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December 2, 2011

Personal and Confidential

Certified Mail – Return Receipt Requested

Danny Eugene Hale, D.O.
9123 Cross Park Drive, Suite 200
Knoxville, TN 37923

Dear Dr. Hale:

This is to inform you that the North Carolina Medical Board has denied your application for reinstatement of your license to practice medicine in North Carolina.

Specifically, your application for reinstatement of your North Carolina medical license was denied for the following reasons:

You made false statements or representations to the Board or willfully concealed from the Board material information in connection with an application for reinstatement within the meaning of N.C. Gen. Stat. §90-14(a)(3).

You failed to disclose on your application that you were reprimanded by the Tennessee Board of Osteopathic Examination (“Tennessee Board”) in 1988.

You failed to disclose that you were excluded from participating in the Medicare and Medicaid programs after you were convicted in 1995 of multiple federal felonies related to fraud and racketeering.

You also failed to disclose that you were denied a medical license by the Michigan Board of Osteopathic Medicine and Surgery (“Michigan Board”) in April 2002. The denial of your application for a Michigan medical license should have also been disclosed in response to question number two (#2) on your application.

You failed to disclose your ownership of HRC Medical in the “chronology” section of your application.

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As previously stated, in 1995, you were convicted of multiple federal felonies. In your written statement about your conviction you disclosed other regulatory actions, including the 1995 surrender and 1997 revocation of your Tennessee medical license as well as the 2003 and 2004 denials of your applications for restoration of your United States Drug Enforcement Administration ("DEA") privileges to prescribe controlled substances.

Although these actions were disclosed in your written statement, except for the 1995 surrender of your Tennessee medical license, you did not disclose any of the other above regulatory actions in the actual section of your application that inquires about regulatory actions taken against you. They should have been disclosed in this section of your application. Furthermore, not only should these matters have been disclosed in the regulatory actions section of your application, they should have also been disclosed in response to question number (#1) of your application. Question number one asks whether "you were aware of any complaint or investigation, past or present, regarding you that has been received or conducted by any governmental agency or any professional licensing board or agency?" In response to question number one, you simply responded that "[i]n 1995 I was convicted of insurance fraud in my family practice."

Your response to question number one was wholly inadequate because it substantially sought to minimize and diminish your responsibility for your felonious conduct. In 1995, you were convicted of multiple federal felonies. Those felonies include convictions on one count of Racketeering, one count of Racketeering Conspiracy, one count of Conspiracy to Commit Mail Fraud, one count of Forfeiture, and 18 counts of Aiding and Abetting and Mail Fraud. As a result of the convictions, you received a fifty-seven (57) month prison sentence of which you served about thirty-four (34) months in federal prison according to your own report.

In your written explanation of the circumstances surrounding your conviction, you sought to shift blame for your actions on your office staff. Again, you demonstrated little, if any, acceptance of responsibility for your actions. To be clear, you were indicted for serious crimes. You were convicted by a jury of your peers. Your convictions were appealed to the United States Sixth Circuit Court of Appeals. The Sixth Circuit unanimously upheld your convictions on all counts.

In its opinion affirming your conviction and sentence, the Sixth Circuit wrote the following:

Defendant began practicing medicine in Morristown, Tennessee, in 1977. For many years he worked in loose association with Dr. Gene Lynch, eventually purchasing his practice in 1992, at which time Lynch became an employee of defendant's professional service corporation, Boulevard West Medical Center ("BWMC").

In the early 1990s, several insurance companies contacted the United States Postal Service to report their belief that a large-scale insurance fraud was ongoing in Kentucky

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and Tennessee. The Lexington, Kentucky, office of the Postal Inspection Service looked into the matter. Inspector Lanny Miller contacted insurance companies in an effort to

determine the extent of the fraud and the identity of the perpetrators. Eventually, the Inspection Service focused on about forty people living near Mt. Vernon and Corbin, Kentucky.

The fraud worked simply. Participants would buy numerous hospital indemnity policies that paid a sum certain in the event of a hospital admission. They would then fake injuries, present themselves to a "sympathetic" doctor, and gain admission to a hospital, typically for a soft tissue injury. The participants then filed claims for coverage with numerous insurance companies. After investigators developed a detailed understanding of how the fraud operated, they confronted some of the participants, thirteen of whom testified against defendant, explaining how he helped them by authorizing hospital stays. Russell Ramsey, who directed many of the participants, recalled how defendant had facilitated the enterprise. Ramsey would simply tell defendant that he had somebody who needed "doctoring." So certain was Ramsey that his charges would be admitted to the hospital that he explained in advance what they needed in the way of supplies for a stay of ten to fifteen days.

The fraud spanned several years, during which time Ramsey estimated that he orchestrated as many as 100 admissions to the Morristown hospitals. He also indicated during trial that defendant seemed to know what was going on with respect to the fraud although they did not discuss it specifically because, in Ramsey's view, "I was kind of protecting him." According to Ramsey, defendant suggested that the people he brought in for admission should "ride in wheelchairs." As further evidence of their close association, Ramsey testified that defendant once asked to borrow \$ 200,000 to buy equipment for the office.

A primary issue at trial and on appeal involves when, and if, defendant knew of the fraud. Defendant focuses on what he sees as inconsistencies in three pretrial interviews of Ramsey by law enforcement officials. In two of them, Ramsey insisted "there was no predetermined agreement between he [sic] and the doctors." In the last interview, however, after having "had a good bit of time to reflect on his relationship with Dr. Dan Hale," Ramsey claimed that he would talk to defendant the day before he was to bring in a new "patient." Defendant would tell Ramsey how to have the patient behave: bend over in pain, use a wheelchair, and request pain medication. He also discouraged Ramsey's fondness for staging car accidents because they involved police; rather, "a bathtub was a good place to have an accident."

Other testimony that pertained to defendant's knowledge of the fraud came from Steven Taylor, who administered a hospital in Morristown. In 1990, he was warned that the hospital was being used for fraud. Testifying from contemporaneous file memorandum, Taylor recalled that he discussed the fraud with defendant and Lynch. Defendant indicated that he was aware of it. Although the admissions stopped for a few months, they soon resumed.

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While the insurance fraud investigation moved forward, the Tennessee Bureau of Investigation began looking into possible overbilling by defendant in an attempt to defraud the Medicare and Medicaid programs. Testimony during trial indicated that his goal was to see as many patients and perform as many tests as the government would pay for. To that end, he used a three-minute egg timer to pace himself, and posed special challenges to staff. During "EKG month," for instance, they would be rewarded if they exceeded the number of EKGs performed during the same month the year before. A doctor who worked briefly for defendant was told by him that he must test patients every time they walk in the door. As a result of this policy, tests were often scheduled before the doctor even saw the patient.

In short, the testimony at trial from former employees, including doctors, nurses, and staff about unnecessary testing and dubious billing was overwhelming.

Defendant does not dispute this but rather argues that an avalanche of inadmissible evidence unfairly prejudiced his defense.

Defendant was charged with numerous counts of mail fraud in violation of 18 U.S.C. § 1341, as well as criminal and civil violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"). 18 U.S.C. §§ 1961-68. After a lengthy trial, a jury convicted him on all counts.

United States v. Hale, 1997 U.S. App. LEXIS 1729, pp 1-6 (emphasis added).

Your application is being denied pursuant to N.C. Gen. Stat. §90-14(a)(7) and N.C. Gen. Stat. §90-14(a)(6). Your felony convictions in 1995 constitute your being convicted of a felony and violating laws involving the practice of medicine within the meaning of N.C. Gen. Stat. §90-14(a)(7). Furthermore, your fraudulent conduct, for which you were criminally charged, convicted and went to federal prison for, constitutes unprofessional conduct within the meaning of N.C. Gen. Stat. §90-14(a)(6).

Your application is also being denied pursuant to N.C. Gen. Stat. §90-14(a)(13). The actions by the Tennessee and Michigan Boards constitute your having a license to practice medicine or the authority to practice medicine revoked, suspended, restricted, or acted against or having a license to practice medicine denied by the licensing authority of any jurisdiction within the meaning of N.C. Gen. Stat. §90-14(a)(13).

Your license is also being denied because you practiced medicine in North Carolina without a license in violation of N.C. Gen. Stat. §90-14(a)(7) and N.C. Gen. Stat. §90-14(a)(6). Specifically, you are the owner of HRC Medical, a foreign professional corporation that practices medicine in North Carolina. HRC Medical specializes in providing hormone replacement therapy to patients. The therapy consists of testosterone pellets being implanted into the buttocks of patients. The implantation procedure is a surgical procedure. You travelled to North Carolina for the purpose of demonstrating to HRC Medical staff the pellet implantation procedure. In so doing, you entered North Carolina without Danny Eugene Hale, D.O.

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a medical license, and performed surgery unlawfully, in violation of N.C. Gen. Stat. §90-18(a).

You also practiced medicine in North Carolina without a license by controlling how hormone replacement therapy was delivered by HRC Medical clinical staff. During the past year, the Board received patient complaints and had cause to investigate HRC Medical. It became clear during the Board's investigation that you controlled how hormone replacement therapy would be administered by the professional, clinical staff at HRC Medical. The Medical Directors employed by HRC Medical were directors in name only and had no meaningful control over clinical decisions or HRC's practice model. A relative of yours was the office manager at HRC Medical and all clinical guidelines and protocols were developed and implemented by you as the majority shareholder in HRC Medical.

During its investigation, the Board had several patient charts reviewed by outside expert reviewers. Those charts revealed that the clinical staff at HRC Medical delivered care that was uniformly below acceptable and prevailing standards of medical practice in North Carolina. The following is a partial description of the poor medical care that was being practiced at HRC Medical.

- There is no documentation of a history and physical being performed before therapy;
- For female patients, there is no evidence that HRC staff ascertained or confirmed a negative mammogram result or performed a breast exam prior to ordering therapy;
- Patients lab results showed normal levels of estradiol, progesterone, and/or testosterone, yet patients received hormone replacement therapy nonetheless;
- The "Therapy Agreement Form" utilized by HRC indicates that estrogen (estradiol) and testosterone pellets have been approved for human use by the 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;
- The use of progesterone in hormone replacement therapy can significantly increase the risk of coronary artery disease; furthermore its use in women who have undergone a hysterectomy is generally not indicated;
- Patients with normal B12 levels were given B12 injections;
- Patients were prescribed antibiotics for side effects such as cystic acne, yet there is no documented indication that the HRC Medical Director ever ordered the use of this medication indicating that the Medical Director impermissibly delegated medical tasks to HRC staff or failed to supervise his staff appropriately;
- When patients were prescribed antibiotics, such as doxycycline, there is no evidence that the HRC Medical Director considered the possible adverse interactions that the doxycycline would have with other medications the patients were taking;
- Procedure notes clearly indicated that nurses, not the HRC Medical Director, performed the surgical implant procedures, thus indicating that the HRC Medical Director 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;
- Patients enter into a financing agreements with lending institutions to pay for their hormone replacement therapy but these agreements do not disclose what role the HRC Medical Director has in regard to these agreements, thus raising potential conflict of interest issues;
- If a patient did have demonstrable hypogonadism (low testosterone) there was no assessment of the patient's pituitary function to fully evaluate whether the hypogonadism was a function of a pituitary or hypothalamic disorder;
- 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.

The above deficiencies can be attributed, in whole or in part, by the poor practice model you developed for HRC Medical. Accordingly, your roles as owner of HRC Medical and the creator and developer of its practice model constitute you practicing medicine in North Carolina without a license and in violation of a law involving the practice of medicine within the meaning of N.C. Gen. Stat. §90-14(a)(7). By implementing guidelines and protocols at HRC Medical that produced a practice model that consistently provided substandard care to HRC patients, you committed unprofessional conduct within the meaning of N.C. Gen. Stat. §90-14(a)(6).

Because you are a licensed out-of-state physician, your entering North Carolina for the expressed purpose of practicing medicine and surgery without a license constitutes a Class I felony. *See*, N.C. Gen. Stat. §90-18(a)(No person shall practice medicine or surgery unless the person shall have been first licensed and registered to do so... "[t]he person so practicing without a license shall be guilty of a Class 1 misdemeanor, **except that if the person so practicing without a license is an out-of-state practitioner who has not been licensed and registered to practice medicine or surgery in this State, the person shall be guilty of a Class I felony.**")(emphasis added).

For all of the above reasons, this Board is denying your application for a North Carolina medical license. Furthermore, a copy of this letter is being provided to the Wake County District Attorney for possible criminal investigation into your activities involving the unlicensed practice of medicine.

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You are entitled to a formal hearing before the Board upon your request filed with or mailed by certified mail to the Executive Director of the Board at the address shown hereon within 10 days after you receive this letter. You must state the reasons for your request. The Board shall within 20 days of receipt of your request notify you of the time and place of this public hearing. The burden of satisfying the Board of your qualifications for approval shall be upon you.

Sincerely,

A handwritten signature in black ink that reads "R. David Henderson". The signature is written in a cursive style with a large initial "R".

R. David Henderson
Executive Director

RDH/MJ/coh

pc: Colon Willoughby, District Attorney for Wake County