

Commonwealth Of Kentucky

Court Of Appeals

NO. 2001-CA-001486-MR

COMMONWEALTH OF KENTUCKY, CABINET
FOR HEALTH SERVICES

APPELLANT

v. APPEAL FROM FRANKLIN CIRCUIT COURT
HONORABLE ROGER L. CRITTENDEN, JUDGE
ACTION NO. 99-CI-01272

FAMILY HOME HEALTH CARE, INC.

APPELLEE

and NO. 2001-CA-001859-MR

INTEGRITY HEALTH CARE SERVICES, INC.

APPELLANT

v. APPEAL FROM FRANKLIN CIRCUIT COURT
HONORABLE ROGER L. CRITTENDEN, JUDGE
ACTION NO. 99-CI-01272

FAMILY HOME HEALTH CARE, INC.

APPELLEE

OPINION
REVERSING AND REMANDING WITH DIRECTIONS

** ** * * * * *

BEFORE: COMBS and PAISLEY, Judges; and MILLER, Special Judge.¹

COMBS, JUDGE: The Commonwealth of Kentucky, Cabinet for Health Services (Cabinet), and Integrity Health Care Services, Inc. (Integrity), have appealed the June 11, 2001, judgment of the Franklin Circuit Court reversing a final decision of the Cabinet. The Cabinet had affirmed an Advisory Opinion issued by the Certificate of Need (CON) Office which authorized Integrity to draw blood from patients in conjunction with its license to provide mobile infusion (IV) therapy services. The appellee, Family Home Health Care, Inc. (FHHC), argued that the procedure of drawing of blood is a service that exceeds the scope of Integrity's license. The Franklin Circuit Court agreed and entered judgment in favor of FHHC. After our review of the statutes and the regulatory provisions relevant to mobile health services, we believe that Integrity was indeed acting within the legitimate parameters of its license. Therefore, we reverse and remand.

Integrity and FHHC are both licensed providers of health care services. Integrity provides mobile health services. C more specifically, home infusion (IV) therapy services, as defined at 902 KAR² 20:275, Section 1 (4) and (5):

(4) AIV therapy@means the administration, by a registered nurse under the supervision of a

¹ Senior Status Judge John D. Miller sitting as Special Judge by assignment of the Chief Justice pursuant to Section 110(5)(b) of the Kentucky Constitution.

²Kentucky Administrative Regulations.

licensed physician, of various pharmaceutical and nutritional products by intravenous, subcutaneous or epidural routes.

(5) AIV therapy service@means pharmaceutical and nursing services, including direct hands-on care, limited to and necessary for the:

(a) Preparation, dispensing and delivery of pharmaceutical and nutritional products and equipment; and

(b) Related clinical consultation, training, and assessment or care incidental to initial start-up of IV therapy.

FHHC is a licensed Ahome health agency@which is defined in 902 KAR 20:081, Section 2 as follows:

a public agency or private organization, or a subdivision of such an agency or organization which provides intermittent health and health related services, to patients in their place of residence, either singly or in combination as required by a plan of treatment prescribed by a licensed physician.

Shortly after obtaining its license in November 1998, Integrity sought an advisory opinion from the CON office as to whether it needed an additional certificate of need in order to draw blood from its infusion patients. On February 22, 1999, John Gray, the Director of the CON Office, issued an advisory opinion which provided in relevant part as follows:

An additional certificate of need is not required for Integrity Health Care Services, Inc. to employ appropriately trained personnel to draw blood from their patients for the purpose of laboratory testing to provide the treating physician with information necessary to determine the appropriate dosage of the home infusion therapy medications which the patient is receiving.

After the opinion was published in the CON newsletter, FHHC requested a hearing. No evidence was presented to the Cabinet, and the matter was submitted on briefs alone. FHHC contended that the provisions of 902 KAR 20:275, Section 5 (2)(d), limited Integrity to drawing blood from its patients only at the initial start-up of the therapy program. That regulation provides:

Other treatment services, including IV therapy services, shall be performed only on the order of a physician.

1. IV therapy shall only be performed by a registered nurse and shall be limited to nursing services which are required for the initial start-up of an IV therapy program.

2. If nursing services are required which exceed the initial start-up of IV therapy, they shall be provided by an appropriately licensed agency to provide care under a physician's plan of care.

On August 30, 1999, the Cabinet rendered its opinion addressing these issues:

12. Given the fact that Integrity is already operating under a Certificate of Need, and a license as a provider of mobile health IV therapy services, and that the language of the licensure regulation for IV therapy service includes the care necessary for the ~~A~~preparation, dispensing, and delivery of pharmaceutical and nutritional products and equipment, @the Cabinet opines that drawing blood, to enable the patient's treating physician to determine the dosage that the physician is prescribing, is within the meaning of the regulation's definition of IV therapy services. See 902 KAR 20:275, Section 1(5).

13. Family Home Health counters that if the blood draw is incident to IV infusion and related to initial start-up, the service is subject to licensure as a mobile health service pursuant to 902 KAR 20:275. However, Family Home Health argues that any services beyond initial start-up of IV therapy are subject to licensure as a home health agency pursuant to 902 KAR 20:081. Consequently, Family Home Health argues that the service would be the addition of a health service subject to licensure under KRS 216B and would, therefore, be a substantial change to the health service as defined in KRS 216B.015(19).

14. Family Home Health has failed to prove that the Cabinet's February 22, 1999, Advisory Opinion reached an erroneous conclusion. The Cabinet based its decision on its interpretation of the language of 902 KAR 20:275, Section 1(5), a regulation which it promulgated. An agency's interpretation and application of its own statutes and regulations are to be afforded great weight and deference. [Citations omitted.] An adequate legal basis has been presented by Integrity and the Cabinet to support the conclusion of the Advisory Opinion dated February 22, 1999, that a Certificate of Need is not required under the circumstances herein because there has not been a substantial change in Integrity's mobile health service as defined in KRS 216B.015(19).

FHHC appealed the Cabinet's decision to the Franklin Circuit Court. In reversing the Cabinet's decision, the court determined that:

ongoing blood testing of the kind proposed by Integrity exceeds the scope of the mobile health services regulation as the additional service of drawing blood is not within the initial start-up services as set forth in 902 KAR 20:27[5], Section 1(5).

The court concluded that Integrity must obtain an additional certificate of need and license in order to draw blood from its patients for continued IV therapy treatment purposes. Both the Cabinet and Integrity filed appeals against FHHC.

The sole issue for this Court's review is whether the circuit court erred in its determination that on-going drawing of blood is a ~~A~~substantial change in a health service~~@~~as contemplated by KRS³ 216B.015(28)⁴ and whether the Cabinet misinterpreted its own regulations in ruling that Integrity could draw blood from its patients without obtaining an additional certificate of need.

When our review is one of questions of law, it is *de novo*; our standard of review, therefore, does not defer to the interpretation of the circuit court. Bob Hook Chevrolet Isuzu, Inc. v. Commonwealth, Transportation Cabinet, Ky., 983 S.W.2d 488, 490 (1998). In contrast, we note that an administrative agency's interpretation of its own regulations is entitled to substantial deference. Camera Center, Inc. v. Revenue Cabinet, Ky., 34 S.W.3d 39 (2000). A reviewing court is not free to substitute its judgment as to the proper interpretation of the agency's regulations as long as that interpretation is compatible and consistent with the statute under which it was promulgated

³Kentucky Revised Statutes.

⁴At the time this action was initiated, the language of the regulation was contained in KRS 216B.015(20). The language is now contained in KRS 216B.015(**28**). (Emphasis added). This opinion will be identified by the current cite.

and is not otherwise defective as arbitrary or capricious. City of Louisville by Kuster v. Milligan, Ky., 798 S.W.2d 454, 458 (1990).

The Cabinet is the state agency authorized by statute to administer the CON program consistent with the State Health Plan. See, KRS 216B.010. In carrying out this function, the Cabinet is required to promulgate administrative regulations ~~to~~ establish criteria for issuance and denial of certificates of need. ~~@~~ KRS 216B.040(2)(a)2. The General Assembly has established the circumstances under which a person or entity is required to obtain a certificate of need. KRS 216B.061. The specific section of the statute at issue in this case, KRS 216B.061(1)(d), provides that a licensed health provider such as Integrity must obtain a certificate of need before making ~~A~~ substantial change in a health service. ~~@~~ ~~A~~[S]ubstantial change in a health service ~~@~~ is defined at KRS 216B.015(28) as:

- (a) The addition of a health service for which there are review criteria and standards in the state health plan;
- (b) The addition of a health service subject to licensure under this chapter; or
- (c) The reduction or termination of a health service which had previously been provided in the health facility.`

The procedure of drawing blood was not specifically mentioned in the regulation defining ~~A~~IV therapy service, ~~@~~ 902 KAR 20:275(1)(5). Accordingly, the circuit court cautiously held that the procedure constituted a ~~A~~substantial change in a health

service@as contemplated by KRS 216B.061(d). However, after analyzing the language of the statute and the relevant portions of the administrative regulation, we believe that the Cabinet's more expansive interpretation of these internal contradictions more properly harmonizes with the legislature's intent in establishing the CON program.

We look for guidance to the rules of statutory construction, which dictate that we attempt to determine and then to give effect to the intent of the legislature. Commonwealth v. Gaitherwright, Ky. 70 S.W.3d 411 (2002). KRS 216B.010 sets forth a variety of reasons that caused the General Assembly to enact the CON scheme. A top priority was to enable Kentucky citizens to obtain needed health care in the most cost-efficient manner. There is no dispute in this case that it is necessary to draw blood periodically from a patient undergoing IV therapy in order to enable a treating physician to analyze the ongoing effectiveness of the treatment and to make any adjustments to the medication being infused. Under the interpretation of the regulatory scheme urged by FHHC, after an IV-therapy is commenced by Integrity, the patient would then have to be monitored by yet another medical provider (presumably a licensed home health service like FHHC). Requiring an IV therapy patient to obtain the services of another health care provider surely would result in additional costs as well as medical inconveniences -- burdening the goal of efficiency on two fronts.

FHHC does not dispute that Integrity is authorized to draw blood from its patients when commencing the intravenous drug therapy. Thus, there is no change in the scope or character of the health service that Integrity provides C much less a Asubstantial change@within the meaning of KRS 216B.061(1) and KRS 216B.015(28). At the very most, there is merely an extension or continuation of an activity that has already been properly initiated.

In construing the same statutes in Commonwealth, Cabinet for Human Resources v. Jewish Hospital Healthcare Services, Inc., Ky.App., 932 S.W.2d 388, 390 (1996), this Court held that A merely increasing the quantity@of a service already being provided (in that case, the number of cardiac catheterization labs) does not amount to a Asubstantial change in a health service.@ There is no factual dispute that drawing blood is a medical procedure that is integral and essential to the success of any IV therapy protocol; although not directly mentioned in the definition, the act of drawing blood is necessarily implied within the regulation. As we can find no conflict in the Cabinet's interpretation of its regulation with reference to KRS 216B.015(28) or KRS 216B.061, it is entitled to the deference of a reviewing court.

FHHC argues that the regulations allow Integrity to draw blood from a patient only at the start-up of IV therapy (based on the language of 902 KAR 20:275, Section 5; see infra at

p.3). This regulation provides that IV therapy must be performed by a registered nurse and that nursing services are limited to those needed for the start-up of IV therapy. However, the regulation does not require that all medical procedures incidental to the IV therapy be performed by a registered nurse.

Nor has FHHC pointed to any regulation requiring that any blood be drawn only by a registered nurse. Therefore, we do not find this argument to be persuasive -- especially in light of the Cabinet's interpretation of the totality of the regulatory process.

The judgment of the Franklin Circuit Court is reversed, and this matter is remanded with directions to re-instate the final order of the Cabinet.

ALL CONCUR.

BRIEF FOR APPELLANT
CABINET FOR HEALTH
SERVICES:

Anne Dooling Clarke
Frankfort, Kentucky

BRIEF FOR APPELLANT
INTEGRITY HEALTH CARE
SERVICES, INC.:

Robert W. Riley
Louisville, Kentucky

BRIEF FOR APPELLEE:

Marian J. Hayden
Frankfort, Kentucky