

Laura S. Rhodes, M.S.N., R.N.
Executive Director

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STATE OF WEST VIRGINIA
BOARD OF EXAMINERS FOR REGISTERED PROFESSIONAL NURSES
101 Dee Drive, Suite 102
Charleston, WV 25311-1620

August 10, 2004

Joe Manchin, III, Secretary of State
State Capitol, Suite 157K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Secretary Manchin:

The West Virginia Board of Examiners for Registered Professional Nurses held an Emergency Teleconference board meeting this morning for the purposes of discussing the withdrawal of the Emergency Rule for Dialysis Technicians based upon comments received about the rule. The Board voted to withdraw the emergency rule and submits this letter as notice of this decision. The Board's plan now is to proceed with review and revision of the rule based upon comments and input from interested parties and submit the rule as a legislative rule.

Should you have any questions or require more information please contact me at this office.

For the Board,

A handwritten signature in cursive script that reads "Laura Skidmore Rhodes".

Laura Skidmore Rhodes, MSN, RN
Executive Director

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2004 AUG 10 A 3:37
OFFICE WEST VIRGINIA
SECRETARY OF STATE



**HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE**

BUILDING 1, ROOM E-214
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3192

J. D. BEANE, Chair
COMMITTEE ON GOVERNMENT ORGANIZATION
P.O. BOX 4275
PARKERSBURG, WV 26104-4275
PHONE: (304) 422-3925
FAX: (304) 422-6399
EMAIL: jdbeane@mail.wvnet.edu

August 6, 2004

Committees:
House Rules
Joint Committee on
Government Operations
Joint Committee on
Government Organization

The Honorable Joe Manchin
Secretary of State
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Secretary Manchin:

In response to the proposed emergency rule filed by the West Virginia Board of Registered Nurses, I am writing to ask you to deny its implementation. While I do not question the need for the regulation of this procedure, the proposal as written is unduly restrictive. It contains staffing ratios and education standards which exceed national standards.

I would encourage the Board to work closely with dialysis units in the state, to draft a rule which would protect the patients without having a negative effect on the accessibility of this vital service. For this reason, I urge you to disapprove this emergency rule.

Sincerely,

J. D. Beane, Chairman
House Committee on Government Organization

OFFICE WEST VIRGINIA
SECRETARY OF STATE

2004 AUG 10 A 8:52

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2004 AUG -8 A 9:13

**HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE**

BUILDING 1, ROOM 208-E
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3269

OFFICE WEST VIRGINIA
SECRETARY OF STATE

DON C. PERDUE, Chair
HEALTH AND HUMAN RESOURCES
ROUTE 1, BOX 98
PRICHARD, WV 25555
PHONE: (304) 486-5173
E-MAIL: DPerduerx@aol.com

Committees:
Banking and Insurance
Government Organization

Ms. Judy Cooper
Team Leader
WV Secretary of State

VIA FAX

RE: Dialysis Tech Emergency Rule

Dear Ms. Cooper:

I am in receipt of copy of the proposed emergency rule for HB 4641 and would hasten to reply.

I believe that, while certainly well-crafted, this rule may actually have the opposite effect of the legislation which we propounded during last session.

Our intent was to expand the availability of dialysis technicians in rural and poorly served areas of West Virginia. As our age and illness demographic shows, over time, more and more of our citizens will likely become dependent upon kidney dialysis. Taking this view, it was clear that increasing the aforesaid availability of the professionals needed to administer dialysis is of prime concern.

I fear, however, because of the lugubrious criteria attached within this emergency rule, that we may have actually (and inadvertently) pushed the pendulum in the opposite direction.

As such, I respectfully ask that this rule be reconsidered by the Board of Nursing Examiners for Registered Professional Nurses with a view to reversing that motion.

Sincerely,

Don Perdue



**HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE**

BUILDING 1, ROOM E-230
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3135

DAN FOSTER
3 MONTICELLO PLACE
CHARLESTON, WV 25314
PHONE: (304) 344-1060
EMAIL: dfooster@mail.wvnet.edu

Committees:
Finance
Banking & Insurance
Health & Human Resources

August 6, 2004

Joe Manchin, III
Secretary of State
Secretary of State's Office
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Secretary Manchin:

I am writing this letter to respond to the emergency rule relating to dialysis technicians proposed by the West Virginia Board of Professional Nurses.

It has been brought to my attention that the proposed rule could have a negative effect on the delivery of dialysis services in this state. As a sponsor of this legislation, I had no intention to create a difficult business environment for dialysis facilities, which many patients in Kanawha County are dependent upon. It appears that these rules are more restrictive than the present Medicare regulations and in particular the staffing ratio requirement exceeds the present national standards. The rule establishes educational requirements that could make it difficult for long time nurses at these units to fulfill, which may create staffing issues for these critical facilities.

I do not believe that this proposed rule provides the benefits that I assumed would come from this legislation, and I request that you deny the implementation of this emergency rule and suggest that the Board of Professional Nurses work more closely with the appropriate stakeholders to enhance quality of care without jeopardizing the financial liability of their entities.

Sincerely,

Daniel S. Foster

WV SECRETARY OF STATE
JOE MANCHIN III

AUG 09 2004

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2004 AUG - 8 A 10 36
OFFICE WEST VIRGINIA
SECRETARY OF STATE

DSF/jlw



**HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE
BUILDING 1, ROOM M-212
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3200**

OFFICE WEST VIRGINIA
SECRETARY OF STATE

2004 AUG 10 A 8:51

FILED

MARGARETTE R. LEACH
1538 RUGBY ROAD
HUNTINGTON, WV 25705
PHONE (304) 523-3055

August 5, 2004

Committees:
Finance
Constitutional Revision
Health & Human Resources

The Honorable Joe Manchin, III
Secretary of State
State Capitol, Suite 157K
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Secretary Manchin:

I am writing to respond to the emergency rule relating to Dialysis Technicians proposed by the West Virginia Board of Professional Nurses.

It is my understanding that the proposed rule could have a negative effect on the provision of dialysis services in this state. It was not my intent as a sponsor of this legislation to create a difficult business environment for dialysis units. Dialysis units have provided services to kidney patients for many years and provide a critical service for those patients.

Based on my review of the proposed rule, a number of criteria have been established that will make it difficult for the units to comply. To make the rules significantly more restrictive than the Medicare regulations appears to have been done without much input by nephrologists and other providers of this service. For example, the staffing ratio exceeds the national standards that currently exist and have proven successful in protecting patient safety. Educational requirements that are established in this rule will place a burden on many of the nurses who have worked in this area for many years. As many understand, experience in a specialty area is often recognized as more valuable than a bachelor's degree. It is also important to acknowledge that it is often difficult for nurses in rural parts of the state to return to school to get their bachelor's degree.

Because I do not believe that this rule would be in the best interests of the citizens of the state, I ask that you deny the implementation of this emergency rule and ask that the Board of Professional Nurses work more closely with dialysis units and other experts in the field to ensure that the rule protects patients but is not unduly burdensome for the dialysis units.

Thank you for asking me for my comments on this important rule.

Sincerely,

Margarette Leach
Margarette Leach *me*

c: John Sylvia, Performance Evaluation & Research Division



**HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE**

STATE CAPITOL, ROOM 462-M
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3230

HAROLD K. MICHAEL, Chair
COMMITTEE ON FINANCE

August 5, 2004

OFFICE WEST VIRGINIA
SECRETARY OF STATE

2004 AUG 10 A 8 55
FILED
Committees:
House Rules
Int Committee on
Government & Finance

The Honorable Joe Manchin, III
Secretary of State
State Capitol, Suite 157K
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Secretary Manchin:

I am writing to respond to the emergency rule relating to Dialysis Technicians proposed by the West Virginia Board of Professional Nurses.

It is my understanding that the proposed rule could have a negative effect on the provision of dialysis services in this state. In my own area, a dialysis unit recently opened for the first time enabling dialysis patients to receive services closer to home. This unit has been a dream of my area for some time and any consequences of the proposed rule could be devastating.

I have specific concerns about the staffing ratio reflected in the proposed rule and the fact that it is greater than the Medicare regulations require. Reimbursement rates are established to enable a dialysis unit to comply with the federal requirements. The standards proposed in the rule before you, will create a financial burden on units in this state and will be difficult to meet due to the nursing shortage that is occurring in the state. A number of the criteria seem excessive and will make the provision of this important service much more difficult.

Additionally, it appears to me that the fees being proposed are quite high and are not reflected in the fees charged by any other state. I do agree that fees must cover the cost of the program but the apparent profit built into the fees seems unusually high.

Based on these concerns, I am requesting that you deny this proposed rule as an emergency rule and encourage the Board of Professional Nurses to work more closely with those who work in this area to establish a rule that will protect public safety without unnecessarily hurting the provision of services.

Sincerely,

Harold K. Michael

c: John Sylvia, Performance Evaluation & Research Division

LAW OFFICES

GOODWIN & GOODWIN, LLP

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P.O. Box 349
500 CHURCH STREET
RIPLEY, WEST VIRGINIA 25271
(304) 372-2651

August 4, 2004

HAND DELIVERED

Ms. Laura Rhodes, Executive Director
West Virginia Board of Registered Professional Nurses
101 Dee Drive
Suite 102
Charleston, WV 25311

Dear Ms. Rhodes,

On behalf of Bio-Medical Applications of West Virginia, Inc. (BMA), we are submitting this letter in response to your request for comments, regarding the Board's emergency rule 19CSR13 "Dialysis Technicians." BMA is a wholly owned subsidiary of Fresenius Medical Care of North America. BMA operates twelve of the twenty-five dialysis facilities currently certified in West Virginia. BMA treats over 2000 West Virginians per year, who suffer from kidney failure.

Section 2.5 "Initiation of dialysis care" This definition would unnecessarily restrict the dialysis technician from accessing the hemodialysis catheter site. Appropriately trained and experienced dialysis technicians should be permitted to independently access the catheter site and initiate dialysis without the nurse or physician performing these tasks. BMA's training program specifically trains dialysis technicians to perform this duty. Other states do not similarly restrict technicians.

Section 2.7 Requiring a "preceptor" to have at least two years of experience is too restrictive. None of the surrounding states require such experience. We suggest that a "preceptor" mean a registered professional nurse or a dialysis technician with at least one year of experience and who has successfully completed a preceptor program.

Section 2.9 How does a dialysis technician register with the Board?

Section 2.10 We recommend that the 12-month requirement before examination only apply to those testing organizations that require it. A proposal to approve a third organization is described below in Section 11.1.

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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FILED

Section 3.3.b The words “immediately prior to” are too ambiguous and restrictive and should be deleted.

Section 3.3.e The establishment of staffing ratios should be left to the federal and/or state facility licensure and/or certification agencies, not to a professional licensing board. We are unaware of any prior Board policy setting staffing ratios for nurses at a health care facility and question the Board’s legal authority to set them. We are also unaware of any other West Virginia professional licensing and/or certification board that has mandated required staffing ratios. In summary, the Board has exceeded its lawful authority by mandating staffing ratios for facilities that are certified and/or licensed by other federal and/or state agencies. Thus, this entire section should be eliminated.

If the Board elects to retain this paragraph, then we submit that the ratios are too restrictive and burdensome. The staffing ratios of nurse to patient and nurse to technician result in a minimum of 1:3 ratio. This exceeds normal industry staffing models and those in federal (Medicare Condition of Coverage) criteria. Neither Ohio, Kentucky, Pennsylvania or Virginia have any staffing requirements. If the Board insists on maintaining staffing ratios, then a 1:12 or 1:14 caregiver (total nurse and technician) to patient should be the only ratio. The proposed rule will cause serious recruitment, retention and patient scheduling problems at West Virginia facilities.

Section 4.2 We recommend adding as “except as outlined in Section 4.1” after the word responsibility to avoid any confusion about what medications dialysis technicians are authorized to administer.

Section 5.2 160 days is too long. We recommend 60 days for a conditional approval. The Board could suggest changes to the training program before granting final approval.

Section 6.1.a.4 and Section 6.1.a.5 The bachelor’s degree education requirement for the training program administrator exceeds that required by Medicare and other states for the Director of Nursing, let alone the training administrator, at a dialysis facility. Other states do not have this unduly burdensome requirement. Thus, it should be eliminated. Many registered nurses do not have bachelor’s degrees; however, they have practical experience that compensates for this. This is especially true with nephrology nurses. We recommend that 6.1.a.4 be eliminated. This would also negate 6.1.a.5.

Section 6.1.f.3.G Same comments as describe above in Section 2.7. We recommend the following language: “Include a registered professional nurse or a dialysis technician preceptor with at least one year of experience in providing dialysis care and who has successfully completed a preceptor program.”

Sections 6.1.g.6., 6.1.g.6. A, thru C Delete. We recommend the process used in Kentucky. We feel it is more practical and efficient. Sample language is set out below.

210 KAR 20:470. Kentucky program:

(7) **Completion Requirements.** Requirements for successful completion of the dialysis technician-training program shall be clearly specified. The requirements shall include demonstration of clinical competency and successful completion of a comprehensive, written final examination. There shall be a statement of policy regarding a trainee who fails to successfully complete the training program. The statement of policy adopted by the training program shall include requirements that a person:

- (a) Shall not be enrolled in a training program more than two (2) times;
- (b) Shall show continuing progress toward completion of the program; and
- (c) Who fails to successfully complete the program within twenty (20) calendar weeks shall cease functioning as a trainee until that person is reenrolled in a subsequent training program if that opportunity still exists pursuant to paragraph (a) of this subsection.

(8) At a minimum, the following records shall be maintained by the program:

- (a) Provider name, date and site of the training program
- (b) The program code number issued by the board; and
- (c) Trainee roster, with minimum of name, date of birth, Social Security number, and program completion date.

(9) An individual who successfully completed the training program shall receive a certificate of completion that documents the following:

- (a) Name of individual;
- (b) Title of training program, date of completion, and location;
- (c) Provider's name;
- (d) The program code number issued by the board; and
- (e) Name and signature of program administrator.

Section 7.1 90 days is too far for an advance notice. We suggest 60 days.

Section 11.1 We suggest adding NNCC to the list of approved testing organizations. The Nephrology Nursing Certification Commission (NNCC) is an independent, separately incorporated, professional certification organization that was originally established in 1987. The NNCC currently offers three different examinations: the Certified Nephrology Nurse (CNN), the Certified Dialysis Nurse (CDN), and the Certified Clinical Hemodialysis Technician (CCHT). All examinations are endorsed by the American Nephrology Nurses Association (ANNA) and the CCHT examination also is endorsed by the National Association of Nephrology Technicians/Technologists (NANT). NNCC has submitted information to the Board.

Section 12.1 The fees for program approval are too high. The Board's estimated budget is \$69,910 for the first two years and \$61,910 thereafter. There are twenty-five dialysis facilities listed with the West Virginia Office of Health Facility Licensure and Certification. Even if one or two of those are hospital acute dialysis centers that elect not

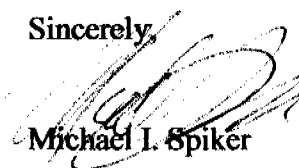
to have technicians, there are still twenty-three facilities that have to pay the fee. This would result in \$230,000 for two years' certification approval or \$115,000 per year. This is an excess of \$45,000 per year above the program cost.

Section 12.3 What is a reinstatement fee? If such a fee is appropriate, then \$10,000 is far too much, especially since an applicant would have already paid the \$10,000 initial approval fee or the \$8,000 renewal fee. This is not a fee, but a penalty.

Section 12.6 What is a "periodic evaluation of a training program." If a program is approved for two years at a cost of \$10,000 then an additional \$2000 fee should not be assessed.

We appreciate the time and effort the Board has spent on these very important regulations. We thank you for the opportunity to comment on areas we believe need modified. Some of these areas, if not changed, will cause serious problems to providers of dialysis care and will actually hinder the delivery of quality care to hemodialysis patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael I. Spiker", is written over the typed name.

Michael I. Spiker



FILED

August 4, 2004

2004 AUG -4 A 2:09

The Honorable Joe Manchin III
Secretary of State
Building I, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Subject: Proposed Emergency Rule for Dialysis Technicians

Dear Secretary Manchin,

Physicians Dialysis, Inc. ("PDI") is a national provider of dialysis and related management services. PDI provides management services to Charleston Area Medical Center ("CAMC") for its acute dialysis program. As a Program Manager at CAMC, PDI employs five (5) patient care dialysis technicians that are utilized to provide certain direct patient care dialysis services in the immediate presence and under the direct supervision of a registered professional nurse. In this management capacity, PDI has an interest in ensuring that all dialysis technicians are properly trained, supervised and capable of providing high quality dialysis care. With this vested interest, PDI offers the Board of Examiners (the "Board") both our general support for the Proposed Emergency Rule for Dialysis Technicians (the "Proposal") and offers the following comments on two areas of the Proposal that PDI believes would not be in the best interest of dialysis providers, technicians, or patients.

PDI supports the Board's efforts to regulate and to standardize the training, education, and scope of practice of dialysis technicians. It is our opinion that this will provide a benchmark and help to maintain a high quality of care for West Virginia patients suffering from Chronic Kidney Disease and requiring dialysis treatment.

However, PDI strongly urges the Board to re-evaluate the following provisions:

- **Section 2.5. The definition of "initiation of dialysis care" contains the statement that the dialysis technician may start dialysis "after the hemodialysis catheter site has been accessed by the registered professional nurse".**

A limitation on the ability of properly trained dialysis technicians to access catheter sites will result in increased treatment costs by necessitating changes to staffing ratios. This change will also cause delays in initiation of treatment and require patients to spend longer periods in the dialysis facility. There is no clinical data or other evidence to show that quality of care will, in any way, be improved or that the patients will benefit from a restriction placed on competent dialysis technicians. The actual outcome will likely be increased treatment costs and increased time that patients who are already compromised by their medical status, will need to wait for access to their treatment.

A second factor to consider is that the industry trend is to decrease the need for long-term dialysis catheters by better access management. The proposed shift would require registered nurses to take on additional job duties and require dialysis facilities to hire more registered nurses in the midst of a nursing shortage. Again, this translates to increased cost per treatment and will only be a short-term remedy because of the trend of going towards AV fistula access. AV access is commonly a technician service. For example, the North Carolina Board of Nursing states in their interpretive statement for Utilization of Unlicensed Assistive Personnel in the Performance of Hemodialysis for Client with ESRD, "accessing vascular hemodialysis device may be done by the licensed nurse or delegated to a

competent dialysis technician.” In addition, the Ohio Board of Nursing does not restrict the dialysis technician to accessing the AV access only.

The Federal government has collected data that supports the need to decrease the use of long-term catheters, but, importantly, the clinical performance analysis does not discuss or find any need to address a shift in performance of this aspect of treatment by competent and trained technicians, as is the industry practice. Data collected from October-December 2002 was published by the Department of Health and Human Services in the End Stage Renal Disease Clinical Performance Measures Project 2003 Annual Report: Twenty-eight (28%) of prevalent outpatients were dialyzing by a long-term dialysis catheter in the Mid Atlantic Renal Coalition (Network 5) in which West Virginia is included. Network 5 has set a goal of reducing this rate to ten percent (10%). This initiative will be achieved by a gradual transition in West Virginia due to the rural status of our state, but there is no evidence that costs need to increase or changes in staffing ratios are supported by any of the clinical analysis. The fundamental principle that will improve quality of care and improve outcomes is based on early referral to nephrologists or vascular surgeons for an AV fistula to be created that will mature and provide a better access option.

Finally, in addition to the above mentioned concerns regarding the negative impact that the proposal would have on staffing and treatment is even more significant for the acute patient population that PDI manages. Acute Renal Failure (“ARF”) patients have a higher need for temporary catheter utilization than chronic patients. For patients with ARF, a permanent AV access is not possible or necessary. Thus PDI technicians have extensive experience working with catheter access and PDI, through its aggressive quality assurance programs has not seen data to support any shift in the technician’s performance of this aspect of treatment. In conclusion, based on extensive clinical experience by PDI managers and leaders with decades of experience in this industry, PDI maintains the position that with the appropriate training, education and validation of competency, that a dialysis technician can safely initiate dialysis by accessing the hemodialysis catheter site with assessment by the supervising nurse, as is the current standard of practice.

- **Section 12.1. & 12.2. The dialysis technician training program approval fee of \$10,000 and the continued re-approval fee of \$8,000.**

The fee proposed for the training program approval and re-approval is exorbitant and would place a financial burden on dialysis facilities that are not supported by large corporate partners. PDI, for example would view this approval fee as a significant added administrative cost. In sum, these proposed fees are so high and unprecedented that it is likely that rather than meet the objective of improving the quality of services, they would drive quality service providers out of West Virginia. Providers that are unable to absorb these administrative costs will be immediately impacted in the areas of recruitment and training for dialysis technicians. This, in turn, will trigger staffing shortages. As a result, the providers will be forced to limit care of patients and it will impact the access to care for the dialysis population in our state. The utilization of competent dialysis technicians is crucial to providing the access to care that is necessary. In sum, PDI supports the training program approval process but recommends a fee schedule similar to that adopted by the Ohio Board of Nursing: Fee for approval and re-approval of a dialysis technician training program in Ohio is \$300.

In summary, please consider our recommendations to expand the scope of practice for dialysis technicians to include the initiation of dialysis by accessing dialysis catheters and adopting a more reasonable fee schedule for approval of the training program to dialysis providers. In addition, PDI recommends that there be involvement from the local nephrology community in the development of such rulings or amendments, which will involve the care to our patients. This will ensure that all patients with Chronic Kidney Disease receive access to the life sustaining treatment they require.

Respectfully,

Carla VanWyck, RN, CNN
Center Director
CAMC Acute Dialysis Program

cc: Asif Rahman, MD, Medical Director, CAMC Dialysis Program
Josh Floren, Assistant Administrator, CAMC General Hospital
Daniel Foster, MD
Mid Atlantic Renal Coalition
Board of Examiners For Registered Professional Nurses

August 2, 2004

The Honorable Joe Manchin
Secretary of State
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

FILED

2004 AUG -3 A 10:48

**OFFICE WEST VIRGINIA
SECRETARY OF STATE**

Dear Secretary Manchin:

I would like to respond to the West Virginia Board of Registered Nurses proposed rule for Dialysis Technicians. Although none of my prestigious colleagues or I were asked for input in the development of this proposal, I feel I must comment.

I am currently the elected Chief of Staff for CAMC (2004-2005). I chaired the CAMC Medical Ethics Committee for the past fifteen years. I am an appointed Ethics Officer for 2005 at CAMC. I was awarded the Governor's Certificate of Appreciation in Developing and Establishing the Standards and Practices for the Care of Nephrology Patients by Governor Underwood in 2000.

I was the first nephrologists in West Virginia (1971) and performed the first hemodialysis treatment (1972) at Charleston Memorial Hospital. I was the Medical Director for the first dialysis unit in West Virginia (located in Charleston Memorial Hospital) and was the Medical Director for the unit when located at McMillan Hospital and West Virginia Dialysis Facility (now Fresenius) in Kanawha City. I was the Medical Director for the dialysis unit at CAMC for many years. I was the Medical Director for Beckley, Mann and Bluefield when their initial program was developed. I was instrumental in helping Parkersburg and Cabell Huntington develop their first dialysis unit.

Because I was the "first" to provide this therapy in West Virginia, I was also the first to train staff to perform dialysis. These trained dialysis nurses and I then developed the first dialysis training program in West Virginia. I must say, the newly proposed guidelines as stated by the nursing board do resemble the classes we taught for years to many dialysis personnel.

I speak for many seasoned nephrology professionals when I say that we all want and agree upon the need for certification of dialysis technicians. However, we do not agree with some of the elements the nursing board has included in their proposal.

First, we do not feel the registered nursing board is qualified to oversee and/or develop a training program that should be developed by those of us in the dialysis field. If the board does hire seasoned dialysis professionals to oversee the program, who will they be accountable to? Will they be accountable to the State Medical Board, the legislature and the renal community itself? And, who will evaluate the results of the program and by what means? What incentive is there for the board to work with the dialysis facilities when so much money is involved?

Second, staffing ratios are reviewed and regulated by Medicare according to strict guidelines. Medicare has always been focused on patient safety – what are the boards guidelines based on? Very few small facilities will be able to justify a staffing ratio suggested by the board and many of the larger chains may decide to take their business out of state when faced with such rigid and unreasonable ratios. Staffing in the hospital is at least based on acuity – what is the basis of a 3:1 ratio?

Third, the fees stated in the proposal are out of line with every state that requires certification. I understand that the board has its own reasons for demanding at least 10 times what other states require, but the financial restrictions already in place for dialysis units are severe – further restrictions could be insurmountable.

Last, as a well known and highly respected nephrologists in West Virginia, I would like to know why I wasn't contacted before this proposal was developed? Why did none of my colleagues know of this proposal? I am certain we would have all donated our time to help develop a training program that would have been beneficial to patients, technicians, dialysis facilities and to the board.

Please reconsider the bill as it is currently written and let us develop a task force consisting of both local nephrology professionals and nursing board members. I am certain a fair proposal that the entire renal community would support could be developed.

Thank you for considering these suggestions,

Mary Lou Lewis, MD

We would like to make it known that we fully agree with the above statements made by Dr. Mary Lou Lewis regarding the West Virginia Board of Registered Nurses proposed rule for Dialysis Technicians.

Julian Espiritu, MD

Vaughn Lamb, MD



100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
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Web Page: www.wvha.org

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HAND DELIVERED

2004 AUG -4 A 12: 03

OFFICE WEST VIRGINIA
SECRETARY OF STATE

August 5, 2004

Judy Cooper
Administrative Law Division
Secretary of State
Bldg. 1, Suite 157-K
1900 Kanawha Blvd. East
Charleston, WV 25305-0770

Dear Ms. Cooper:

Attached for your information are the written comments of the West Virginia Hospital Association submitted to the WV Board of Examiners for Registered Professional Nurses concerning proposed emergency rule 19CSR13 "Dialysis Technicians".

As noted in the letter, we believe the Board has exceeded its statutory authority by establishing staffing ratios for dialysis facilities, and that the proposed fees are excessive.

Thank you for including this document in your files.

Sincerely,

A handwritten signature in cursive script that reads "Jill McDaniel".

Jill McDaniel
Vice-President Strategic Planning and Rural Health

Attachment



100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.org

August 3, 2004

Laura Skidmore Rhodes
Executive Director
West Virginia Board of Examiners for Registered Professional Nurses
101 Dee Drive
Charleston, WV 25311-1620

Dear Ms. Rhodes:

On behalf of the West Virginia and its 73 hospitals and health systems, I respectfully submit this letter in response to your request for comments regarding the Board's emergency rule 19CSR13 "Dialysis Technicians."

While several hospitals provide acute inpatient dialysis, registered nurses rather than technicians perform the procedures addressed in the proposed rule and are unaffected by the legislation and rule. However, in the ambulatory ESRD facilities owned-by or affiliated-with hospitals, the proposed rule will have a significant impact. WVHA supports the efforts of the Board to establish standards for training of dialysis technicians; however, our concerns are focused on the following two sections of the proposed rule.

Section 3.3.e

We believe that the Board has exceeded its statutory authority by setting forth staffing ratios for dialysis facilities. House Bill 4641 that established W.Va. Code §30-7C-4 does not include any mandate to the Board to establish staffing ratios for ESRD facilities.

Health care facilities including ESRDs, hospitals, nursing homes, home health agencies, and clinical laboratories are subject to regulation under federal certification and/or accreditation standards. The Conditions of Participation for Medicare and Medicaid set forth the requirements with which ESRD facilities must comply in order to be certified and receive payment. Those standards do not include any specific staffing ratios, nor do the standards established by the Joint Commission on Accreditation of Healthcare Organizations. Additionally, state health care facility licensure laws provide oversight of healthcare facilities with respect to care delivery. These organizations assure compliance with standards of health care delivery through on-site surveys.

While the Board is authorized to define standards for the training of dialysis technicians that are under the supervision of registered nurses, we do not believe it is appropriate for the Board to regulate health care facilities and encroach upon the authority of the appropriate facility licensing, certification, and accreditation bodies by establishing staffing ratios.

Laura Skidmore Rhodes
August 3, 2004
Page 2

Section 12

We believe the \$10,000 assessment of facilities that establish training programs for dialysis technicians as required is excessive. Facilities will incur significant expense to provide the training as required by the proposed rule, in addition to the proposed fee to support the Board in its oversight of the training programs. We also believe the additional \$8,000 reinstatement fee is excessive and unnecessary.

Thank you for consideration of these comments.

Steven J. Summer

A handwritten signature in black ink, appearing to read "Steve Summer", written over a horizontal line.

President & CEO
SJS/jm

5318 Morning Dove Lane
Cross Lanes, WV 25313

July 31, 2004

Honorable Joe Manchin III
Secretary of State
Building 1 Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

OFFICE WEST VIRGINIA
SECRETARY OF STATE

2004 AUG -2 A 10:48

FILED

Dear Secretary Manchin,

I am a Certified Nephrology Nurse, Certified Hemodialysis Nurse, and a Certified Peritoneal Dialysis Nurse. I am a board member of the National Kidney Foundation of the VA's, and the secretary of the Mountain State Chapter of the American Nephrology Nurses Association. I am the Clinical Management Coordinator of the renal (kidney) unit at CAMC and I am also employed as per diem by two local kidney dialysis units. I have 25 years experience as a dialysis nurse. As you can see, I have extensive experience and a devoted connection to the quality of care of the kidney dialysis patients in WV.

I would like to take this opportunity to comment on the legislative rule **CSR 19-13 titled Dialysis Technicians (HB4641)**. I support the delegation of tasks to technicians and the registration of kidney dialysis technicians in order to assure quality of patient care. I would like to submit to you my comments/concerns regarding this rule (see attached).

I appreciate your time in reviewing the attachment and would be grateful for your reply. I would be happy to meet with anyone in order to further explain my comments or offer additional information. I may be contacted via: (pager) 330-7579 or e-mail: tammie.mitchell@camc.org or tlmitch100@aol.com

Respectfully,

Tammie Mitchell

Mrs. Tammie Mitchell BSN, RN

19CSR13 Dialysis Technician

Chapter	Wording Of Rule	Comment
19-13-1	General:	FILED
1.1	Scope-Establishes the general requirements for delegation of actions by RN to technician.....	RN may delegate to LPN Both may delegate to tech (under direction of RN) RECOMMENDATION: to include Licensed Practical Nurse, under direction of Registered Nurse <i>throughout this rule</i>
19-13-2	Definition of terms	2004 AUG -2 A 10:48 OFFICE WEST VIRGINIA SECRETARY OF STATE
2.5	<p>“Initiation of dialysis care” means starting dialysis procedure after pt assessment by RN nor MD is completed and immediately prior to starting the dialysate</p> <p>and after the HD catheter site has been accessed by the RN or MD or the fistula site has been accessed by the tech</p>	<p>In order to initiate dialysis in a timely manner (as required by 3.3.h.1) the patient should not need to wait to begin treatment until the RN is able to perform an assessment. The electrolytes/minerals/etc. in the dialysate do not cause an immediate danger if not assessed pre-dialysis. Recommendation: “.....starting dialysis prior or soon after starting the dialysate...”</p> <p>Once the technician has completed the training and achieved competence in initiation of the treatment via vascular catheter, they should be permitted to perform this task. Connecting the 2 tubes together requires less competence than inserting a 16 gauge metal needle into an artery. Initiation via AV Graft (most common access) or other access (ie. VASCA port) is not included. Recommendation: remove this requirement and permit the technician to utilize all vascular accesses after competency has been achieved.</p>
2.7	“Preceptor” is an RN or technician with at least 2 years experience in dialysis in the previous 3 years.	<p>It is not uncommon for a dialysis technician to leave the dialysis unit and work for the Nephrologist (for instance) then return to the dialysis setting years later. This position, of being employed by the physician, only broadens their knowledge base and makes them a better preceptor. The administrator of the training program should be able to choose the best preceptor <i>based upon their competence instead of their years of service.</i> LPN's should be included as potential preceptors as well Recommendation: “....an RN, LPN, or technician that has had greater than 1 year experience in providing dialysis care and that has demonstrated a high level of competence in dialysis care”</p>
2.9	“WV dialysis technician or dialysis technician” means an individual who has successfully completed an approved dialysis technician training program and who has achieved national certification Or Individual who meets the requirements set forth in Board's rule pertaining to dialysis technicians practicing prior to the first day of July 2004 under supervision of RN or MD and has registered with Board	<p>This rule only addresses HEMODIALYSIS and does not address peritoneal dialysis. It is possible to have a technician working in the home Peritoneal Dialysis (different type of kidney dialysis) arena as well. Recommendation: change the definition to “hemodialysis” technician. There are different “technicians” in the dialysis field: Patient Care Technicians (PCT), Equipment technicians, Reuse technicians, etc. Recommendation: change the term to “Hemodialysis Patient Care Technician”</p>

2.10	<p>"WV dialysis technician trainee" is an individual currently enrolled in an approved training program ,</p> <p>has completed the in-class portion and is working to fulfill the twelve month work requirement to sit for the certification exam</p>	<p>Recommendation: change title of "trainee" to "apprentice" (especially for a year long period). The patients may feel more at ease if their care-giver is an "apprentice" vs. a "trainee"</p> <p>Our rule should not state any criteria to sit for the exam, since the certification organization sets the criteria—they could potentially change their criteria in the future. This rule identifies the approved certification organizations under 19-113-11</p> <p>Recommendation: change the definition to match the certification company's requirement: " ... fulfill the requirements to sit for the certification exam."</p>
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19-13-3 Standards for Delegation of Safe Dialysis Care		
3.1care be delegated to the technician by a MD or RN	<p>Recommendation:care be delegated to the technician by a MD or RN (or LPN under supervision of RN)</p>
3.2	RN shall not delegate medication administration to the temporary dialysis technician trainee until medication administration competencies have been validated.	<p>Not sure what "temporary" means here. It is not included in the <u>Definition Of Terms</u> section. Is it referring to a tech through an agency?</p> <p>Recommendation: remove the word "temporary" –it should apply to all technicians</p>
3.3	The RN who is delegating to the technician shall assure that:	
3.3.e	Staffing the treatment facility provides for adequate supervision of the delegated tasks by maintaining a 12:1 pt to RN ratio with a maximum of 12 pts to a minimum of one RN. In addition to the 12:1 pt to RN ratio, the staffing will also include at least 4-6 technicians to one RN	<p>Recommendation: The facility provides for adequate supervision of the delegated tasks by employing a 12:1 patient to RN ratio with a maximum of 12 patients to a minimum of one RN.</p>
3.3.h	The dialysis technician timely: 1. implements the prescribed dialysis care for a pt unless the dialysis technician believes or should have reason to believe that the prescribed order is inaccurate, not properly authorized, not current or valid, harmful or potentially harmful to the patient, or contraindicated by other documented information	
3.3.h.2	clarifies any prescribed orders	<p>Recommendation: add a section " initiates dialysis care after assuring that the equipment has been properly prepared and the environment is safe" (such as no water on the floor, chair/machine is cleaned, etc)</p>
3.3.i	When clarifying the prescribed dialysis care order.....	<p>Recommendation: move this section to be a subsection under 3.3.h.2</p>

19-13-4 Standards for Medication Administration by a Dialysis Technician	
4.1	Dialysis technician shall administer only the following medication Recommendation: "...only the following medications as included in the dialysis prescription or as delegated by MD, RN (or LPN delegated by RN)
4.1.d	...specific dialysate to which the dialysis technician may add only electrolytes Recommendation: add "...electrolytes and minerals" (calcium is a mineral-not an electrolyte)
4.2	Administration of any blood products or intravenous medications is a nursing Recommendation: "or other intravenous medications..." so it will include the intravenous heparin and normal saline described in 4.1
19-13-5 Procedures for Obtaining Approval as a Dialysis Technician Training Program	
5.1	The board shall approve the training...
5.1.a.1	Submit to the board a completed application on a form specified by the board which includes the following: Any other information requested by the board
5.1.a.1.E	
5.4	Dialysis training programs in existence on or before July 1, 2004 shall submit all items for application of approval required by the Board in this subsection on or before October 15, 2004 Recommendation: add "...requested by the board that is pertinent to the training program or competency of the technician or faculty" This will not give adequate time for the facility to revise their current program to meet the requirements (hiring of an BSN administrator, curriculum/test development, development of process for admission/re-enrollment/ record keeping and board notification of changes). Facilities will not be able to begin action on this rule until it is passed. Recommendation: change "on or before October 15" to "...on or before 60 days after notification that this legislative rule is enacted/effective"
5.5	... programs in existence after July 1, 2004 shall submit all items for application of approval required by the Board in this subsection at least 160 days prior to the beginning of the first day of the training program. Recommendation: see the next subsection In the instance of a new dialysis unit opening, it would not be reasonable to hire a training program administrator ≥ 6 months prior to the opening date and give him/her enough time to develop the program and submit all the information to the board 5 ½ months prior to opening of the unit.
5.6	A program in existence before July 1, 2004 that fails to meet the initial requirements of the board, will have 3 months to provide the board with evidence of meeting the identified deficiencies, and six months to submit evidence of providing the additional required training to individuals completing the program within the last 12 months Recommendation: remove the date of July 1 so that any program that fails to meet the initial requirements will have 3 months to provide the board with evidence of meeting the deficiencies. This will allow the newly opening units an opportunity to meet all the requirements. Change to: "Any program that fails to meet the initial requirements of the board, will have 3 months to provide the board with"

19-13-5 Minimum Standards of a Dialysis Technician Training Program	
6.1	To be approved by the board a dialysis technician training program shall meet and maintain the following standards and requirements
6.1.a	Administered by RN with:
6.1.a.2	36 months experience as RN 24 months in the care of renal pt 12 months in dialysis care (occurring within the last 3 years)
6.1.c	When RN vacates the position or is replaced, the board shall be immediately informed in writing of the vacancy and provided the name and qualification of the new administrator. A training program shall not initiate a new dialysis technician training course unless an administrator who meets the requirement of this rule are in place
6.1.f	Curriculum offered by the program.....
6.1.f.1	Classroom instruction shall be face to face instruction with may be supported by audio-visuals which include:
6.1.f.1.F	blood work and laboratory values related to dialysis
6.1.f.H	Pharmacology of the drugs
6.1.f.1.I	Medication administration techniques
6.1.f.1.N	Principles of and requirements for documentation of hemodialysis care and interventions
???	

It is not uncommon for technicians to be enrolled in a nursing program and become RN's. In this case they may have renal care experience as technician for several years and hold more expertise when becoming an RN than an RN just entering the dialysis arena with 36 months experience as a general RN.
Kentucky requires "One (1) year of experience in dialysis care"

Recommendation:

Delete: 36 months experience as an RN.

Change to "at least 24 months experience in direct patient dialysis care-- including time employed as a technician or LPN or RN in the dialysis setting"

Recommendation: clarify that the technicians currently in training will be able to complete the course guided by a temporary program administrator until the new training program administrator is hired.

Recommendation:

Remove "blood work" and keep "laboratory values" (these are redundant). Remove "related to dialysis" as the elevated potassium or protein or phosphorus may be related to food intake, not the dialysis procedure. May add "...related to dialysis patient"

Recommendation: Add "basic" pharmacology and combine with next subsection to include medication administration techniques

Recommendation: (see above)

Recommendation: Remove "principles of and" as the principles of dialysis are listed in 6.1.f.1.G

Recommendation: Add a subsection to address " evaluation and utilization of hemodialysis vascular accesses"

6.1.f.3.G	Include a RN or technician preceptor with at least 2 years of experience....	<p>Training program administrator should have the responsibility to choose the preceptor that they have selected to have the highest competency/knowledge/interpersonal skills—not a person just based upon their years of service. The person with 2 years of service may not be a good trainer or have a desire or ability to learn or teach</p> <p>Recommendation: change wording to “include a RN or LPN or technician preceptor(s) selected by the program administrator based upon qualifications of a high level of competency/knowledge/interpersonal skills”. More than one preceptor may be chosen based upon the learning need (ie. One preceptor may demonstrate expertise in speed/accuracy of machine set-up, another demonstrates patient subjective and objective data gathering/evaluation, and another in knowledge base regarding theory). You do not want to limit quality of teaching/learning by selecting the preceptor based on years of service instead of quality of performance/knowledge.</p>	
6.1.g.6.A	When a trainee enrolls or re-enrolls in a program, board notification, on a form specified by the board, no later than the first day the trainee begin the program.	<p>Recommendation: change to “...on a form specified by the board, to be mailed no later than the first day the trainee begins the program” in order to clarify that this form does not need to be received by the board by the first day.</p>	
6.1.g.6.B	A completion certificate is awarded to a student who has successfully completed the training.	<p>Recommendation: change to “...certificate is awarded by the Board to a student who has successfully completed the training which authorizes an individual to provide dialysis care ...” Ohio rule states “certificate issued by the board which authorizes an individual to provide dialysis care and to use the title Ohio certified dialysis technician”</p>	
???		<p>There is no subsection that addresses the technician that is certified in another state and wishes to practice in WV</p> <p>Recommendation: “A technician, approved by another state, that meets the requirements of WV 19CSR13 subsection 2.9 is permitted to function as such in WV”</p>	
???		<p>There is no subsection that addresses the training of a dialysis technician that transfers from one dialysis unit to another within the state (where the equipment is different)</p> <p>Recommendation: “An experienced technician that is transferred/hired at a dialysis facility must receive training on equipment/supplies/procedures that are differing from the facility that they have previous experience with. Competency is to be validated prior to allowing the technician to function without a preceptor”</p>	
???		<p>There is no subsection that addresses continued learning for the dialysis technician. Based upon this rule, once the technician completes their training upon hire, and the certification examination, they would no longer need to continue their learning.</p> <p>Recommendation: “Each year after certification is obtained, the Hemodialysis Patient Care Technician will obtain a minimum of 5 continuing credit hours pertinent to the care of the patient with renal disease”</p>	

19-13-7 Procedures of Obtaining Re-approval as a Dialysis Technician Training Program	
8.4	At any time, the board may give probationary approval to a dialysis training program or a training program seeking approval or re-approval when there is evidence of:
8.4.a.	Non-compliance with the "minimum standards for approval of dialysis technician training programs" in section 13-6.5
	Subsection 9.1 states "board may deny approval of a training program when program fails to provide evidence of compliance with the "minimum standard for approval of dialysis technician training program" in section 13.6 <i>Not clear re: what will warrant a "probationary approval" vs. denial of approval</i>

19-13-9 Criteria for Denial or Withdrawal of Approval	
9.1	(see comment with 8.4.a)
9.2	The board may withdraw approval of a training program if the program fails to correct deficiencies resulting in non-compliance with the "minimum standards for approval of dialysis technician training programs"
	Recommendation: add a timeframe for the program to correct deficiencies "...if the program fails to correct deficiencies, within the negotiated timeframe, resulting in non-compliance....."

19-13-10 Requirements of Approval and Re-approval of a Testing Organization that Conducts an Examination of a Dialysis Technician	
10.1	To be approved by the board a testing organization that conducts an examination of a dialysis technician shall meet all of the following requirements:
10.1.e	Require a minimum of 12 months experience in dialysis care before the candidate is allowed to take the examination
	Recommendation: remove this subsection in order to allow the testing organizations to set the requirements and change them as needed –the WV Board should not be able to set requirements (that may or may not match) for permission to take another organization's testing

19-13-11 Board Approved Testing Organization for Dialysis Technicians	
11.1	The approved testing organization are:
	<p>Recommendation: to add: NNCC East Holly Ave Box 56 Pitman NJ 08071 1.888.884.NNCC nncc@ajj.com</p> <p>This is the most widely approved testing organization. This organization is recommended by our Mid-Atlantic Renal Coalition –ESRD Network 5</p>

19-13-12 Fees

<p>12.1</p>	<p>The dialysis technician training program initial approval fee is \$10,000 for each site where training occurs including all the clinical experiences.</p>	<p>There are currently over 20 dialysis units in WV that could provide clinical experience for training technicians –with a potential of additional units opening in the future. (Potential of \$200,000 first year) . In order to save money dialysis units will limit training to specific facilities, then make the employee move to another one when training is completed. This will compromise safety as supplies and equipment may be different in each facility. The individual will be unfamiliar with the patients in the facility that they are moved to and this will make the patients and the new employee uneasy. The Medicare reimbursement for dialysis treatment is capitated-in order to pay \$10,000 the facility would need to decrease cost in equipment/supplies or personnel which would greatly impact the quality of the care to the patient. Virginia has no fees Ohio has an approval fee of \$300 Kentucky has an approval fee of \$ 950</p>
<p>12.2</p>	<p>The dialysis technician training program continues re-approval fee is \$8,000.</p>	<p>Virginia has no fees included in the rule Ohio's is the same as their approval \$300 Kentucky's fee for re-approval is \$800</p>
<p>12.3</p>	<p>The dialysis technician training program re-instatement fee is \$10,000.</p>	<p>There would be a financial incentive for the board to deny, re-approval and then re-instate</p>
<p>12.5</p>	<p>Fee for subsequent reviews....when a change has been required</p>	<p>Virginia has NO fees included in the rule Ohio does not have this Kentucky does not have this</p>
<p>12.6</p>	<p>The fee for periodic evaluation of a training program, not to exceed \$2000.</p>	<p>The board will be able to charge for evaluation of the facility training program (\$2000), deny their approval, then charge a re-instatement fee (\$10,000) In Virginia, the individual is responsible only to pay for the certification exam In Ohio, the technician submits an application fee of \$35 (18 months) In Kentucky the technician submits application fee of \$60</p>
		<p>Could the law not state the requirements and if found to be out of compliance- then the facility would be fined by the state? Concerns re: the dialysis facilities could be reported to the State Health Dept. The cost of the certification would be the responsibility of the facility or the technician</p>

19-13-14 Individuals Working as Dialysis Technician Prior to July 1, 2004

14.2	...individuals who have been employed and worked as dialysis technicians prior to July 1, 2004 and who do not meet all of the requirements in 13-14.1 shall:	
14.2.a	Complete an approved education program for the training of dialysis technicians on or before October 31, 2005; or	Recommendation: change to "complete the areas of deficiency in past training as compared to the curriculum requirements of the board (outlined in 6.1.f)"

Commonwealth of Virginia



**VIRGINIA DEPARTMENT OF HEALTH
PROFESSIONS
REGULATIONS
GOVERNING THE CERTIFICATION OF
DIALYSIS TECHNICIANS**

Title of Regulations: 18 VAC 75-40-10 et seq.

OFFICE WEST VIRGINIA
SECRETARY OF STATE

2004 AUG - 2 A 10: 49

FILED

Statutory Authority: Chapter 27.01 of Title 54.1 of the *Code of Virginia*

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Regulations for Certified Dialysis Technicians

18 VAC 75-40-10. Definitions.

The following terms when used in this chapter shall have the following meaning unless the context clearly indicates otherwise:

“Board” means the Board of Health Professions.

“Dialysis patient care technician” or “dialysis care technician” means a person who has obtained certification from an organization approved by the Board to provide, under the supervision of a licensed practitioner of medicine or a registered nurse, direct care to patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility. Such direct care may include, but need not be limited to, the administration of heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers in accordance with the order of a licensed physician, nurse practitioner or physician assistant.

18 VAC 75-40-20. General provisions; scope of practice.

A. In accordance with Chapter 27.01 of Title 54.1 of the Code of Virginia and this chapter, only those persons who hold certification from an entity approved by the Board as prescribed in 18 VAC 75-40-30 shall:

1. Provide direct patient care in a Medicare-certified renal dialysis facility.

2. Administer medications in accordance with subsection O of § 54.1-3408 of the Code of Virginia.

B. Dialysis patient care technicians or dialysis care technicians shall practice only under the supervision of a licensed practitioner of medicine or a registered nurse.

C. Dialysis patient care technicians or dialysis care technicians shall administer medications only under the orders of a licensed physician, nurse practitioner, or physician assistant and under the direct and immediate supervision of a registered nurse.

D. Persons who do not hold such certification shall not hold the restricted titles or use any other title or term that implies a minimum level of education, training and competence. Unregulated persons shall only perform services relating to the technical elements of dialysis, such as equipment maintenance and preparation of dialyzers for reuse by the same patient.

18 VAC 75-40-30. Criteria for use of the titles of dialysis patient care technician or dialysis care technician.

In order to use the titles of dialysis patient care technician or dialysis care technician or administer medications in a Medicare-certified renal dialysis facility, a person shall hold one of the following certifications:

1. Certified Clinical Hemodialysis Technician (CCHT) by the Nephrology Nursing Certification Commission (NNCC);
2. Certified Hemodialysis Technician (CHT) by the Board of Nephrology Examiners Nursing and Technology (BONENT);
3. Certified in Clinical Nephrology Technology (CCNT) by the National Nephrology Certification Organization (NNCO); or
4. Certification or licensure as a dialysis technician or similar title by another jurisdiction in the United States provided the standards for certification or licensure or substantially equivalent to those in Virginia.

F a c s i m i l e



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FILED
2004 AUG -6 A 2:03
OFFICE WEST VIRGINIA
SECRETARY OF STATE

TO: Ms. Judy Cooper

FAX NUMBER: 558-0900

FROM: Amy N. Tolliver, MS

DATE: 08/06/04

PAGES: 3

MESSAGE:

Per our conversation a week ago, I am faxing you the letter that we filed with the Nurses Board in regard to their request for comments on Emergency Rule 19 CSR 13.

I know that you have already gotten additional comments from other groups. Our main issues are the same as most groups have touched on - staffing ratios and the fees. Of course each group has other individual concerns as well.

Thank you for taking a look at this letter and for your consideration of all the concerns that have been raised regarding this rule.

If you do not receive all pages of this transmission, please call 304-925-0342

This facsimile contains confidential information intended for use or distribution by the person(s) named above. Any other distribution, copying or disclosure is strictly prohibited. If you have received this facsimile in error, please notify us by telephone and destroy the original transmission or return it to us by mail without making a copy.



August 5, 2004

Ms. Laura Skidmore Rhodes, MSN, RN
Executive Director
WV Board of Examiners for Registered Professional Nurses
101 Dee Drive
Suite 102
Charleston, WV 25311-1620

Dear Ms. Rhodes,

I am writing to you on behalf of the West Virginia State Medical Association (WVSMA) in response to the request for comment on the proposed emergency rule 19 CSR 13, Dialysis Technicians, as authorized under House Bill 4641 in the 2004 Legislative Session.

The WVSMA does recognize the need to ensure qualified and properly trained healthcare workers, including dialysis technicians, are caring for patients in End Stage Renal Disease (ESRD) facilities in West Virginia. The WVSMA supports the intent of the legislation and the rule to accomplish this point. However, there are a few areas of concern that we would like to articulate in regard to the rule as it is currently written. In addition, we observe without taking a position, that the oversight of Dialysis Technicians might be better achieved through their own licensing board.

19-13-3, 3.3.e

We believe that it is beyond the statutory scope of the Board's authority to write a rule that establishes staffing ratios for the ESRD's. The legislation that authorized the Board to draft the rule, HB 4641, does not include matters which would reasonably include staffing ratio rules. Additionally, the Office of Health Facility Licensure and Certification (OHFLAC) is responsible for site reviews for Medicare Certification of the state's twenty-five ESRD's. Arguably, the Board is, at the least, creating a conflict with the scope of OHFLAC's jurisdiction by attempting to set staffing ratios.

19-13-4, 4.3.a

This section is inartfully written. The language should include appropriate medical terminology and should not include the concept that anyone other than the physician determines the appropriate medication. (i.e do not us the phrase "for the right reason")

19-13-6, 6.1.f.1

The requirement for face-to-face instruction is antiquated and does not acknowledge the current widespread use of television and other electronic technology. By requiring face-to-face instruction the technicians could be missing out on the ability to be trained by highly qualified instructors from

West Virginia State Medical Association

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FROM-WV State Medical Association

AUG-08-2004 02:01PM

another area, which would enhance the quality of their training program. This mode of instruction is certainly accepted in our state's medical schools. At a time when distance learning programs are being increasingly utilized in educational programs of all types, it just makes no sense to require that dialysis technicians are only permitted to receive face-to-face training.

19-13-7, 1.b

The requirement for a review and re-approval of the dialysis technician training program every two years seems excessive and burdensome. It would seem that the program would not change that often to merit a review every two years.

19-13-12

The fees set out for the training programs are exorbitant, especially for the fact that they are assessed per site. By setting the fee at \$10,000 per site the end result may in fact be that the number of sites where the training occurs will be reduced. This could result in fewer people being trained and therefore exacerbating healthcare professional shortages; ultimately, negatively impacting access to care for these high need hemodialysis patients. Possibly the more appropriate solution would be to assess the fees by program regardless of the number of sites where that particular program is delivered. The re-approval fee of \$8,000 is also excessive.

I thank you on behalf of the WVSMA for the opportunity to comment on this proposed rule and for your serious consideration of the concerns we have articulated. If you have any questions regarding any of the points mentioned, please do not hesitate to call the WVSMA at 925-0342 ext. 25.

Sincerely,



Ron D. Stollings, MD
President