June 7, 2012

Allen Childs, MD; Employee ID #32503
9208 Grand Summit Blvd
Dripping Springs, Texas 78620

via email: [redacted]
via registered mail, return receipt requested; and
via regular mail

RE: Notice of Possible Disciplinary Action

Dear Dr. Childs:

This is to notify you of the allegations that may give rise to possible disciplinary action against you, up to and including dismissal from employment, as a Psychiatrist III at the North Texas State Hospital, Texas Department of State Health Services.

It is alleged that:

- You conducted, and then published results of, unauthorized and unapproved research on patients at North Texas State Hospital ("NTSH"); and failed to obtain approval of this research from an appropriate Institutional Review Board.
- From April 2006 through November 2011, while employed by and treating patients at North Texas State Hospital, you were also employed as the medical director of a company whose products you used to treat, and then to conduct and publish results of, unauthorized and unapproved research on patients at North Texas State Hospital; and that this constituted a potential or actual conflict of interest with your employment at North Texas State Hospital.
- Violated the privacy rights of patients at North Texas State Hospital by using videotaped materials which clearly identified patients as part of a presentation you made to individuals not employed by, or involved in the care of, patients at North Texas State Hospital.

Specifically, it is alleged that:

- On or about April 21, 2004 you submitted an article, entitled "Cranial Electrotherapy Stimulation Reduces Aggression in a Violent Retarded Population: A Preliminary Report", to the Journal of Neuropsychiatry and Clinical Neurosciences. On or about June 18, 2004 you revised that submission. On or about August 16, 2004 that submission was accepted for publication, and it was published in this journal on November 1, 2005. Throughout this period of time, you were employed full time by North Texas State Hospital in the capacity of Chief Unit Psychiatrist.

In this article, you describe "nine aggressive, retarded patients refractory to conventional care at a maximum security hospital" who "were given a 3 month course of cranial electrotherapy stimulation." You describe the methodology of your study, highlight in particular the administration of Cranial Electrotherapy Stimulation ("CES") to two specific NTSH patients, analyze and discuss patient responses to the intervention, and conclude that "while controlled studies should be undertaken, CES appears to be an efficacious, safe and cost-effective
addition to the treatment regimen in this patient population.” There is no evidence that you ever submitted a request to the responsible Institutional Review Board for approval to undertake these studies, nor is there evidence that any IRB ever approved these studies.

- In March 2007, the journal *Primary Psychiatry* published an article written by you and Larry Price Ph.D, entitled “Cranial Electrotherapy Stimulation Reduces Aggression in Violent Neuropsychiatric Patients.” In this article, you refer to the “preliminary report of the first nine cases” described above, and go on to discuss the entire cohort of 48 patients. Once again you describe your “materials and methods,” aggregate and analyze patient data, and “confirm the previously reported anti-aggressive effect of CES.” You conclude that “the CES treatment resulted in the significant decreases in aggression in these 48 patients,” and that “as a safe, efficacious, and cost-effective intervention, CES should be considered for wider use in seriously ill patients.” There is no evidence that you ever submitted a request to the responsible Institutional Review Board for approval to undertake these studies, nor is there evidence that any IRB ever approved these studies.

- Although at the time the March 2007 article was published in *Primary Psychiatry*, you were the Medical Director at Electromedical Products International, Inc., which manufactured the “Alpha-Stim” CES device that you used in your treatment of and research on the patients described in the article, the article contains a statement that “Drs. Childs and Price report no affiliation with or financial interest in any organization that may pose a conflict of interest.”

- On October 21, 2005 you provided a lecture on the premises of Electromedical Products International, Inc. (EPII) entitled “Aggressive patients treated with Alpha-Stim at North Texas State Hospital”. As seen in a recording of this lecture produced by EPII, you wore your NTSH employee badge while speaking to the audience. You showed approximately 45 minutes of a videotape, filmed at NTSH in 2004-05 for NTSH clinical purposes, that included extended footage of NTSH patients before, during and after receiving CES treatment. The NTSH videotape contained frequent close-up shots of these patients, and you were present in all of the NTSH footage with all of these patients. In one instance, you called a patient by his first name, and in another instance you referred to a patient by his last name. You made numerous disparaging remarks about patients’ behavior, demeanor and personal appearance to an audience of individuals not connected with these patients’ care and treatment at NTSH. In addition, in at least one instance you told a patient that she was required to leave the CES device on for an hour. In another instance, when a patient complained that the CES treatment was hurting him, you acknowledged to your audience that you had turned the machine up too high. There is no evidence that you obtained permission from these patients to show the videotape to individuals not connected with their treatment. In addition, there is no evidence that you notified, or obtained permission from, NTSH to use its confidential videotape of these patients for this purpose.

Your actions with respect to the above cited events violate the following rules, policies and procedures:

25 TAC Chapter 414, Subchapter A – Protected Health Information.

In addition, your conduct violates the following HHS Human Resources Manual provisions:

**HHS HR Manual, Chapter 4 Employee Conduct Work Rules:**

HHS employees must
1. be familiar with and follow all HHS policies and procedures relating to job performance and work rules;
2. perform their job duties, meet HHS standards for job performance, and follow job-related instructions from HHS supervisors;
3. avoid situations in which personal or private gain or benefit may conflict with the public interest;
4. protect state information and property;
5. keep all HHS information and all information obtained as an HHS employee confidential, except as otherwise required by law, e.g., the Public Information Act, Texas Government Code, Chapter 552 (client-related information may be released only in accordance with sound professional practices, state and federal regulations, and HHS policies and procedures); and
6. not act in a manner that interferes with the proper performance of duties, office operations, or HHS agency and program goals and objectives, or act in a manner that violates HHS agency or program rules, regulations, or policies.

Before I decide what action would be appropriate in this matter, I would like to have you provide me with any information that you feel is relevant to this allegation or which might mitigate the circumstances. You may present this information to me personally, either orally or in writing or both, in my office on Monday, June 11, 2012 at 5:00 p.m.

Sincerely,

Michael D. Maples
Assistant Commissioner
Mental Health and Substance Abuse Services

Cc: Martha Yancey, HHS HR Specialist
Cc: John L. Foster - Dr. Allen Childs’ attorney via fax at (512) 610-1617