BEFORE THE NORTH CAROLINA MEDICAL BOARD

In re:)		
)		
Clarence Joseph Washington, M.D.,)	CONSENT ORDE	R
)		
Respondent.)		

This matter is before the North Carolina Medical Board ("Board") on information regarding Clarence Joseph Washington, M.D., ("Dr. Washington"). Dr. Washington admits and the Board finds and concludes that:

Whereas, the Board is a body duly organized under the laws of North Carolina and is the proper party to bring this proceeding under the authority granted it in Article 1 of Chapter 90 of the North Carolina General Statutes and the rules and regulations promulgated thereto; and

Whereas, Dr. Washington is a physician licensed by the Board on March 12, 1988, license number 32295; and

Whereas, at all times relevant herein, Dr. Washington practiced medicine in Cary, North Carolina; and

Whereas, in August 2010, Dr. Washington began work as the medical director of HRC Medical of North Carolina ("HRC"); and

Whereas, HRC is a foreign professional corporation whose main office is located in Tennessee and whose chief shareholder

is an out of state physician named Dan Hale, D.O., a licensed Tennessee physician; and

Whereas, HRC was founded by Dr. Hale to provide hormone replacement therapy to patients for a multitude of ailments, typically involving fatigue, malaise and sexual dysfunction; and

Whereas, HRC advertises aggressively in the markets where it maintains a practice making claims that it can improve the quality of life for those patients who obtain hormone replacement therapy from HRC; and

Whereas, in 2009 HRC located to North Carolina and opened practices in Cary and Charlotte, and then later in Greensboro; and

Whereas, Patients A through H presented to HRC for hormone replacement therapy; and

Whereas, when a patient presents to HRC for hormone replacement therapy, including Patients A - H, that patient is seen and evaluated by a non-physician staff person or healthcare worker, usually a registered nurse (RN), but not Dr. Washington; and

Whereas, pursuant to standing orders signed by Dr.

Washington a patient will undergo a blood test to determine

certain hormone and vitamin levels within the patient; and

Whereas, HRC administered hormone replacement therapy by implanting pellets, containing either testosterone or estradiol, into the buttocks of a patient; and

Whereas, these pellets would dissolve over time releasing either testosterone or estradiol into the patient's body, and as a consequence increase the levels of those hormones within the patient; and

Whereas, Patients A - H received substandard care from HRC staff; and

Whereas, a review of the medical records of Patients A - H demonstrates the following deficiencies in these patients' care:

- There is no documentation of a history and physical being performed before therapy;
- For female patients, there is no evidence that Dr.

 Washington ascertained or confirmed a negative mammogram

 result or performed a breast exam prior to ordering

 therapy;
- The "Therapy Agreement Form" utilized by HRC indicates that estrogen (estradiol) and testosterone pellets have been approved for human use by the United States Food and Drug Administration ("FDA"), when in fact, the FDA has not approved the use of pelletized dosage forms of estrogen in the United States, and the use of

- testosterone pellets for hormone replacement in postmenopausal women is generally not indicated;
- Patients with normal B12 levels were given B12 injections;
- Procedure notes clearly indicated that nurses, not Dr. Washington, performed the surgical implant procedures, thus indicating that Dr. Washington inappropriately allowed nurses to perform procedures outside of their permissible scope of practice;
- The Therapy Agreement Form fails to mention serious side effects of hormone replacement therapy such as malignancy, pulmonary embolism, venous thrombosis, coronary artery disease, liver disease, as well as other serious contraindications and risks;
- Vital signs are not documented in procedure notes or other notations in the chart
- During the implant procedure, a high dose (24 milliliter)
 of 2% lidocaine was used raising the possibility of
 lidocaine toxicity in some patients; and
- A male patient was provided with Femara® (letrozole) to counteract the feminization side effects of testosterone therapy. The use of Femara® for this purpose is not FDA approved, although it is used commonly "off-label" for this purpose in the body building arena to counter

bloating and unwanted breast development brought about by anabolic steroid abuse.

Whereas, Dr. Hale is an out of state Tennessee physician who holds no license to practice medicine in North Carolina; and

Whereas, Dr. Hale has, on more than one occasion, come within the borders of North Carolina to train HRC staff on how to perform the pellet implant surgical procedure; and

Whereas, Dr. Hale's venture into North Carolina to practice medicine by performing the implant procedure on North Carolina patients represents Dr. Hale engaging in the unlicensed practice of medicine in North Carolina which in turn constitutes a felony pursuant to N.C. Gen. Stat. \$90-18; and

Whereas, pursuant to Board rules, specifically, 21 NCAC 32C .0105, only licensed North Carolina physicians can make professional clinical decisions regarding how medicine is practiced in North Carolina on behalf of a professional corporation, domestic or foreign; and

Whereas, Dr. Hale directed, controlled and determined how medicine was practiced at the North Carolina HRCs, and not Dr. Washington; and

Whereas, HRC utilized the services of Dr. Washington solely as a figurehead in order for it to appear that HRC was practicing medicine through a North Carolina licensed physician, when in fact, the medicine that was being offered and

administered at HRC was by and through protocols, policies and guidelines developed by Dr. Hale; and

Whereas, Dr. Washington relied on representations that were made to him by HRC regarding the permissibility of HRC's operations in North Carolina; and

Whereas, Dr. Washington relied on the fact that ERC was a national multi-state company with facilities operating throughout the country in several states; and

Whereas, Dr. Washington relied on representations by HRC that the protocols, policies and guidelines developed by HRC were consistent with standards of acceptable medical practice; and

Whereas, HRC had been offering its services in North Carolina for over one year before Dr. Washington was recruited as Medical Director; and

Whereas, Dr. Washington admits that notwithstanding the above, he possessed an independent duty to ensure that the medicine practiced at HRC conformed with acceptable and prevailing standards of medical practice in North Carolina; and

Whereas, Dr. Washington's conduct as described above, constitutes unprofessional conduct, including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, within the meaning of N.C. Gen. Stat. § 90-14(a)(6) which is grounds under

that section of the North Carolina General Statutes for the Board to annul, suspend, revoke, condition, or limit Dr. Washington's license to practice medicine or to deny any application he may make in the future; and

Whereas, the admissions and findings contained herein are intended solely for the purpose of resolving the case at hand between the North Carolina Medical Board and Dr. Washington; and

Whereas, Dr. Washington would like to resolve this matter without the need for more formal proceedings; and

Whereas, the Board has determined that it is in the public interest to resolve this case as set forth below;

NOW, THEREFORE, with Dr. Washington's consent, it is ORDERED that:

- 1. Dr. Washington's license to practice medicine in North Carolina is hereby SUSPENDED for TWELVE (12) MONTHS from the date of this Consent Order, however, such suspension is immediately STAYED, except for a period of NINETY (90) DAYS, beginning on May 1, 2012 and ending on July 30, 2012, during which Dr. Washington shall serve an active suspension.
- 2. Dr. Washington shall obey all laws. Likewise, he shall obey all rules and regulations involving the practice of medicine.

- 3. Dr. Washington shall notify the Board in writing of any change in his residence or practice addresses within ten (10) days of the change.
- 4. Dr. Washington shall meet with the Board or members of the Board for an interview at such times as requested by the Board.
- 5. If Dr. Washington fails to comply with any of the terms of this Consent Order, that failure shall constitute unprofessional conduct within the meaning of N.C. Gen. Stat. § 90-14(a)(6) and shall be grounds, after any required notice and hearing, for the Board to annul, suspend or revoke his license to practice medicine and surgery and to deny any application he might make in the future or then have pending for a license.
- 6. This Consent Order shall take effect immediately upon its execution by both Dr. Washington and the Board and it shall continue in effect until specifically ordered otherwise by the Board.
- 7. Dr. Washington hereby waives any requirement under any law or rule that this Consent Order be served on him.
- 8. Upon execution by Dr. Washington and the Board, this Consent Order shall become a public record within the meaning of Chapter 132 of the North Carolina General Statutes and shall be subject to public inspection and dissemination pursuant to the provisions thereof. Additionally, it will be reported to

persons, entities, agencies and clearinghouses as required and permitted by law including, but not limited to, the National Practitioner Data Bank and Healthcare Integrity and Protection Data Bank.

By Order of the North Carolina Medical Board this the $13^{\rm th}$ day of March, 2012.

NORTH CAROLINA MEDICAL BOARD

By:

Ralph C. Loomis, M.D.

Relph (Lamin on D

President

Consented to this the 13 day of March, 2012.
Clarence Joseph Washington, M.D.
State of North Carolina
County of Wake
I, <u>Senjamin</u> M. Spite , a Notary Public for the above named County and State, do hereby certify that Clarence Joseph Washington, M.D. personally appeared before me this day and acknowledged the due execution of the foregoing instrument.
Witness my hand and official seal
this the 13th day of March, 2012.
Notary Public Benjamin M. Spiker
Notary Public Benjamin M. Spiker
(SEAL)
My Commission Expires: 2/28/17