



COLORADO

**Department of
Regulatory Agencies**

Colorado Office of Policy, Research &
Regulatory Reform

2018 Sunset Review: Regulation of Hemodialysis Technicians

October 15, 2018



COLORADO

Department of
Regulatory Agencies

Executive Director's Office

October 15, 2018

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 General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Since that time, Colorado's sunset process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), directs the Department of Regulatory Agencies to:

- Conduct an analysis of the performance of each division, board or agency or each function scheduled for termination; and
- Submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed the evaluation of the regulation of hemodialysis technicians. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2019 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Section 108 of Article 1.5 of Title 25, C.R.S. The report also discusses the effectiveness of the Colorado Department of Public Health and Environment in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Marguerite Salazar
Executive Director





COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research &
Regulatory Reform

2018 Sunset Review Regulation of Hemodialysis Technicians

SUMMARY

What is regulated?

Hemodialysis technicians provide direct patient care in dialysis treatment clinics. Their duties include preparing and maintaining dialysis equipment, initiating dialysis, and monitoring patients during treatment.

Why is it regulated?

Attaining national certification assures that hemodialysis technicians possess the basic knowledge and skills to provide safe and competent care.

Who is regulated?

There are a total of 82 licensed dialysis treatment clinics in Colorado. Since Colorado regulates dialysis clinics, rather than individual technicians, the exact number of technicians in the state is unknown, but according to data from national credentialing bodies, there are over 500.

How is it regulated?

The Colorado Department of Public Health and Environment (CDPHE) licenses dialysis treatment clinics. As a condition of such licensure, a clinic must demonstrate that all hemodialysis technicians it employs hold national certification and work under the supervision of a licensed physician or a licensed professional nurse. CDPHE verifies the credentials of hemodialysis technicians before granting initial licensure to a dialysis treatment clinic and during routine on-site inspections, which occur every three years.

What does it cost?

The cost of regulation is rolled into the licensing and renewal fees for dialysis clinics. CDPHE receives between \$200,500 and \$217,000 in licensing fees from dialysis clinics per year.

What disciplinary activity is there?

From fiscal year 12-13 to fiscal year 16-17, CDPHE received a total of 45 complaints against licensed dialysis clinics. None of the complaints contained allegations against hemodialysis technicians.

KEY RECOMMENDATIONS

Continue the regulation of hemodialysis technicians indefinitely.

As the front-line providers of care in dialysis clinics, hemodialysis technicians must possess the proper education and training to safely perform routine dialysis tasks and to know when to alert the supervising nurse or physician to any concerning changes in a patient's condition. Therefore, regulation is justified. The regulatory environment has changed, however, since the General Assembly first imposed regulation on hemodialysis technicians. The federal Centers for Medicare and Medicaid Services now requires hemodialysis technicians to be certified. Now that there are explicit federal standards in place, the utility of continuing to subject Colorado's hemodialysis technician statutes to sunset review is unclear. While the specific requirement that hemodialysis technicians work under physician or RN supervision is unique to Colorado law—federal rule imposes no such specific requirement—the typical administrative structure of any licensed dialysis clinic means that such supervision is inevitable, and no stakeholders reported finding the supervision requirement unduly burdensome. The past two sunset reviews—this one, and the one conducted in 2011—have identified no issues with the competence of hemodialysis technicians that would warrant additional regulation. CDPHE surveys have revealed that Colorado dialysis clinics are employing hemodialysis technicians who are properly educated, certified, and supervised. The regulatory framework at both state and federal levels assures that hemodialysis technicians will continue to work under supervision in tightly regulated environments.

METHODOLOGY

As part of this review, Colorado Office of Policy, Research and Regulatory Reform staff interviewed CDPHE staff, federal regulators, and representatives of dialysis clinics; and reviewed federal laws and Colorado statutes and rules.

MAJOR CONTACTS MADE DURING THIS REVIEW

American Renal Associates
Colorado Department of Public Health and Environment
DaVita
Health Services Advisory Group, End Stage Renal Disease Network #15
Fresenius

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria¹ and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

¹ Criteria may be found at § 24-34-104, C.R.S.

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- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
 - Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection - only those individuals who are properly licensed may use a particular title(s) - and practice exclusivity - only those individuals

who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements - typically non-practice related items, such as insurance or the use of a disclosure form - and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency - depending upon the prescribed preconditions for use of the protected title(s) - and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at: www.dora.colorado.gov/opr.

The functions of the Colorado Department of Public Health and Environment (CDPHE) as enumerated in Section 108 of Article 1.5 of Title 25, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2019, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the regulation of hemodialysis technicians pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation of hemodialysis technicians should be continued and to evaluate the performance of CDPHE. During this review, CDPHE must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff interviewed Division staff, reviewed program records, interviewed representatives of dialysis clinics, and reviewed federal laws and rules and Colorado statutes and rules.

Profile of the Profession

Dialysis² is the most common treatment for end-stage renal disease (ESRD), which occurs when a person’s kidneys can no longer effectively remove impurities, salts, and excess water from the body. In dialysis, a machine performs the function of the kidneys. A tube is inserted in the patient’s arm, via a catheter, graft, or a fistula,³ which is connected to a hemodialysis machine. The patient’s blood is pumped out of the body and into a filtration device called a dialyzer, which removes impurities from the blood. The cleansed blood is then pumped back into the patient’s body.

Although some dialysis patients undergo treatment in the home, most patients receive treatment in an outpatient dialysis clinic three times a week. Each session lasts from three to four hours.

Hemodialysis technicians, also called “patient care dialysis technicians” or “patient care technicians,” are the primary care providers in dialysis clinics. Colorado law defines a hemodialysis technician as any person who provides direct care to dialysis patients and who is not a physician or a licensed professional nurse (RN). The duties of hemodialysis technicians typically include:

- Monitoring and recording patients’ vital signs before, during, and after treatment;
- Cleaning and maintaining equipment, including dialyzers;
- Observing and continually assessing patients during treatment, and taking emergency measures if needed;
- Administering drugs and local anesthetics (under the supervision of a licensed physician or RN); and
- Educating patients on home dialysis, if appropriate.

The federal Centers for Medicare and Medicaid Services (CMS) set standards for dialysis clinics and clinic personnel, including hemodialysis technicians.

Under CMS rule, prospective hemodialysis technicians must complete a training program addressing specific topics. Most dialysis treatment clinics offer training programs on-site. A typical training program is 90 days long and consists of a didactic portion, where the prospective hemodialysis technician learns basic anatomy and

² There are two types of dialysis: hemodialysis and peritoneal dialysis. This report focuses exclusively on hemodialysis, so all uses of the term “dialysis” refer to hemodialysis.

³ Fistula: A surgically created connection of an artery to a vein.

principles of dialysis, followed by a clinical portion, where the prospective technician shadows an experienced RN or certified technician.

Federal rule also requires hemodialysis technicians to be certified either under a state program or under a national certification program. Colorado does not offer its own certification program, so prospective hemodialysis technicians must gain certification by passing one of three national credentialing examinations.

Patients with ESRD must undergo dialysis for the rest of their lives, unless they receive a kidney transplant. However, because the demand for donor kidneys far exceeds the supply, potential kidney recipients typically face a considerable wait before becoming eligible for a transplant.⁴ According to data from the United States Renal Data System, in 2015, there were nearly 500,000 Americans receiving dialysis treatment.⁵

Both the incidence (the number of new diagnoses) and the overall prevalence (the number of people living with any stage of the disease) of ESRD increased from 2009 to 2015, due to an increasing U.S. population, the aging of the population, and the fact that people with ESRD are living longer.⁶ This trend seems to support an ongoing need for hemodialysis technicians.

According to CDPHE's website, in August 2018, there were 82 licensed dialysis centers in Colorado,⁷ having a total number of 1,346 dialysis stations.

⁴ According to data from the Organ Procurement and Transplantation Network, as of May 2018, there were 95,143 people on the waiting list for a kidney transplant; in 2017, 15,222 kidneys were donated. Source: U.S. Department of Health and Human Services. *Organ Procurement and Transplantation Network*. Retrieved on May 30, 2018, from <https://optn.transplant.hrsa.gov/data/>

⁵ United States Renal Data System. *2017 USRDS Annual Data Report: Executive Summary*. Retrieved on September 10, 2018, from https://www.usrds.org/2017/view/v1_00.aspx

⁶ United States Renal Data System. *2017 USRDS Annual Data Report: Executive Summary*. Retrieved on September 10, 2018, from https://www.usrds.org/2017/view/v1_00.aspx

⁷ Colorado Department of Public Health and Environment. *Health Facility Demographic Information: End-Stage Renal Facilities*. Retrieved on July 31, 2018, from <http://www.hfemsd2.dphe.state.co.us/hfd2003/homebase.aspx?Ftype=esrd&Do=list>

Legal Framework

History of Regulation

Before the creation of the hemodialysis technician regulatory program, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) conducted four separate sunrise reviews⁸ of hemodialysis technicians. While the 1992 report recommended establishing standards for hemodialysis technician education programs, the 1994, 1995, and 2006 reports recommended against imposing any regulations on hemodialysis technicians, finding it unnecessary since hemodialysis technicians worked under supervision in highly regulated environments (i.e., dialysis clinics).

The General Assembly established basic requirements for hemodialysis technicians in 2007, with the passage of House Bill 07-1131 (HB 1131). The bill was a grassroots initiative brought forth by dialysis patients, who supported uniform training and certification requirements for hemodialysis technicians.

Rather than creating a traditional licensure or certification program, HB 1131 made the new requirements for hemodialysis technicians part of the state's regulation of dialysis clinics. The bill established that after January 1, 2009, dialysis treatment clinics licensed by the Colorado Department of Public Health and Environment (CDPHE) must ensure all hemodialysis technicians they employ are credentialed by a national credentialing program and working under the supervision of a licensed physician or licensed professional nurse (RN). The bill also directed the State Board of Health to adopt rules establishing a process for CDPHE to verify that all hemodialysis technicians meet those requirements.

At the time the General Assembly passed the bill, the federal Centers for Medicare and Medicaid Services (CMS) had no specific certification requirement, requiring only that hemodialysis technicians meet any applicable state requirements and be generally qualified to perform their duties. In April 2008, however, CMS revised its regulations to mandate that hemodialysis technicians meet specific education and certification requirements. The revised CMS rule also laid out specific content areas that education programs for hemodialysis technicians must cover.

Following the 2011 sunset review, the General Assembly extended the regulation of hemodialysis technicians for seven years and added language clarifying that CDPHE verifies hemodialysis technicians' credentials whenever it conducts a routine survey of a dialysis clinic.

⁸ A sunrise review is a comprehensive study of a currently unregulated profession or occupation that recommends to the General Assembly whether regulation of such profession or occupation should be imposed to protect the public.

Legal Summary

The federal laws governing hemodialysis technicians are located in Title 42 of the Code of Federal Regulations (C.F.R.), section 494.140, and Section 108 of Article 1.5 of Title 25, Colorado Revised Statutes (C.R.S.).

Under federal law, all hemodialysis technicians must:⁹

- Meet all applicable state requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the state in which he or she is employed;
- Have a high school diploma or equivalency;
- Have completed a training program—approved by the medical director and governing body and directed by an RN—that focuses on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects:
 - Principles of dialysis.
 - Care of patients with kidney failure, including interpersonal skills.
 - Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.
 - Possible complications of dialysis.
 - Water treatment and dialysate preparation.
 - Infection control.
 - Safety.
 - Dialyzer reprocessing, if applicable.
- Be certified under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis patient care technician.

Colorado law requires hemodialysis technicians to be credentialed by a national credentialing program and to work under the supervision of a licensed physician or a RN who has training or experience in dialysis treatment.¹⁰

State law exempts from the certification requirement people providing dialysis care either to themselves or to friends or family members, as long as such people provide the care free of charge and do not represent themselves as hemodialysis technicians.¹¹ Participants in a hemodialysis technician training program may work as hemodialysis technicians as long as they are under the direct supervision of a

⁹ 42 C.F.R. § 494.140.

¹⁰ § 25-1.5-108(3)(a), C.R.S.

¹¹ § 25-1.5-108(3)(c)(I), C.R.S.

physician or RN with dialysis training or experience. The supervising physician or RN must be on the premises and available for prompt consultation or treatment.¹²

Section 25-1.5-103, C.R.S., grants CDPHE the authority to regulate dialysis treatment clinics. Under Colorado law, licensed dialysis treatment clinics cannot allow anyone to work as a hemodialysis technician unless he or she has obtained the required credential,¹³ except that people enrolled in a hemodialysis technician training program may work as hemodialysis technicians for up to 18 months without being certified.¹⁴ Clinics must comply with this requirement as a condition of licensure, and CDPHE is responsible for verifying clinics' compliance.¹⁵

To this end, dialysis treatment clinics must maintain records documenting the credentials of all the hemodialysis technicians they employ. At the time of initial licensure, re-licensure, and upon request, clinics must provide to CDPHE a list of all the technicians on staff, their dates of hire, and the name of each applicable certification organization. For employees who are enrolled in a hemodialysis technician training program and are not yet certified, clinics must provide the date they entered the technician training program.¹⁶

If a dialysis treatment clinic fails to ensure its technicians meet the certification requirement, CDPHE can revoke, suspend, or impose conditions on the clinic's license.¹⁷ Typically when CDPHE finds a clinic is not in compliance with applicable laws and rules, it issues a public report citing the clinic for deficiencies. The clinic then has a specified time period within which to correct the deficiencies.

¹² § 25-105-108(3)(c)(II), C.R.S.

¹³ §§ 25-1.5-108(3)(b), C.R.S.

¹⁴ § 25-1.5-108(3)(c)(II), C.R.S.

¹⁵ § 25-1.5-108(4), C.R.S.

¹⁶ 6 CCR § 1011-1-5.6.2, Standards for Hospitals and Health Facilities, Chapter XV, Dialysis Treatment Clinics.

¹⁷ 6 CCR § 1011-1-2.9.3, Standards for Hospitals and Health Facilities, Chapter II, General Licensure Standards.

Program Description and Administration

The Colorado Department of Public Health and Environment (CDPHE) is vested with the authority to regulate dialysis treatment clinics in Colorado. As a condition of licensure, such clinics must ensure that all hemodialysis technicians are credentialed as required by state and federal law.

When the credentialing and supervision requirements were first implemented, CDPHE charged dialysis treatment clinics a separate \$200 fee to support the program. However, CDPHE found that the cost to administer the program was low and did not warrant maintaining a separate fee. Consequently, the cost of the program is rolled into the licensing and renewal fees for dialysis clinics. CDPHE receives between \$200,500 and \$217,000 in licensing fees from dialysis clinics per year.

Currently, dialysis treatment clinics pay a \$5,140 fee for the initial license, which must be renewed annually. Renewal fees are based upon the number of dialysis procedure stations a clinic has:

- 1-12 stations: \$1,600 per facility.
- 13-23 stations: \$2,520 per facility.
- 24 or more stations: \$3,435 per facility.¹⁸

While CDPHE is responsible for licensing, surveying, and enforcing state and federal standards for dialysis treatment clinics, the federal Centers for Medicare and Medicaid Services (CMS) contracts with the Health Service Advisory Group (HSAG) to implement the End Stage Renal Disease (ESRD) program for Network 15—an area encompassing Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming.

HSAG's responsibilities include assuring that the 1,400 dialysis clinics in Network 15 meet CMS quality standards; collecting and reporting data; and investigating consumer complaints.

Certification of Hemodialysis Technicians

Under the current regulatory regime, hemodialysis technicians must obtain certification from either a state program or a national, commercially available credentialing program. Colorado does not have its own credentialing program, so accepts credentialing from three nationally available programs: the Certified Clinical Hemodialysis Technician (CCHT) examination offered by the Nephrology Nursing Certification Commission, the Board of Nephrology Examiners for Nursing and Technology (BONENT) examination, and the National Nephrology Certification Organization (NNCO) examination.

¹⁸ 6 CCR § 1011-1-3.1, Standards for Hospitals and Health Facilities, Chapter XV, Dialysis Treatment Clinics.

In order to sit for any of the three examinations, candidates must have a high school diploma or equivalent and have either completed a hemodialysis technician training program or possess equivalent experience providing patient care in a dialysis treatment clinic. Almost all dialysis treatment clinics offer training programs on-site. Typically, programs are 90 days long and include a didactic and a clinical component.

All three examinations are offered at multiple test sites across Colorado. The examinations consist of 150 to 200 multiple-choice questions and have a three-hour time limit. The examination fees range from \$220 to \$255.

The examinations cover similar subject matter, in different proportions. The general areas the examinations cover include:

- Principles of dialysis;
- Patient care, including monitoring and documenting vital signs and recognizing complications;
- Dialysis equipment and procedures;
- Water treatment and dialysate preparation;
- Infection control, sanitation, and universal precautions; and
- Interpersonal skills and professional development.

Once they have passed the certification examination, hemodialysis technicians must periodically recertify. BONENT and NNCO require recertification every four years; CCHT, every three years. In order to qualify for recertification, hemodialysis technicians must complete a certain number of hours of continuing education or document a specified number of hours of work experience. Recertification fees for NNCO and CCHT are \$150 for four years and \$100 for three years, respectively. BONENT does not charge a recertification fee.

All three credentialing programs also permit candidates to recertify by retaking the certification examination.

Verification of Hemodialysis Technician Credentials

Individual hemodialysis technicians are not required to apply to CDPHE for licensure or certification, and CDPHE does not maintain a registry of credentialed technicians. Rather, dialysis treatment clinics are responsible for employing only those hemodialysis technicians who have met the credentialing requirement. CDPHE must verify that licensed clinics are in compliance with this requirement as part of its regulation of such clinics.

CDPHE verifies the credentials of hemodialysis technicians before granting initial licensure to a dialysis treatment clinic and during routine on-site inspections, which occur every three years.

Anyone seeking to establish a dialysis treatment clinic must submit an application with the required supporting materials and fees. If after reviewing the completed application, CDPHE finds the applicant complies with all applicable laws and rules, CDPHE conducts an inspection of the proposed clinic. As part of the initial inspection, CDPHE reviews the personnel files of all employees, including hemodialysis technicians. Following this inspection, CDPHE may grant the initial license.

Dialysis treatment clinics must renew their licenses annually.

When submitting a renewal application to CDPHE, clinics must submit a list of all the hemodialysis technicians it employs, their date of hire—or, for technicians that are not certified, the date they entered a technician training program—and the name of each applicable credentialing organization. Upon receiving the renewal application, CDPHE’s administrative staff randomly selects one in three hemodialysis technicians from the submitted list, and verifies those technicians’ certification directly with the credentialing body. This verification process takes approximately one hour per clinic.

CDPHE conducts a routine, on-site inspection of each licensed dialysis treatment clinic at least once every three years. As part of this routine inspection, CDPHE reviews the personnel files of all employees, including hemodialysis technicians.

In July 2018, there were 82 licensed dialysis treatment clinics in Colorado. CDPHE does not maintain a registry of individual hemodialysis technicians and cannot provide an exact count of the number of hemodialysis technicians the clinics employ. However, in July 2018, the website of the Nephrology Nursing Certification Commission listed 506 Colorado hemodialysis technicians holding the CCHT certification; the NNCO website listed 9 holding the NNCO certification. At this writing, the number of Colorado hemodialysis technicians holding the BONENT certification was unavailable.

Complaints/Disciplinary Actions

Anyone who has a complaint about a hemodialysis technician can file with CDPHE a complaint against the dialysis treatment clinic where the incident occurred.

From fiscal year 12-13 to fiscal year 16-17, CDPHE received a total of 45 complaints against licensed dialysis clinics. None of the complaints contained allegations against hemodialysis technicians.

Another way that practice problems come to the attention of CDPHE is via occurrence reports. Dialysis treatment clinics are compelled to self-report to CDPHE when certain incidents occur, such as unexplained deaths, patient abuse or neglect, misappropriation of property, and malfunction or misuse of equipment. Clinics must file an occurrence report within one business day. CDPHE investigates the occurrence to determine whether the clinic took appropriate action following the incident.

CDPHE did not report identifying any problems with hemodialysis technicians stemming from an occurrence report.

The Health Service Advisory Group, which has contracted with CMS to implement the ESRD program for Colorado and several other western states, fields consumer complaints regarding hemodialysis technicians. Although no specific complaint data were available, a representative of the Health Service Advisory Group reported that the agency had not received any recent complaints regarding the competence of hemodialysis technicians.

Finally, CDPHE might discover inappropriate care by a hemodialysis technician when conducting a survey at the behest of CMS. As part of their participation in the Medicare ESRD network, licensed dialysis treatment clinics must report certain clinical data to CMS. CMS contracts with the University of Michigan's Kidney Epidemiology and Cost Center to evaluate these data, and notify CMS of any clinics having patient outcomes or clinical data that fall outside generally accepted standards. Once a year, CMS forwards a list of such clinics to CDPHE, which conducts an inspection.

During the inspection, CDPHE can require the dialysis treatment clinic to produce the list of hemodialysis technicians working in the facility, with the respective credentialing information. CDPHE inspects an average of seven facilities per year. To date, no problems with the care delivered by hemodialysis technicians have been identified during these surveys. Furthermore, none of CDPHE's investigations or inspections uncovered any instances of hemodialysis technicians working without the required credential.

Collateral Consequences – Criminal Convictions

Section 24-34-104(6)(b)(IX), C.R.S., requires the Colorado Office of Policy, Research and Regulatory Reform to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or registrants based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

Because CDPHE does not grant licenses or certifications to individual hemodialysis technicians under this program, this criterion does not apply.

Analysis and Recommendations

Recommendation 1 – Continue the regulation of hemodialysis technicians indefinitely.

The Colorado Department of Public Health and Environment (CDPHE) has the authority to regulate dialysis treatment clinics in Colorado. Section 25.5-1.5-108, Colorado Revised Statutes (C.R.S.), establishes the requirements dialysis treatment clinics must meet to qualify for licensure. One such requirement is that clinics must assure that each hemodialysis technician—defined as anyone who is not a licensed physician or licensed professional nurse (RN) and who provides dialysis care¹⁹—they employ has been nationally certified and is under the supervision of a licensed physician or RN. CDPHE is responsible for verifying clinics meet this requirement, which is the focus of this sunset review.

The central question of this sunset review is whether the certification and supervision requirement for hemodialysis technicians serves to protect the public health, safety, and welfare.

A common treatment for end-stage renal disease (ESRD), dialysis involves removing a person’s blood, cleansing it, and returning it to the body. Dialysis poses inherent risks. While rare, acute complications can happen: access sites can rupture or become infected; improper placement of tubing can lead to blood loss; and failure to prime a dialysis machine properly can cause an air embolism to enter a patient’s vein or artery. Also, patients with ESRD often have other chronic health conditions, such as hypertension or diabetes, which makes them particularly vulnerable to complications. Because of the potential risks of dialysis, it is in the public interest to impose requirements that ensure the people providing dialysis care are competent and properly supervised.

As the front-line providers of care in dialysis clinics, hemodialysis technicians must possess the proper education and training to safely perform the routine dialysis tasks and to know when to alert the supervising nurse or physician to any concerning changes in a patient’s condition. Therefore, regulation is justified.

The regulatory environment has changed, however, since the General Assembly first imposed regulation on hemodialysis technicians. When the General Assembly passed House Bill 1131 (HB 1131) in 2007, the Centers for Medicare and Medicaid Services (CMS) required only that hemodialysis technicians meet state requirements and be qualified to perform their duties. But within a year of HB 1131’s passage, CMS revised its rules to impose specific education and certification requirements on hemodialysis technicians and to define specific content areas that education programs for technicians must cover.

¹⁹ § 25-1.5-108(1)(c), C.R.S.

Now that there are explicit federal standards in place, the utility of continuing to subject Colorado’s hemodialysis technician statutes to sunset review is unclear. While the specific requirement that hemodialysis technicians work under physician or RN supervision is unique to Colorado law—federal rule imposes no such specific requirement—the typical administrative structure of any licensed dialysis clinic means that such supervision is inevitable, and no stakeholders reported finding the supervision requirement unduly burdensome. The past two sunset reviews—this one, and the one conducted in 2011—have identified no issues with the competence of hemodialysis technicians that would warrant additional regulation. CDPHE surveys have revealed that Colorado dialysis clinics are employing hemodialysis technicians who are properly educated, certified, and supervised.

The regulatory framework at both state and federal levels assures that hemodialysis technicians will continue to work under supervision in tightly regulated environments. Therefore, the General Assembly should continue the regulation of hemodialysis technicians indefinitely.

Recommendation 2 – Make technical changes to the law.

The law contains instances of obsolete language that can be repealed. These changes are technical in nature, meaning that they have no substantive impact on the regulation of hemodialysis technicians in Colorado.

The General Assembly should make the following technical changes:

- **Section 25-1.5-108(2), C.R.S.** Strike “By January 1, 2008,” as this date has passed.
- **Section 25.1.5-108(3)(a), C.R.S.** Strike “On or after January 1, 2009,” as this date has passed.
- **Section 25.1.5-108(3)(b), C.R.S.** Strike “On or after January 1, 2009,” as this date has passed.
- **Sections 25-1.5-108(1)(c) and (3)(c)(II)(A), C.R.S.** Change “registered nurse” to “licensed professional nurse” to align the language with current terminology as used in section 25-1.5-108(3)(a), C.R.S.