REPORT: **Directed 407 Review of Chelation Therapy**

FROM: **Richard P. Nelson**
Director, Nebraska Department of Health and Human Services Regulation and Licensure

TO: **Speaker of the Nebraska Legislature**
Chairperson, Executive Board of the Legislature
Chairperson, Health and Human Services Committee

DATE: **January 27, 2000**

Introduction

The Nebraska Regulation of Health Professions Act provides an administrative process to review and present to the Legislature recommendations regarding change in scope of practice of licensed health care professionals and related issues. Neb. Rev. Stat. sections 71-6201 *et seq*. The process is commonly known as a "407 Review" because it was authorized by LB 407, Laws 1985. The Department of Health and Human Services Regulation and Licensure administers the Act. As director of the department, I am presenting this report under the authority of the Nebraska Regulation of Health Professions Act.

The Chairperson of the Legislature's Health and Human Services Committee and the Director of Regulation and Licensure directed a study of chelation therapy on April 19, 1999. A directed review, defined at Neb. Rev. Stat. section 71-6207.02, is authorized when no appropriate applicant group exists but there is an issue regarding scope of practice or other issues regarding a regulated health profession on which the Legislature may wish to act (Neb. Rev. Stat. section 71-6223.02).

The issue directed by the Chairperson of the Health and Human Services Committee and the Director of Regulation and Licensure to be reviewed was whether or not chelation therapy can be safely and effectively used to treat diseases and conditions other than heavy metal poisoning.

A technical committee reviewed the charge. In a directed review, the role of the technical committee is to formulate an initial proposal on the issue. The technical committee recommended that no legislation be enacted with regard to this issue. The technical committee limited its review to the most commonly used chelation agent,

ethylenediaminetetraacetic acid (EDTA). The technical committee found that chelation therapy is probably safe if standard protocols are used in the infusion of EDTA. The technical committee also found that it cannot determine whether chelation is an effective therapy for anything other than the removal of heavy metals. A review of the technical committee's minutes and report establishes that the technical committee believed that the use of chelation therapy for purposes other than the removal of heavy metals is not prohibited presently but is subject to the customary standard of due care applicable to other treatment modalities.

In a directed review, the role of the Board of Health is to evaluate the proposal of the technical committee using the appropriate criteria. The Board of Health determined that the proposal of the technical committee met each of the four applicable criteria in Neb. Rev. Stat. section 71-6221(3), as adapted to the chelation therapy issue, and recommended in favor of the proposal. The reports of the technical committee and the Board of Health are attached to this Director's Report.

In a directed review, the role of the Director, like that of the Board of Health, is to evaluate the proposal using the appropriate criteria.

I find that chelation therapy, specifically EDTA, can be safely used to treat diseases and conditions other than heavy metal poisoning when administered under standard protocols. I find that available evidence does not establish that chelation therapy is effective for treatment of diseases and conditions other than heavy metal poisoning. I find, likewise, that available evidence does not establish that chelation therapy is not effective for treatment of diseases and conditions other than heavy metal poisoning.

Regulatory Policy and Philosophy

The Legislature has provided four criteria which should be satisfied before a change in scope of practice is adopted. Neb. Rev. Stat. section 71-6221(3). These criteria focus on the health, safety and welfare of the public. These criteria were modified to address the review of a particular *therapy*, chelation, rather than *scope of practice*.

People in Nebraska should be confident that health professionals licensed by the state are competent to provide quality services. It is also important that those quality services be accessible and affordable. It is equally important that people have a choice in health services when that choice can be offered without endangering health and safety.

Findings and Recommendation

Criterion One states:

> "The present situation wherein there are no statutory restrictions on the use of EDTA chelation does not create harm or danger to the health, safety, or welfare of the public, and the potential for this

harm is easily recognizable and not remote or dependent upon tenuous argument."

I find this criterion has been satisfied.

Criterion Two states:

"The technical committee recommendations do not create a significant new danger to the health, safety, and welfare of the public."

I find this criterion has been satisfied.

Criterion Three states:

"The technical committee recommendations which call for continuing the current situation wherein there are no statutory restrictions on the use of EDTA chelation by the state would benefit the health, safety, or welfare of the public."

I find this criterion has been satisfied.

Criterion Four states:

"The technical committee recommendations represent the most cost-effective means of dealing with the issue of EDTA chelation."

I find this criterion has been satisfied.

I recommend that no new legislation be enacted with regard to the issue of chelation therapy.

Discussion

A starting place for the discussion is an understanding of the current standards regarding the use of chelation therapy by licensed health care professionals. EDTA was patented in the 1940's to remove heavy metals, such as lead, from the blood stream. More recently, some medical practitioners have also used EDTA as a treatment for cardiopulmonary disease. The technical committee concluded that chelation therapy can be used to treat other conditions, subject to the general obligation of a licensee to use due care.

The technical committee determined that chelation therapy is probably safe if standard protocols are used in the infusion of EDTA. The technical committee cited the protocols of the American College for the Advancement of Medicine as an example. Of course, as a premise to the directed review, chelation therapy has been determined to be safe in the treatment of heavy metal poisoning.

The information before the technical committee established that EDTA can be safely administered by physicians, advance practice nurses, and physician's assistants within their respective scopes of practice. However, the technical committee members also stated that there was insufficient evidence to determine whether EDTA chelation is effective in treating cardiopulmonary disease. Because of the inconclusive nature of their findings, the technical committee members did not feel that imposing statutory restrictions on the use of EDTA was indicated, and recommended that no new legislation be enacted at this time.

The technical committee members were informed by expert witnesses that there are no "double-blind" studies upon which judgment can be made regarding the effectiveness of chelation therapy to treat health problems and conditions other than heavy metal poisoning. The committee members were informed that the costs of conducting such studies have become prohibitive, and that only those projects that hold the promise of great profits for the pharmaceutical companies or the insurance companies get approved for this kind of research. The organizations that make decisions regarding this kind of research apparently do not consider chelation therapy to warrant this kind of attention. The technical committee was also informed that it is common for some treatment modalities to be used in ways that have not been proven by double-blind studies.

The current Nebraska statutes neither prohibit nor protect the use of chelation therapy. There are Nebraska physicians who currently use chelation therapy to treat conditions other than heavy metals. They openly advertise the availability of this therapy. The Attorney General has not prosecuted any physicians for using chelation therapy. In one high profile case, a physician was prosecuted for administering laetrile. There has been some confusion about whether he was prosecuted for using chelation therapy. He was not.

The issue of chelation therapy was considered during the recent changes to the regulations governing the conduct of the practice of Medicine and Surgery. The department reached the same conclusion at that time that I reach now: regulation of the practice of medicine should not focus on the use of any particular modality, but upon the use of all therapies, drugs, and devices in a manner that does not cause unnecessary harm to the patient.

This principle is reflected in Title 172 Neb. Admin. Code, ch. 88 section 88-013.18 which provides that "[a]ny conduct or practice outside the normal standard of care in the State of Nebraska which is or might be harmful or dangerous to the health of the

patient or the public" is unprofessional. The technical committee has determined, and I agree, that chelation therapy is safe when standard protocols are followed. This would take the use of chelation therapy, in itself, outside of the conduct proscribed by the regulation.

The department recognizes that federal law impacts the conduct of health professionals regulated by the department. This principle is reflected in Title 172 Neb. Admin. Code, ch. 88 section 88-013.11 which provides that "[u]se of any therapy, drug or device in a manner inconsistent with the federal Food, Drug and Cosmetic Act" is unprofessional. This section was intended to allow Nebraska practitioners to be able to practice within Nebraska to the maximum extent consistent with federal law.

Use of EDTA in chelation therapy has been approved by the FDA. The use of an approved modality for a purpose other than that for which it was approved is allowed under this federal law. In other words, although EDTA was initially approved by the FDA to treat heavy metal poisoning, the Food, Drug and Cosmetic Act does not prohibit its use to treat other conditions.

In regard to chelation therapy, the *existing* provisions of Nebraska law are adequate to protect the recipients of care without additional legislation and do not restrict the access of patients to the care they desire. Physicians may use chelation therapy when, under the circumstances of each case, the patient consents and it is reasonable to conclude the risk of harm does not outweigh the possible benefits of treatment.

Respectfully submitted,

Richard P. Nelson

Richard P. Nelson, Director
Department of Health and Human
Services Regulation and Licensure