

REPORT OF RECOMMENDATIONS AND FINDINGS  
ON CHELATION THERAPY

**By** The Technical Review Committee for the  
Review on Chelation Therapy

**To** The Nebraska State Board of Health,  
The Director, Department of HHS Regulation and Licensure,  
The Legislature

October 21, 1999



## INTRODUCTION

The Credentialing Review Program is a review process advisory to the Legislature which is designed to assess the need for state regulation of health professionals. The credentialing review statute requires that review bodies assess the need for credentialing proposals by examining whether such proposals are in the public interest.

The law directs those health occupations and professions seeking credentialing or a change in scope of practice to submit an application for review to the Health and Human Services Department of Regulation and Licensure. The Director of this agency will then appoint an appropriate technical review committee to review the application and make recommendations regarding whether or not the application in question should be approved. These recommendations are made in accordance with four statutory criteria contained in Section 71-6221 of the Nebraska Revised Statutes. These criteria focus the attention of committee members on the public health, safety, and welfare.

The recommendations of technical review committees take the form of written reports that are submitted to the State Board of Health and the Director of the agency along with any other materials requested by these review bodies. These two review bodies formulate their own independent reports on credentialing proposals. All reports that are generated by the program are submitted to the Legislature to assist state senators in their review of proposed legislation pertinent to the credentialing of health care professions.



THE FOLLOWING PERSONS WERE APPOINTED TO SERVE AS MEMBERS OF THE  
CHELATION THERAPY TECHNICAL REVIEW COMMITTEE

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## THE CHARGE TO THE CHELATION THERAPY TECHNICAL COMMITTEE

### 1) THE PRODUCT OF THE REVIEW

The technical committee must create a report that is advisory to the Board of Health, the Director of HHS Regulation and Licensure, and the Legislature on chelation therapy.

This report may take the form of a specific recommendation or may identify policy options pertinent to the use of chelation therapy to treat human health problems and conditions.

Currently chelation therapy is used to treat lead poisoning. The committee members must determine whether or not there is compelling evidence to indicate that chelation therapy can be used to treat other illnesses or conditions of human beings safely and effectively.

### 2) THE NATURE OF THE REVIEW

This committee's review is unique in that it will be reviewing a type of therapy rather than reviewing a given health profession.





SUMMARY OF THE RECOMMENDATIONS OF THE CHELATION THERAPY  
TECHNICAL REVIEW COMMITTEE

**AFTER AN EXTENSIVE REVIEW OF AVAILABLE RESEARCH, LITERATURE, AND EXPERT TESTIMONY, THE CHELATION THERAPY TECHNICAL REVIEW COMMITTEE HAS FOUND THAT CHELATION THERAPY IS PROBABLY SAFE IF STANDARD PROTOCOLS (THE AMERICAN COLLEGE FOR THE ADVANCEMENT OF MEDICINE, FOR EXAMPLE) ARE USED IN THE INFUSION OF ETHYLENEDIAMINETETRAACETIC ACID ("EDTA"). THE TECHNICAL COMMITTEE CANNOT DETERMINE AT THIS TIME WHETHER OR NOT CHELATION IS AN EFFECTIVE THERAPY FOR ANYTHING OTHER THAN THE REMOVAL OF HEAVY METALS, AND CONSEQUENTLY, RECOMMENDS THAT THERE BE NO NEW LEGISLATION ENACTED WITH REGARD TO THIS ISSUE.**



## DISCUSSION AND DEFINITION OF ISSUES FOR THE REVIEW

How does chelation therapy work? What chelating substances are under review?

The committee members were informed that there are many chelating agents, but decided to limit the review to "EDTA." EDTA is short for Ethylenediaminetetraacetic acid, and is used to remove heavy metals from the blood stream. "EDTA," a synthetic amino acid, combines with calcium and other metals in the blood and removes them via urination.

How is EDTA administered?

EDTA is usually administered intravenously. The committee members were informed that for the most cost-effective results, the intravenous administration is the best method because it is more direct.

Is chelation therapy safe?

The committee members were informed that chelation therapy is safe if applied in a manner consistent with established protocols and appropriate standards of care by health care practitioners who possess the necessary medical education and training. This includes medical doctors, advanced practice nurses, and physician assistants.

The committee members were informed that the administration of chelation therapy can be easily managed by adjusting the amount of EDTA administered per session, by adjusting the amount of time between sessions, and by adjusting a patient's diet and exercise regimens.

Is chelation therapy effective?

The committee members were informed that EDTA is an effective remedy for the removal of heavy metals from the blood stream, and was patented in the 1940's for that purpose.

What scientific research has been done to demonstrate the validity of chelation therapy?

The 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. One expert witness informed the committee members that the costs of doing "double-blind" studies has become prohibitive, and that the price tag for such research has reached two-hundred million dollars. This expert witness stated that only those projects that hold promise of bringing great profits to pharmaceutical or insurance companies get approved for this kind of research, and that chelation doesn't attract that kind of attention.

The committee members were informed by this expert witness that the importance of "double-blind" studies in determining the efficacy of health care procedures has been greatly exaggerated, and that according to the Office of Technology Assessment only ten to twenty percent of the medical procedures used by physicians are supported by this kind of scientific research. (Assessing the Efficacy and Safety of Medical Technologies, Office of Technology Assessment, (September, 1978), Page 7)

What health care practitioners should provide chelation therapy?

The committee members were informed that only medical doctors, advanced practice nurses, and physician assistants have the necessary education and training to use EDTA for patient care.

## TECHNICAL COMMITTEE FINDINGS AND CONCLUSIONS

The technical committee members made the following recommendation regarding chelation therapy:

**AFTER AN EXTENSIVE REVIEW OF AVAILABLE RESEARCH, LITERATURE, AND EXPERT TESTIMONY, THE CHELATION THERAPY TECHNICAL REVIEW COMMITTEE HAS FOUND THAT CHELATION THERAPY IS PROBABLY SAFE IF STANDARD PROTOCOLS (THE AMERICAN COLLEGE FOR THE ADVANCEMENT OF MEDICINE, FOR EXAMPLE) ARE USED IN THE INFUSION OF ETHYLENEDIAMINETETRAACETIC ACID ("EDTA"). THE TECHNICAL COMMITTEE CANNOT DETERMINE AT THIS TIME WHETHER OR NOT CHELATION IS AN EFFECTIVE THERAPY FOR ANYTHING OTHER THAN THE REMOVAL OF HEAVY METALS, AND CONSEQUENTLY, RECOMMENDS THAT THERE BE NO NEW LEGISLATION ENACTED WITH REGARD TO THIS ISSUE.**

The committee members determined that there is insufficient scientific evidence to recommend any changes in public policy pertinent to this modality.

The committee members were informed by expert witnesses that it is unlikely that there will ever be the kind of compelling scientific research done on this issue to demonstrate whether or not chelation therapy is effective in treating human health problems and conditions other than heavy metal poisoning. The committee members were informed that the costs of doing the necessary research has become prohibitive.

The technical committee members made several wording changes in the draft version of the report to improve its accuracy, and then took action to approve the report. Committee member Vlach moved, and committee member Rochford seconded that the committee approve the report with the wording changes. Voting aye were Douglas, Gabel, Klutman, Nichols, Rochford, and Vlach. Chairperson Foote abstained from voting.



## TECHNICAL REVIEW COMMITTEE MEETINGS

The committee members met for their first meeting on July 14, 1999 in Hearing Room 1507 in the State Capitol Building, in Lincoln. This meeting was an orientation to the Credentialing Review Program and the role of technical committee members in the review process.

The committee members met for their second meeting on August 18, 1999 in the Womens' Club, in Lincoln. This meeting was to discuss the issues surrounding chelation therapy and to define the parameters of the review and to identify what kinds of research the committee would need to do its work.

The committee members met for their third meeting on September 23, 1999 in the Womens' Club, in Lincoln. This meeting was to hear presentations by expert witnesses and to discuss outstanding issues. The committee members formulated a tentative recommendation at this meeting.

The committee members met for their fourth meeting on October 21, 1999 in the Womens' Club, in Lincoln for a public hearing. After hearing testimony from the public, the committee members finalized their recommendations, and advice to policy makers on the chelation therapy issue. The committee members then adjourned sine die.

