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OF
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HEALTH DEPARTMENT

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Ohio Department of Health
Theodore E. Wymyslo MD, Director
246 N High Street
Columbus, OH 45215

May 19, 2011

Reference: Transfer Waiver Agreement #0980AS -- OHL41447 – Lebanon Road Surgery Center

Dear Dr. Wymyslo,

The Sharonville Health District (SHD) objects to the Transfer Waiver/Variance granted on October 21, 2010 for the ODH Variance request submitted by the Lebanon Road Medical Center, LLC; dba Lebanon Road Surgery Center; as an Ambulatory Surgical Facility (ASF). It is the belief of the Sharonville Board of Health that this waiver/variance was improperly granted and compromises the health, safety and welfare of the general public.

It is the belief of the SHD that there are serious flaws in the waiver/variance process that are, in part, a direct result of incorrect and/or missing information that was provided by the applicant; and, in part, by the actions and/or assumptions of the ODH.

It is the belief of the SHD that OAC 3701-83-14 (A) Waivers/Variations are to be limited to "any building or safety requirement, unless the requirement is mandated by statute" and an ASF is required to provide a valid Ambulatory Transfer agreement, or all Physicians of the ASF are required to have admitting privileges at a local qualified hospital. However, there appear to be publicized 4 physicians to perform surgery by this ASF and only two of those physicians, Dr Martin Haskell and Dr Roslyn Kade, have submitted hospital privileges to the ODH.

It is the belief of the SHD that exterior signage does not indicate a surgery center, now or at the time of the 10-7-2010 survey by the ODH (Exhibit A), and this is an EMS Safety issue. The ASF appears to be operating under multiple names, which the SHD believes to be improper and confusing to the public. (Exhibit B2, B3)

It is the belief of the Sharonville Health District that the following issues exist, and the collective sum of these issues fail to meet the spirit and intent of Federal and State Laws, and Administrative Codes that pertain to ASF's. These are the very Laws and Regulations that have been created to protect consumers from intrastate and interstate fraud and abuse.

1. The waiver/variance request was received by ODH on 9/27/2010 as Certified Mail (Exhibit C2). It was processed in an expedited manner and license was issued on 10/21/2010 (Exhibit C5,C6). However, the DQA Certification and Licensure division of the ODH approved the ASF for initial inspection on 9/17/2010 (Exhibit C1), which is 10 days prior to receipt of the Waiver/Variance request. (see Exhibit C3). A Time Line of the entire process is attached (Exhibit C8).

2. The Transfer Waiver/variance states that it is based on hospital privileges for Drs Haskell & Kade (Exhibit D1-D6), and yet there are 4 Physicians presented to the public (Exhibits B1,B2). The following has been found:
 - a. Dr. Martin Haskell, courtesy privileges in Family Medicine at Jewish Hospital Cincinnati (Exhibit D1)
 - b. Dr. Roslyn Kade, admitting privileges in Family Practice at Christ Hospital Cincinnati (Exhibit D2-D6)
 - c. Dr. Neil Richard Strickland, was not identified to ODH by applicant, has not submitted hospital privileges to ODH, was named on the ASF signage and website, and was a part of the ASF at time of ODH Survey. (Exhibit B1)
 - d. Dr. Ronald Norman Yeomans, was not identified to ODH by applicant, has no hospital privileges in Cincinnati, does not have a valid Ohio Medical license, and is represented on the ASF website in the forms "Referring Physician Information" and "Consent to Medical Services, Surgery & Anesthesia". (Exhibit B1)
3. The facility was not licensed by the OEPA as a generator of Bio-Waste at the time of the Transfer Waiver/variance. On December 2, 2010 it was not listed by OEPA as a generator of such. On December 8, 2010 it was listed as a large generator of Bio-Waste and the Sharonville Health District became responsible for inspection requirements. The facility was operating prior to that license.
4. The ASF advised the Sharonville Health District and Sharonville Fire Department (SFD) that the procedure of "Inducing" is not conducted at this facility. They stated that the ASF refers patients who require an Induced procedure to the Indiana office. Yet, the ASF website has a section titled "D&E patients (Ohio centers only)" and "Some more advanced pregnancies (19 through 24 weeks LMP)...". (Exhibit E10) The ASF website also states, "most Indiana women travel out of state for second trimester abortions. Our Ohio Centers in Cincinnati and Dayton provide second trimester abortions to many out-of-state women" (Exhibit E19) The ASF also states to the SHD and SFD that they do not house Sharonville patients in local hotels, which is a patient care issue for the disposal of Bio-Waste and for EMS Services. However, the ASF website states that, "For patients 22-24 weeks LMP and living 1 hour or more from the Cincinnati or Dayton Center we provide a hotel room." (Exhibit E25)
5. According to the Surveyor Notes Worksheet of the ODH inspection on October 7, 2010, the facility is deficient on items #5,13,17,19,20,21,22,24,25,27,28,29,30,31,33,34,36,39. (See Exhibit F1-F5)
6. The ASF did not satisfy the requirements of Malpractice Coverage. (Exhibit F2,F5)
7. The ASF did not satisfy the requirements of Anesthesia. (Exhibit F1,F4)
8. The ASF did not satisfy the requirements of Blood Products. (Exhibit F1,F4)
9. At the time of the waiver/variance, the deficiencies of the ASF were in violation of OAC 3701-83-06, which outlines inspection requirements for ASF's; and, therefore, should not have been issued a license due to incompleteness, inconsistencies, and reasons beyond the scope of the variance. (Exhibit F1-F5)
10. The SHD believes that providers associated with the ASF do not comply with federal and state laws and regulations. The understanding of the SHD is that an NPI number is required to match all information provided to all health care entities and governmental bodies. OAC 3701-83-03

- (D), states HCF/ASF “shall comply with Federal and State applicable laws.” ORC 3702.30(E)(1) states that no Health Care Facility shall operate without a license issued under this section. If the status or facts of a provider changes, said provider is required to report it within a set time to PECOS (Provider Enrollment). Although the ASF does not appear to have an NPI number, it is registered as a CLIA lab, 3 of the physicians presented to the public as part of the ASF have NPI numbers and there are inconsistencies in records. (Exhibit B1,B2) The SHD has reason to believe that these types of updates are not being done in an acceptable time frame. This may be an intended pattern, so as to confuse the public when providing patient care and information.
11. At the time of the waiver/variance, Dr Martin Haskell provided information to the ODH that is materially inconsistent with the NPPES (National Plan & Provider Enumeration System) ,NPI number, and the Courtesy Privileges for Family Medicine at Jewish Hospital Cincinnati. (See Exhibit B1)
 12. At the time of the waiver/variance, Dr Roslyn Kade provided information to the ODH that is materially inconsistent with the NPPES, NPI number, and the Admitting Privileges for Family Practice at Christ Hospital Cincinnati. (See Exhibit B1)
 13. At the time of the waiver/variance, Dr Neil Richard Strickland, was not represented to the ODH as an associated physician in the ASF, has professional information that is inconsistent with NPPES, and did not submit hospital privileges to ODH. (See Exhibit B1)
 14. At the time of the waiver/variance, Dr Ronald Norman Yeomans, was not represented to the ODH as an associated physician in the ASF, has professional information that is inconsistent with NPPES, did not have hospital privileges and did not have an Ohio Medical License. (See Exhibit B2)
 15. At the time of the waiver/variance, the CLIA Certification Information for the ASF included information that was materially inconsistent with the NPPES, NPI number, ASF website and consent forms. (See Exhibit B2)
 16. The waiver/ variance requires, by condition 3, that Dr Haskell and Dr Kade will back up each other for emergency hospital care.(Exhibit C5,C6) However, their privileges are at different hospitals. Also, Dr Kade’s privileges for Family Practice at Christ Hospital require her to have a written agreement with an OB/GYN practice with privileges at Christ Hospital that “will provide consultative, emergency and operative obstetric care”. (Exhibit D6,#4) It appears that Dr Kade cannot treat hospital emergencies on her own standing. Therefore, she may not be able to back up Dr Haskell for the waiver/variance requirement.
 17. The current exterior signage on the ASF does not represent the name of the ASF , Lebanon Road Surgery Center, and does not identify it as an Ambulatory Surgical Facility, which is a Fire Safety issue. Rather, it identifies the ASF as a business name that is different from the name it is licensed; signage indicates “Women’s Med Center”. (Exhibit A)
 18. The ASF may not have met all of the local Building Codes. Exterior signage was installed without a permit and the current parking may not be sufficient to satisfy zoning code requirements.

It is the belief of the SHD, that OAC 3701-83-06 states, Director of ODH may “make unannounced or announced inspections of ASF” for (A) compliance check, and (E) alleged violations, and (F) follow up inspection on violations. It is the belief of the SHD that the Director of ODH has the ability, and duty, on behalf of the citizens of Ohio, to perform an unannounced

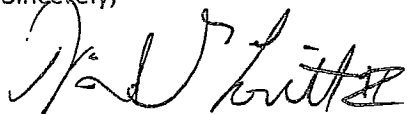
inspection of The Lebanon Road Surgery Center and verify compliance with all applicable Federal and State Regulations. This should include a review of all aspects of the Surveyor Notes Worksheet, all exterior signage, all advertising and website materials. The SHD requests the Director of ODH to perform said inspection and review.

It is the position of the Sharonville Health District that this waiver/variance was granted without full disclosure by the applicant, without complete inspection by the ODH and without complete review of all available resources. The SHD maintains that the waiver/variance was granted prematurely, and that the applicant is responsible, in large part, for not providing complete and accurate information and for not operating the business and maintaining records to the requirements of Federal and State Laws and Regulations. Therefore, this business cannot, and should not, be protected from a reversal of the waiver/variance, because the improper actions of the applicant materially influenced the previous process.

The Sharonville Health District requests that the ODH reopen and reconsider this waiver/variance. The SHD also strongly urges the ODH to permit a public input process on the waiver/variance request. Additionally, the SHD requests the ODH provide written notice of the public input process to the local health jurisdiction, Sharonville Health District; the local municipality, City of Sharonville; and all hospitals and other medical providers if their rights, privileges and/or other documents are a material part of granting the waiver/variance. For a waiver/variance, the ODH should require an understanding of the privileges and limitations from such hospitals and receive documentation of the physician's and ASF's ability to protect patients with complete, quality patient care. This should include transfers from the ASF to a hospital; transfers between hospitals; inpatient care; and any other situations that involve said limitations.

The Sharonville Health District is confident that the Ohio Department of Health mutually shares concern for the safety and well being of the general public. It is based in this belief that the SHD requests reconsideration and review of this waiver/variance in a public forum. The SHD is willing to provide assistance, as needed.

Sincerely,



Virgil G. Lovitt II

President, Sharonville Board of Health

Cc: John Kasich, Governor State of Ohio
Mike Dewine, Attorney General State of Ohio
Tom Niehaus, President Ohio Senate
William Batchelder, Speaker Ohio House of Representatives
William Seitz, Senator Ohio District 8
Sharonville City Council
Sharonville Board of Health