new medical care service." Each type of governed activity will be addressed below.

We must first determine whether the CT head scanner acquisition involves the institution of a new medical care service. The term "new medical care service" is not now defined in the statute, so we must look to other sources for a definition.

We have reviewed the complete transcript, briefs, and exhibits in the administrative proceedings entitled Department of Health v. Trinity Medical Center, Administrative No. 79-301. Testimony illustrated a sharp conflict of opinion as to whether a CT head scanner provides a new medical care service or whether it is a technological advance within an existing medical care service, thereby substituting for and improving upon existing diagnostic techniques. It is our opinion that the more persuasive testimony explained that a CT head scanner does not provide a new medical care service.

For examples, your attention is called to the testimony of Dr. Olson, Dr. Johnson, and Mr. Snow:

Q. In your professional opinion, is this >the CT head scanner! another diagnostic tool?

A. >Dr. Olson! Yes. I would just like to amplify on that a little bit, if I may. . . .I personally do not feel that this is a new service. I think the classical medical definition of service refers to, for example, surgery, obstetrics, psychiatry, radiology, if you will. But what we are discussing is a procedure or a technique. I think any radiologist who thinks this through -- I am sure not all would agree with me, but I think the majority of them would agree this is, in essence, simply a replacement, an improvement, if you will, of an existing service. The service is radiology. The service is the professional opinion that we render regardless of what methods or means is necessary to obtain that information.

(tr. at p. 495, l. 8-24)

A. >Dr. Johnson! . . .The American College of Radiology, in 1978, did come out with a statement. . ."American College of Radiology deems CT scanning to be a refinement in image production utilizing radiant energy and tomographic principles and an extension of established radiologic methods. That the American College of Radiology opposes any statement that would define CT as a fundamentally new or substantively different service." So the American College of Radiology then distinctly opposes any statement saying that this is a new service or a different service.

Q. And you base your opinion, in part, on this statement?

A. Yes; yes.

(tr. at p. 515, l. 5-17)

A. >Mr. Snow! . . .What is a service? And there is a tremendous amount of ambiguity regarding what is a service. I believe it is essential to distinguish between services and contract services with technology, techniques or procedures.

For example, radiology is a service. CT scanning is a particular technique. . .Typically, when we talk in health planning about services, we are talking about a program such as alcoholism, psychiatry, obstetrics. That's a service.

>tr. at p. 406, l. 23 - p. 407, l.9.!

It appears that the North Dakota Supreme Court concurs that diagnostic techniques or procedures are not a medical care service for the purposes of the certificate of need statute. In *City of LaMoure v. State Health Council*, 213 N.W.2d. 869, 873 (1973), the Court stated:

Second, we believe the reference to "new medical care service" was intended to cover situations where a medical care facility was being converted to a different type of medical care, such as conversion of an old hospital into an alcoholic or psychiatric treatment center, or the like, or a situation where an existing hospital was adding new facilities or programs not covered by existing licenses from the Department of Health. This interpretation is fortified by the language of the public policy statement of the statute, found in section 23-17.2-01, subsection 2, which declares it to be the public policy of the State:

"That the general welfare and the protection of the lives, health, and property of the people of this state require that the type, level, and kind of care needed in proposed construction or expansion of services in hospitals and related medical facilities within this state be subject to

review and evaluation before commencing construction in order that proper facilities are made available for such care, that proposed new or expanded medical facilities provide, within the economic means of this state, the type, level, and kind of care necessary for the continued well-being and comfort of the patients of such hospitals and related medical facilities and to ensure that medical facilities are not constructed or services expanded which exceed the needs of patients or of persons in the area to be served." >Emphasis added.!

We interpret the reference in section 23-17.2-04 to "new medical care service" to be intended to be equivalent to the triple reference to "expansion of services in hospitals" or equivalent terms in section 23-17.2-01, subsection 2, quoted above.

Regulations of the Health Council to implement chapter 23-17.2 do not specifically cover the CT head scanner. "Health care services" as defined by R23-17.2-01.102(25) -- the regulation adopted by the Health Council on October 18, 1977, and in effect when the CT head scanner was acquired by Trinity Medical Center -- means "clinically related (i.e. diagnostic, treatment, or rehabilitative) services, and includes alcohol, drug abuse, and mental health services." The reference is to identifiable programs, not components of programs.

The second activity governed by the certificate of need statute is the construction or expansion of a hospital or related medical facility. The term "construction" is defined at section 23-17.2-02(4) to mean:

- a. The proposed construction of any facility or proposed program which would expand service or increase of bed capacity.
- b. Addition of any health service not previously provided by a health care facility or health care service. . .

Part "b" of the definition needs no further consideration since we have previously determined that the acquisition of a CT head scanner is not the addition of a health service. It is also our understanding that there was no increase in bed capacity associated with the acquisition of the CT head scanner.

The definition contained in part "a" is thoroughly confusing. It does not lend itself to a better understanding of the term "construction." Unfortunately, the definition itself uses the word being defined: "'Construction' means: The proposed construction of any facility. . ." In addition, the syntax of part "a" is not coherent.

The October 18, 1977, regulations (along with the regulations currently in effect) do not provide much assistance. They drop the word shown in brackets from section 23-17.2-02(4)(a), thereby significantly changing the definition. The regulation states: "'Construction' means. . .The proposed construction of any facility or proposed program which would expand service or increase >of! bed

capacity" >R23-17.2-01.102(12)!.

Due to the ambiguities within the statute, we will consider section 1-02-39 in determining the application of section 23-17.2-02. Section 1-02-39 reads, in part, as follows:

If a statute is ambiguous, the court, in determining the intention of the legislation, may consider among other matters:

1. The object sought to be attained.
2. The circumstances under which the statute was enacted.
3. The legislative history. . . .

The term "construction" was first defined in the 1971 act (Section 2, Ch. 263, 1971 S.L.):

"Construction" means the proposed construction of any new facility or proposed program which would expand the scope of service, or any increase of bed count. . . .

The definition of "construction" was amended in 1977 (Section 2, Ch. 227, 1977 S.L.). The redefinition contained in the legislation was not modified as it went through the legislative process. However, attempts to modify the redefinition were made in committee by the State Health Officer, the State Health Coordinating Council, and Health Department staff, but such attempts were rejected by committees of the House and Senate.

The vice chairman of the State Health Coordinating Council presented proposed amendments to the Senate Social Welfare and Veterans Affairs Committee and the House Social Welfare Committee for Senate Bill 2369. One amendment would have added the following subdivision to the definition of "construction":

- c. The purchase, lease, or acquisition of diagnostic or therapeutic equipment which:
 - (1) requires a capital expenditure in excess of one hundred thousand dollars for any one item of equipment or in excess of two hundred thousand dollars for two or more items or equipment; or
 - (2) is determined by the state department of health to be designed to circumvent the provisions of this chapter.

Letters of transmittal to the committees contained the following explanation:

In support of these amendments the following information is offered:

- 1) Major capital expenditures such as those in excess of \$100,000 are limited to include only diagnostic and therapeutic equipment.

- 2) Examples of such expenditures are currently being made for such items as Computerized Axial Tomography Whole Body Scanners whose initial >sic! cost approximate \$450,000-\$500,000, plus up to \$350,000 annual operating costs, plus approximately \$30,000 for annual service contracts, in addition to a substantial fee for modernization as new or improved components are developed.
. . .

Senate committee minutes reveal the following testimony:

Mr. Hamilton referred to "CAT scanner", cost of purchase of such being \$450,000-500,000, plus up to \$350,000 annual operating costs, also approximately \$30,000 for annual service contracts, etc.

. . .Again pointed out to committee that purchase of equipment such as CAT scanner is not covered under present law thus no control of such equipment and overlapping available. . .Felt that hospitals etc. must accept idea that some control of purchasing of extremely expensive diagnostic equipment must be made so that hospitals, clinics do not compete with each other on medical costs and care.

House committee minutes reveal the following testimony:

Mr. R. Lee Hamilton, Grand Forks, State Health Coordinating Council: As the bill is written, there is a large omission, an individual would be able to purchase equipment without any control. We are not concerned about doctors buying equipment or setting up a library, but we are concerned where people spend about \$200,000.00 on a piece of equipment. On today's market some of the equipment such as a fancy X-Ray machine for diagnostic purposes are very expensive. Costs are always escalating. . .

Mr. Gil Olson, Bismarck Q and R Clinic, North Dakota Association of Clinic Administrators: . . .The amendments are geared to the CAT Scanner. I am in favor of the bill without the amendments.

* * *

Rep. Herman Was the CAT Scanner the reason that precipitated >sic! the one part of the amendment (the one in Minot)

Answer Not really, we had two applications in Minot. It took more time. This particular amendment is based nationally to the CAT Scanner. If >sic! the Scanner went into every village, the increased cost would be in the billions of dollars and that would escalate the cost to the patient.

Rep. Haugland You solved the problem in Minot without S.B. 2369 or the amendment.

Answer I agree

* * *

Rep. Haugland References are being eluded >sic! to CAT Scanners. I am thinking of >sic! helping western North Dakota. If three or four doctors want to start a clinic, they would come under this bill.

Answer No, they would be a Diagnostic Center. This just relates to one major piece of equipment of \$100,000.00 or more, then they would come under the bill with the amendments.

The amendments proposed by the State Health Coordinating Council, apparently designed specifically for CT scanners, were rejected by both committees. Consequently, it is our opinion that the legislative history of S.B. 2369 (1977) clearly indicates that the 1977 legislation did not cover the acquisition of CT scanners by a hospital or health care facility.

It has been suggested by the Department of Health (see transcript of administrative hearing) that Policy Notice No. 78-05, issued by the Department of Health, Education and Welfare on February 3, 1978, concerning regulations implementing section 1122 of the Social Security Act >42 USC 1320a-1! provides necessary guidance to interpret the certificate of need program since the federal regulations parallel the state regulations in many respects. However, the respective laws were (1) enacted by differing governmental entities, (2) designed to accomplish differing objectives, and (3) implemented by regulations containing substantive variations.

Since the two programs are recognizably separate and distinct, policy decisions concerning the section 1122 program cannot be applied to the state certificate of need program. The state certificate of need program must be based only upon chapter 23-17.2 of the North Dakota Century Code and rules and regulations thereunder promulgated in the prescribed manner.

Your letter also relates the Health Council position that a certificate of need is required because Trinity Medical Center expended over \$100,000 for the CT head scanner. However, such position appears to be based upon a misinterpretation of chapter 23-17.2 and the regulations reflect that misunderstanding.

Section 23-17.2-05 authorizes the Health Council to adopt implementing regulations which would, among other things, establish a "dollar minimum as to the inclusion or exclusion of a proposal." But this "dollar minimum" can only relate to activities governed by the certificate of need law. Although the language of the regulation provides, among other things: "Any capital expenditure by or on behalf of a health care facility or health maintenance organization in excess of one hundred thousand dollars, including acquisition by lease or donation" is subject to a certificate of need review, it cannot be applied in areas not authorized by the Legislature.

However, it was suggested in the documents constituting the record for Department of Health v. Trinity Medical Center, Administrative

No. 79-301, that implied authority for this regulation (along with any other regulation "required for Pub. L. 93-641 purposes" but not contemplated by chapter 23-17.2 of the North Dakota Century Code) may be found in section 23-17.2-05 which provides in part:

The health council is hereby empowered to promote and execute the purposes contemplated by this chapter including but not limited to the following activities: . . .

2. The promulgation of such rules and regulations as may be required for Pub. L. 93-641 purposes.¹

¹Public Law 93-641 is the National Health Planning and Resources Development Act of 1974 (88 Stat. 2225; 42 USC Section 300k, et seq.). Section 1523, now codified as 42 USC section 300m-2 provides, in part:

Each designated State Agency of a State . . . shall . . . perform within the State the following functions: . . . administer a State certificate of need program which applies to new institutional health services proposed to be offered or developed within the State and which is satisfactory to the Secretary. Such program shall provide for review and determination of need prior to the time such services, facilities, and organizations are offered or developed or substantial expenditures are undertaken in preparation for such offering or development, and provide that only those services, facilities, and organizations found to be needed shall be offered or developed in the State.

Such a position is inconsistent with the guidance of the North Dakota Supreme Court concerning administrative regulations. The Health Council may not give interpretation to and make application of its own regulations in a manner that is inconsistent with or beyond the authority granted by the Legislature pursuant to chapter 23-17.2 merely to comply with federal guidelines or regulations. The Health Council existence and authority is governed by state law rather than federal law or regulations. Consequently, the Health Council may not adopt regulations or give interpretation to existing regulations for the purpose of governing the acquisition of CT scanners when chapter 23-17.2 does not govern the acquisition of CT scanners -- as clearly indicated by the legislative history detailed above.

Your attention is directed to *Steele v. North Dakota Workmen's Compensation Bureau*, 273 N.W.2d. 701, 692 (N.D. 1979), wherein the North Dakota Supreme Court said: "A rule may not exceed statutory authority or supersede a statute." See also, *Lanterman v. Dorgan*, 255 N.W.2d. 891, 895 (N.D. 1977), and *Medical Properties v. North Dakota Board of Pharmacy*, 80 N.W.2d. 87, 89 (N.D. 1956), in which the Court stated: "It is a basic rule of administrative law that administrative regulations which go beyond what the Legislature has authorized are void." Thus, it is our view that CT scanners were not included in the regulatory authority delegated by the Legislature.

If the Health Council has concluded the acquisition of diagnostic equipment, such as a CT scanner, should be regulated, the Council could again attempt to secure the appropriate legislature authority.

It is hoped that the foregoing will be of assistance.

Sincerely,

ALLEN I. OLSON

Attorney General