

STATE OF OHIO
DEPARTMENT OF HEALTH

OCT 10 PM
GENERAL COUNCIL

IN THE MATTER OF:

HEARING EXAMINER
WILLIAM J. KEPKO

LEBANON ROAD SURGERY CENTER
LICENSE NO. 0980 AS

HEARING DATE: SEPTEMBER 06, 2013

REPORT AND RECOMMENDATION

This matter came on for an administrative hearing as a result of a request for a hearing filed on December 03, 2012 on behalf of Lebanon Road Surgery Center ("LRSC"). The timely request for a hearing was filed in response to the Ohio Department of Health's proposed non-renewal and proposed revocation of LRSC's health care facility license to operate as an ambulatory surgical center. Appearing on behalf of LRSC were W. Martin Haskell, M.D. and Valerie Haskell. LRSC was represented by Jennifer L. Branch, Gerhardstein & Branch. Appearing on behalf of The Ohio Department of Health was Tamara Malkoff. The Ohio Department of Health was represented by Melinda Ryans Snyder and Tara L. Paciorek, Office of the Ohio Attorney General. (Hereinafter the Director of the Ohio Department of Health and the Ohio Department of Health are referred to as the "Director" and "ODH").

I. STATEMENT OF THE CASE

LRSC operates an abortion clinic in Cincinnati, Ohio. Pursuant to Ohio law, LRSC is required to be licensed by ODH. R.C. §3702.30(D). In order to be licensed, LRSC must meet certain quality standards and, pursuant to Ohio Administrative Code ("OAC") §3701-83-19(E), must have a transfer agreement. A transfer agreement is a written agreement between the facility and a hospital for transfer of patients in the event of medical complications, emergency situations and for other needs as they arise.

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In the event a facility is unable to secure a transfer agreement, Ohio law provides for a waiver or variance of the transfer agreement requirement. OAC§3701-83-14(A). In order to obtain a waiver or variance, a facility must submit a written request with ODH and provide certain information in the request including, without limitation, the reason for the waiver, the rationale behind the request and an explanation of how the facility will meet the intent of the requirement in an alternative manner. OAC §3701-83-14(B). The decision to approve or disapprove a waiver is within the sole discretion of the Director.

LRSC was initially issued a license in 2010. (State's Exhibit 4). On October 08, 2012, LRSC applied for renewal of its license to operate as a Health Care Facility (HCF)/Ambulatory Surgical Facility (ASF). (State's Exhibit 2). On October 08, 2012 LRSC also requested a variance. (State's Exhibit 3). On November 23, 2012 the Director informed LRSC that ODH intended to revoke LRSC's license on the grounds that the Director was "no longer confident that LRSC can or will, without interruption, maintain plans to provide for the timely and effective continuity of care of its patients in the event of an emergency or for other needs as they arise as required by Ohio Law and regulations." (State's Exhibit 1, pg. 2). In addition, the Director alleged that LRSC had not met its obligation to keep ODH continually updated about any changes to the variance. (Id.).

Testifying on behalf of ODH was Tamara Malkoff, W. Martin Haskell, M.D., on cross-examination, and Shannon Richey. Tamara Malkoff is employed by ODH and is Chief of the Bureau of Information and Operational Support ("BIOS") and the Division of Quality Assurance. Shannon Richey is Assistant Chief of the Bureau of Community Health Care Facilities and Services. State's Exhibits 1-25 were also admitted into

evidence. Testifying on behalf of LRSC were Roy D. Croy and W. Martin Haskell, M.D. Croy was formerly ODH's Chief of the Bureau of Community Health Care Facilities and Services. Exhibits A through Z and Exhibits AA, CC, HH, II and JJ were admitted into evidence on behalf of LRSC.

At the conclusion of the hearing, the parties, in lieu of closing arguments, agreed to a briefing schedule. The parties filed joint stipulation of facts on September 16, 2013. The parties filed simultaneous briefs on September 23, 2013 and each party filed a reply brief on September 30, 2013.

From the testimony, the exhibits that were admitted into the record and the arguments of counsel, and after a thorough review of all of the evidence, this Report and Recommendation constitutes the Hearing Examiner's Findings of Fact and Conclusions of Law as required by Chapter 119 of the Ohio Revised Code.

II. FINDINGS OF FACT

1. LRSC is located in Sharonville, Ohio, a suburb of Cincinnati, Ohio. LRSC provides surgical abortions to women.
2. Respondent Lebanon Road Medical Building, LLC owns LRSC, located at 11250 Lebanon Road, Cincinnati, Ohio. Plaintiff, W. Martin Haskell, M.D. ("Dr. Haskell") is the Medical Director of LRSC.
3. Dr. Haskell is a physician who has been licensed to practice medicine in the state of Ohio since 1974. Dr. Haskell performs surgical abortion procedures at LRSC. Dr. Haskell currently holds an affiliate staff position at Jewish Hospital.
4. Dr. Haskell is also the medical director for an affiliate ASF, Women's Med Center of Dayton.

5. ODH is a state agency established under Ohio Revised Code §121.02(G).

ODH's principal office is 246 North High Street, Columbus, Ohio 43215. Theodore E. Wymyslo, M.D. ("Director Wymyslo") is the Director of ODH. Director Wymyslo is licensed to practice medicine in the state of Ohio.

6. LRSC is an Ambulatory Surgical Facility ("ASF") as defined under Ohio Revised Code §3702.30(A)(1). Ohio Revised Code §3702.30 states:

(A) As used in this section:

(1) "Ambulatory surgical facility" means a facility, whether or not part of the same organization as a hospital, that is located in a building distinct from another in which inpatient care is provided, and to which any of the following apply:

(a) Outpatient surgery is routinely performed in the facility, and the facility functions separately from a hospital's inpatient surgical service and from the offices of private physicians, podiatrists, and dentists;

(b) Anesthesia is administered in the facility by an anesthesiologist or certified registered nurse anesthetist and the facility functions separately from a hospital's inpatient surgical service and from the offices of private physicians, podiatrists, and dentists;

(c) The facility applies to be certified by the United States health care financing administration as an ambulatory surgical center for purposes of reimbursement under Part B of the medicare program, Part B of Title XVIII of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended;

(d) The facility applies to be certified by a national accrediting body approved by the health care financing administration for purposes of deemed compliance with the conditions for participating in the medicare program as an ambulatory surgical center;

(e) The facility bills or receives from any third-party payer, governmental health care program, or other person or government entity any ambulatory surgical facility fee that is billed or paid in addition to any fee for professional services;

(f) The facility is held out to any person or governmental entity as an ambulatory surgical facility or similar facility by means of signage, advertising, or other promotional efforts.

(Id.).

7. ASFs are "Health Care Facilities" as that term is defined in Ohio Revised Code

§3702.30(A)(4). The ODH regulates and licenses Ambulatory Surgical Facilities and Health Care Facilities.

8. An ASF must renew its license on an annual basis by submitting a written application to ODH. Ohio Administrative Code rule §3701-83-04(B).

9. Ohio Administrative Code Chapter 3701-83 sets forth numerous requirements governing the operation of health care facilities, which include ASFs. Specifically, Ohio Administrative Code §3701-83-19(E) states: "The ASF shall have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations, and for other needs as they arise."

10. Pursuant to Ohio Administrative Code §3701-83-14, the Director has the authority and discretion to grant variances from any requirement set forth in OAC Chapter 3701-83, unless the requirement is mandated by statute. A variance can be granted when the requirement is met in an alternative manner. The Director's denial of a variance, whether in whole or in part, is final and does not create the right to a hearing under Ohio Revised Code Chapter 119. Each request for a variance is considered on a case-by-case basis. O.A.C. §3701-83-14(G).

11. In June, 2010 LRSC applied for an ASF license from ODH. (State's Exhibit 4).

12. At the time of its initial application for licensure, LRSC did not have a written transfer agreement with any hospital.

13. LRSC applied for a variance to the written transfer agreement requirement in September, 2010. (State's Exhibit 5).

14. On October 21, 2010 the then Director, Dr. Jackson, granted the variance request, finding that LRSC had met the written transfer agreement requirement in an

alternative way. ODH's conditional approval was four-fold:

1. The continued association with LRSC of Haskell and Kade with admitting privileges to a Cincinnati area hospital;
2. Strict adherence to the LRSC Emergency Protocol;
3. The continued provision of timely and quality back-up emergency care;
4. The provision of the letters of courtesy staff reappointments to The Jewish Hospital and The Christ Hospital, as approved by the medical staff of the respective hospitals. (State's Exhibit 6).

15. On October 21, 2010 ODH issued LRSC an ASF license. (State's Exhibit 7).

16. In August, 2011 LRSC applied for a modification of the variance, asking to substitute backup physicians Drs. Schwartz and Bowers for Dr. Haskell. (State's Exhibit 8). Dr. Schwartz had admitting privileges in obstetrics and gynecology at The Christ Hospital, and Dr. Bowers had admitting privileges in gynecology at The Christ Hospital. These privileges were verified by ODH. (States Exhibit 8, pp.2-3 and State's Exhibit 10).

17. On September 13, 2011 Director Wymyslo granted the modification to the variance and conditioned it, in part, upon the unrestricted admitting privileges of Drs. Kade, Bowers and Schwartz. (State's Exhibit 10).

18. On November 17, 2011 ODH documented, in a written protocol, operational procedures on how to process a request seeking a variance of the written transfer agreement. (Hereinafter the "November Protocol"). (State's Exhibit 11; LRSC's Exhibit B). In December, 2011 ODH notified all ASFs, including LRSC, of the written procedure. (LRSC's Exhibit A). At all times relevant, the facilities where Dr. Haskell practiced were the only ASFs which sought a variance of the written transfer

agreement.

The November Protocol stated that any variance shall not exceed the life of the requesting facility's license and shall be requested each applicable license period.

19. On February 29, 2012 Dr. Kade's reappointment status at The Christ Hospital was transferred from Courtesy Privileges to Affiliate staff status with no clinical privileges. (State's Exhibit 13).

20. In March, 2012 ODH contacted Dr. Haskell about whether Dr. Kade's privileges at The Christ Hospital had been renewed. Dr. Haskell responded the same day with a copy of the reappointment letter. (LRSC's Exhibit L, p. 2; State's Exhibit 13).

21. ODH and LRSC engaged in a dialogue regarding the extent of Dr. Kade's admitting privileges over the next two months. (LRSC's Exhibits L, O, P; State's Exhibits 14, 15, 16, 17, 18). On May 4, 2012 ODH requested Dr. Haskell to explain how he would provide continuity of care for patients in light of the change of Dr. Kade's status. (State's Exhibit 18).

22. LRSC responded by letter dated May 24, 2012 with a plan of how LRSC would provide for patient safety and continuity of care if a patient needed to be transferred to a hospital. (State's Exhibit 19). As part of that plan, LRSC notified the Department that the Facility had contracted with Drs. Schwartz, Gravely, and Hansel to provide emergency back-up services for LRSC. Dr. Schwartz, M.D. had unrestricted admitting privileges in Obstetrics and Gynecology at the Christ Hospital. Dr. Chandra Gravely, M.D. and Dr. Cynthia Hansel, M.D. had unrestricted admitting privileges in Obstetrics and Gynecology at the Bethesda North Hospital. (State's Exhibit 3).

23. ODH's last correspondence with LRSC on this matter was July 27, 2012 and

indicated that LRSC's "variance continues at the Director's discretion, and that [the facility], not ODH, have the obligation to continually update ODH as to any changes in circumstances, and to request whether the new conditions will satisfy the Director's assessment as to whether patient safety is being protected." (State's Exhibit 20).

24. LRSC must apply to renew its ASF license annually each October.

25. In October, 2012 LRSC applied to renew its ASF license. (State's Exhibit 2).

26. LRSC did not obtain a written transfer agreement with a hospital and, therefore, also renewed its request for a variance, following ODH's written protocol. (State's Exhibit 3).

27. Pursuant to the November Protocol, paragraph 7, any variance or modification of any variance that LRSC had received from ODH in the past expired in October, 2012.

28. On October 18, 2012 Bridgette C. Smith sent an e-mail to Dr. Haskell attaching a letter stating that the renewal application was approved. (LRSC's Exhibit T).

29. The same day, Bridgette C. Smith, Licensure Program Administrator with ODH, sent an e-mail to Dr. Haskell notifying him that the letter informing him that his Facility's license had been renewed had been sent in error and that the Facility's renewal application was still under review. (State's Exhibit 23).

30. On October 19, 2012 ODH proposed to issue an order refusing to renew LRSC's ASF license. (State's Exhibit 1, pp. 7-9). The Notice stated that the proposed action was based on the Facility's lack of compliance with Ohio Administrative Code §3701-83-19(E) (State's Exhibit 1, p. 7). The Notice also stated that the Facility may request a hearing concerning this proposal and, at any such hearing, evidence regarding the variance may also be presented for consideration. (State's Exhibit 1, p. 8). This letter

was sent certified mail. (State's Exhibit 1, p. 10). LRSC timely filed a notice of hearing.

31. On November 23, 2012 ODH proposed to issue an order to revoke LRSC's license. (State's Exhibit 1, pp. 1-3). The Notice stated that Director Wymyslo's proposed action was based upon the Facility's lack of compliance with Ohio Administrative Code § 3701-83-19(E). (State's Exhibit 1, p. 1). LRSC received a copy of the aforementioned Notice on November 28, 2012. (State's Exhibit 1, p. 4). The Notice also stated that the Facility may request a hearing concerning this proposal and, at such hearing, evidence regarding the variance may also be presented for consideration. (State's Exhibit 1, p. 3). LRSC timely filed a notice of hearing. (State's Exhibit 1 p. 5).

32. As of the date of the hearing, LRSC does not have a written transfer agreement as required by OAC 3701-83-19(E).

33. As of the date of the hearing, the Director has not granted LRSC a variance from the requirement of a written transfer agreement. LRSC's request for a variance is still pending with the Director. (Transcript. pp. 28 and 46).

III. LEGAL DISCUSSION

LRSC is an Ambulatory Surgical Facility ("ASF") as defined in R.C. §3702.30(A)(1)(a) and (f). OAC Chapter 3701.83 sets forth numerous requirements for the licensing of health care facilities, including ASFs. OAC§ 3701-83-19(E) requires an ASF to have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations and for other needs as they arise.

Notwithstanding the requirement for a written transfer agreement, the Director, pursuant to OAC §3701-83-14, may grant a waiver or a variance of the requirement. If

the request is for a variance, OAC §3701-83-14(B)(4) requires a statement of how the ASF will meet the intent of the requirement in an alternative manner. All variance requests are considered on a case-by-case basis. OAC §3701-83-14(G). It is solely within the Director's discretion as to whether a waiver or a variance shall be granted or denied and the Director's decision to grant or deny a variance or waiver, in whole or in part, shall be final and shall not be construed as creating any rights to a hearing under Chapter 119 of the Revised Code. OAC §3701-83-14(F).

At the administrative hearing in this case, ODH raised an issue regarding the jurisdiction of the Hearing Examiner. It is ODH's position that the only issue for adjudication, and the only issue within the Hearing Examiner's jurisdiction, is whether LRSC meets the criteria for a license to operate as an ASF. According to ODH, the variance request is not an issue for adjudication in this administrative proceeding, nor does the Hearing Examiner have jurisdiction to consider the variance or to make recommendations or conclusions regarding the variance. Consequently, since LRSC does not have a written transfer agreement, it does not meet the licensing requirements to operate as an ASF, and this Hearing Examiner must so hold.

LRSC disagrees. LRSC argues that the Hearing Examiner has the authority to issue conclusions of law holding that LRSC's emergency transfer protocol and backup doctors adequately protect LRSC's patients who need transferred to a hospital. In addition, according to LRSC, the Hearing Examiner has the authority to recommend to the Director that he grant the variance because the evidence in the record supports a variance being issued.

Both parties in this case rely on *Women's Medical Professional Corporation v. J.*

Nick Baird, 438 F.3d 595 (February 17, 2006, 6th Cir.). In *WMPC*, ODH denied *WMPC*'s request for a waiver, proposed to issue an order denying its license application and issued a cease-and-desist order requiring the clinic to close immediately. Rather than filing an administrative appeal, *WMPC* filed a complaint in the United States District Court for the Southern District of Ohio seeking a temporary restraining order ("TRO") and an injunction against enforcement of the cease-and-desist order. (Id at 598). The District Court granted *WMPC*'s motion for a permanent injunction, preventing Director Baird from enforcing the written transfer agreement requirement against the Dayton clinic. (Id.).

The 6th Circuit reversed the District Court's decision with respect to its conclusions that the application of the transfer agreement requirement (and license requirement) to the Dayton clinic constituted an undue burden and that the Dayton-area hospitals had an unconstitutional third-party veto over the Dayton clinic's license. The 6th Circuit affirmed the District Court's conclusion that Director Baird violated the plaintiffs' procedural due process rights when he ordered the clinic closed before a hearing could be held on the proposed denial of the license application. (Id. at 616).

ODH relies on a discussion in the *WMPC* case wherein the 6th Circuit Court, at pg. 615, discussed the variance and opined as follows:

Ohio law grants him (the "Director) absolute discretion when he is deciding whether to approve a waiver request. Ohio Admin. Code § 3701-83-14(D). This court has held that "a party cannot possess a property interest in the receipt of a benefit when the state's decision to award or withhold the benefit is wholly discretionary." *Med Corp., Inc. v. City of Lima*, 296 F.3d 404, 409 (6th Cir. 2002). Where "an official has unconstrained discretion to deny the benefit, a prospective recipient of that benefit can establish no more than a 'unilateral expectation' to it." *Id.* at 409-10 (quoting *Roth*, 408 U.S. at 577). Thus, *WMPC* had no property interest in the waiver and no right to due process before the waiver was denied. The district court erred

in concluding that the denial of the waiver violated *WMPC*'s right to procedural due process.

LRSC, however, cites the following language in *WMPC* at pg. 614:

Finally, the dissent takes the position that no hearing is required, either pre-deprivation or post-deprivation, because there is no material fact for resolution at a hearing. In my judgment, there is a fact issue for hearing, that is, whether Dr. Haskell's alternative arrangements for emergency treatment for his patients will adequately protect them. Director Baird's ability to exercise discretion in acting on a waiver means that he can deny the waiver after hearing, but it also means that he could grant the waiver--without departing from any regulation or any legal requirements. The decision is properly his, not ours.

In this case, LRSC argues that the record demonstrates that LRSC's alternate arrangements for backup emergency care will protect its patients and further demonstrates that LRSC has met its burden to show that it has met the written transfer requirement in an alternative manner. Therefore, in reliance on *WMPC*, LRSC argues that the Hearing Examiner should recommend to the Director that he approve the variance request.

In the *WMPC* case, the Court suggests that, after ODH denies a request for a waiver and proposes to deny and/or revoke an ASF's license, the ASF is entitled to a hearing where the fact issue will be whether the alternative arrangements for emergency treatment for the ASF's patients will adequately protect them. The *WMPC* case, however, can be distinguished from this case. In this case, the Director has not denied LRSC's request for a variance and, in fact, has not made a decision whether to grant or deny a variance. The Director's decision is pending. The Director has issued a proposed order to revoke or deny LRSC's operating license because of LRSC's failure to have a written transfer agreement. As such, what is presented for adjudication by the Hearing Examiner is the single issue of whether LRSC met the licensing

requirements at the time of its application. There is no dispute that LRSC does not have a written transfer agreement and, therefore, is not in compliance with OAC 3701-83-19.

The 6th Circuit has made clear that a decision by ODH to deny or grant a variance does not implicate a constitutionally protected property interest. The determination to deny or grant a waiver is within the exclusive discretion of the Director. As stated by the 6th Circuit, the decision (to deny or grant a waiver) is properly his, not ours. (*WMPC* at 614).

The Hearing Examiner and this proceeding have no jurisdiction to make a recommendation to grant or deny a variance when the Director has not. Borrowing language from the 6th Circuit, the decision is his, not mine. The Hearing Examiner's role is to apply the law and the regulations as they are written. OAC §3701-83-14(F) states that the refusal of the Director to grant a variance or waiver, in whole or in part, shall be final and shall not be construed as creating any rights to a hearing under Chapter 119 of the Revised Code. In this case, the facts indicate that the Director has not decided to grant or deny a variance. Without a variance, LRSC fails to meet the licensing requirements of OAC §3701-83-19(E) because it does not have a written transfer agreement.

IV. CONCLUSIONS OF LAW

1. ODH has jurisdiction over this matter.
2. The record indicates that LRSC received notice of the date, time and place of the hearing, all in accordance with law. (State's Exhibit 1).
3. LRSC, pursuant to R.C. §3702.30, is a health care facility operating as an

ambulatory surgical facility.

4. Each ambulatory surgical facility must be licensed and meet certain quality standards established by ODH. R.C. §3702.30(D).
5. The licensing provisions for health care facilities and ambulatory surgical facilities are contained in OAC Chapter 3701-83.
6. Pursuant to OAC §3701-83-19(E), an ASF must have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations and for other needs as they arise.
7. Pursuant to OAC §3701-83-14(A), the Director may grant a variance or waiver of the transfer agreement requirement.
8. Pursuant to OAC §3701-83-14(F), the refusal of the Director to grant a variance or waiver, in whole or in part, shall be final and shall not be construed as creating any rights to a hearing under Chapter 119 of the Revised Code.
9. Because LRSC does not have a written transfer agreement or a variance, LRSC does not meet the licensing requirements of R.C. Chapter 3702.83.
10. Because LRSC does not meet the licensing requirements of R.C. Chapter 3702.83, the Director's decision to not renew, or to revoke the license of LRSC, is valid.

V. RECOMMENDATION

Based on the testimony, the exhibits, the briefs submitted by the parties and, for the reasons expressed herein, it is the finding of the Hearing Examiner that the Director's proposed revocation of the licensure of Lebanon Road Surgical Center is in accordance with the rules adopted under Chapter 3701.83 of the Ohio Administrative Code and It is **THEREFORE RECOMMENDED** that the Director's October 19, 2012

proposed non-renewal of Lebanon Road Surgical Center's license and the Director's November 23, 2012 proposed revocation of Lebanon Road Surgical Center's license are valid as a matter of law.



William J. Kepko (0033613)
Hearing Examiner
October 08, 2013

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing REPORT AND RECOMMENDATION was served by certified U.S. mail, postage prepaid, return receipt requested, to the Ohio Department of Health, c/o Kaye Norton, Office of Legal Services, 246 North High Street, 7th Floor, Columbus, Ohio 43215 CMRRR# 7010.1060 0000 1762 4959, on October 08, 2013.



William J. Kepko (0033613)