



**Dora**  
Department of Regulatory Agencies

**Office of Policy, Research and Regulatory Reform**

# **2011 Sunset Review: Hemodialysis Technicians**

October 14, 2011





## Executive Director's Office

Barbara J. Kelley  
Executive Director

John W. Hickenlooper  
Governor

October 14, 2011

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of Colorado's regulation of hemodialysis technicians. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2012 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...

The department of regulatory agencies shall 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 report discusses the question of whether there is a need for the regulation provided under Article 1.5 of Title 25, C.R.S. The report also discusses the effectiveness of the Colorado Department of Public Health and Environment and staff 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,

Barbara J. Kelley  
Executive Director





John W. Hickenlooper  
Governor

Barbara J. Kelley  
Executive Director

## **2011 Sunset Review: Hemodialysis Technicians**

### **Summary**

#### ***What Is Regulated?***

Hemodialysis technicians provide direct patient care in dialysis treatment clinics. Technicians' duties include preparing and maintaining dialysis equipment, initiating dialysis, monitoring patients during treatment, and removing patients from the dialysis machines at the end of 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 61 licensed dialysis treatment clinics in Colorado. These clinics employ approximately 400 hemodialysis technicians.

#### ***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. CDPHE verifies the credentials of hemodialysis technicians before granting initial licensure to a dialysis treatment clinic; once a year after granting the license, during the renewal period; and during routine on-site inspections, which occur every three years.

#### ***What Does It Cost?***

In fiscal year 09-10, the total cost of the hemodialysis technician regulatory program was \$1,818, and there were 0.2 full-time equivalent employees associated with the program.

#### ***What Disciplinary Activity Is There?***

Since Colorado's requirement for credentialing hemodialysis technicians went into effect on January 1, 2009, CDPHE has cited two dialysis treatment clinics for deficiencies. However, none of the cited deficiencies had to do with the certification requirement.

#### ***Where Do I Get the Full Report?***

The full sunset review can be found on the internet at: [www.dora.state.co.us/opr/oprpublications.htm](http://www.dora.state.co.us/opr/oprpublications.htm).

## Key Recommendations

### **Continue the regulation of hemodialysis technicians for seven years, until 2019.**

Dialysis is an inherently risky procedure. Given the nature of dialysis, and the central role of hemodialysis technicians in delivering care, it is important that technicians have sufficient training to perform the tasks competently, recognize symptoms that are out of the ordinary, and know when to appropriately refer to other staff. Requiring hemodialysis technicians to be nationally certified assures that technicians are minimally competent, and placing them under the supervision of an RN or physician assures that help and guidance is immediately available should problems arise.

### **Clarify that CDPHE verifies the credentials of hemodialysis technicians as part of the survey/inspection process for dialysis treatment clinics.**

Section 25-1.5-108(2), Colorado Revised Statutes, establishes that CDPHE must verify the credentials of hemodialysis technicians as part of its licensing of dialysis treatment clinics. This wording implies that such credentials are verified only at the time of initial licensure. In fact, CDPHE verifies the qualifications of all clinic staff, including those of hemodialysis technicians, each time it conducts a routine survey of a licensed dialysis clinic. This provision should be revised accordingly.

## Major Contacts Made During This Review

Colorado Department of Public Health and Environment  
DaVita  
Dialysis Clinic, Inc.  
DialysisEthics  
ESRD Network #15  
Fresenius  
Front Range Kidney Patients' Association  
Liberty Dialysis  
National Association of Nephrology Technicians and Technologists

## What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not 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:  
Colorado Department of Regulatory Agencies  
Office of Policy, Research and Regulatory Reform  
1560 Broadway, Suite 1550, Denver, CO 80202  
[www.dora.state.co.us/opr](http://www.dora.state.co.us/opr)

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## Background

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### 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 Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria<sup>1</sup> 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;
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

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

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## **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.

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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.



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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 via DORA's website at: [www.dora.state.co.us/pls/real/OPR\\_Review\\_Comments.Main](http://www.dora.state.co.us/pls/real/OPR_Review_Comments.Main).

The regulatory 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 July 1, 2012, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the regulation of hemodialysis technicians by CDPHE 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 for the protection of the public and to evaluate the performance of CDPHE. During this review, CDPHE must demonstrate that the regulation serves to protect the public health, safety or welfare, and that the regulation is the least restrictive regulation consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

### **Methodology**

As part of this review, DORA staff interviewed CDPHE staff; reviewed dialysis clinic inspection records including complaint and disciplinary actions; interviewed health care providers, patients and their advocates, and representatives of dialysis clinics; and reviewed federal statutes and rules, Colorado statutes and CDPHE rules, and the laws of other states.

### **About Dialysis**

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.

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Dialysis is a treatment prescribed for people with end-stage renal disease (ESRD). ESRD occurs when a person's kidneys can no longer properly remove impurities, salts, and excess water from the body.<sup>2</sup> Diabetes and high blood pressure are the two leading causes of ESRD.

People with ESRD have two options for treatment: dialysis or 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.<sup>3</sup> Consequently, dialysis is the more common treatment. According to data from the National Kidney Foundation, of the 526,000 Americans who are currently being treated for ESRD, more than 367,000 are undergoing dialysis.<sup>4</sup>

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,<sup>5</sup> 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.

Some dialyzers can be reused; others must be destroyed after a single use. Clinics using reusable dialyzers must assign each patient his or her own dedicated dialyzer and are responsible for properly sterilizing (or, "reprocessing") the dialyzers after each treatment.

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.

Patients with ESRD must undergo dialysis for the rest of their lives, unless they receive a kidney transplant.

In the early days of dialysis, dialysis was very expensive and virtually inaccessible for many ESRD patients due to the low number of dialysis machines. Hospital committees reviewed the case files of ESRD patients and determined who should receive treatment.

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<sup>2</sup> Medline Plus. *End Stage Kidney Disease*. Retrieved on May 4, 2011, from <http://www.nlm.nih.gov/medlineplus/ency/article/000500.htm>

<sup>3</sup> According to data from the Organ Procurement and Transplantation Network, as of May 2011, there were 88,605 people on the waiting list for a kidney transplant; in 2010, 13,522 kidneys were donated. Source: OPTN: Organ Procurement and Transplantation Network. Retrieved on May 23, 2011, from <http://optn.transplant.hrsa.gov/latestData/rptData.asp>

<sup>4</sup> National Kidney Foundation. *Key Facts about Chronic Kidney Disease (CKD)*. Retrieved on May 11, 2011, from [http://www.kidney.org/news/newsroom/fs\\_new/keyFactsCKD.cfm](http://www.kidney.org/news/newsroom/fs_new/keyFactsCKD.cfm)

<sup>5</sup> Fistula: A surgically created connection of an artery to a vein.

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Testimony before Congress on the difficulty of obtaining dialysis led to the formation of the Medicare ESRD program in 1972, when Congress amended the Social Security laws to extend Medicare coverage to ESRD patients. Anyone with ESRD may enroll in the program as long as he or she is eligible for Social Security, or is the spouse or dependent child of such an eligible person.<sup>6</sup> The program pays for most dialysis services and supplies.

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

### **Profile of the Profession**

Colorado law defines a hemodialysis technician—also called a “patient care dialysis technician” or “patient care technician”—as any person who provides direct care to dialysis patients and who is not a physician or registered nurse (RN). Duties that technicians typically perform 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.

In order to become a hemodialysis technician, a person must complete a training program that covers specific topics laid out in federal rule and pass one of three national credentialing examinations.

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

After passing a national certification examination, hemodialysis technicians must keep their certification current by meeting annual recertification requirements.

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<sup>6</sup> *Medicare Coverage of Kidney Dialysis and Kidney Transplant Services*, Centers for Medicare and Medicaid Services, p. 8.

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Under federal law, all hemodialysis technicians must be certified, either by a state certification program, or a national, commercially available certifying body. Although some states, such as California, require technicians to secure a state credential before entering the profession, most states, including Colorado, do not.

When the ESRD program was first established, in 1976, it was common for an RN to provide dialysis care to two dialysis patients at a time. Currently, dialysis patient care technicians are the primary caregivers in most dialysis treatment clinics, and it is not unusual for a single technician to provide dialysis care to three or four patients at a time.<sup>7</sup> The average annual salary for hemodialysis technicians is \$32,499.<sup>8</sup>

After increasing steadily between 1991 and 2006, the number of ESRD patients needing dialysis has decreased slightly over the past several years. However, because the number of patients with diabetes, a leading cause of ESRD, continues to grow,<sup>9</sup> it is likely that over time, the number of dialysis patients and the demand for qualified hemodialysis technicians will increase accordingly.

According to CDPHE, in March 2011, there were roughly 400 hemodialysis technicians in Colorado.

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<sup>7</sup> 70 Fed. Reg. 6,222 (2005).

<sup>8</sup> Salary.com. *Renal Dialysis Technician*. Retrieved on June 20, 2011, from <http://www1.salary.com/Renal-Dialysis-Technician-salary.html#JD>

<sup>9</sup> *Annual Data Report Atlas Volume Two: ESRD*, U. S. Renal Data System (2010), p. 224.

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## **Legal Framework**

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### ***History of Regulation***

Before the creation of the hemodialysis technician regulatory program, consumer stakeholders submitted a total of four sunrise applications (in 1992, 1994, 1995, and 2006), to the Department of Regulatory Agencies (DORA) requesting the creation of a licensure or certification program for hemodialysis technicians. In all four cases, DORA recommended against establishing such a regulatory program.

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 employ hemodialysis technicians who have been credentialed by a national credentialing program. The bill also directed the State Board of Health to adopt rules establishing a process for CDPHE to verify that all hemodialysis technicians meet that requirement.

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 be licensed as required by state law and be generally qualified to perform their duties.

Subsequent to the passage of HB 1131, CMS revised its own regulations, establishing specific education and certification requirements for hemodialysis technicians, rather than simply requiring them to meet state requirements.

### ***Summary of Statutes***

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

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Under federal law, all hemodialysis technicians must:

- Meet all applicable requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the state in which they are employed;
- Have a high school diploma or equivalency;
- 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; and
- Complete a training program focused on operating dialysis equipment and machines, providing direct patient care, and developing communication and interpersonal skills, including patient sensitivity training and care of difficult patients.

The training program must cover:

- Principles of dialysis;
- Care of patients with kidney failure, including interpersonal skills;
- Dialysis procedures and documentation, including initiation, proper cannulation<sup>10</sup> techniques, monitoring, and termination of dialysis;
- Possible complications of dialysis;
- Water treatment and dialysate<sup>11</sup> preparation;
- Infection control;
- Safety; and
- Dialyzer reprocessing, if applicable.

Colorado law requires hemodialysis technicians to work under the supervision of a physician or registered nurse (RN).<sup>12</sup>

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.<sup>13</sup> Participants in a hemodialysis technician training program may work as hemodialysis technicians as long as they are under the direct supervision of a 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.

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<sup>10</sup> Cannulation: the insertion of a cannula, or tube, into a body duct or cavity.

<sup>11</sup> Dialysate: the fluid and solutes that flow through the dialyzer.

<sup>12</sup> § 25-1.5-108(3)(a), C.R.S.

<sup>13</sup> § 25-1.5-108(3)(c)(I), C.R.S.

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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 for more than 18 months unless he or she has obtained the required credential.<sup>14</sup> Clinics must comply with this requirement as a condition of licensure,<sup>15</sup> and CDPHE is responsible for verifying clinics' compliance.

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—or, for technicians that are not certified, the date they entered the technician training program—and the name of each applicable certification organization.<sup>16</sup>

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.<sup>17</sup> 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.

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<sup>14</sup> §§ 25-1.5-108(3)(b) and (c)(II)(B), C.R.S.

<sup>15</sup> § 25-1.5-108(4), C.R.S.

<sup>16</sup> Standards for Hospitals and Health Facilities, Chapter XV, Dialysis Treatment Clinics, Rule 5.6.2.

<sup>17</sup> Standards for Hospitals and Health Facilities, Chapter II, General Licensure Standards, Rule 2.9.3.

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## Program Description and Administration

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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.

To implement the End Stage Renal Disease (ESRD) Network program in Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming, the federal Centers for Medicare and Medicaid Services (CMS) contracts with the Intermountain ESRD Network (Network #15). Network #15 monitors the quality of care delivered to patients and collects and reports information about, and treatment of persons with ESRD. Network #15 also fields consumer complaints, which could potentially relate to care received from a hemodialysis technician. However, CDPHE is responsible for licensing, surveying, and enforcing state and federal standards for dialysis treatment clinics.

When it established the hemodialysis technician regulatory program in 2007, the General Assembly appropriated \$5,862 from the General Fund and 0.1 full-time equivalent (FTE) employees to implement the program. Thereafter, the program has been funded by license fees paid by dialysis treatment clinics.

Table 1 illustrates, for the two fiscal years indicated, the expenditures and staff associated with hemodialysis technician regulation.

**Table 1  
Agency Fiscal Information**

<b>Fiscal Year</b>	<b>Total Program Expenditure</b>	<b>FTE</b>
08-09*	\$841	0.2
09-10	\$1,818	0.2

\*Because the requirement went into effect on January 1, data reflect the period from January 1 through June 30, 2009.

The rise in FTE from the initial allocation (0.1 FTE) is due to the increased workload of CDPHE having to verify technicians' credentials during the survey/inspection process and renewal.

When the credentialing requirement was first implemented, CDPHE charged dialysis treatment clinics—at the time of initial licensing and upon each license renewal—a separate, \$200 fee to support the program. However, CDPHE found that the cost to administer the program was relatively low, and did not warrant maintaining a separate fee. The cost of the program is now rolled into the licensing and renewal fees.



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

- 1-12 stations: \$1,750 per facility.
- 13-23 stations: \$2,750 per facility.
- 24 or more stations: \$3,750 per facility.<sup>18</sup>

### **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 program, so accepts credentialing from three approved, 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.

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. Interestingly, most dialysis treatment clinics also require newly hired registered nurses to complete this basic training program.

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 \$200 to \$245.

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

- Principles of dialysis;
- Patient care, including monitoring and documenting vital signs and recognizing complications;
- Operation of dialysis equipment;
- Infection control, sanitation, and universal precautions; and
- Interpersonal skills and professional development.

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<sup>18</sup> Standards for Hospitals and Health Facilities, Chapter XV, Dialysis Treatment Clinics, Rule 3.1.

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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, retake the certification examination, or demonstrate a specified number of hours of work experience. Recertification fees for NNCO and CCHT are \$125 for four years and \$75 for three years, respectively. BONENT charges an annual fee of \$55 to maintain certification.

A representative of BONENT declined to provide examination statistics, stating that board policy prohibited providing the data.

According to data from the NNCO examination vendor, 17 Colorado residents have taken the NNCO in the past five years, with a pass rate of 77 percent.

Table 2 illustrates the number of CCHT examinations administered to Colorado candidates for the five calendar years indicated, and the respective pass rates.

**Table 2**  
**Number of Colorado Candidates Taking the CCHT Examination and Pass Rates**

Calendar Year	Number of Examinations Given*	Pass Rate (%)
2006	29	93
2007	3	100
2008	295	88
2009	69	80
2010	45	93

\* Includes first-time test takers only.

The dramatic spike in the number of examinees in 2008 corresponds to the implementation of Colorado's credentialing requirement.

### ***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; once a year after granting the license, during the renewal period; and during routine on-site inspections, which occur every three years.

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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.

There are currently 61 licensed dialysis treatment clinics in Colorado. CDPHE does not maintain a registry of hemodialysis technicians and was unable to provide an exact count of the number of hemodialysis technicians the clinics employ, but estimated that there are about 400.

### ***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.

The Colorado requirement for credentialing hemodialysis technicians went into effect on January 1, 2009. Since then, CDPHE has received a total of seven complaints against licensed dialysis treatment clinics.

Of these, three complaints contained allegations of patient abuse or neglect by staff members providing patient care who were not nurses or physicians, in other words, by hemodialysis technicians.

These complaints can be broken down as follows:

- One complaint related to an incident where a patient was dialyzed using the dialyzer of another patient, who had Hepatitis C. CDPHE found the allegations to be substantiated, and cited the clinic for deficiencies. After subsequent inspections, CDPHE found the clinic had corrected the deficiencies.

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- One complaint related to an incident at another facility where a dialyzer was misused: in this case, a patient was dialyzed using the dialyzer of another patient, who had MRSA (Methicillin-resistant *Staphylococcus aureus*), a serious bacterial infection. CDPHE found the allegations to be substantiated, and cited the clinic for deficiencies. After subsequent inspections, CDPHE found the clinic had corrected the deficiencies.
  - One complaint alleged that the dialysis treatment clinic failed to provide adequate nursing oversight for its technicians. Although this complaint is directed at the clinic management and nursing staff, it implies that the care given by the hemodialysis technicians was somehow lacking. After an investigation, CDPHE found the allegations to be unsubstantiated and dismissed the complaint.

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.

Since January 1, 2009, one dialysis treatment clinic has filed an occurrence report. The report described a staff member who mistakenly assumed a new patient's treatment orders had been reviewed and approved by a physician. After investigating the incident, CDPHE found that the clinic handled the occurrence properly, and did not cite any deficiencies.

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.

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## **Analysis and Recommendations**

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### ***Recommendation 1 – Continue the regulation of hemodialysis technicians for seven years, until 2019.***

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 all hemodialysis technicians they employ have been nationally certified and are under the supervision of a registered nurse (RN) or physician. 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.

Colorado law defines a hemodialysis technician as anyone who is not an RN or physician and who provides dialysis care. At one time, RNs were the primary providers of dialysis care; however, over the past 20 years, the role of the technician has expanded. In today's dialysis clinics, RNs perform patient assessments, provide oversight, and address any problems, while hemodialysis technicians provide most of the routine dialysis care.

Hemodialysis technicians' duties include preparing and maintaining dialysis equipment; initiating dialysis, which involves inserting large-gauge needles into patients' access points; taking and documenting vital signs; monitoring patients during treatment; and removing patients from the dialysis machines at the end of treatment.

Dialysis is an inherently risky procedure: it involves removing a person's blood, cleansing it, and returning it to the body. Although serious adverse events are uncommon, the potential for patient harm is high: improper cannulation can cause painful bruising and delay dialysis treatment, and incorrectly placed tubing could cause potentially life-threatening bleeding. People undergoing dialysis often have other health problems such as diabetes or hypertension, which make them particularly fragile.

Given the nature of dialysis, and the central role of hemodialysis technicians in delivering care, it is important that technicians have sufficient training to perform the tasks competently, recognize symptoms that are out of the ordinary, and know when to appropriately refer to other staff. To obtain national certification, technicians must meet educational and experiential requirements and pass a comprehensive written examination. Requiring technicians to obtain national certification assures that they possess the basic knowledge and clinical skills required to provide safe care.

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Further, given the risk for complications that might require more extensive medical training to address, it is appropriate to require technicians to work under the supervision of an RN or physician.

Over the course of this review, the Department of Regulatory Agencies (DORA) found that there is strong support for the certification requirement across a wide spectrum of stakeholders, including CDPHE, the executive leadership of the companies that run most of the dialysis treatment clinics in Colorado, the RNs and technicians who staff such clinics, and patients and their advocates. Although there is no objective evidence conclusively demonstrating that patient outcomes have improved as a result of the certification requirement, anecdotally, patients interviewed for this report feel that care has improved, and RN clinic managers report that the certification requirement has resulted in more competent technicians, and lower staff turnover.

The current regulation allows hemodialysis technicians 18 months to obtain certification, which allows ample time for candidates to complete their training and sit for one of the three certification examinations. RN clinic managers interviewed for this report agreed that it takes at least 12 months of training and experience to master dialysis. A shorter window might mean more candidates would fail the examination, which might negatively affect clinics' ability to maintain appropriate staffing levels. Based on the complaint and occurrence reports from CDPHE, there is no evidence that this 18-month window poses a risk to the public.

Requiring hemodialysis technicians to be nationally certified assures that technicians are minimally competent, and placing them under the supervision of an RN or physician assures that help and guidance is immediately available should problems arise. For these reasons, DORA recommends that the regulation of hemodialysis technicians be continued.

Colorado's law mirrors the federal rule. The General Assembly established Colorado's requirement that hemodialysis technicians obtain national certification in 2007, a year before the federal Centers for Medicare and Medicaid Services established the same requirement in its Conditions for Coverage. Colorado's law aligns precisely with the federal rule. It imposes no additional requirements on technicians.

Some might argue that because the federal requirement is in place, the state statute is no longer needed. DORA carefully considered but ultimately rejected this option.

It is difficult to predict what impact new technologies and changes in health care policy might have on American dialysis clinics. Twenty years ago, when RNs were the primary caregivers in dialysis clinics, it might have seemed excessive to require the few technicians on staff to obtain national certification. One RN interviewed for this report stated that when she first started working in a dialysis clinic, there was one technician on staff for every four RNs. Today, that ratio is reversed, and requiring such certification seems entirely appropriate.

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Keeping Colorado’s law intact and subjecting it to periodic sunset reviews preserves Colorado’s ability to impose more stringent requirements on technicians, should changes in the regulatory environment necessitate them.

For these reasons, the General Assembly should continue the regulation of hemodialysis technicians for seven years, until 2019.

***Recommendation 2 – Clarify that CDPHE verifies the credentials of hemodialysis technicians as part of the survey/inspection process for dialysis treatment clinics.***

Section 25-1.5-108(2), C.R.S., establishes that CDPHE must verify the credentials of hemodialysis technicians as part of its licensing of dialysis treatment clinics. This wording implies that such credentials are verified only at the time of initial licensure.

In fact, CDPHE verifies the qualifications of all clinic staff, including those of hemodialysis technicians, each time it conducts a routine survey of a licensed dialysis clinic.

This provision should be revised to reflect that CDPHE verifies hemodialysis technicians’ credentials as part of the survey/inspection process.

***Recommendation 3 – Revise the provision regarding who may supervise hemodialysis technicians.***

Section 25-1.5-108(3)(a), C.R.S., establishes that hemodialysis technicians must work under the supervision of a physician or an RN.

This wording should be revised to be parallel to the Medical Practice Act and the Nurse Practice Act. Specifically, “physician” should be changed to “licensed physician,” and “registered nurse” should be changed to “licensed professional nurse.” These changes would align the statute with each profession’s respective practice act and more accurately reflect current terminology.

Therefore, the General Assembly should change the provision to state that technicians must work under the supervision of a licensed physician or licensed professional nurse.