1992 SUNRISE REVIEW

OF

HEMODIALYSIS TECHNICIANS

SUBMITTED BY

THE COLORADO DEPARTMENT OF REGULATORY AGENCIES

JUNE 1992

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June 5, 1992

The Honorable Bob Schaffer
Joint Sunrise/Sunset Review Committee Chairman
Room 348, State Capitol Building
Denver, Colorado 80203

Dear Senator Schaffer:

We have completed our evaluation of the sunrise application for licensure of hemodialysis technicians and are pleased to submit this written report which will be the basis for my office's oral testimony before the Sunrise and Sunset Review Committee. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, the "Sunrise Act", which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs and would benefit from the regulation.

The report discusses the question of whether there is a need for the regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm and, whether the public can be adequately protected by other means in a more cost effective manner.

Sincerely,

Steven V. Berson
Executive Director

EXECUTIVE SUMMARY

Hemodialysis technicians have been providing patient care services to dialysis patients in the State of Colorado since 1964. There are regulations from both the state and federal government to provide oversight and minimum standards in hemodialysis units (free standing facilities that provide dialysis services). The existing regulations provide requirements relating to such concerns as infection control, patient safety and staffing but there are no basic training or competency standards for hemodialysis technicians.

Training programs are currently provided by the hemodialysis treatment facilities but there is no consistency of content or minimum knowledge requirement to enter the profession.

In applying the sunrise criteria, there has been little data indicating that consumer harm is occurring. Complaints to the Colorado Department of Health and the End Stage Renal Dialysis (ESRD) Network established by federal mandate are almost nonexistent. Yet, both patient and medical provider feedback indicates that a standardized training requirement in the State of Colorado would be beneficial to the quality of patient care.

During the 1992 Legislative Session, SB 96 was approved by the General Assembly. This bill adds a delegatory clause to the Nurse Practice Act which enables a nurse to delegate nursing functions to unlicensed persons based on an evaluation of the patient's needs and the unlicensed person's ability.

The Department of Regulatory Agencies believes that this newly created power, along with training standards established through regulations promulgated by the Colorado Department of Health, will better ensure a high quality of care for hemodialysis patients in the least restrictive regulatory environment.

I. INTRODUCTION

The Department of Regulatory Agencies has evaluated the application for regulation of hemodialysis technicians submitted by a consumer of dialysis services. Pursuant to the Colorado Sunrise Act, C.R.S. 24-34-104.1, the applicant must prove the benefit to the public of the proposal for regulation according to the following criteria.

1) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependant on tenuous argument.

2) Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence; and

3) Whether the public can be adequately protected by other means in a more cost-effective manner.

The scope of this review was comprehensive in nature. State and federal regulations relating to this area were reviewed. Interviews with nephrologists, nurses and technicians were performed. Site visits to several hemodialysis units were done to discuss the sunrise application with service providers. Several patients were personally interviewed also. Results of this process are reflected in the outcome of this report.

II. BACKGROUND

End-Stage Renal Disease (ESRD) occurs when both kidneys are permanently damaged with the loss of about 95% of their functional abilities. In order to survive, the patient requires dialysis treatment or a kidney transplant. Dialysis provides some of the functions a normal kidney would: removal of wastes, salt, and extra water; regulation of blood for a safe level of chemicals; and assistance in controlling blood pressure.

Dialysis as a life-saving treatment began in the early 1960's. Currently, there are two types: peritoneal dialysis and hemodialysis. In peritoneal dialysis, wastes are filtered out of the blood across the lining of the patient's abdominal cavity. This process is usually performed four to six times during a 24 hour period, typically in the patient's home. The patient self administers this process thus making regulation inappropriate. Conversely, during hemodialysis, blood is pumped outside the body into an artificial kidney machine, called a dialyzer, which cleans the blood. Treatments are usually done three times a week for three to four hours at a time. For treatments, patients may go to a dialysis center or learn to treat themselves at home.

Nationally, as of 1987, there were 157,944 persons receiving treatment. The number of new ESRD patients doubled from 1977 to 1987 and by the year 2000, it is expected to grow to a quarter of a million patients who will need dialysis. As of December 31, 1990, 1125 Colorado residents received care, with an additional 434 new patients that year. A majority of these patients will remain on dialysis for the rest of their lives with some being candidates for kidney transplants.

The profession of hemodialysis technician was identified in the 1976 Federal Register, "Conditions for Coverage of Suppliers of ESRD services". It stated further study was needed to define allowable practices within the profession. This study has never been done and no information has been provided by the federal government on appropriate practice standards.

At this time, there are two national certification exams offered: one by the Board of Nephrology Examiners, Inc. (BONENT) and one by the American Nephrology Nurses Association (ANNA). BONENT's tests are offered to hemodialysis technicians or nurses and to peritoneal dialysis nurses. ANNA's exam can only be taken by nephrology nurses with a current R.N. license. Both tests evaluate technical knowledge in the area of dialysis. There is a large contingent of nurses in Colorado working in the area of dialysis

who are certified through the ANNA process. The hemodialysis technician certifying test offered by BONENT has historically been taken by a small number of technicians because being nationally certified had no impact on career or pay rates. Recently, in Colorado, several dialysis facilities have recognized the importance of knowledgeable technicians by establishing salary differentials based on a technician's successful completion of a national certification process. For more information about related national organizations, please see Appendix B.

Federal and state governments are trying to address the ESRD growth rate. The Medicare ESRD program was established in 1973 to help cover the expenses patients incur. This program is very costly with 1987 Health Care Financing Administration (HCFA) data estimating the annual Medicare expenditure for a dialysis patient at $32,000 a year. In 1988, Medicare reportedly spent a total of $3.7 billion for ESRD beneficiaries. Current allowable charges in the Denver area are approximately $130 per dialysis treatment per patient. Funding allowances have not increased in several years and have actually decreased in certain areas.

In 1978, Congress further addressed ESRD related issues. The ESRD amendments of 1978 created an ESRD Network made up of oversight organizations with responsibility for designated areas of the country. This was an effort by Congress to divide the country into groups of states and establish regional ESRD Network organizations to provide information, oversight and data collection to all dialysis patients in a given area. In 1984, Congress worked to consolidate the 32 network organizations in the U.S. to 18. Finally, with the Omnibus Budget Reconciliation Act of 1987, 18 network organizations were defined with functions to be performed. The 18 ESRD "Networks", as referred to in the field, are funded by the federal government through the Health Care Financing Administration (HCFA). These network organizations provide oversight to dialysis treatment facilities in all fifty states and the U.S. territories. Defined legislative responsibilities include:

1) Encourage the use of treatment settings most compatible with the successful rehabilitation of patients.

2) Encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable for such treatment.

3) Encourage patient and staff participation in vocational rehabilitation programs.

4) Provide a patient grievance mechanism.

5) Collect, validate, and analyze data concerning ESRD patients and their treatment.

6) Provide accurate, timely data to local, state, and federal government agencies and to the public.

7) Develop criteria and standards relating to quality and appropriateness of patient care.

One of the most important functions of the Network organizations was laid out in Section 9335 of PL 99-509, Obra 1987, which amended section 1881 (c) of the Social Security Act. This requires ESRD Networks to implement procedures to resolve patient grievances by acting as a facilitator. Each hemodialysis facility has a duty to inform patients of the grievance protocol and their rights and responsibilities as set forth in the ESRD Federal Regulations of June 3, 1976.

III. THE COLORADO EXPERIENCE

The Sunrise application for Hemodialysis Technicians was submitted by a dialysis patient. Many of the expressed concerns are based on personal observations of the applicant and include the following:

* There is no standardized training program.

* R.N.s are sometimes placed in positions of responsibility with little exposure to the area of dialysis treatment.

* Hemodialysis technicians and R.N.s are unsupervised after a few weeks of training.

* Accesses or entrances to the blood system can be destroyed due to an improper needle insertion by a poorly trained technician. Access to the blood stream becomes critically important to dialysis patients.

* Hemodialysis technicians are sometimes unable to provide requested information to patients on areas of basic knowledge.

* Hemodialysis technicians are sometimes unresponsive to patient problems (quick drop in blood pressure) due to lack of training.

* Hemodialysis patients are sometimes not appropriately attached to the heparin pump (Heparin is a drug supplied to the blood flow to thin the blood and prevent clotting problems) which can ultimately result in a patient being removed from the dialyzer early, which could prevent a thorough cleansing of the blood.

* Hemodialysis technicians sometimes do not respond to patient emergencies (fainting, cardiac arrest, convulsions) because they were not aware of how to provide assistance.

As stated in a recent article entitled: "The Technician Dilemma" from Contemporary Dialysis and Nephrology, June, 1991, "Respect, dignity and recognition of the technician will never occur without the standardization of their educational process..."

The applicant believes these problems could be eliminated or at least decreased by a state certified training program that would ensure basic standards in training.

In Colorado, there are 19 hemodialysis treatment facilities currently operating pursuant to 25-1-107(1)(I)(II) C.R.S. under oversight by the Colorado Department of Health. At these sites, hemodialysis patient care technicians, Licensed Practical Nurses (L.P.N.s), or Registered Nurses (R.N.s) work directly with the patient. In some instances, a hemodialysis technician

could be an unlicensed person, an L.P.N. or an R.N. All new employees who provide the functions of a hemodialysis technician participate in whatever training is offered by each unit. The functions performed by these health care workers are as follows: prepare necessary supplies, including the dialyzer; assess patient before treatment, which includes blood pressure, pulse, weight and temperature; inspect access areas to the blood stream, administer local anesthesia and perform venipuncture (inserting needles into blood vessels); monitor patient during treatment; respond appropriately to dialysis related emergencies; document actions and results; draw lab samples; and sanitize equipment and stations.

It is significant to note that there are two types of hemodialysis technicians. A patient care technician performs the functions listed above while an equipment technician performs maintenance work on dialyzers. This report focuses on patient care hemodialysis technicians because they are directly responsible for patient care.

In reviewing the responsibilities of a patient care hemodialysis technician, it can be argued that the patient care technicians are practicing nursing without a license. These technicians are performing invasive procedures such as the administration of local anesthesia by injection and venipuncture or the insertion of needles into blood vessels. Yet, R.N.s are present but have not been able to legally delegate their functions to the technicians. With Senate Bill 96 passed during the 1992 Legislative Session, this problem will be resolved. R.N.s can legally delegate nursing functions after an analysis of the delegatee's ability and the patient's needs.

Here in Colorado, there are no regulations in the areas of education and training of hemodialysis patient care technicians. Therefore, hemodialysis technicians do not go through a certified training program. Nor are there minimal background requirements in order for a person to be trained as a technician. In fact, training across the state varies in requirements at each facility. (See Appendix A.) Generally, training structures can be described as follows. The training will depend on how much experience a person brings to the job. A very experienced person may receive an additional two to four weeks of training, while an inexperienced person undergoes six weeks to two months of training. Tests are then given on both the theoretical and practical applications. Technicians that pass the theory portions of the test are paired with an experienced R.N. for approximately one week and then are paired with another technician until able to perform duties on their own. Some facilities offer further training, but it is optional. Some facilities encourage continuing education and retest everyone for competency on a yearly basis. Some provide incentives and bonuses for persons who receive their national certification.

Some dialysis units respond to this concern by stating that hemodialysis technicians are physician extenders. In fact, regulations promulgated by the Colorado Board of Medical Examiners specifically limit the number of physician extenders a physician may supervise to two and require that the physician be present at the location where the physician extender is practicing. These regulations also require physicians to report physician extenders to the Board. These three criteria are not met in the typical hemodialysis unit.

IV. OTHER STATES' RESPONSES

To respond to the concern about patient care technician training needs, New Mexico and California have addressed the problem in alternative manners. These states are concerned with the quality of care and the education level of hemodialysis technicians. Both states have established training programs with certification of technicians upon completion.

New Mexico's program was implemented in March of 1990. It's purpose is to "establish minimum standards for certification of hemodialysis technician training programs", (N.M. Stat. Ann. Article III, Sec. B (1989)). In addition, each hemodialysis technician will go through 80 hours of classroom study and a minimum of 160 hours of supervised clinical experience. Training will be supervised by a nurse educator, who is an R.N. with a current expertise in hemodialysis and a minimum of nine contact hours annually of continuing education in dialysis. A Hemodialysis Technician Training Program Advisory Committee was also created under the auspices of the New Mexico Board of Nursing. Duties include the review of applications, annual program evaluations, consultation to training programs, and the reporting of suggested changes in training programs to the Board of Nursing. Each dialysis facility is encouraged to create its own training program which is approved by the Board of Nursing and evaluated by the Advisory Committee. The New Mexico Board of Nursing reports that only four of the twenty-one units in New Mexico have requested certification. The Board additionally reports that it has no authority to penalize those units which have chosen not to participate in the certification process. The law was passed primarily in response to the realization that patient care technicians were practicing nursing without a license. The program has not resolved the problem at this time and amendments are being considered for the 1993 Legislative Session in New Mexico.

California also certifies patient care technicians pursuant to the Hemodialysis Technician Training Act of 1987, which establishes minimum training standards for the state. The program includes 80 hours of theory and direct observation of a qualified worker. Upon completion, the newly qualified hemodialysis technician or licensed nurse must be directly supervised by an R.N. for a minimum of three treatments prior to performing independently. A hemodialysis agency shall then continue to provide continuing education at least semiannually. Duties of a hemodialysis technician are limited. The technician cannot administer blood, blood products, antibiotics, albumin, insulin or mesylate, draw arterial blood gases, or initiate patient home education, which is provided by an R.N. California reports that the training program has had a positive impact on patient care services but that the lack of ability to discipline has hampered the positive effect. A bill to increase disciplinary options was submitted to the California Legislature during the 1992 session but was defeated. Plans for the future have not yet been established.

In addition, Medical Media in Madison Wisconsin has been funded to develop a care curriculum for a patient care hemodialysis technician that will be made available to educational

institutions in the future.

Two other states, Arkansas and Mississippi, have chosen to use only R.N.s in the daily roles of patient care hemodialysis technician. They report that this decision was made because unlicensed technicians performing these functions would be in direct conflict with their Nurse Practice Acts. Although specific information is not yet available, professionals from national organizations report that a number of states are evaluating the need to standardize training for hemodialysis technicians.

V. IS THERE ADEQUATE OVERSIGHT?

In the State of Colorado, regulations promulgated by the Department of Health require one R.N. with at least one year of experience in the area of dialysis to be in attendance in a dialysis unit. In surveying a number of dialysis units, the actual ratio of R.N.s to dialysis technicians is one nurse for every three technicians.

In addition, the Nurse Practice Act, section 12-38-117 C.R.S., states the following under grounds for discipline:

> (c) Has willfully or negligently acted in a manner inconsistent with the health or safety of a person under his care; and
>
> (f) Has negligently or willfully practiced nursing in a manner which fails to meet generally accepted standards for such nursing practice;

These provisions authorize the Colorado Board of Nursing to investigate any complaint against a nurse for practicing nursing beyond the nurse's scope of knowledge. Nurses are held responsible for deciding the range of their knowledge and ability and deciding their practice limitations on the basis of this information. If a consumer believes care is being provided inadequately, the consumer has an option to report such concerns to the Colorado Board of Nursing for investigation.

In addition, each hemodialysis unit is mandated by federal law to inform patients of their right to file any concerns about their care with the End Stage Renal Dialysis (ESRD) Network. Upon receiving such a complaint, the ESRD Network is required to investigate, and if a concern is valid, the proper licensing authority within the state will be notified. Because of the limited number of complaints and the resolution of these complaints, it has not been possible to evaluate the effectiveness of this reporting requirement in Colorado.

The Colorado Department of Health, Division of Health Facilities also provides a survey of each facility approximately every four years. If a complaint is reported, the Division of Health Facilities' Investigation Unit will investigate. There have been approximately three complaints filed with the ESRD Network and the Colorado Department of Health combined during the last four years.

In considering the sunrise criteria, documentation of consumer harm occurring in the State of Colorado is currently unavailable. A number of established procedures to deal with patient concerns are available through the ESRD Network, the Colorado Board of Nursing and the Colorado Department of Health. Rather than creating a new regulatory program to deal with the concerns of patients and professionals alike, established systems can be used and improved. Patients must be educated and encouraged to file complaints when they are

concerned. It should be noted that several patients were interviewed for purposes of this evaluation. These patients expressed similar concerns to those indicated by the applicant and documented previously in this report. Yet, because of the absolute dependency on dialysis for survival, patients with concerns are hesitant to file a complaint. Several patients indicated that they were not aware of the complaint options available to them. Both dialysis facilities and patient advocacy organizations need to better educate patients of their rights. Yet, the Department of Regulatory Agencies observed that both patients and professionals experienced with this area of medicine report that the inconsistency of training has been an identified problem for some time. The Department concluded that a state response to this concern will be beneficial to the health and well being of the public.

Therefore, the Department of Regulatory Agencies makes the following recommendations.

VI. RECOMMENDATIONS

Recommendation 1: **The General Assembly should provide authority to the Colorado Department of Health to promulgate regulations establishing standardized training requirements for all hemodialysis units in the State of Colorado by adding the following to section 25-1-107 C.R.S. entitled Powers and Duties of the Department:**

(e)(I)(a) To establish standardized training requirements for hemodialysis technicians providing services in end stage renal disease facilities certified pursuant to Title XVIII and XIX of the Social Security Act.

Discussion: The Colorado Department of Health currently licenses these ESRD facilities upon proof of compliance with state regulations. Thus, adding training requirements to the current state regulations will result in improved standardized training throughout the state. It will also enable the federal survey teams from the Colorado Department of Health to ensure compliance through their survey process. During the past year, a policy committee of the National Kidney Foundation has worked in cooperation with a national task force representing experts from the professions of hemodialysis technicians, nephrology nurses and Nephrologists (M.D.'s specializing in kidney disease) to establish a standardized training model to become a policy of the National Kidney Foundation. The final outcome of this process is not currently available to the public but is expected to be released this summer, thus providing a model program for consideration of adoption by the Colorado Department of Health. A number of the dialysis units are currently providing extensive training programs comparable to the expected model. In addition, the Colorado Department of Health is scheduled to review hemodialysis unit regulations in the near future.

Recommendation 2: **The Colorado Board of Nursing should create a policy statement clarifying the role of nurse delegation in the area of hemodialysis.**

Discussion: In 1992, SB 96 was passed by the Colorado General Assembly with an effective date of July 1, 1992. This newly enacted law is an amendment to the Nurse Practice Act, giving registered nurses the authority to delegate nursing functions to unlicensed persons after a careful analysis of the patient's condition, the unlicensed person's ability and the nursing function to be delegated. This nursing oversight and assessment responsibility will more specifically assure that patient care hemodialysis technicians will be adequately trained and supervised and also competent to perform the required tasks. Nurses will be in the position of assessing skills and will be solely responsible for the decision to delegate.

This policy statement should include the following:

1. The functions of a hemodialysis technician can only be performed by an R.N. or an individual to whom authority has been legally delegated.

2. Delegation shall occur only upon assurance that the technician has been properly trained and performs with necessary skill to ensure patient safety.

With the additional authority of nurses to take an active role in evaluation of technician competency and the addition of a standardized training curriculum, regulatory oversight will be provided in the least restrictive environment. The ultimate impact of these two recommendations will be increased safety to consumers of dialysis services.

Appendix A

Some Hemodialysis Units in Colorado

(Examples of Training Offered)

AMI Presbyterian, Denver

The training varies depending on the amount of prior experience the person has. A very experienced person, i.e.: transferred directly from another hospital's dialysis center or licensed in another state, would undergo a two week course covering theory and clinical experience of how to set up the machines and what problems may occur. Then, the very experienced person would complete two weeks of hands on training. There are exams for the theory, and a clinical skills check list monitored by an R.N. for the practical applications. Less experienced people would undergo the same type of training in more detail, for a longer duration. They have received no complaints, and there have been no deaths. AMI Presbyterian does give incentives and bonuses for people who get certified.

Children's Hospital Association

The Hemodialysis program has just started, no patient care technicians at this time. The only technician is in charge of equipment maintenance and repair.

Community Dialysis Services

Students for the training program come from three main schools: Pikes Peak Community College, Baley Community College, and Denver Tech. These students participate in a six week externship, always under the supervision of a head nurse or R.N. Then if hired, each technician has a three month probation period. They are given a manual for further training and complete a test at the end of each chapter.

Mile High Dialysis

Most patient technicians have had previous experience. If not, one is trained on the job with a preceptor and additional reading material is provided. Usually, one is placed with an R.N. for one week, this depends on previous individual training. After this time, the student is paired with a technician until able to perform duties alone. Once a year, everyone is retested for competency, usually in April.

Willow Station Dialysis

A six to eight week training course is provided in this facility under the supervision of an R.N. or under the supervision of another technician. This course includes I.V. training. The students are given five quizzes and a final exam. Certification is posted and signed by the Inservice Director, the Medical Director, and the Director of Nursing. These facilities are owned by a corporation with locations across the country.

Pikes Peak Dialysis Center

A six week training program is provided. A manual is used which includes a checklist of patient care technician functions. At the beginning, the student is paired with an R.N., near the end s/he is paired with a technician. A written post test is given at the end of the training period.

Porter Hospital

There is no actual course for training developed at this unit. They attempt to hire trained technicians, which can be further familiarized with the unit. They are interested in developing a training program in the future.

Rocky Mountain Kidney Center

The training is comprised of six weeks in the classroom and on the floor. Progress is checked through written materials, oral examination and checklists. The technicians are supervised by an R.N. at first and then a trained technician. There is always an R.N. available on the floor.

Saint Luke's Hospital

Formal training sessions are provided depending on the amount of previous knowledge. If the person has a medical background, five weeks of theory and work with an R.N. is provided. If the student has no previous background, two months of training with an R.N. and technician is required.

St. Mary Corwin Hospital

Currently, staff is gathering information on areas such as causes of renal failure, access and access complications, what lab values, and diets mean, and related issues for a handbook to be used in training. Now, there is a seven week training period. The student is paired first with a nurse educator and then, after one month, with a technician. Tests are given after each area is discussed.

St. Mary's Hospital and Medical

St. Mary's hires R.N.s only. Physicians at this unit prefer to work with R.N.s. Reasons that contribute to this preference include problems with delegation, technician training and supervision. Now, one technician is employed who was originally trained at Western Dialysis.

University of Colorado Hospital

A patient care technician can do more than a practical nurse who has had much more training. Currently this unit employs two technicians. One is an R.N. Administration is not sure if they would hire another patient care technician because of the lack of control over previous education. For this reason, the University of Colorado Hospital does not have a current training program.

Appendix B

Professional Organizations Relating to Dialysis

1. **The National Association of Nephrology Technologists (NANT)**
   Founded in May of 1983. Its long range plan is to develop a certification process with uniform education for all technologists.

2. **Board of Nephrology Examiners, Inc. (BONENT)**
   In existence since 1974. Offers three nationally recognized exams for hemodialysis technicians or nurses and nursing peritoneal dialysis technicians. Cost is $125 for each applicant and certification is valid for four years. There is an additional cost of $25 for recertification.

3. **American Nephrology Nurses Association (ANNA)**
   It was founded in 1968. Offers a certification examination for nephrology nurses with a current R.N. license. Cost is $150 for ANNA members and $175 for nonmembers. Recertification is $75/$100 every three years through continuing education or re-examination.

4. **National Kidney Foundation of Colorado Inc.**
   This organization has been operating since 1965. It is one of 50 affiliates. Fifty-two percent of contributions received are spent to sponsor local research for answers to diseases of the kidney and urinary tract.

5. **ESRD Network #15**
   The territory of ESRD Network #15 includes the states of Arizona, Colorado, Nevada, New Mexico, Utah and Wyoming. One hundred and eleven renal facilities fall under Network #15. These facilities serve approximately 5,000 dialysis patients and 2,800 transplant patients. The Network is funded by the federal government Health Care Financing Administration (HCFA).