



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Vos, M.D.
Ambassador (Ret.)
Secretary DHHS
Drexdal Pratt, Director

HAND DELIVERED

**NOTICE OF ADMINISTRATIVE ACTION
ABORTION CERTIFICATE**

TO: Ms. Lois Turner, Owner
A Preferred Women's Health Center, LLC
3320 Latrobe Drive
Charlotte, North Carolina 28211

FROM: Azzie Y. Conley, RN
Section Chief
Acute and Home Care Licensure and Certification Section

SUBJECT: Summary Suspension of Your Certificate to Operate
Certificate No. AB 0055
FID No. 990459

DATE: May 10, 2013

Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHHS), **HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE A Preferred Women's Health Center, LLC**, an abortion clinic. **YOU ARE HEREBY DIRECTED TO CLOSE A Preferred Women's Health Center, LLC, BY NO LATER THAN 5:00 O'CLOCK P.M. ON May 10, 2013.**

AGENCY FINDINGS

This Summary Suspension is based on this agency's findings that conditions at A Preferred Women's Health Center, LLC, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. This agency has identified the facility failed to be in substantial compliance with Rules for which they are certified.



Acute and Home Care Licensure and Certification Section

<http://www.ncdhhs.gov/dhsr/>

Phone: (919) 855-4620 v Fax: (919) 715-3073

Mailing Address: 2712 Mail Service Center • Raleigh, North Carolina 27699-2712

Location: 1205 Umstead Drive (Lineberger Building) v Dorothea Dix Hospital Campus v Raleigh, N.C. 27603

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On April 19 – 20, 2013, in response to a complaint, staff with the Acute and Home Care Licensure and Certification Section conducted an onsite survey at A Preferred Women's Health Center. Based on the investigative findings, violations of the rules were identified. The investigation remained open to collect data to validate the findings related to the administration of an injectable medication administered to patients orally for Medical Abortion Procedures (MABP). Subsequent to the onsite visit, additional interviews and review of the literature was conducted April 20, 2013 through May 9, 2013.

A telephone interview was conducted on April 20, 2013, with the Medical Affairs Representative for Fresenius Kabi (pharmaceutical company that manufactured the Methotrexate used by the clinic). The interview revealed the packet insert contains the indications and dosages for administration of the Methotrexate. Further interview revealed there is no recommendation for the usage of injectable Methotrexate to be given orally.

Telephone interview on April 23, 2013, with the Assistant Director, Education with Carolina Poison Center (PharmD, DABAT) revealed Methotrexate injectable is not usually given orally. The interview revealed a concern whether the patient is absorbing the dosage intended due to the fact that as the dosage increases the percent that is absorbed decreases. Further interview revealed the Assistant Director was unsure why injectable Methotrexate would be given orally when there is an oral Methotrexate available.

Telephone interview on May 9, 2013, with the Medical Advisor of the Division of Health Service Regulation revealed he does not advise the usage of injectable Methotrexate be given orally. The interview revealed he had a concern with the absorption of injectable Methotrexate given orally. The interview revealed the questioning of the usage of injectable Methotrexate being given orally.

In summary, interviews with the Medical Affairs for Fresenius KABI (manufacturer of Methotrexate), Assistant Director Education Carolina Poison Center and Medical Advisor for the Division of Health Service Regulation do not recommend the administration of injectable Methotrexate be given orally to patients

As a result of the investigative findings, the Section substantiated Rule violations that include:

- 10 NCAC 14E. .0302 Person in Authority
- 10 NCAC 14E. .0305 Medical Records
- 10 NCAC 14E. .0311 Surgical Services

Based on the investigative findings, an imminent threat to the health and safety of patients was identified. The facility failed to ensure medical abortion procedures were performed in accordance with the manufacturer's recommendations for administration of medications. The findings revealed patients receiving medical abortion procedures were administered Methotrexate orally as opposed to injectable. The facility's failure to administer the medication according to the manufacturer's recommendation could affect the absorption of the medication. Therefore, the patient would not receive the intended dosage of medication ordered by the physician for the medical abortion procedure.

The Report of Survey upon which the agency's decision is based is enclosed.

During the onsite survey, deficiencies were identified and discussed with facility staff on April 20, 2013. Therefore, it is the finding of this agency that the facility has neglected to provide the services to assure the health, safety and welfare of the patients.

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APPEAL NOTICE

You have the right to contest this summary suspension of your certificate by filing a petition for a contested case hearing with the Office of Administrative Hearings (OAH) within sixty (60) days of your receipt of this letter. For complete instructions on the filing of petitions, please contact OAH at (919) 733-2698. The mailing address for OAH is as follows:

Office of Administrative Hearing
6714 Mail Services Center
Raleigh, NC 27699-6714

N.C.G.S. § 150B-23 provides that you must also serve a copy of the petition on all other parties, which includes DHHS. The Department's representative for such actions is Ms. Emery Edwards Milliken, General Counsel. This person may receive service of process by mail at the following address:

Ms. Emery Edwards Milliken, General Counsel
NC Department of Health and Human Services
Office of Legal Affairs
2005 Mail Service Center
Raleigh, NC 27699-2005

If you do not file a petition within the sixty (60) day period, you will lose your right to appeal this Summary Suspension. In addition to your right to file a petition for a contested case hearing, N.C. Gen. Stat. § 150B-22 encourages the settlement of disputes through informal procedures. In keeping with this law, this office remains readily available for discussion or other informal procedures to assist in resolving any dispute you may have with our findings and action. Please note that the use of informal procedures does not extend the sixty (60) days allowed to file for a contested case hearing as explained above.

Should you have any questions regarding any aspect of this letter, please do not hesitate to contact me at the Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section, 2712 Mail Service Center, Raleigh, North Carolina 27699-2712 or contact me at (919) 855-4646.

cc: Drexdal Pratt, Director, Division of Health Service Regulation
Dr. Patsy Christian, Assistant Director of Health Care Quality and Safety
Cheryl Quimet, COO, Division of Health Service Regulation
Emery Edwards Milliken, General Counsel, Department of Health and Human Services

File

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STATE OF NORTH CAROLINA

COUNTY OF MECKLENBURG

The Notice of Administrative Action, dated May 10, 2013, was delivered in person by **Dana McGee-Haynes, RN/Facility Survey Consultant I**, with the Acute and Home Care Licensure and Certification Section on **May 10, 2013**.

Signature of Recipient

Signature of Section Representative

Date