SUNRISE REVIEW

OF

HEMODIALYSIS TECHNICIANS

Submitted by
The Colorado Department of Regulatory Agencies
Office of Policy & Research

June 1994

July 28, 1994

The Honorable Vickie Agler, Chair
Joint Sunrise/Sunset Review Committee
State Capitol Building
Denver, Colorado 80203

Dear Representative Agler:

We have completed our evaluation of the sunrise application for regulation 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, 1988 Repl. Vol., (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,

Joseph A. Garcia
Executive Director

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INTRODUCTION AND METHODOLOGY

This sunrise review is in response to a re-submission for regulation of hemodialysis technician training. The previous application was reviewed in the Department of Regulatory Agencies'1992 sunrise review. Because the substantive information concerning the occupation is much the same, this review relies upon the background information of that report. Changes to statutes impacting the practice of hemodialysis technicians and incidents of public harm are addressed in the conclusion and recommendation section of this report.

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.

In Colorado, some hemodialysis treatment facilities operate pursuant to 25-1-107(1)(l)(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; prepare dialysate; prepare the hemodialysis machine, including the testing of monitors, alarms and conductivity; assess patient before treatment, which includes blood pressure, pulse, weight and temperature; inspect and sterilize 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; establish hemostasis, clean and dress access; perform post treatment assessment; document actions and results; draw lab samples; and sanitize equipment and stations.

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.

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.

PROPOSAL FOR REGULATION

The Sunrise application for the regulation of training programs for hemodialysis technicians was submitted by a 12+ year dialysis patient. Many of the expressed concerns are based on personal observations of the applicant and include the following:

* 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 health care 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.

Also of concern to the applicant is the alleged lack of concern or compassion shown to hemodialysis patients in some units. She states that patients are sometimes denied the use of restroom facilities, due to the technicians stating that they are too busy to clamp off their tubing.

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 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 and due to the passage of Senate Bill 96 passed during the 1992 Legislative Session, this problem has been 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. 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 contend 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 may not be met in a hemodialysis unit employing hemodialysis technicians as physician extenders.

REGULATION IN OTHER STATES

As noted in the 1992 review, New Mexico and California have addressed the problem in alternative manners. 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.

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.

EXISTING REGULATION

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.

CONCLUSION

The application for sunrise review requests that the applicant provide updated information substantiating the need for regulation. Since the 1992 sunrise review, the most significant occurrence in this area has been one death in a hemodialysis facility in Colorado. Cause of that death is unknown, however, a Department of Health inspection of the facility found no validity to the allegation that it was the fault of the health care providers administering the treatment. The applicant has stated that patients are at risk because dialysis technicians are not adequately trained. There is no doubt that hemodialysis is a life threatening procedure. Many medical procedures involve the chance that complications may cause unforeseen circumstances. However, there is no evidence to indicate that the training technicians receive is inadequate and thereby places the patient's care at risk. Training alone does not make a procedure risk free. In the case of the death at the hemodialysis facility, registered nurses were providing the patient care and not technicians. At that facility, there were two nurses on duty for the three patients receiving treatment. There were no technicians involved in the treatment.

In 1992, DORA suggested and the General Assembly adopted a recommendation that DOH establish standardized training requirements for hemodialysis technicians. DOH surveyed the industry and found that there was no consensus on standards for hemodialysis technicians. This lack of identifiable standards coupled with DOH receiving no complaints about hemodialysis facilities has made the establishment of standardized training requirements a low priority for DOH.

It is likely that this lack of consensus exists because of concerns about the cost of imposing a certain type of training when most facilities perceive no problem with the present training. Similarly, the Colorado Hospital Association, contacted for this sunrise review, opposes a standard training requirement when no problems attributable to poor training are demonstrated. The Colorado Hospital Association believes that such regulation will only increase health care costs needlessly.

DORA also suggested in the earlier report, which was also adopted by the General Assembly, that the Board of Nursing (BON) create protocols clarifying the role of nurse delegation in the area of hemodialysis. However, the enactment of C.R.S. 12-38-132, Delegation of Nursing Tasks, of the Nurse Practice Act made this suggestion moot. This section outlines the duties and responsibilities of nurses when they delegate duties to others. Consequently, there was no need to provide additional regulation on delegation that was specific to hemodialysis. Section 12-38-132, C.R.S. states:

> ***Delegation of nursing tasks. (1) Any registered nurse, as defined in section 12-38-103(11), may delegate any task included in the practice of professional nursing, as defined in section 12-38-103(10), subject to the requirements of this section. In no event may a registered nurse delegate to another person the authority to select medications if such person is not, independent of such delegation, authorized by law to select medications.***
>
> ***(2) Delegated tasks shall be within the area of responsibility of the delegating nurse and shall not require any delegatee to exercise the judgment required of a nurse.***
>
> ***(3) No delegation shall be made without the delegating nurse making a determination that, in his or her professional judgment, the delegated task can be properly and safely performed by the delegatee and that such delegation is commensurate with the patient's safety and welfare.***
>
> ***(4) The delegating nurse shall be solely responsible for determining the required degree of supervision the delegatee will need, after an evaluation of the appropriate factors which shall include but not be limited to the following:***
>
> ***(a) The stability of the condition of the patient;***
>
> ***(b) The training and ability of the delegatee;***
>
> ***(c) The nature of the nursing task being delegated; and***
>
> ***(d) Whether the delegated task has a predictable outcome.***
>
> ***(5) An employer of a nurse may establish policies, procedures, protocols, or standards of care which limit or prohibit delegations by nurses in specified circumstances.***
>
> ***(6) The board may promulgate rules and regulations pursuant to this section, including but not limited to standards on the assessment of the proficiency of the delegatee to perform delegated tasks, and standards for accountability of any nurse who delegates nursing tasks. Such rules and regulations shall be consistent with the provisions of sections 25-1-107(1)(ee) and 27-10.5-103(2)(k), C.R.S.***

Although the role of the hemodialysis technician is an important one, that alone is not reason enough to create government regulation. Colorado's existing laws and requirements are performing their intended purposes and provide protection of patients.

RECOMMENDATION 1: THE GENERAL ASSEMBLY SHOULD NOT REGULATE THE TRAINING OF HEMODIALYSIS TECHNICIANS.

APPENDIX A

SUNRISE CRITERIA

Pursuant to the Colorado Sunrise Act, C.R.S. 24-4-104.1, the applicants must prove the benefit to the public of their 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, whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument;*

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

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