2006 SUNRISE REVIEW

Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform

Hemodialysis Technicians

October 12, 2006

STATE OF COLORADO

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Bill Owens
Governor

October 12, 2006

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed its evaluation of the sunrise application for regulation of hemodialysis technicians and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, 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,

Tambor Williams

Tambor Williams
Executive Director

Table of Contents

The Sunrise Process 1

Background 1

Methodology 2

Proposal for Regulation 3

Profile of the Profession 4

Summary of Current Regulation 14

Rules, Regulations, Standards and Statutes 14

Proposed Federal Regulation 15

Colorado Department of Public Health and Environment 18

Regulation in Other States 19

Analysis and Recommendations 20

Public Harm 20

Need for Regulation 30

Alternatives to Regulation 32

Conclusion 33

Recommendation - Do not license, certify, or otherwise regulate hemodialysis technicians. 35

Appendix A – Network 15 Statistical Analysis 36

Appendix B – Vascular Access Type 37

Appendix C – Network 15 Complaint Notification Poster 38

Appendix D – Diagram of Local Dialysis Facility 39

The Sunrise Process

Background

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

> (I) 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 the harm is easily recognizable and not remote or dependent upon tenuous argument;
>
> (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation. Applications received by December 1 must have a review completed by DORA by October 15 of the year following the year of submission.

Methodology

DORA has completed its evaluation of the proposal for regulation of hemodialysis technicians. During the sunrise review process, DORA performed a literature search, contacted and interviewed the individual applicants, reviewed licensure laws in other states, conducted interviews of administrators of those programs, and interviewed numerous patients, technicians, and individuals involved in the industry. DORA also interviewed members of nationally recognized dialysis certification and advocacy organizations in addition to representatives of the federal Centers for Medicare and Medicaid Services, and the director and staff of Network 15, a federal oversight organization for dialysis patients. In order to determine the degree of state and federal oversight, and the number and types of complaints filed against dialysis technicians in Colorado, DORA staff contacted representatives of the Colorado Department of Public Health and Environment and the Colorado Board of Nursing. To better understand the hemodialysis occupation, the author of this report visited individual hemodialysis facilities in the Denver Metro area, and reviewed education and training programs at various Colorado hemodialysis facilities.

Proposal for Regulation

Individual hemodialysis patients and the Front Range Kidney Patients Association submitted two independent sunrise applications to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes, (C.R.S.). As the appropriate level of regulation for hemodialysis technicians (sometimes referred to as patient care technicians, or PCTs), the first applicant (Applicant #1) recommends licensure, while the second applicant, The Front Range Kidney Patients Association (Applicant #2), suggests that certification would be a sufficient level of regulation for Colorado.

Licensure is the most restrictive of the various forms of what is known as "credentialing," i.e., the process of granting or gaining a "credential." "Licensure" generally refers to the mandatory governmental requirement necessary to practice in a particular profession or occupation, and usually includes an examination, sometimes in addition to the completion of appropriate training or experience. A regulatory program requiring licensure frequently includes occupational practice standards and provisions for imposing discipline on licensees for violating those standards.

"Certification," on the other hand, is usually a voluntary process instituted by a non-governmental entity in which individuals are recognized for their knowledge and skill. Certification only becomes mandatory if it is adopted by a state or federal agency as the basis of a licensing program or if an employer requires it as a basis for employment. Under the proposed regulatory program requiring certification as the regulatory standard, the sole ground for imposing any form of discipline would be limited to whether a hemodialysis technician had acquired the appropriate certification.

In its sunrise application, Applicant #1 states that licensure is the appropriate level of regulation and notes that,

> many hemodialysis technicians begin their career without any previous medical training or related experience. The lack of any requirements has created a situation where the quality of care varies.

Applicant #1 further states that,

> the pool of possible workers to fill openings in this profession would not be adversely affected if licensing became mandatory. Licensing would raise the standard of professionalism for those already in the field.

Applicant #1 does not elaborate on the assertion of increased professionalism based solely upon licensure. This proposal recommends a nominal licensing fee for dialysis technicians.

In its sunrise application, Applicant #2 indicates that certification is the desired level of regulation (without licensure) because, "All dialysis units are already licensed by the State of Colorado." Applicant #2 believes that the certification requirement would have no impact on the supply of practitioners in this profession. In the sunrise application, this applicant further notes that certification would weed out the people who are not qualified to follow this type of position as a career. However, Applicant #2 does not offer any support for these two assertions, and they are somewhat contradictory. Applicant #2 states that the certification process would not affect the cost of services to the patients, as the fees are capped by the Centers for Medicare and Medicaid Services (CMS). Although this is correct for Medicare patients, this is not correct as to hemodialysis patients that compensate their dialysis facility through their own private medical insurance. Applicant #2 does not address the potential financial impact of certification and recertification on the individual hemodialysis technicians.

This is the fourth time sunrise applications for hemodialysis technicians have been submitted in Colorado. The three prior applications were submitted in 1992, 1993, and 1995. The Colorado General Assembly decided not to take action on these previous applications after reviewing the sunrise reports prepared by DORA, and has consequently declined to regulate this occupation.

Profile of the Profession

End-Stage Renal Disease (ESRD) occurs when an individual's kidneys lose about 95 percent of functional ability. In order to survive, the patient requires dialysis treatment or a kidney transplant. Dialysis removes wastes, salt, and extra water from the patient, regulates the blood for a safe level of chemicals, and assists in controlling blood pressure.

Dialysis as a life saving treatment began in the early 1960s. 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 self-administered by the patient four to six times daily, typically in the patient's home. During hemodialysis, blood is pumped outside the body into an artificial kidney machine, called a dialyzer, which cleans the blood. Hemodialysis treatments are usually done three times a week for three to four hours at a time. For hemodialysis treatments, patients generally go to a dialysis treatment center. A small percentage of patients receive hemodialysis in their homes, either with the assistance of a hemodialysis technician, nurse, or a family member trained in providing hemodialysis care.

Nationally, as of December 2004, CMS's hemodialysis oversight network system reports there were over 321,000 persons receiving dialysis treatment,[1] in contrast to the approximate 171,000 patients receiving dialysis 10 years prior, as indicated in the 1995 sunrise report. Since ESRD is more prevalent in older individuals, this number is expected to grow dramatically over the next decade as the population ages. Freestanding hemodialysis facilities (as opposed to hospital-based hemodialysis) currently provide the majority of dialysis services for patients nationwide, accounting for 84 percent of all facilities, and 87 percent of all hemodialysis treatments.[2]

The 1995 sunrise report noted that in 1994, 1,690 Colorado residents received dialysis care. However, in 2005, Network 15 reports at least 3,086 Colorado patients received dialysis care and treatment. Most of these patients will remain on dialysis for the rest of their lives, with some being candidates for, and receiving, kidney transplants.

Table 1
Total Number of Patients Receiving Dialysis in Colorado Facilities

Year	Number of Facilities	Number of Patients	Percent Increase in Number of Patients Each Year
1997	28	1,973	--
1998	30	2,187	10.85
1999	32	2,318	5.99
2000	34	2,456	5.95
2001	36	2,532	3.09
2002	40	2,663	5.17
2003	41	2,781	4.43
2004	43	2,980	7.16

Intermountain End-Stage Renal Disease Network, Inc. 2004 Annual Report.

Table 1 above indicates that the number of hemodialysis patients and facilities in Colorado steadily increased between 1997 and 2004.

The data contained in Appendix A, on page 36, indicates the number of ESRD dialysis patients by age categories in each of Network 15's six states, as of the end of 2004. This data indicates that the majority of dialysis patients are over the age of 55, which suggests that the individual instances of this disease may increase as the general population ages.

[1] End-Stage Renal Disease Network, Program Overview, p. 5, December 2005.
[2] Report to the Congress: Medicare Payment Policy, March 2005, p. 123.

Based on the number of dialysis facilities located in Colorado, industry members interviewed in Colorado estimate that the number of active hemodialysis technicians in Colorado range between 300 and 500. Meetings and discussions with representatives of many Colorado dialysis facilities indicate that most Colorado hemodialysis technicians are not certified by a national certifying entity.

The two largest private operators of hemodialysis clinics in Colorado are the companies – DaVita, Inc. (DaVita) and Fresenius Medical Care (Fresenius), although neither company has its corporate headquarters located here. Together, they account for approximately two-thirds of the hemodialysis facilities in this state, with DaVita operating at least 22 facilities, and Fresenius operating at least 12 hemodialysis facilities. Nationwide, DaVita operates over 1,400 facilities, and Fresenius operates about 1,200.

The occupation of hemodialysis technicians was identified in the 1976 Federal Register, "Conditions for Coverage of Suppliers of ESRD Services." At that time, the Federal Register indicated further study was needed to define allowable practices within the occupation. This study has never been accomplished and consequently no definitive information has been provided by the federal government on appropriate training and practice standards for hemodialysis technicians.

There are two basic types of hemodialysis technicians: equipment technicians and patient care technicians. Equipment technicians do not provide direct patient care. Rather, they perform repair and maintenance work on dialysis machinery and equipment. This report focuses on the hemodialysis patient care technicians based on the sunrise applications' request to regulate that specific occupation. Additionally, the hemodialysis patient care technicians are directly responsible for patient care and providing the actual dialysis treatments to the patients. In Colorado dialysis centers, hemodialysis technicians, Licensed Practical Nurses (L.P.N.s), or Registered Nurses (R.N.s) work directly with the patient. In some instances, a hemodialysis provider could be an unlicensed person, a L.P.N., or a R.N.

In most Colorado dialysis facilities, dialysis technicians now provide a large percentage of direct patient care services, and in most instances, care is provided under the supervision and authority of a R.N. However, the degree of supervision and the technician-to-patient ratio will often vary somewhat from facility to facility. However, it is not unusual for a single technician to provide dialysis care to three or four patients simultaneously.

Under authority provided in the delegatory clause of the Nurse Practice Act, an R.N. may delegate various tasks included in the practice of professional nursing to hemodialysis technicians. Section 12-38-132, C.R.S., reads, in part, as follows:

> (1) Any registered nurse, as defined in section 12-38-103(11), may delegate any task included in the practice of professional nursing, to hemodialysis technicians subject to the delegation requirements set forth in 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 is responsible for determining the required degree of supervision the delegatee will need, after an evaluation of the appropriate factors that 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 that limit or prohibit delegations by nurses in specified circumstances.

Under this delegatory authority, Colorado hemodialysis technicians perform the following functions:

- Prepare dialysis apparatus and supplies;
- Perform equipment safety checks;
- Initiate dialysis (including cannulation and venipucture with large gauge needles);
- Perform intravenous administration of heparin and sodium chloride solutions;

- Administer subcutaneous or topical local anesthetics in conjunction with placement of fistula needles;
- Administer intraperitoneal sterile electrolyte solutions and heparin for peritoneal dialysis;
- Monitor patients during dialysis procedures;
- Take vital signs, including blood pressure, pulse, temperature, and weight;
- Document tasks, actions, results, and staff/patient observations;
- Monitor and maintain water systems;
- Perform quality control measures; and
- Perform inventory functions.

Colorado's largest hemodialysis companies indicate that hemodialysis technicians (with no medical background) generally start at the rate of approximately $10 per hour. This translates to about $21,000 per year, assuming that the hemodialysis technician works 40 hours per week. Hemodialysis technicians' wages increase over time as they complete training, gain experience and enhance their skills. Looking at other medical technicians, by way of contrast, the U. S. Bureau of Labor Statistics reports that in May 2004, the median annual earnings of radiological technicians nationwide was $43,350, while the median annual earnings of respiratory therapy technicians nationwide was $36,740.[3] In Colorado, radiological technicians earn an average median hourly wage of $22.77 per hour, or $47,840 per year, and Colorado respiratory therapy technicians earn an average median salary of $19.08 per hour, or $39,240 per year.[4]

Work Setting and Supervision

In Colorado, 48 licensed hemodialysis treatment clinics currently operate under licenses issued by the Colorado Department of Public Health and Environment (CDPHE), pursuant to section 25-1.5-103(1)(l), C.R.S. Regulations promulgated by the CDPHE require that at least one R.N., with a minimum of one year of experience in the area of dialysis, be in attendance in a dialysis center at all times. This R.N. is often referred to as the "charge nurse."

[3] U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook, 2006–07 Edition.*

[4] U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2005 State Occupational Employment and Wage Estimates, Colorado, accessed from www.bls.gov/oes/current/oes_co.htm on August 16, 2006.

Colorado dialysis facilities must comply with numerous regulations promulgated by both the CDPHE and CMS. These regulations address the safety and emergency preparedness of a center and staff, the cleanliness and infection control practices of a center, the appropriateness of the patient treatment area, the character of patient/staff interaction, and patient grievance protocols. While these regulations do not provide a standard training program for dialysis centers to follow, the regulations do generally require that all personnel be properly trained and competent.

Many Colorado hospitals also provide dialysis services for their patients who require dialysis. These facilities operate under the hospital's license and authority rather than a freestanding dialysis facility license.

National Certification Associations

The National Association of Nephrology Technicians/Technologists (NANT) recognizes three national credentialing programs for hemodialysis technicians. Each of these programs is designed to measure a hemodialysis technician's technical knowledge in a specific area of hemodialysis through examinations. These examinations generally consist of numerous multiple-choice questions (between 100 and 200 questions), and at least one of the certification examinations can be taken on a computer.

Nephrology Nursing Certification Commission

The Nephrology Nursing Certification Commission (NNCC) offers the Certified Clinical Hemodialysis Technician (CCHT) credential. A joint task force of the NANT, and the American Nephrology Nurses' Association (ANNA) initiated the development of the CCHT examination. Technicians are eligible to take the CCHT examination with a suggested minimum of six months experience in nephrology technology. The CCHT examination measures cognitive levels in four dialysis practice areas: clinical (50 percent), technical (23 percent), environmental (15 percent), and role (12 percent). The examination fee is $125, with a $50 certification renewal fee every two years. As of December 31, 2005, the NNCC had certified 20 Colorado hemodialysis technicians.[5]

[5] Nephrology Nursing Certification Commission, 2005-2006 Annual Report, p. 4.

Board of Nephrology Examiners Nursing and Technology

The Board of Nephrology Examiners Nursing and Technology (BONENT) offers an examination for hemodialysis technician certification, leading to the Certified Hemodialysis Technician (CHT) designation. Technicians are eligible to take the CHT exam with a minimum of 12 months experience in nephrology technology. The BONENT Hemodialysis Technician Certification Examination measures technical proficiency in five major domains of practice and tasks performed in the scope of hemodialysis technology: patient care (65 percent), machine technology (10 percent), water treatment (5 percent), dialyzer reprocessing (5 percent) and education/personal development (15 percent). The examination fee is $195, with a yearly certification renewal fee of $55. According to a representative of BONENT, as of August 31, 2006, BONENT has certified 35 Colorado hemodialysis technicians.

National Nephrology Certification Organization

The National Nephrology Certification Organization (NNCO) offers two examinations: Clinical Nephrology Technology, leading to the Certified in Clinical Nephrology Technology (CCNT) credential and Biomedical Nephrology Technology, leading to the Certified in Biomedical Nephrology Technology (CBNT) credential. Technicians are eligible to take the CCNT and CBNT exams with a minimum of 12 months experience in nephrology technology. Both examination fees are $195, with re-certification every four years at a cost of $55.

The CCNT examination measures knowledge in four major areas: principles of dialysis (25 percent), machine preparation and operation (20 percent), patient assessment (20 percent) and treatment (35 percent).

The CBNT examination measures knowledge in six major areas: principles of dialysis (25 percent), scientific concepts (15 percent), electronic applications (10 percent), water treatment (20 percent), equipment functions (20 percent) and environmental/regulatory issues (10 percent).

Education and Training

The CDPHE licenses each hemodialysis facility in Colorado, and generally requires that all hemodialysis technicians be competent. The CDPHE does not offer a definition for the competent standard, or require a specific training program for technicians in the individual centers. As a result, the training that a technician receives varies, although all training programs reviewed by DORA are based on the same materials, and the education and training programs are somewhat similar in content and curriculum.

According to currently practicing hemodialysis technicians, nurses, and hemodialysis educators, training programs at Colorado hemodialysis clinics

can be described as extensive and thorough. The extent of training a technician receives depends on how much experience the individual brings to the job. An inexperienced hemodialysis trainee undergoes at least an extensive 12-week, hands-on education and training course, while a trainee with extensive hemodialysis experience may not require every aspect of the training program.

The major companies operating hemodialysis facilities in Colorado, DaVita and Fresenius, indicate that they have recently become substantially more selective in the initial hiring process, requiring some medical background of all trainees. The trainees are paid a full wage during the minimum 12-week training course.

A general list of subject areas and topics which constitute training courses in Colorado, is as follows:

- Principles of dialysis;
- Anatomy and physiology of the kidney;
- Fluid and electrolyte management;
- Infectious diseases;
- Dialysis systems and equipment;
- Initiating and concluding dialysis;
- Vascular access to circulation;
- Patient and equipment monitoring;
- Physical assessments;
- Blood chemistries;
- Complications of renal failure;
- Psychosocial aspects;
- Professional conduct;
- Treatment complications;
- Central venous devices;
- Access complications; and
- Cannulation (needle insertion), lab draws, and needle removal.

Educators in Colorado dialysis clinics test trainee dialysis technicians on both the theoretical and practical applications of hemodialysis. Technicians who pass the theory portions of the test are paired during the hands-on aspects with an experienced R.N. preceptor for at least the entire training period and then are paired with an experienced hemodialysis technician until able to perform duties on their own with reasonable skill and safety.

Subsequent to the completion of the original training program, Colorado dialysis facilities offer periodic training and skills review, and encourage continuing education through national hemodialysis education organizations, and retest hemodialysis technicians for competency on at least a yearly basis. Many hemodialysis facilities also provide financial incentives or bonuses for persons who earn national certification. In addition to continuous quality assurance programs and projects, Colorado's largest provider of dialysis services employs professional staff, many of whom began their careers as hemodialysis technicians, in the following capacities:

- Vascular Access Managers;
- Anemia Managers;
- Bone and Mineral Managers; and
- Infection Control Managers.

These managers are highly trained experts in their individual areas of dialysis care and treatment, and they are available to assist and educate hemodialysis technicians, particularly in difficult or non-routine dialysis situations.

Amgen, Inc. is a pharmaceutical company that manufactures the drug EPOGEN that stimulates the development of red blood cells during dialysis. Under a grant provided by Amgen, Inc., Medical Media, Inc. in Madison, Wisconsin, developed and updated a comprehensive core curriculum for patient care hemodialysis technicians. This curriculum contains most of the topic areas listed above, and is available and utilized as a basis of most of the dialysis facilities' educational training programs in Colorado.

By way of comparison, The National Kidney Foundation, a patient-oriented support group, has recommended a somewhat similar training course curriculum for renal technicians which includes, among other things:

- Introduction to dialysis therapies;
- Principles of hemodialysis;
- Effects on the patient of kidney failure;
- Dialysis procedures;
- Hemodialysis devices;
- Water treatment;
- Reprocessing;
- Patient education;
- Infection control; and
- Techniques used in quality assurance and continuous quality improvement.

Patient Rights and Responsibilities

The CMS contracts with, and funds, 18 ESRD network organizations covering all 50 states and U.S. territories. The territory of Network 15 includes six states: Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming.

Network 15 is involved in the assurance of quality care to individuals with ESRD, and also in the collection and validation of information about and treatment of persons with ESRD.

Through Network 15, the CMS strives to improve dialysis quality through a variety of approaches, including monitoring and reporting on quality improvement activities, vascular access management, dialysis adequacy, and anemia and nutrition levels.

Network 15 sets forth a comprehensive list of patient rights and responsibilities relating to the following topics:

- Respect, privacy and confidentiality;
- Information, education, and counseling;
- Informed consent, transfer, and refusal of treatment;
- Knowledge of facility services;
- Emergency care; and
- Grievance mechanism.

These topics related to patient rights are specifically delineated by CMS through Network 15, and information on these topics is given to all new hemodialysis patients in Colorado. Network 15's expectation is that adherence to these rights and responsibilities by the patients and the dialysis facilities will contribute to more effective dialysis care and greater satisfaction for both patients and facility personnel.

Summary of Current Regulation

Rules, Regulations, Standards and Statutes

The Medicare End-Stage Renal Disease (ESRD) program was established in 1973 to help cover the expenses ESRD patients incur. This program is very costly with 1991 Health Care Financing Administration (HCFA) data estimating the annual Medicare expenditure for a dialysis patient at $38,400. However, by 2003, the expenditure was estimated by the Centers for Medicare and Medicaid Services (CMS) to be almost $63,000 per year. In 1991, the estimated total spent on ESRD services was $8.59 billion. However, by 2003, the estimated total was $18.1 billion for dialysis services.[6] As of 2003, approximately 406,000 Americans had ESRD, and that number is expected to increase substantially.

In 1978, Congress addressed ESRD-related issues by creating 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 collect data and provide information and oversight 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 (OBRA 1987), 18 network organizations were defined with functions to be performed. The federal government, through CMS, funds the 18 ESRD Networks. Defined legislative responsibilities include the following:[7]

- Encourage the use of treatment settings most compatible with the successful rehabilitation of patients;
- Encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable for such treatment;
- Encourage patient and staff participation in vocational rehabilitation programs;
- Provide a patient grievance mechanism;
- Collect, validate, and analyze data concerning ESRD patients and their treatment;
- Provide accurate, timely data to local, state, and federal government agencies and to the public; and
- Develop criteria and standards relating to quality and appropriateness of patient care.

[6] United States Renal Data System (USRDS), 2005 Annual Data Report, available from www.usrds.org/adr.htm, accessed March 1, 2006 and August 18, 2006.
[7] The Centers for Medicare and Medicaid Services, Summary of the ESRD Network Program, January 27, 2006, available from www.cms.hhs.gov/ESRDnetworkorganization.com, accessed February 6, 2006 and August 14, 2006.

One of the most important functions of the network organizations is laid out in section 9335 of Public Law 99-509, OBRA 1987, which amended section 1881(c) of the Social Security Act. This section requires ESRD networks to implement procedures to resolve patient grievances by acting as a facilitator. Each dialysis center must inform patients of the grievance protocol and the patient's rights and responsibilities.

In order for a dialysis center to be eligible for Medicare payments, administrators and staff must comply with regulations (relating to conditions of coverage), located at 42 Code of Federal Regulations (C.F.R.) section 405.2100, *et seq*. In 1995, HCFA, which became the CMS in 2000, developed a patient-centered and outcome-oriented survey protocol for state departments of health to follow when certifying and recertifying dialysis treatment centers, and when conducting investigations concerning dialysis centers. The Colorado Department of Public Health and Environment (CDPHE) administers these federal regulations through periodic CDPHE surveys of each center.

Proposed Federal Regulation

CMS has proposed new rules modifying the current regulations governing dialysis facilities and personnel, 42 C.F.R. section 405.2100. In the proposed rulemaking, CMS has indicated that it is opposed to mandating nationwide standards and criteria for the certification of hemodialysis technicians. Its rational is threefold.[8]

First, there is no consensus within the renal community regarding the efficacy of technician certification to produce improved patient outcomes of care.[9]

Second, there is no standardized national certification test at this time, and the individuals and organizations, including the states, who advocate or have adopted certification are not in agreement regarding which certification test is the most effective. Some states have designed, or are in the process of designing, their own competency examinations, while others have recognized one or more of the existing examinations as evidence of compliance with their requirements.[10]

[8] Conditions for Coverage for End-Stage Renal Disease Facilities, 70 Fed. Reg. 6,223 (2005).
[9] Ibid at 6,223.
[10] Ibid at 6,223.

Finally, a federal certification requirement entailing mandatory competency examinations would necessitate additional costs for transportation, lodging, fees, and preparatory materials associated with the examination. Those costs would have to be borne by either the individuals seeking certification or the dialysis facilities.[11]

Without clear evidence that certification would produce better patient outcomes, CMS is reluctant to propose any new requirements that would drive up costs for hemodialysis technicians in current practice.[12]

Instead, CMS is proposing, in 42 C.F.R. section 494.140(e), a set of minimum qualifications for dialysis technicians that includes a minimum education requirement, minimum requirements for on-the-job training and experience, and proposals for the composition of an effective technician-training program.[13]

Specifically, CMS is proposing, in 42 C.F.R. section 494.140(e)(1), to require that dialysis technicians meet all applicable state requirements (for example, credentialing, certification, and licensure) in the state in which they are employed.[14]

In proposed 42 C.F.R. section 494.140(e)(2), CMS would require dialysis technicians to have at least a high school diploma or equivalency. CMS is proposing this criterion for two reasons. First, some of the states that regulate dialysis technicians (for example, Connecticut and Ohio) require dialysis technicians to have a high school education or equivalency.[15]

Secondly, other states (for example, Texas, California, Oregon, and New Mexico) that require (among other options) certification by one of the national certification organizations (Nephrology Nursing Certification Commission, National Nephrology Certification Organization, Board of Nephrology Examiners Nursing and Technology) also require a high school diploma or equivalency, because that is a prerequisite for taking the certification examination.[16] CMS also indicates that this minimal education requirement is appropriate and necessary to enable an individual to complete the wide variety of patient care functions.

[11] Ibid at 6,223.
[12] Ibid at 6,223.
[13] Ibid at 6,223.
[14] Ibid at 6,223.
[15] Ibid at 6,224.
[16] Ibid at 6,224.

Additionally, CMS is proposing in 42 C.F.R. section 494.140(e)(3), to require that each technician complete at least three months experience following the facility's training program. This experience must be gained under the direct supervision of a registered nurse with a focus on the operation of kidney dialysis equipment and machines and providing direct patient care with particular sensitivity to the management of difficult patients. CMS views dialysis technician training as a cycle that proceeds from written instruction that would provide a basic foundation of knowledge, to a necessary period of on-the-job training under the supervision of a knowledgeable professional trained in all aspects of patient care, including medical emergencies.[17]

While written instruction is essential, CMS also suggests properly supervised on-the-job training must follow to allow the technician to take maximum advantage of the information provided in the training program before the dialysis technician is allowed to provide direct patient care with minimal supervision. CMS indicates that three months of effective on-the-job, supervised training is necessary before a technician is permitted to care for patients without close and direct supervision.[18]

CMS has made this proposal for several reasons. A registered nurse has the necessary professional training and expertise to coordinate care in the unit, perform patient assessments, respond to clinical questions from staff and patients, and coordinate ongoing care. Dialysis technicians, as the primary caregivers in most dialysis units, function as extensions of the unit's professional nursing staff. CMS indicates that it is essential that a dialysis clinic's registered nurse provide the hands-on direct supervision to impart this training to new dialysis technicians.[19]

CMS further notes that a registered nurse can be very effective in instructing new dialysis technicians in necessary aspects of patient care, such as ensuring patient privacy and confidentiality, and demonstrating good interpersonal skills when dealing with patients, including disruptive or challenging patients. In addition, a registered nurse is best equipped, through training and experience, to ensure that every technician can demonstrate the basic skills needed to provide routine patient care (for example, initiating, monitoring, and terminating dialysis; proper aseptic techniques; recognizing and reporting medical errors; and dealing with medical emergencies).[20]

[17] Ibid at 6,224.
[18] Ibid at 6,224.
[19] Ibid at 6,224.
[20] Ibid at 6,224.

Colorado Department of Public Health and Environment

There are five types of ESRD facilities that are subject to CDPHE certification:[21]

1. Renal Transplantation Center - a hospital unit which provides transplantation and other medical/surgical specialty services associated with transplantation, including inpatient dialysis. A transplantation center may also be a renal dialysis center.

2. Renal Dialysis Center - a hospital unit that provides the full spectrum of diagnostic, therapeutic, and rehabilitative services to care for dialysis patients, including inpatient and outpatient dialysis.

3. Renal Dialysis Facility - a unit that provides dialysis services directly (i.e., not through contracted providers).

4. Self-Dialysis Unit - a unit that is part of a renal transplantation center, renal dialysis center, or renal dialysis facility that provides self-dialysis services.

5. Special Purpose Renal Dialysis Facility - a facility or unit that furnishes dialysis services on a short-term basis for special rehabilitative or emergency purposes, when:

    - Patients are on vacation in an area remote from the other types of ESRD facilities or near a facility that does not have the capacity to serve them.
    - Other types of ESRD facilities are closed due to natural disasters, strikes or bankruptcies and the backup facilities in the area cannot accommodate the patients of the closed facilities.

All of the certified facilities in the state, except for renal transplantation centers, are also licensed by CDPHE as dialysis treatment clinics. The transplantation centers are licensed as part of a hospital.

The Health Facilities and Emergency Medical Services Division in CDPHE conducts certification and licensing surveys for compliance with federal and state regulations and investigates any complaints filed against providers by individuals. The licensing requirements of hemodialysis facilities do not encompass specific training or education for hemodialysis technicians.

[21] The Colorado Department of Public Health and Environment, End-Stage Renal Disease Facilities/Dialysis Treatment Clinics, November 10, 2005, available from www.cdphe.state.co.us/hf/static/esrd.htm, accessed February 8, 2006 and August 18, 2006.

Thus, although hemodialysis technicians are not directly regulated, they are subject to a relatively high level of indirect regulation at both the state and federal levels.

Regulation in Other States

Some states have chosen to develop their own competency examinations or to recognize competency examinations prepared and administered by one of the three national organizations that provide competency testing and certification for hemodialysis technicians. Those organizations are the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). The common goal of these organizations is to administer effective tests that serve as a basis to certify technicians for initial or more advanced competencies in knowledge, skill and abilities.

At the time of this report, at least 15 states are using a variety of approaches and methodologies to regulate hemodialysis technicians, including minimum qualification requirements, mandatory competency testing, registration, licensure, and certification. Some states do not allow their licensed registered nurses to delegate hemodialysis care functions and responsibilities to technicians.

Arizona, Ohio, and Oregon now require hemodialysis technician certification via one of the associations that confer national certification (i.e., NNCC, BONENT, and NNCO). California and Texas require specific training and testing, but allow a nationally standardized certification examination to be substituted for their training and testing requirements. Georgia identifies a standardized training program for hemodialysis technicians, but does not require hemodialysis technicians to pass a national certification test unless a facility's training program fails to provide adequate training.

Other states, including Connecticut, South Dakota, Kentucky, Utah, Virginia, Washington, New Mexico, New York, and the District of Columbia require some form of education/training for hemodialysis technicians. States that do not regulate, but have past or ongoing efforts to regulate hemodialysis technicians and technical staff include Illinois, Louisiana, Maryland, and Oklahoma.

In any event, an analysis of regulation by other states is not very useful in this area as there is no real consensus as to the requirements for regulation, or even a consensus for education and training programs. It should be noted here that most federal and state patient advocates, facility administrators and employees, technicians, and patients agree that the regulation of hemodialysis technicians would be more comprehensive and meaningful if said regulations were enacted nationally by Congress.

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

> 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 dependent on tenuous argument.

This first sunrise criterion suggests that regulation is only justified when there is clear evidence that the public, or a segment of the public, is being harmed, or could potentially be harmed. Consequently, identifying whether the unregulated practice of hemodialysis technicians causes public harm, the type of harm caused, and the extent of that harm is critical to determining whether regulation should be imposed on the occupation.

Due to the fact that hemodialysis technicians are in the general category of health care providers, it is reasonable to address the issue of harm in terms of physical injury, damage, or providing substandard care to the patients under their care. The procedure of hemodialysis entails inherent risks to the patient as do many medical procedures.

Neither of the two sunrise applicants provided specific, verifiable examples of harm to individual patients caused by a hemodialysis technician's lack of education or training. Rather, the applicants have delineated a list of problems that can occur, or are important considerations to patients while undergoing dialysis. Combining and summarizing the sunrise applicants' general examples of harm to patients reveals the following concerns:

- Water testing for bacteria;
- Patient bath (consists of different chemicals);
- Unit misuse of a dialyzer;
- Dry weight calculations;
- Infection control;
- Cannulation (needle insertion and infiltration); and
- Inadequate training of hemodialysis technicians.

In relation to the duties and responsibilities of hemodialysis technicians, the primary patient concerns pertain to the cannulation of the patient by the hemodialysis technicians and infection control. Both of these concerns can result in a patient losing the ability to utilize the arteriovenous access.

The cannulation process generally involves the insertion of a needle into an arteriovenous access site usually located in the patients arm.

The two basic types of vascular access are an arteriovenous fistula and an arteriovenous graft. With an arteriovenous fistula, a surgeon makes a fistula by using the patient's own blood vessels; an artery is connected directly to a vein in the patient's lower arm. The increased blood flow makes the vein grow larger and stronger.

One of any hemodialysis patient's greatest fears is that the patient will lose his/her dialysis access site due to infection or a build-up of blood in the event of an infiltration. Infiltration occurs when the dialysis needle penetrates the wall of a blood vessel, causing blood to be released into the surrounding tissue. When a hemodialysis access site fails or becomes non-viable, another site must be surgically created. A new access site is prepared through surgery performed at least six to eight weeks prior to the cannulation. Until this arteriovenous access site is mature enough to accept the cannulation needle and process, the patient can only survive by receiving dialysis through a tunneled cuffed catheter placed in the patient's chest. Basically, chest catheters are hollow tubes which allow blood to flow in and out of the body, and are most commonly used as a temporary access prior to fistula maturity or if the arteriovenous fistula or graft fails or becomes infected. Appendix B on page 37 sets forth a breakdown of the types of vascular access utilized by patients in Colorado, Network 15, and nationally.

An arteriovenous graft utilizes a synthetic tube to connect the patient's artery to a vein, and does not need to physically develop as a fistula does, therefore allowing it to be used sooner after surgical placement than the fistula. However, the graft is more likely to have clotting or infection complications.

The survival rate for the individual access sites is of greater duration for those patients who utilize the arteriovenous fistula as opposed to the arteriovenous graft or the tunneled cuffed catheter. The American Nephrology Nurses' Association indicates that the three-year access survival rate for patients who use the arteriovenous fistula is 70 percent. However, the three-year access survival rate for patients who use the arteriovenous graft declines to 30 percent. Hemodialysis patients utilizing access through the tunneled cuffed catheter face a one-year access survival rate of 48 percent.[22]

[22] Nancy Szymanski, Nancy Sharp, and Kathleen T. Smith, The American Nephrology Nurses' Association, *ESRD Briefing Book for State and Federal Policymakers*, p. 11, available from www.annanurse.org/download/reference/practice/legbrief.pdf, accessed February 3, 2006 and August 21, 2006.

Specific Complaints

The Department of Regulatory Agencies (DORA) collected information from the Colorado Board of Nursing, Network 15, and the Colorado Department of Public Health and Environment (CDPHE) to help determine the actual or potential harm occurring to dialysis patients in Colorado.

Colorado Board of Nursing

Due to the fact that hemodialysis technicians operate under the delegation authority of a nurse's license pursuant to section 12-38-132, Colorado Revised Statutes, (C.R.S.), and that hemodialysis nurses provide the oversight of hemodialysis technicians, it is reasonable to ascertain whether complaints were filed against hemodialysis health care providers or technicians with the Colorado Board of Nursing (Board).

The Colorado Nurse Practice Act, section 12-38-117(1), C.R.S., allows the Board to discipline the license of any nurse who:

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

However, over the past five-year period, the Board reports that it has not received any complaints about dialysis facilities, nurses, or technicians that are employed by or provide hemodialysis services in those facilities. This is especially enlightening in light of the fact that both the CDPHE and Network 15 indicated that they would, in fact, refer appropriate patient complaints or grievances to the Board for adjudication and resolution.

Network 15

The Centers for Medicare and Medicaid Services (CMS) contracts with and funds 18 End-Stage Renal Disease (ESRD) Network organizations covering all 50 states and U.S. territories. The territory of Network 15 includes six states: Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming.

Network 15 is involved in the assurance of quality care to individuals with ESRD, and also in the collection and validation of information about and treatment of persons with ESRD.

Through Network 15, the CMS strives to improve dialysis quality through a variety of approaches, including monitoring and reporting on quality improvement activities, vascular access management, dialysis adequacy, and anemia and nutrition levels. Most recently, CMS and the network organizations have collaborated to improve vascular access. This effort, called "Fistula First," is a nationwide initiative to increase the use of arteriovenous fistulas, a type of vascular access that is associated with improved patient outcomes when compared with other types of vascular access. Network 15 provides a poster for each dialysis facility to place in the patient waiting room, which indicates where complaints are to be filed (Appendix C on page 38).

The Network Council is a major advisory committee to Network 15 and includes representatives from: all Network 15 dialysis and transplant facilities; professional disciplines involved in renal care; agencies involved in the treatment of kidney disease; and patients. Network 15, a consortium of approximately 225 dialysis and 14 transplant facilities, serves a population of approximately 14,250 dialysis patients and nearly 800 transplant patients each year.

Most of Network 15's outreach is accomplished through volunteers, health care professionals who deal with kidney disease (physicians, nurses, dieticians, social workers, hemodialysis technicians, and administrators), as well as patients. These volunteers work through the Medical Review Board, the Education Committee, the Board of Directors, and the Patient Advisory Committee.

As set forth on its website, the stated goals of Network 15 include:

- To facilitate optimal care to all ESRD patients working in cooperation with facilities' internal quality improvement programs and through the support of the CMS Health Care Quality Initiative Program (HCQIP). CMS's definition of quality care, under the HCQIP, includes access to care, appropriateness of care, desired outcomes of care, and consumer satisfaction;
- To sustain the Network 15 administrative framework to optimally plan, implement and evaluate Network 15 responsibilities and goals and to complete all CMS contract requirements;
- To maintain a patient-specific medical information system based on the data set required by CMS and to meet and/or exceed all data reporting requirements of CMS;
- To support the CMS goal for the network program of improving data reporting, reliability, and validity between ESRD providers/facilities, networks, and CMS;
- To promote access to appropriate modalities, including self-care and transplantation;

- To promote patient knowledge of and involvement in their ESRD care, and to promote patient rehabilitation;
- To serve as a resource and clearinghouse for information to the renal community including information concerning patterns, processes, and outcomes of care to aid in identifying opportunities for improvement as well as the results of both successful and unsuccessful improvement projects;
- To assist facilities in developing, implementing, and evaluating intervention strategies to improve patient care and outcomes;
- To facilitate resolution of patient grievances;
- To work collaboratively with other organizations to facilitate the improvement of care for ESRD patients; and
- To promote patient-centered care.

Grievances filed with Network 15 are confidential, although it did not receive or process any formal grievances in 2004. However, a representative of Network 15 indicated that it receives and resolves numerous informal complaints, which are somewhat different in nature then the formal grievances. In addition to receiving complaints related to the medical care and treatment provided through a facility, many of the informal complaints concern issues relating to areas such as lifestyle changes caused by ESRD, discomfort with facility ambience or policies, or a clash of personalities between the patient and a hemodialysis health care provider or employee.

In 2004, Network 15 received 36 facility-specific complaints. In 2005, Network 15 received 32 facility-specific complaints. However, none of these complaints were related to the specific care provided by a hemodialysis technician, and only two originated from Colorado.

Upon receiving a complaint, Network 15 must investigate, and if a concern is valid, the proper licensing authority within the state, CDPHE, or the appropriate regulatory agency, (depending on the individual licensee[23]), is notified.

Because of the limited number of complaints, it has not been possible to evaluate the effectiveness of this reporting requirement in Colorado.

[23] For example, if the individual is a Registered Nurse, then the complaint should go to the Colorado Board of Nursing, or if the individual is a Physician, then the complaint should be forwarded to the Colorado Board of Medical Examiners.

Colorado Department of Public Health and Environment

The CDPHE, Health Facilities and Emergency Medical Services Division (Division), pursuant to sections 25-1.5-103 and 25-3-101, *et seq.,* C.R.S., is required to annually license, and establish and enforce standards of operation for dialysis treatment facilities. Facilities and providers of dialysis services who serve Medicare and Medicaid clients must be federally certified. The goal of facility certification is to measure the ability of the facility to provide care that is safe and adequate, and in accordance with federal law and regulations.

Regulations promulgated by the CDPHE require one Registered Nurse (R.N.) with at least one year of experience in the area of dialysis, to be in attendance in all certified dialysis facilities during operating hours. A diagram of a local dialysis facility has been attached as Appendix D on page 39. This diagram indicates the close proximity of the nurse's station to the patient treatment areas.

As part of this sunrise review, DORA requested that the CDPHE provide all complaints filed by or about hemodialysis patients or technicians over the past five years.

Approximately 44 complaints were consequently submitted to DORA by CDPHE relating to the care and treatment provided to dialysis patients in 10 individual facilities in Colorado. Of the complaints, 12 were considered substantiated by the CDPHE, and 32 were deemed unsubstantiated.

The CDPHE indicated that its investigation response time reflects the severity of the complaint. That is, if the complaint is life threatening, then the response time is short, and if the complaint is not deemed serious, then the response time is longer. The two largest general categories of complaints are related to infection control and quality of care.

Although most of the following complaints did not directly relate to hemodialysis technicians' training or skills, they constitute the only complaints available in Colorado. Due to privacy concerns for the patients in these complaints, independent verification of the accuracy of these situations was not possible.

A synopsis of the complaints found to be substantiated by the CDHPE is as follows:

Incident #1

October 2003. This complaint related to the hemodialysis facility's staff's failure to properly assess a blocked stent, combined with a new fistula access site that apparently was not mature enough to accept the insertion of a needle as part of the cannulation process, even though the patient's nephrologist indicated that the fistula was ready for dialysis access. The patient's fistula site became infiltrated even though the hemodialysis technician was experienced in fistula cannulization. The result was a loss of the patient's fistula access site, thereby necessitating that a catheter be inserted into the patients chest. The patient was then dialyzed through the chest catheter that leaked large quantities of blood on the patient's shirt and body. This patient was blind and did not realize the extent of the leakage. The hemodialysis technician and the nurse subsequently allowed the patient to travel home in a public transportation van without adequately cleaning or prepping the patient for public contact.

This was basically a systematic failure by the facility's employees (doctors, nurses, and hemodialysis technicians) as the patient should not have been allowed to sustain excessive leakage and appropriate infection control would have prevented him from traveling home with blood soaked garments. The hemodialysis technician was at fault for not placing the patient in clean, dry clothing after the leakage occurred.

Incident #2

June 2005. Lack of documentation in relation to machine disinfection log. This complaint was not the hemodialysis technician's transgression.

Incident #3

July 2003. This matter was the only real complaint related to the unqualified or untrained status of an individual working as a hemodialysis technician. The CDHPE investigated this allegation, based upon patient complaints of lack of competency and poor cannulation technique, and issued a deficient practice citation to the facility.

The individual hemodialysis technician in question was originally hired as an assistant. As such, she helped in the office and with the patients, checking blood pressure and weight, but did not actually provide patient care. At the time, this northern Colorado facility experienced some hemodialysis technician turnover, and this employee went directly to the floor as a hemodialysis technician without receiving appropriate education and training for the position.

This individual was subsequently terminated as she did not adequately complete a subsequent training program and was unable to follow company/facility policy and procedures related to safe practices. Patients indicated concerns relating to the length and quality of the hemodialysis technician-training program, and the skill level of hemodialysis technicians in general, and specifically the hemodialysis technician who was the subject of this complaint. The facility acknowledged its mistakes and instituted mandatory continuing education programs as well as ensuring that hemodialysis technicians could not by-pass the original training and assessment program.

Incident #4

February 2005. The patient complained that the facility failed to infuse the patient with 150 cubic centimeters (cc) of water every 30 minutes. Although this complaint was substantiated, there was no physician order for the infusion and infusing 150 cc of water every 30 minutes is contraindicated in the dialysis process. This was not an issue relating to hemodialysis technician training, education, or performance.

Incident #5

December 2004. The allegation noted that at least four patients lost their graft access to infection, Methicillin Resistant Staphylococcus Aureus (MRSA). The CDHPE found that three of the four patients did acquire a MRSA infection at their graft access resulting in the loss of their grafts. It was not determined during the investigation whether the facility was at fault for failure to adhere to quality infection control. However, two of the four staff members responsible for the care of these patients separated from the facility shortly after this event, and the entire staff was reeducated on sterile technique and hand washing.

Incident #6

April 2004. The allegation in this complaint involved a failure to ensure patient medications were given pursuant to a physician's orders. This complaint does not relate to the care provided by a hemodialysis technician. The facility subsequently faulted a computer system that was difficult to work with.

Incident #7

December 2004. The allegation in this complaint also involved a failure to provide a patient with ordered medications. This is the same facility as Incident #6 above, and was due to the patient's change of schedule, and the computer operator's failure to enter the modification. No hemodialysis technician involvement in this complaint.

Incident #8

July 2004. The complaint alleged that the facility's nursing staff failed to provide to a patient, prescribed medication to assist in the clearing of clots in the dialysis catheter. Again, this problem did not involve a hemodialysis technician.

Other complaints deemed substantiated by the CDPHE consisted of such allegations as a failure to have an access door for physically disabled patients, uncomfortable chairs, failure to notify a spouse of a problem, and a patient denied hemodialysis at the facility because of a tight schedule when the patient arrived much later than expected.

Many other complaints were received by the CDPHE from hemodialysis patients. However, the CDPHE considered them unsubstantiated, so action to correct any alleged deficiency was not ordered by the CDHPE. The types of complaints in this category include:

- Nurses' and hemodialysis technicians' infection control practices, such as hand washing, use of gloves, reuse of dropped/nonsterile items, or blood on floor, table, or chairs;
- Privacy of patient records;
- Adequacy of training of nurses and hemodialysis technicians;
- Age of dialysis machines;
- Staff-patient ratios;
- Physician visits;
- Interruption/cutting short dialysis;
- Waiting times/scheduling;
- Medication control; and
- Medical emergency or transfer to hospital.

The question of whether the unregulated practice of hemodialysis technicians 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 dependent on tenuous argument hinges in part on the complaints/allegations provided by the CDPHE, and the lack of complaints relating to the profession from the Colorado Board of Nursing and the federally funded Network 15.

Every state-certified hemodialysis facility is mandated by federal law to inform patients of their right to file any concerns or complaints with the ESRD network about the care they received. Dialysis facilities in Colorado utilize a poster prepared by CMS, which is prominently displayed (usually in the patient waiting room) setting forth the telephone number and address of both CDPHE and Network 15, should any complaints or problems be unresolved at the facility level or otherwise (See Appendix C on page 38.).

Incident #1 indicates that the hemodialysis technician clearly made an error in judgment by allowing the patient to sit for a period of time in a blood soaked garment, and then allowing the patient to travel home in a public transportation van. This exhibited a lack of infection control by the individual hemodialysis technician and the facility by placing the patient in a position of exposing the public to airborne/blood-borne material (i.e., bloody clothing). Although no actual harm occurred to the patient, this transgression although serious, seems more of a lack of common sense than an error caused by lack of education or training. Nonetheless, infection control is one of the main curriculum areas in the educational training process for new, prospective hemodialysis trainees, consequently, this hemodialysis technician might have been the subject of a disciplinary action if a state board of hemodialysis technicians existed.

None of the other CDPHE-substantiated complaints relate directly to the expertise of a hemodialysis technician, with the exception of Incident #3. Incident #3 is the only substantiated allegation of a hemodialysis technician being untrained or uneducated in the area of hemodialysis care. When evaluating this type of occurrence, it is the type of transgression that could be classified as a facility error. Of course, this untrained individual was not really a hemodialysis technician, which entails completing a training and education course, and then successfully passing all written and hands-on testing associated with said training and education prior to providing hemodialysis patient care services. Of the hundreds of hemodialysis technicians practicing in Colorado, this is the only documented allegation of a lack of proper education and training.

Individual patients point out that, as a generalization, hemodialysis patients are a vulnerable and fragile group who depend on their hemodialysis technician for life saving (and life continuing) services. The patients note that they are very reluctant to complain to the facility, Network 15, or the CDPHE, as they fear that consequences such as poor care from their hemodialysis technician could result should they be identified as a complainer or troublemaker. This argument has some merit to it as many individual patients suggested it as the reason why more complaints were not filed, especially considering the large number of hemodialysis patients and technicians in Colorado.

Based upon the number and type of complaints filed with the CDPHE, and the lack of complaints filed elsewhere, the unregulated practice of hemodialysis technicians does not clearly harm or endanger the health, welfare, or safety of the public.

Need for Regulation

The second sunrise criterion asks:

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

Both of the sunrise applicants propose that either certification or licensure will generally serve to protect the patients and public by enhancing education, training, and professionalism. These individual goals should be considered in the context of what they actually offer to the ESRD patient and the public.

There is no evidence to indicate that the education and training Colorado hemodialysis technicians receive is inadequate, and thereby places the patient's care at risk. Of course, kidney failure and hemodialysis can be and are life-threatening/saving events. No amount of education and training can make the inherently dangerous procedure of hemodialysis totally risk-free.

Of great importance, there have been no studies, either on a state or federal level, that indicate or suggest that certification or licensure enhance or improve the medical care provided to patients by hemodialysis technicians. However, the most compelling factor in providing quality care and treatment to hemodialysis patients is the training process which lasts for at least 12 weeks, and is designed to test a prospective technician's specific knowledge, skills and competency. Another purpose is to eliminate those individuals that are unable to master the knowledge and skills necessary to provide quality services to patients.

Certification

The process of acquiring national certification as a hemodialysis technician is limited to the three testing organizations, the National Association of Nephrology Technicians/Technologists (NANT), the Nephrology Nursing Certification Commission (NNCC), and the Board of Nephrology Examiners Nursing and Technology (BONENT). Certification does not include an aspect of hands-on training or other meaningful training between a hemodialysis technician and another experienced heath care provider, although these three organizations require that a candidate complete a training program, and suggest active participation in an ESRD facility prior to taking the examinations. Nonetheless, their examinations test the applicant's knowledge of hemodialysis through a multiple-choice test, frequently administered by and through a computer program.

These certification programs, consisting only of multiple-choice tests, are not equal to the 12-week, hands-on education and training courses currently in effect at Colorado hemodialysis facilities contacted by DORA. All of the educational materials currently in use throughout Colorado are based on the same information and data, which was generally derived from the comprehensive Core Curriculum for the Dialysis Technician, by Amgen, Inc.

Licensure

The licensure process generally entails the oversight by a state entity (board or program) and, in addition to a possible form of certification as a condition of licensure, contains many of these following items:

- Authority to establish licensure criteria;
- Authority to investigate complaints;
- Rulemaking authority; and
- Complaint, disciplinary, and administrative processes.

The sunrise application requesting regulation by licensure did not contain references to these items.

Alternatives to Regulation

The third sunrise criterion asks:

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

Alternatives to the regulation of hemodialysis technicians exist that are more cost effective approaches for Colorado without compromising the quality of patient care. The underlying basis for the request for regulation is to standardize the education and training programs for hemodialysis technicians.

The current education and training programs in effect in hemodialysis facilities contacted by DORA in connection with this sunrise review afford a greater degree of competency and protection to dialysis patients than the requirements of either national certification or state licensure. This is evidenced by the lack of discernable harm to the patients as noted in the complaint review. Unfortunately, it is the perception of the individual patients that the hemodialysis technicians do not receive appropriate training prior to providing hemodialysis services to the patients.

The two largest private operators of hemodialysis clinics in Colorado account for approximately two-thirds of the hemodialysis facilities in this state. Both of these companies employ numerous nurses and hemodialysis technicians to staff and provide hemodialysis services at their Colorado clinics. Both companies have a similar education and training program in effect for newly hired employees. Generally, if a trainee fails to perform up to expectations in either the educational or clinical aspect, that trainee is terminated from the program. The companies' curriculum, training, and education process has evolved and improved over the past five years.

DORA also reviewed the education and training programs of some of the smaller companies operating hemodialysis facilities in Colorado. These companies operate 11 hemodialysis facilities in Colorado, although the exact number of facilities changes frequently. These facilities have mandatory training programs, which include nurse preceptors who are trained as one-on-one educators. As an example, upon completing the 12-week training course, new hemodialysis technicians must perform at least 15 supervised cannulizations before they are allowed to perform one unsupervised.

Most hemodialysis facilities have a well-defined and voluntary quality assurance program in effect, which often includes a quarterly quality index rating. Colorado hemodialysis facilities have demonstrated that they strive to offer the best medical care and treatment possible, and Colorado's largest operator of dialysis clinics reports that it has a higher quality control rating in Colorado than its dialysis facilities in most other states. Consequently, the current system of education and training, performed by the companies responsible for providing hemodialysis services in Colorado, is the most viable alternative to the start-up of a regulatory program.

Conclusion

Although kidney failure and hemodialysis is a life threatening and life saving procedure, there is a lack of evidence to indicate that any risk associated with dialysis would be lessened or decreased by creating a certified training program, or requiring licensure, for hemodialysis technicians.

The evidence, in general, does not support the applicants' contentions that the training that the technicians currently receive is inadequate or consequently places the patient at medical risk. To the contrary, the training programs in place in Colorado exceed programs that provide certification on a national level, but offer nothing in the way of hands-on training and education.

The individual companies that provide the hemodialysis services to the patients pay for these education and training programs in Colorado, and there is no cost to the state or to members of the occupation. The hemodialysis technician trainee is fully compensated by the facility throughout the 12-week training course.

Allegations from patients suggesting that the individual companies do not care about patients are unsubstantiated. To the contrary, the individual companies and facilities are apparently providing appropriate education and training, and at their own expense.

The specific complaints filed with the CDPHE fail to indicate that hemodialysis technicians are causing harm to the patients. The lack of complaints, even in light of the patients' alleged reluctance to file complaints, also supports this contention.

Some national associations (for example the American Nephrology Nurses' Association and the National Association of Nephrology Technicians) have advocated for national uniform training and certification requirements for dialysis technicians for several years, and continue to advocate for these measures at the state and national levels. Their primary concern is to ensure that dialysis care and treatment is provided by qualified and trained health care workers who are able to demonstrate the necessary competencies to perform the assigned duties of their positions. Most of the individuals interviewed by DORA indicated that regulation at the federal level would be much more desirous and comprehensive than state regulation.

The current national certification programs do not offer any training or hands-on experience; rather they simply offer a multiple-choice examination to test an applicant's general knowledge of hemodialysis patient care and technology.

Although there is little if any support for regulation of hemodialysis technicians in the occupation and industry, there appears to be strong support for regulation among the patients and patient groups. This support is sometimes misplaced, as the patients often believe that the certification/licensure process is more meaningful and comprehensive then the actual reality of such programs.

Those patients that, for different and varied reasons, are hesitant or afraid to offer complaints to the individual hemodialysis facilities, the Colorado Board of Nursing, Network 15, or the CDPHE, would likely be reluctant or hesitant to file a complaint with a state board overseeing hemodialysis technicians for the same reasons: fear of retaliation or retribution. Pursuant to due process requirements, a hypothetical State Board of Hemodialysis Technicians would send a copy of any patient complaint to the individual hemodialysis technician in question for a response or explanation. For the patients, this would have the same perceived "chilling effect" as complaints currently filed with the existing state and federal agencies.

The most compelling argument raised in support of imposing new regulation concerns the potential for harm among ESRD patients in the areas of infection control and cannulization, both could lead to the loss of intravenous access, infection, and compromise a patient's life. Although the hemodialysis procedure carries the potential for a risk of harm to the patients, there is no definitive or conclusive evidence demonstrating that hemodialysis technician certification or licensure reduces or eliminates the major problems and concerns inherent in receiving dialysis therapy. As mentioned above, the national certification process does not train individuals regarding the techniques required for the proper and competent cannulation of the patients.

Federal CMS regulators have declined to request regulation of this occupation even though the federal government finances the national Network program through CMS. CMS's rationale is three-fold:

1) There is no consensus within the hemodialysis community regarding the efficacy of technician certification to provide improved patient outcomes and care.

2) There is no one generally-accepted national certification test available to the profession.

3) A certification (or licensure) requirement would necessitate additional costs for transportation, fees, and preparatory materials associated with an examination.

These factors are also relevant and determinative in Colorado. This is especially true in light of the 12-week, hands-on training programs that each new technician must complete satisfactorily prior to being allowed to work directly with hemodialysis patients. As noted, a two-hour, multiple-choice examination does not address the patients' most overwhelming complaint, cannulation with the potential complication of infiltration. There is insufficient evidence to conclude that certification or licensure by the State of Colorado will reduce or eliminate this concern.

Recommendation - Do not license, certify, or otherwise regulate hemodialysis technicians.

Appendix A – Network 15 Statistical Analysis

Newly Diagnosed Chronic ESRD Patients

(ESRD Incidence)

Newly diagnosed chronic ESRD patients by state of residence, age, gender, race and primary diagnosis for calendar year 2004

Age Group	AZ	CO	NM	NV	UT	WY	Other	Total
00-04	4	0	1	1	3	0	0	9
05-09	2	4	1	1	1	0	0	9
10-14	7	3	3	3	2	0	0	18
15-19	10	12	6	7	6	0	2	43
20-24	18	16	7	12	8	0	2	63
25-29	35	26	7	8	14	2	0	92
30-34	27	26	16	17	11	5	1	103
35-39	57	33	24	22	15	3	1	155
40-44	90	48	18	26	21	3	5	211
45-49	111	52	41	43	24	3	4	278
50-54	144	90	57	47	25	5	5	373
55-59	202	91	76	74	31	8	8	490
60-64	233	107	81	88	45	6	6	566
65-69	252	103	74	96	38	7	8	578
70-74	272	106	65	107	47	9	9	615
75-79	219	99	38	86	38	7	9	496
80-84	186	70	39	64	23	7	3	392
>=85	124	41	16	36	11	1	2	231
Missing	0	0	0	0	0	0	0	0
Total	**1993**	**927**	**570**	**738**	**363**	**66**	**65**	**4722**

Table #2

Living ESRD Dialysis Patients

(ESRD Dialysis Prevalence)

All active Dialysis Patients by state of residence, age, race, gender and primary diagnosis as of 12/31/2004.

Age Group	AZ	CO	NM	NV	UT	WY	Other	Total
00-04	4	2	0	2	3	0	0	11
05-09	3	8	1	1	6	0	0	19
10-14	10	7	8	12	2	1	2	42
15-19	31	22	8	11	5	1	1	79
20-24	58	36	24	28	23	3	3	175
25-29	89	52	43	36	36	5	1	262
30-34	116	88	48	56	37	8	4	357
35-39	195	121	91	77	40	8	6	538
40-44	314	172	99	116	56	14	6	777
45-49	393	209	179	133	51	16	9	990
50-54	513	304	247	184	83	22	10	1363
55-59	696	311	292	209	112	34	13	1667
60-64	724	335	301	210	127	16	12	1725
65-69	767	355	275	223	120	28	17	1785
70-74	710	346	275	227	117	25	6	1706
75-79	573	290	186	181	104	30	20	1384
80-84	430	212	126	105	64	24	7	968
>=85	226	91	36	58	30	1	4	446
Missing	0	0	0	0	0	0	0	0
Total	**5852**	**2961**	**2239**	**1869**	**1016**	**236**	**121**	**14294**

Appendix B – Vascular Access Type

Regional Averages 2004			
Vascular Access Type In Use	Colorado	Network 15	United States
Arteriovenous Fistula	48.7%	43.6%	36.6%
Arteriovenous Graft	27.4%	27.6%	34.9%
Catheter	23.0%	26.4%	27.5%

Appendix C – Network 15 Complaint Notification Poster

I have a Problem?

Patients and family members should not hesitate to discuss facility problems. To fix a problem you should:

- Talk to your staff members first (social worker, head nurse, administrator, or doctor)
- Follow the steps of your facility's grievance procedure

If the problem remains and is about quality of care issues, you can contact:

ESRD Network #15:

Intermountain End-Stage Renal Disease Network
1301 Pennsylvania St, #750
Denver, CO 80203
1-800-783-8818
E-mail: info@nw15.esrd.net

OR

Your State Survey Agency:

Colorado Dept of Public Health
4300 Cherry Creek Dr South
HFD, Bldg A, 2nd Floor
Denver, CO 80246
1-800-886-7689 (toll free in-state)
303-692-2800

- For Medicare billing issues call Noridian Mutual Ins. Co. . . . . (800) 332-6681
- For Medicare coverage issues call the Medicare Hotline . . . . (800) 633-4227
- If problem remains, call your Centers for Medicare & Medicaid Services (CMS) Regional Office . . . . . (303) 844-4024

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Appendix D – Diagram of Local Dialysis Facility