STATE OF OHIO DEPARTMENT OF HEALTH

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IN THE MATTER OF:

HEARING EXAMINER GENERAL COUNSEL WILLIAM J. KEPKO

WOMENS MED CENTER OF DAYTON LICENSE NO. 0600AS

Hearing Date: April 26, 2016

REPORT AND RECOMMENDATION

This matter came on for an administrative hearing on April 26, 2016 as a result of a request for a hearing timely filed on October 23, 2015 on behalf of Women's Med Center of Dayton ("WMCD"). The request for a hearing was in response to the Ohio Department of Health's September 25, 2015 proposal to revoke and not renew WMCD's health care facility license to operate as an ambulatory surgical center. WMCD was represented by Jennifer L. Branch, Gerhardstein & Branch. Appearing on behalf of the Ohio Department of Health was Heather Coglianese. The Ohio Department of Health was represented by James T. Wakely, 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

WMCD operates a clinic in Kettering, Ohio providing pregnancy testing and abortions. Pursuant to Ohio Revised Code ("R.C.") §3702.30(D), WMCD is required to be licensed by ODH. In order to be licensed, WMCD must meet certain quality standards and, pursuant to R.C. §3702.303(A) and Ohio Administrative Code ("OAC") §3701-83-19(E), must have a written transfer agreement ("WTA"). A WTA 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.

On September 25, 2015, ODH notified WMCD that ODH proposed to revoke and not renew WMCD's health care facility license to operate as an ambulatory surgical center because WMCD did not have a WTA. On October 23, 2015 WMCD filed a timely request for a hearing regarding ODH's proposed revocation.

The hearing was held on April 26, 2016. ODH called no witnesses. ODH's Exhibits A1, A2, A3, A4, A5, A5(B) and A5(C) were admitted without objection. WMCD called Richard Hodges, Director of the Ohio Department of Health. WMCD's Exhibits 1-26 were admitted. Also admitted was Joint Exhibit A. At the conclusion of the hearing, the parties, in lieu of closing arguments, agreed to a briefing schedule. ODH filed its closing brief on May 26, 2016. WMCD filed its closing brief on June 27, 2016. ODH filed a reply on July 29, 2016. On August 04, 2016, WMCD filed a notice of supplemental authority that included the decision in *Capital Care Network of Toledo v. State of Ohio Department of Health*, COA No. L-15-1186 (Lucas County, 6th App. Dist., July 29, 2016). In the *Capital Care Network* case the Sixth District Court of Appeals held the licensing provisions in H.B. 59 unconstitutional, as contrary to the single-subject rule of the Ohio Constitution. The Sixth District Court of Appeals also found R.C. §3702.303, §3702.304 and §3727.60 unconstitutional. Fourteen days have passed and ODH has not responded to WMCD's supplemental authority.

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. WMCD is located at 1401 East Stroop Road, Kettering, Ohio. (Joint Exhibit A).
- WMCD is operated by Women's Medical Group ("WMGPC"). W. Martin Haskell,
 M.D. ("Dr. Haskell") is the sole shareholder of WMGPC and is the Medical Director of
 WMCD. (Joint Exhibit A).
- 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 WMCD and has regularly performed abortions since 1978. (WMCD Exhibit 26).
- 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. Richard
 Hodges is the Director of ODH. Mary DiOrio is the Medical Director. (Joint Exhibit A).
- 5. WMCD 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.).
- 6. 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. (Joint Exhibit A).
- 7. 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).
- 8. 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."
- 9. Pursuant to Ohio Administrative Code §3701-83-14, the Director has the authority and discretion to grant variances from the WTA requirement. A variance can be granted when the WTA 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. O.A.C. §3701-83-14(F). Each request for a variance is considered on a case-by-case basis. O.A.C. §3701-83-14(G).
- 10. WMCD had a WTA for a short time in 2002 but, since then, has never been able to obtain a WTA from a local hospital.

- 11. From July 11, 2006 through August 31, 2012, ODH approved WMCD to operate as an ASF. (WMCD Exhibit 2).
- 12. On February 14, 2008, ODH denied WMCD's request for a variance. The basis for the denial was that the names of the members of the group of physicians that committed to assume responsibilities for the patients were not identified. (WMCD Exhibit 3).
- 13. On February 28, 2008, WMCD supplemented its variance request by submitting the name of three physicians who had admitting privileges at Miami Valley Hospital. (WMCD Exhibit 3).
- 14. On March 04, 2008, Alvin D. Jackson, M.D., ODH's Director at the time, granted WMCD a conditional variance and found that WMCD had met the written transfer agreement requirement in an alternative way. (WMCD Exhibit 4).
- 15. On August 24, 2012, ODH notified WMCD that its conditional variance would expire at the end of WMCD's license term and, if an additional variance was needed, to submit a variance request as soon as possible. ODH also attached a variance protocol listing the factors that ODH would consider when evaluating a variance request. (WMCD Exhibit 5).
- 16. On August 27, 2012, WMCD, through counsel, submitted a request for a variance of the written transfer agreement requirement. (WMCD Exhibit 6). In the request for a variance, WMCD provided a contract with three physicians who had admitting privileges in Gynecology at Miami Valley Hospital in Dayton, Ohio.
- 17. On November 20, 2013, WMCD supplemented its variance request and provided information to ODH that was required by HB 59. (WMCD Exhibit 7). In the

supplemented variance request, WMCD proposed to satisfy the written transfer agreement requirement by utilizing backup physician services through Wright State Women's Physicians Health Care ("WSWPHC") that had admitting privileges in Gynecology at Miami Valley Hospital in Dayton, Ohio.

- 18. On July 25, 2014, WMCD submitted a written request for a variance. (WMCD Exhibit 8). In the July 25, 2014 request, WMCD proposed to satisfy the written transfer agreement requirement by providing backup physician services with WSWPHC and two physicians who are members of Wright State Physicians Obstetrics & Gynecology. (WMCD Exhibit 8). WMCD's August 27, 2012 request for a variance and WMCD's November 30, 2012 supplemental request for a variance were still pending. (WMCD Exhibit 8).
- 19. On June 25, 2015, ODH denied WMCD's variance requests for the 2012, 2013 and 2014 license periods. (WMCD Exhibit 10). The Director denied the 2013 and the 2014 variance requests because they did "not meet the department's expectation for 24/7 back-up coverage and uninterrupted continuity of care, as a WTA with a hospital would provide." (WMCD Exhibit 10).
- 20. On July 24, 2015, WMCD submitted a request for a variance of the written transfer agreement requirement for the 2014 and 2015 licensure periods. (WMCD Exhibit 9). The July 24, 2015 variance request added a third back-up physician. The July 24, 2015 variance request also provided back-up coverage through Wright State Physicians Obstetrics & Gynecology and Wright State Physicians Women's Health Care. The July 24, 2015 variance request also indicated that Miami Valley Hospital would continue to treat any and all patients presenting to the hospital's emergency

room. (WMCD Exhibit 9).

- 21. On July 31, 2015, ODH received a letter from Mark Shaker, President and CEO of Miami Valley Hospital ("MVH"). (WMCD Exhibit 16). In the letter, MVH objected to the use of its name in any backup physician services agreement between WMCD and certain physicians. MVH also requested that its name and all references to MVH be removed and MVH reiterated to ODH that MVH does not have a backup agreement with WMCD. (WMCD Exhibit 16).
- 22. On September 25, 2015, ODH denied WMCD's 2012, 2013, 2014 and 2015 variance requests. (WMCD Exhibit 11). In part, the denial was based on the objections ODH received from MVH and ODH's concerns that the objections could jeopardize WMCD's backup physician services agreement or lead to a change in the physician's admitting privileges at MVH. (WMCD Exhibit 11). In the September 25, 2015 variance denial, ODH also notified WMCD that the denial of WMCD's application for a variance was final and did not give any rights to a hearing under Chapter 119 of the Ohio Revised Code. (WMCD Exhibit 11).
- 23. On September 25, 2015, ODH issued an order proposing to revoke and not renew WMCD's health care facility license to operate as an ambulatory surgical facility. (WMCD Exhibit 12). The reason for the proposed revocation and non-renewal was that WMCD did not have a written transfer agreement with a local hospital and was not in compliance with R.C. §3701.303 of OAC §3701-83-19(E). (WMCD Exhibit 12). The proposed order also advised WMCD of its right to a hearing and explained the procedure for requesting a hearing. (WMCD Exhibit 12).
- 24. On October 22, 2015, WMCD timely requested a hearing regarding ODH's

proposed revocation and non-renewal. (WMCD Exhibit 21).

- 25. On January 19, 2016, and March 7, 2016, ODH notified WMCD of the date, time and location of the hearing. (ODH Exhibits A4 and A5).
- 26. The hearing in this matter was held on April 26, 2016. All parties were present with counsel. In lieu of closing arguments, the parties filed post-hearing briefs. Briefing was completed on July 29, 2016.
- 27. On August 04, 2016, WMCD filed a notice of supplemental authority that included the decision in *Capital Care Network of Toledo v. State of Ohio Department of Health*, COA No. L-15-1186 (Lucas County, 6th App. Dist., July 29, 2016). In the *Capital Care Network* case the Sixth District Court of Appeals held the licensing provisions in H.B. 59 unconstitutional, as contrary to the single-subject rule of the Ohio Constitution. At the time of the writing of this Report and Recommendation, the time period to appeal the decision in the *Capital Care Network* case has not expired.

III. <u>LEGAL DISCUSSION</u>

WMCD 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. R.C. §3702.303(A) and OAC §3701-83-19(E) require 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 R.C. §3702.304(A) and OAC §3701-83-14, may grant 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, there were extensive arguments as to the scope of review and the jurisdiction of the Hearing Examiner. ODH argued that the only issue for adjudication, and the only issue within the Hearing Examiner's jurisdiction, is whether WMCD had a transfer agreement as required by R.C. §3702.303. According to ODH, because of the finality language in OAC §3701-83-14(F), 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 as to whether WMCD met the requirements of a WTA in an alternative manner. Consequently, since WMCD 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.

WMCD argues that the Hearing Examiner has the authority to issue findings of fact and conclusions of law holding that WMCD's emergency transfer protocol and backup doctors adequately protect WMCD's patients who need transferred to a hospital. In addition, according to WMCD, 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.

At the hearing, this Hearing Examiner, relying on OAC §3701-83-14(F), ruled that he had no jurisdiction to make a recommendation to grant or deny a variance. The decision to grant a variance lies within the sole discretion of the Director and the Director's decision to grant a variance or not is final and does not give rise to any rights to a hearing under Chapter 119 of the Revised Code. OAC §3701-83-14(F). The Hearing Examiner also gave wide discretion and latitude to WMCD to proffer any evidence regarding the issue in order to preserve WMCD's appeal rights.

IV. CONCLUSIONS OF LAW

- 1. ODH has jurisdiction over this matter.
- 2. The record indicates that WMCD received notice of the date, time and place of the hearing, all in accordance with law. (State's Exhibits A4 and A5).
- 3. WMCD, 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 R.C. §3702.303(A) and 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 R.C. §3702.304(A) and OAC §3701-83-14(A), the Director may grant a variance or waiver of the transfer agreement requirement.

- 8. Pursuant to R.C. §3702.304(C) and 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.
- Because WMCD does not have a written transfer agreement or a variance,
 WMCD does not meet the licensing requirements of OAC Chapter 3701.83.
- 10. Because WMCD does not meet the licensing requirements of OAC Chapter 3701.83, the Director's decision to not renew, or to revoke, the license of WMCD, 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 Women's Medical Center of Dayton 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 September 25, 2015 proposed revocation and refusal to renew Women's Medical Center of Dayton's health care facility license are valid as a matter of law.

William J. Kepko (0033613) Hearing Examiner August 29, 2016

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# 7015 1730 0001 1147 8257 on August 29, 2016.

William J. Kepko (0033613)