

2840

May 25, 2010

Ann Steffanic Administrator State Board of Nursing P.O. Box 2649 Harrisburg, PA 17105-2649

Dear Ms. Steffanic:

JUN - 2 2010

JU

This letter in reference to the Board of Nursing Proposed Rule which amends 49 PA Code Chapter 21 §§ 21.141 and 21.145 relating to the scope of duties of Licensed Practical Nurses ("LPN") in Intravenous ("IV") Therapy. Fresenius Medical Care North America ("Fresenius") is the largest provider in the country of dialysis services for individuals undergoing dialysis due to end stage renal disease ("ESRD"). In Pennsylvania, Fresenius provides dialysis services to nearly 5,000 individuals at 88 dialysis facilities across the state.

We commend the Board of Nursing for addressing the role of LPNs in IV therapy, and we are in agreement with the Board on most provisions of the Proposed Rule. However, we are concerned that the Proposed Rule does not fully take into consideration the unique role of the LPN working in the hemodialysis setting. Specifically, we would like to address LPN administration of IV medications incident to hemodialysis treatments.

The Proposed Rule permits LPNs to administer medications in the dialysis setting with appropriate supervision<sup>1</sup> and creates an exception for dialysis to the prohibition on LPNs administering medications or fluid via an arteriovenous fistula or graft<sup>2</sup> (§ 21.145a (12). The Proposed Rule also permits an LPN who has met established education and training requirements to administer solutions to maintain patency of an IV access device via direct push or bolus route,<sup>3</sup> while prohibiting them from administering other medications via push or bolus.

Anticoagulation therapy is a necessary component of the dialysis treatment, and must be administered at initiation of treatment to prevent clotting of the patient's blood as it passes through the extracorporeal circuit. The general practice is for the anticoagulant to be administered by direct IV push in accordance with attending physician orders and clinical protocols approved by the Medical Director. If an LPN cannot initiate dialysis treatment, which includes the anticoagulant administration in this way, it limits their ability to work in the hemodialysis setting.

<sup>49</sup> PA Code Chapter 21 § 21.145 (5)(iii)

<sup>&</sup>lt;sup>2</sup> 49 PA Code Chapter 21 § 21.145a (12)

<sup>&</sup>lt;sup>3</sup> 49 PA Code Chapter 21 § 21.145 (g)(10)

Federal Medicare regulations require Registered Nurses to supervise all clinical staff while patients are undoing treatment in the chronic outpatient hemodialysis setting. In addition, the physical layout of most dialysis facilities is an open room so all patients and staff can be visualized at all times. Therefore, LPN's are under the constant supervision and observation of the RN, who is responsible to ensure that all staff comply with facility medication administration and general patient care policies. All dialysis treatment procedures, including initiation of hemodialysis treatment and administration of anticoagulants, are performed in accordance with strict facility protocols.

A number of states have specifically addressed the role of the LPN in the dialysis setting, including Maryland, which permits LPNs to administer IV medications and solutions during hemodialysis, and administration of specific medications by IV "push" per physician order and nationally recognized standards of care. Those medications include: anticoagulant agents, saline, erythropoietic agents, Vitamin D products, iron preparation agents, and anti-emetic agents. <sup>4</sup> In addition, Ohio and Delaware have enacted nursing rules that permit the LPN to administer IV push or bolus medications via central and peripheral lines. <sup>5 6</sup>

We respectfully request the Board of Nursing to reconsider its position and permit LPNs in the dialysis setting to administer IV medications via push or bolus routes. We would be happy to have members of Board who are unfamiliar with the hemodialysis treatment setting visit any of our facilities in Pennsylvania.

Sincerely,

Cathleen O'Keefe, RN, JD

Vice President, Regulatory Government Affairs

Fresenius Medical Care North America

920 Winter Street

Waltham, MA 02451

Cathleen.OKeefe@fmc-na.com

1 (800) 662-1237 x 4560

<sup>&</sup>lt;sup>7</sup> COMAR 10.27.20.05 E and F

<sup>&</sup>lt;sup>5</sup> Ohio Administrative Code Chapter 4723-17-03

Delaware Administrative Code, 1900, 7.8.3.3.5