

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

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

Drexdal Pratt, Director

August 1, 2013

VIA EMAIL

Lorraine Cummings, MD, Owner FEMCARE, Inc. 62 Orange Street Asheville, NC 28801

Dear Dr. Cummings:

Thank you for the opportunity to discuss the re-opening of FEMCARE, Inc. upon the remedies put in place to correct the deficiencies found in the July 19, 2013 survey. I feel obligated to continue this dialogue by clarifying a statement attributed to you by WLOS on July 31, 2013. The statement reads:

Since the State's last site visit in August 2006 there have been no changes in our operating protocols, but increasing regulations require us to make changes. Standards that were acceptable when we were last inspected have changed and, as soon as we were notified of them two weeks ago, we began the process of meeting each one of them.

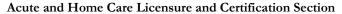
The survey conducted on July 18, 2013 through July 19, 2013 was conducted as a routine inspection under North Carolina's licensure requirements for ambulatory surgical facilities as set forth in 10A NCAC 13C. These regulations have not been revised since 2003. Therefore, it is inaccurate to suggest that increasing or changing regulations led to the closure of your facility.

As you know, the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulations is responsible for licensing, regulating and inspecting hundreds of facilities covering 19 different program areas. All state-licensed and federally-certified providers must remain compliant with state and federal laws governing the quality of health care provided. Our mission is to protect the health, safety and welfare of all North Carolinians and the visitors to our State. We take this role very seriously.

Enclosed is a copy of the inspection report which outlines the violations found during the inspection, including:

- Failed to sweep and mop the operating room floor and failed to properly clean operating room beds.
- Failed to maintain anesthesia (nitrous oxide gas) delivery systems in good working condition, with torn masks and tubing held together with tape. This could lead to patients not receiving the intended dosage and risk patients not being fully sedated during surgical procedures, leading to pain and physical harm.
- Failed to ensure emergency equipment had weekly checks to ensure the equipment was suitable for use in patient care and failed to ensure that emergency medicine wasn't expired.





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- Failed to have a resuscitator available in the event of a medical emergency.
- Failed to have a director of nursing responsible and accountable for all nursing services.
- Failed to have an agreement/contract with an anesthetist or anesthesiologist.
- Failed to have an agreement/contract with a registered pharmacist to assure appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs.

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 Regulations, Acute and Home Care Licensure and Certification Section, 2712 Mail Service Center, Raleigh, North Carolina 27699-2712 or contact me at (919) 855-4646.

Sincerely,

Azzie Y. Conley

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

cc: Drexdal Pratt, Director, Division of Health Service Regulations
Cheryl Quimet, COO, Division of Health Service Regulations
Emery Edwards Milliken, General Counsel, Department of Health and Human Services

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