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Commonwealth of Kentucky

Court of Appeals

NO. 2009-CA-001275-MR

FLEMING COUNTY HOSPITAL DISTRICT,
D/B/A FLEMING COUNTY HOSPITAL; AND
THE KENTUCKY HOSPITAL ASSOCIATION

APPELLANTS

v. APPEAL FROM FRANKLIN CIRCUIT COURT
HONORABLE PHILLIP J. SHEPHERD, JUDGE
ACTION NO. 07-CI-02063

FLEMING REGIONAL MEDICAL IMAGING, PLLC; AND
COMMONWEALTH OF KENTUCKY,
CABINET FOR HEALTH AND
FAMILY SERVICES

APPELLEES

OPINION AFFIRMING

** ** * * * * *

BEFORE: CAPERTON, KELLER, AND LAMBERT, JUDGES.

KELLER, JUDGE: Fleming County Hospital District, D/B/A Fleming County
Hospital (the Hospital) and the Kentucky Hospital Association (the Association)

appeal from the Franklin Circuit Court's finding that Fleming Regional Medical Imaging (Medical Imaging) is exempt from the certificate of need requirements in Kentucky Revised Statutes (KRS) Chapter 216B. For the following reasons, we affirm.

FACTS

The facts, generally, are not in dispute. In January 2007, Drs. Womack, Dineen, and Crutcher formed Medical Imaging. Dr. Womack, a primary care physician, owned 55% of the entity, and Drs. Dineen and Crutcher, radiologists, owned 25% and 20% respectively. When they formed Medical Imaging, Dr. Womack practiced through Buffalo Trace Family Health Care, PSC (Buffalo Trace), an entity he owned with his partner, Dr. Lawson. Drs. Dineen and Crutcher appear to have been engaged in solo practices, reading diagnostic test films at various health-care facilities. The stated purpose of Medical Imaging was to provide MRI services to Dr. Womack's and Buffalo Trace's patients at a site adjacent and connected to Buffalo Trace.

In February 2007, Medical Imaging asked the Cabinet for Health and Family Services (the Cabinet) for an advisory opinion regarding Medical Imaging's status as a facility exempt from the certificate of need requirements. The Cabinet initially determined that Medical Imaging was not exempt because Medical Imaging had not addressed all of the factors the Cabinet deemed it was required to consider. Medical Imaging then supplemented its request and the Cabinet issued an advisory opinion stating that Medical Imaging was exempt from the certificate

of need requirements. In its second advisory opinion, the Cabinet determined that Medical Imaging was exempt based on the following information it received from Medical Imaging:

Fleming Regional Medical Imaging, PLLC is a professional limited liability company which is solely owned by two (2) licensed radiologists and a general practitioner [T]he practice would primarily provide physician services, rather than services or equipment covered by the State Health Plan MRI scans will primarily be provided to the patients whose medical conditions are treated or managed by the practice's lone general practitioner [T]he proposed services would be performed on an outpatient basis and . . . physician's [sic], all licensed to practice medicine within the Commonwealth of Kentucky, would be responsible for the decisions regarding the medical care and treatment provided to patients [T]he provision of MRI services would be related to the professional services offered to the patients of the practice and that practice will not purchase or lease medical equipment in excess of the expenditure minimum provided in 900 KAR 6:030.

The Cabinet also stated that the advisory opinion was only valid as long as "the above elements . . . [are] continually satisfied" In the event Medical Imaging modified the proposed services "in a manner that would render them inconsistent with the position set forth herein" or "[i]f any information provided to [the Cabinet] or assumptions made by [the Cabinet] [were] incorrect," the opinion would "be invalid." The Cabinet then published the advisory opinion in the April edition of "The Certificate of Need Newsletter."

The Hospital requested a public hearing regarding the advisory opinion. The matter was referred to a hearing officer who determined that Medical Imaging bore

the burden of proof because it was seeking an exemption to the certificate of need requirements.

At the hearing, Drs. Womack and Dineen testified that they, along with Dr. Crutcher, were the sole members of Medical Imaging. They did not anticipate that any other members would be added to the entity. Dr. Dineen testified that he or Dr. Crutcher would be at the facility one to two days a week. While at the facility, Drs. Dineen and Crutcher would deal with patients, if necessary, and read MRI films taken by Medical Imaging. Dr. Dineen stated that he would also, time permitting, read scans from other facilities where he practiced.

According to Dr. Womack, the MRI scanner would be housed in a building that Buffalo Trace was having renovated. In addition to housing the scanner, the building would provide office space for Drs. Dineen and Crutcher and additional space to Buffalo Trace. Although there were no leases in place, Dr. Womack anticipated that Buffalo Trace and Medical Imaging would divide the expense of the renovations and the rents proportionately.

Dr. Womack further testified he anticipated that another entity, Pinnacle Management, would own the MRI scanner and lease it to Medical Imaging and would provide the technicians to operate the scanner as well as office management; *e.g.*, scheduling, billing, etc. However, Medical Imaging had not entered into any formal agreements with Pinnacle Management regarding any of those issues.

The Hospital introduced a number of documents that indicated Medical Imaging might accept additional physician members; that it might accept Pinnacle

Management, a non-physician management company, as an additional member; and that it might share profits with Pinnacle Management. Dr. Womack testified that those issues may have been discussed but that there were no formal or informal plans to expand Medical Imaging's membership or to share its profits.

Finally, both Dr. Dineen and Dr. Womack testified that they were not "in practice" together, other than through Medical Imaging. Therefore, each would bill for medical services through his individual practice. Medical Imaging would only bill for the cost of the MRI scan.

Based on the evidence, the hearing officer found that Medical Imaging is not a private office or clinic of physicians that would be exempt from certificate of need requirements. In doing so, the hearing officer noted that the physicians would be billing through their separate entities, not through Medical Imaging; that Medical Imaging would be servicing patients from Buffalo Trace, not just from Dr. Womack; that Dr. Womack's treatment of patients through Buffalo Trace does not transfer the management of patients to Medical Imaging; and that, while Drs. Womack, Dineen, and Crutcher are the only members of Medical Imaging, there is evidence that the physicians contemplated the participation by other physicians and Pinnacle Management in Medical Imaging. The hearing officer stated that she was not concluding, as a matter of law, the MRI facility would be owned by any entity or person other than Medical Imaging. However, she noted that "the evidence of record raises a number of questions regarding the organizational format and ownership interests in [Medical Imaging] and its potential revenue." Finally, the

hearing officer noted that Medical Imaging failed to meet a number of the physician office exemption criteria set forth in 900 KAR 6:050 § 18¹ and therefore, did not meet its burden of proof.

Medical Imaging requested reconsideration. The hearing officer denied that request finding that, even if Medical Imaging did not bear the burden of proof, the evidence supported her findings.

Medical Imaging then sought review by the Franklin Circuit Court. The court first addressed the issue of burden of proof, finding that the burden should be on the party protesting the Cabinet's advisory opinion. The court then determined that Medical Imaging did qualify for the private physician office exemption to the certificate of need requirements. In doing so, the court relied primarily on this Court's opinion in *Gilbert v. Commonwealth*, 291 S.W.3d 712 (Ky. App. 2008).² As noted by the court, in *Gilbert*, this Court held that three factors are important in determining whether a facility is exempt: the ownership of the facility; the activity that takes place in the facility; and the source of patient referrals to the facility. This Court held that ownership by non-physicians would be sufficient reason to deny the exemption. Furthermore, while a physician owner need not actively practice in a facility, there must be some physician participation at the facility. Finally, this Court held that a facility would not be exempt if its patient referrals came primarily from outside the practice of the physician owner(s).

¹ In 2009, the Cabinet revised and renumbered its regulations; however, we refer and cite to the regulations as they existed at the time the underlying litigation took place.

² *Gilbert* was not final at the time the circuit court rendered its opinion. However, it has since become final.

Applying *Gilbert* to the record, the circuit court determined that Medical Imaging would provide services primarily to Dr. Womack's patients; the facility was adjacent to Buffalo Trace; physician owners would regularly be present at the facility; and Medical Imaging was entirely physician-owned. The court noted that there was some evidence that a different ownership configuration had been discussed but no evidence that any such configuration existed.

The Cabinet, the Hospital, and the Association filed a motion to alter, amend, or vacate. The court denied that motion, finding that the parties had

misconstrued the scope of the Cabinet's administrative jurisdiction by assuming that an Advisory Opinion, or any report and order issued after a public hearing on an Advisory Opinion[,] would have the effect of settling this dispute once and for all An Advisory Opinion provides a "safe harbor" for the requesting party only to the limited extent that the actual facts turn out to be the same in all material respects as the facts relied upon by the Cabinet in issuing the opinion.

Therefore, the court found

that hearings on Advisory Opinions must necessarily be confined to the question of whether the CON Office correctly applied the law to the facts *as stated*, and that the party challenging the opinion must bear the burden of proof, including both the burden of going forward and the ultimate burden of persuasion, in any subsequent hearing.

(Emphasis in original). In the event the exempt party put into place a plan that was not consistent with the facts in the advisory opinion, an affected party could seek relief through a show cause action.

The Hospital and the Association appeal from this order.³

³ In a companion but not consolidated case, the Cabinet also appealed. That appeal is addressed by separate opinion. *See Commonwealth of Kentucky Cabinet for Health and Family Services v. Fleming Regional Medical Imaging, PLLC*, 2009-CA-001318-MR.

STANDARD OF REVIEW

“The findings of fact of an administrative agency which are supported by substantial evidence of probative value must be accepted as binding by the reviewing court.” *Kosmos Cement Co., Inc. v. Haney*, 698 S.W.2d 819, 820 (Ky. 1985). Substantial evidence is that which “when taken alone or in . . . light of all the evidence . . . has sufficient probative value to induce conviction in the minds of reasonable men.” *Kentucky State Racing Comm'n v. Fuller*, 481 S.W.2d 298, 308 (Ky. 1972). “The duty of the court is to determine whether the agency misapplied the correct rule of law to the facts as found.” *Kosmos Cement Co., Inc.*, 698 S.W.2d at 820. However, as to questions of law and statutory interpretation, this Court's review is *de novo*. See *Gilbert*, 291 S.W.3d at 715-16.

ANALYSIS

Before we undertake an analysis of the issues raised by the Hospital and the Association, we first review the applicable statutory and regulatory provisions. The legislature determined that "the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth." KRS 216B.010. To prevent this proliferation of facilities, services, and equipment, and "to insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care[.]" the legislature authorized the Cabinet to perform certificate of need functions. *Id.* Those functions include approving, denying,

issuing, and revoking certificates of need; promulgating regulations to establish application and review procedures; conducting due process hearings; issuing and enforcing final determinations; and establishing a mechanism for issuing advisory opinions. KRS 216B.040. The Cabinet has authority over health facilities that provide health services. KRS 216B.015(12)-(13). However, the legislature specifically exempted "[p]rivate offices and clinics of physicians, dentists, and other practitioners of the healing arts" (with an exception that is not relevant herein) from the Cabinet's certificate of need jurisdiction. KRS 216B.020(2)(a).

To fulfill its statutory obligations, the Cabinet promulgated a number of regulations, only one of which is significant herein - 900 KAR 6:050. Section 22 of that regulation provides that, after receiving a request for an advisory opinion, the Cabinet may require verification of information submitted or request additional documentation. Upon receipt of the request and any additional information/documentation, the Cabinet has thirty days to issue its opinion. The Cabinet then is required to publish notice of the advisory opinion in the monthly certificate of need newsletter. Within thirty days thereafter, an affected party may request a public hearing regarding the advisory opinion. If no hearing is requested, the advisory opinion becomes "the final action of the cabinet."

900 KAR 6:050 § 18 provides that the Cabinet, on its own initiative or at the request of an affected person, may conduct a show cause hearing to determine if a health facility or service has been established or is operating in violation of KRS Chapter 216B. Before a show cause hearing can be held, the affected party is

required to present credible, relevant, and substantial evidence demonstrating that there is probable cause that a violation has occurred. We note that the request for a hearing following the issuance of an advisory opinion has no such requirement. Furthermore, there is nothing in the regulations, the statute, or relevant case law that permits grafting that provision from Section 18 onto Section 22.

Based on the preceding, we agree with the circuit court that the parties have misconstrued the statutory and regulatory scheme. The purpose of an advisory opinion is, as noted by the circuit court, to provide a safe harbor for the requester. A requester who is exempt from the certificate of need requirements via an advisory opinion may proceed with the planned facility without a certificate of need. However, the requester is bound to follow the plan outlined to the Cabinet in the request. A requester who deviates from the plan, for example by changing the ownership of the entity, loses that safe harbor and is subject to being called to a show cause hearing. After such a hearing, the requester may be required to obtain a certificate of need or may be found in violation of KRS Chapter 216B.

The appellants argue that this interpretation of the statutory and regulatory scheme will encourage those requesting advisory opinions to prevaricate. However, we believe the opposite is just as likely. A health-care provider, knowing that the harbor will not be safe if incomplete or inaccurate information has been provided to the Cabinet, will want to provide as much accurate information as possible. Otherwise, the provider may be in the position of having expended a substantial sum of money to establish a facility only to see it sit idle

awaiting a certificate of need ruling. Furthermore, the Cabinet, upon review of accurate and complete information, may deny the certificate of need, placing the provider in violation of KRS Chapter 216B.

Similarly, we give little credence to the argument that the Cabinet or affected parties will be hamstrung with regard to discovering facts necessary to support a show cause hearing. The parties were able to conduct a significant amount of discovery in the proceeding before the hearing officer and there is no reason to believe that any less discovery would be available in a show cause hearing. Furthermore, the appellants are at no more disadvantage than they would be if Medical Imaging had simply completed its facility and gone into operation without requesting an advisory opinion or applying for a certificate of need.

With the above in mind, we address the issues raised by the appellants.

1. Burden of Proof

The appellants argue that the circuit court incorrectly found that they bore the burden of proof. We disagree.

In support of their position, the appellants cite cases ranging from domestic violence to taxation holding that the person seeking an exemption bears the burden of proof. *See for example, Kentucky Dept. of Revenue v. Hobart Manufacturing Co.*, 549 S.W.2d 297, 299 (Ky. 1977). On the other hand, Medical Imaging has cited several cases holding that a party challenging an agency determination bears the burden of proof. *See for example, Energy Regulatory Commission v. Kentucky Power Co.*, 605 S.W.2d 46 (Ky. App. 1980). The advisory opinion process is

somewhat of an anomaly. We have not found and the parties have not cited any cases that directly address the burden of proof once a party has received a favorable advisory opinion. Thus, the cited cases, while instructive, are not directly on point.

Furthermore, we find some guidance, but nothing on point, in the regulations. 900 KAR 6:050 § 18 addresses burden of proof with regard to show cause hearings. However, Section 22 is silent on that issue with regard to advisory opinion hearings. Section 16, which regulates all hearings on certificate of need matters, does not directly address burden of proof, but it does provide the hearing officer leeway in conducting hearings and regulating the presentation of evidence.

Based on the preceding, we hold that, once a requester has received a favorable advisory opinion, an affected party seeking to challenge that opinion, bears the burden of proof. In this case, Medical Imaging, as the requester of an advisory opinion, bore the burden of proof at that stage. Once Medical Imaging obtained a favorable opinion from the Cabinet, it had nothing left to prove. The Hospital and the Association, who were seeking to alter the Cabinet's advisory opinion, had the burden of proving that opinion was faulty.

We note the appellants' argument that they were handicapped in the advisory opinion proceedings because they "had no personal knowledge about" Medical Imaging's proposed plans. However, that is not the case. The appellants, through the monthly certificate of need newsletter, had knowledge that Medical Imaging proposed opening an MRI facility. Through discovery, the appellants

determined what plans Medical Imaging submitted to the Cabinet and the basis for the Cabinet's approval of those plans. At that stage of the proceedings, no other knowledge was necessary to challenge the accuracy of the advisory opinion.

Certainly, the appellants could, as they did, challenge whether or not Medical Imaging presented a complete picture to the Cabinet. If an affected party successfully does so, the Cabinet may withdraw its advisory opinion. However, while the appellants put forth evidence that Medical Imaging contemplated changing the plans it had submitted to the Cabinet, they did not put forth any evidence that Medical Imaging had actually deviated from that plan. Therefore, they did not meet their burden of proof.

2. Whether Medical Imaging Meets the Exemption Criteria

As noted above, the Cabinet has broad powers with regard to regulating the provision of certain medical services. However, the Cabinet is not authorized to regulate "[p]rivate offices and clinics of physicians, dentists, and other practitioners of the healing arts[.]" KRS 216B.020(2)(a). Therefore, the issue is whether Medical Imaging is a private office of physicians.

In *Gilbert*, this Court addressed that issue, holding that three factors are important in determining whether a facility is exempt: the ownership of the facility; the activity that takes place in the facility; and the source of patient referrals to the facility. Medical Imaging is, unlike the facilities in *Gilbert*, wholly physician-owned. Furthermore, unlike the facilities in *Gilbert*, Medical Imaging will receive the majority of its patient referrals from one of its physician owners.

Finally, unlike the facilities in *Gilbert*, there will be physicians present at Medical Imaging a portion of the time, and those physicians will be performing services for patients; *i.e.*, reading MRI scans. Therefore, Medical Imaging meets the criteria set forth in *Gilbert* for a physician office.

The appellants argue that the circuit court's reliance on the proximity of Medical Imaging to Buffalo Trace was misplaced. In support of that argument, the appellants point to this Court's unpublished opinion, *Muhlenberg Community Hospital v. Muhlenberg Medical Properties, VI, LLC*, 2009 WL 3231265 (Ky. App. 2009) (2007-CA-002219-MR). In *Muhlenberg*, five general practice physicians and one nurse practitioner requested an advisory opinion regarding the operation of an MRI facility adjacent to their offices. The physicians and nurse practitioner indicated that they would provide medical oversight but no medical services and would take referrals from other medical practices. In analyzing the physician exemption, we indicated that a proximity analysis was simplistic. Looking not just to proximity but to the factors set forth in *Gilbert*, we determined that the facility did not meet the criteria for the physician office exemption.

However, *Muhlenberg* is distinguishable. Unlike the physician owners in Medical Imaging, none of the physician owners in *Muhlenberg* were radiologists. Unlike the facility in Medical Imaging, none of the physicians in *Muhlenberg* would have any significant actual presence at the facility. Finally, unlike Medical Imaging, the patient referrals to *Muhlenberg* would come from outside the physician owners' practice.

3. Physician Ownership of Medical Imaging

The appellants argue that Medical Imaging failed to prove that it was solely owned by physicians. However, the undisputed testimony from Drs. Dineen and Womack was that Medical Imaging had three owners, all of whom were physicians. Dr. Womack admitted that expanding the ownership had been discussed, however, no such expansion had taken place.

As noted by the circuit court, the hearing officer appears to have been persuaded by what the physicians discussed rather than by what they actually did. Whether the physicians discussed permitting Pinnacle Management or any other physicians to become members of the PLLC is not relevant, because no other members joined the PLLC. However, as noted above, if those facts change when Medical Imaging becomes a functioning facility, it faces loss of its safe harbor and may become subject to a show cause hearing.

4. Effect of Advisory Opinion on Affected Parties

The appellants ask us to clarify the advisory opinion process, specifically setting forth whether an affected party waives any rights by failing to ask for a hearing once an advisory opinion has been issued. In essence, the appellants are asking us for an advisory opinion. This we cannot give. *See Nordike v. Nordike*, 231 S.W.3d 733, 739 (Ky. 2007).

However, we can state that we agree with the circuit court that the purpose of an advisory-opinion hearing is to determine if the Cabinet correctly applied the law to the facts presented. That does not mean that the hearing is limited to that

issue. Affected parties may present evidence that the requester presented an incomplete or inaccurate picture to the Cabinet. However, the evidence must be based on actual facts as they exist, not on speculation or supposition. For example, if the appellants had evidence that Medical Imaging had actually admitted non-physician members, then that evidence would be relevant. However, the fact that the parties discussed doing so, and then rejected that idea, is of no relevance.

The issue of whether an affected party loses any rights if it fails to request a hearing is not properly before us because the affected parties did request a hearing. Therefore, we cannot address that issue.

CONCLUSION

For the foregoing reasons, we affirm the Franklin Circuit Court.

ALL CONCUR.

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