

FILED DATE FEB 28 2014
Department of Health

By: *Angela Sanchez*
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF NURSING

IN RE: THE PETITION
FOR DECLARATORY
STATEMENT OF
LANCIA L. SIMMONS, RN
_____ /

AMENDED FINAL ORDER

THIS CAUSE came before the Board of Nursing (hereinafter Board) pursuant to §120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, at a duly-noticed meeting in Deerfield Beach, Florida on December 5, 2013, for the purpose of considering the Petition for Declaratory Statement (attached as Exhibit A) filed on behalf of LANCIA L. SIMMONS, RN (hereinafter Petitioner). Having considered the petition, the arguments submitted by counsel for Petitioner, and being otherwise fully advised in the premises, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. This petition was noticed by the Board in Vol. 39, No. 217, dated November 6, 2013, of the Florida Administrative Register.
2. Petitioner, LANCIA L. SIMMONS, RN, is a nurse licensed to practice in the State of Florida, having license number RN 1619302.
3. Petitioner is employed at Tampa General Hospital in the burn unit and oversees the operations of the unit.
4. Petitioner is ACLS certified and is an instructor in Advance Burn Life support.
5. Petitioner has become aware of the potential to administer ketamine as a pain control adjunct.

6. The ketamine would be administered intravenously via an infusion pump, pursuant to an order of a duly licensed practitioner and the policies and procedures established by the hospital, as follows:

a. at low dosages (up to 50 mcg/kg/min but generally 25 mcg/kg/min or less) to a mechanically ventilated patients in an intensive care bed for purposes of sedation or pain control.

b. at analgesic doses (up to 5 mcg/kg/min) to burn patients for pain control during certain time limited procedures such as dressing changes.

5. The Boards of Nursing in New York and Oregon have determined that administration of low doses of ketamine is within the scope of practice of registered nurses if certain criteria are met.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

2. The petition filed in this cause is in substantial compliance with the provisions of Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

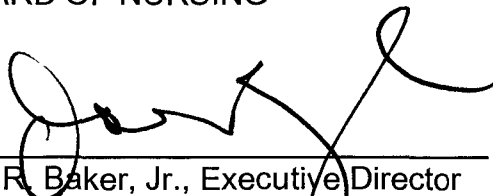
3. Section 464.003(20)(b), Florida Statutes, defines the practice of professional nursing to include the administration of medications prescribed or authorized by a duly authorized practitioner.

WHEREFORE, the Board hereby finds that under the specific facts of the petition, as set forth above, that the administration of ketamine by Petitioner for sedation purpose as non-anesthetic doses to mechanically ventilated patients in ICU beds and the administration of ketamine for analgesic purposes to patients, assessed and

monitored by Petitioner, undergoing time limited procedures, are within the scope of
Petitioner's license.

DONE AND ORDERED this 26th day of Feb, 2014.

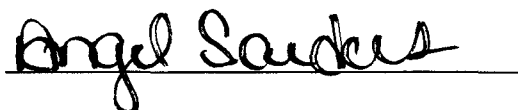
BOARD OF NURSING



Joe R. Baker, Jr., Executive Director
for Lavigne Ann Kirkpatrick, BS, RN
Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order
has been furnished by U.S. Mail to Cynthia A. Mikos, Esquire, Allen Dell, PA, 202 S.
Rome Avenue, Suite 100, Tampa FL 33606-1854 and by interoffice mail to Donna
Oxford, Paralegal Specialist, Department of Legal Affairs, PL-01 The Capitol,
Tallahassee FL 32399-1050 this 28th day of February, 2014.



Deputy Agency Clerk

Final Order No. DOH-14-0289-**DS** -MQA

FILED DATE **FEB 20 2014**

Department of Health

By: Angel Sanders
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF NURSING

IN RE: THE PETITION
FOR DECLARATORY
STATEMENT OF
LANCIA L. SIMMONS, RN

FINAL ORDER

THIS CAUSE came before the Board of Nursing (hereinafter Board) pursuant to §120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, at a duly-noticed meeting in Deerfield Beach, Florida on December 5, 2013, for the purpose of considering the Petition for Declaratory Statement (attached as Exhibit A) filed on behalf of LANCIA L. SIMMONS, RN (hereinafter Petitioner). Having considered the petition, the arguments submitted by counsel for Petitioner, and being otherwise fully advised in the premises, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. This petition was noticed by the Board in Vol. 39, No. 217, dated November 6, 2013, of the Florida Administrative Register.
2. Petitioner, LANCIA L. SIMMONS, RN, is a nurse licensed to practice in the State of Florida, having license number RN 1619302.
3. Petitioner is employed at Tampa General Hospital in the burn unit and oversees the operations of the unit.
4. Petitioner is ACLS certified and is an instructor In Advance Burn Life support.
5. Petitioner has become aware of the potential to administer ketamine as a pain control adjunct.

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6. The ketamine would be administered intravenously via an infusion pump, pursuant to an order of a duly licensed practitioner and the policies and procedures established by the hospital, as follows:

a. at low dosages (up to 50 mcg/kg/hr but generally 25 mcg/kg/min or less) to a mechanically ventilated patients in an intensive care bed for purposes of sedation or pain control.

b. at analgesic doses (up to 5 mcg/kg/hr) to burn patients for pain control during certain time limited procedures such as dressing changes.

5. The Boards of Nursing in New York and Oregon have determined that administration of low doses of ketamine is within the scope of practice of registered nurses if certain criteria are met.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

2. The petition filed in this cause is in substantial compliance with the provisions of Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

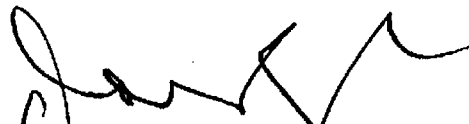
3. Section 464.003(20)(b), Florida Statutes, defines the practice of professional nursing to include the administration of medications prescribed or authorized by a duly authorized practitioner.

WHEREFORE, the Board hereby finds that under the specific facts of the petition, as set forth above, that the administration of ketamine by Petitioner for sedation purpose as non-anesthetic doses to mechanically ventilated patients in ICU beds and the administration of ketamine for analgesic purposes to patients, assessed and

monitored by Petitioner, undergoing time limited procedures, are within the scope of
Petitioner's license.

DONE AND ORDERED this 18th day of Feb, 2014.

BOARD OF NURSING



Joe R. Baker, Jr., Executive Director
for Lavigne Ann Kirkpatrick, BS, RN
Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order
has been furnished by U.S. Mail to Cynthia A. Mikos, Esquire, Allen Dell, PA, 202 S.
Rome Avenue, Suite 100, Tampa FL 33606-1854 and by interoffice mail to Donna
Oxford, Paralegal Specialist, Department of Legal Affairs, PL-01 The Capitol,
Tallahassee FL 32399-1050 this 20th day of February, 2014.



Deputy Agency Clerk

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FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE NOV 05 2013

FLORIDA DEPARTMENT OF HEALTH
BOARD OF NURSING

Petition for Declaratory Statement
before the Board of Nursing

In re Lancia L. Simmons, RN

Petitioner, Lancia L. Simmons, RN, by and through her undersigned attorneys and pursuant to Florida Statutes §120.565 and Florida Administrative Code Rule 28-105, seeks the Florida Board of Nursing's ("Board") opinion as to whether the administration of ketamine in two specific circumstances as set forth more fully below is within the scope of practice of the registered nurse.

1. Petitioner, Lancia L. Simmons is a registered nurse (RN) licensed by the Florida Board of Nursing pursuant to Florida Statutes Chapter 464 holding license number RN 1619302 since 1985. She can be contacted through undersigned counsel.

2. Petitioner, Ms. Simmons is currently employed at Tampa General Hospital (TGH) as a Registered Nurse Clinician in the burn unit, a unit that has 6 intensive care beds and 12 medical/surgical beds where she has worked for most of her 24 year tenure with TGH and all the beds are monitored beds. She holds a current ACLS certification and is a provider and instructor in Advance Burn Life Support. As the Clinician for the burn unit, Ms. Simmons oversees the operations of the burn unit to ensure quality patient care and is involved in much of the complex wound care for the patients.

3. Because pain control and management is an integral part of the care of patients on the burn unit, Petitioner has become aware of the potential to administer ketamine as a possible pain control adjunct. Petitioner seeks a determination as to whether it is within her scope of

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practice as a registered nurse to administer ketamine intravenously via an infusion pump at dosages less than those used to deliver anesthesia in two different situations:

- a. at low dosages (up to 50 mcg/kg/hr), pursuant to an order by a duly licensed practitioner, to a mechanically ventilated patient for purposes of sedation or pain control in an intensive care bed at Tampa General Hospital (TGH) as long as she is ACLS certified and practices pursuant to policies and procedures established by TGH.
- b. at analgesic doses (up to 5 mcg/kg/hr), pursuant to an order by a duly licensed practitioner, to patients for pain control during certain time limited procedures like dressing changes on burn patients, some of whom may not be intubated, as long as she is ACLS certified and practices pursuant to policies and procedures established by TGH.

4. Ketamine is approved by the United States Food and Drug Administration as a nonbarbiturate anesthetic producing an anesthetic state characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, cardiovascular and respiratory stimulation, and occasionally a transient and minimal respiratory depression. Ketamine is noted for its ability to produce a state of anesthesia while preserving respiratory drive and protective airway reflexes¹.

5. Anecdotally, and in limited studies, low dose levels of ketamine have been found to be effective for the relief of chronic intractable pain in some patients. This is currently an off-label use of ketamine, but it has been found to offer unprecedented, long-term pain relief in some patients. It has also been found, at very low doses, to offer excellent pain control to patients undergoing painful, but time limited procedures. Additionally of interest regarding ketamine is

¹ Rakic and Golembicwski, *Low-Dose Ketamine Infusion for Postoperative Pain Management*, 24 *Journal of PeriAnesthesia Nursing*, 254, 254 (August 2009).

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that it is less likely than other sedative agents to cause respiratory depression, even when used as an anesthetic agent.

6. The administration of ketamine by registered nurses has come before Boards of Nursing in other states where similarly, licensees have sought regulatory guidance. The New York and Oregon Boards of Nursing have specifically addressed the issue of ketamine administration by RNs and have issued policy statements which state it is within the scope of practice of registered nurses to administer low dose ketamine as long as specific criteria are met. The Texas Board of Nursing has discussed the issue and while it declined to specifically issue a policy statement, it implies in its FAQs that it may be within the scope of practice for registered nurses with appropriate training and in appropriate settings to administer low dose ketamine.

7. The scope of practice of a registered nurse is defined in Florida Statutes §464.003(20) as follows:

“Practice of professional nursing” means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skill based upon applied principles of psychological, biological, physical, and social sciences which shall include, but not be limited to:

- (a) The observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; health teaching and counseling of the ill, injured, or infirm; and the promotion of wellness, maintenance of health, and prevention of illness of others.
- (b) The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments.
- (c) The supervision and teaching of other personnel in the theory and performance of any of the acts described in this subsection.

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A professional nurse is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing.

8. In *In re: Linda C. Noelke, RN, DOH-03-DS-MQA* (April 29, 2003), a nurse asked the Florida Board of Nursing if it was within a registered nurse's scope of practice to administer ketamine in ambulatory surgery centers, upon an order from a physician, in three circumstances: 1) when the patient is not intubated; 2) for the purposes of rendering the patient insensible to pain; and 3) when there is not an anesthesiologist on staff. The Board of Nursing answered all three questions in the negative and noted that ketamine was a nonbarbituate general anesthetic. This is the only declaratory statement, issued over ten years ago, by the Florida Board of Nursing specific to ketamine.

9. In *In re Mashour-Smith, RN, DOH-03-0408-DS-MQA* (April 24, 2003) and *In re Schellhorn, RN, DOH-03-0405-DS-MQA* (April 24, 2003) nurses asked questions similar to that of Ms. Simmons concerning the administration of another agent which is commonly used as an anesthetic agent, diprivan. The Board declared that these RNs could administer diprivan, for the purposes of sedation, pursuant to an order from a duly authorized practitioner, to mechanically intubated patients and then monitor those patients after administration as long as the nurses were trained and certified in ACLS and practiced in compliance with policies and procedures established by the hospital.

10. The Florida Board has consistently ruled that only certified registered nurse anesthetists (CRNAs) or other anesthesia providers may administer anesthesia and Ms. Simmons' inquiry is specific to low doses of ketamine, specifically levels for sedation and at even lower doses for the purposes of pain control.

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11. In recent years, the Board has received a number of inquiries regarding the administration of sedating drugs by RNs for the use of conscious sedation. Consequently, the Board developed a rule on the administration of conscious sedation by registered nurses, specifically when a registered nurse may administer conscious sedation (including the use of the drug ketamine) without engaging in unprofessional conduct. The rule was challenged and held by an administrative law judge to be invalid, but the ruling is on appeal before the First District Court of Appeal.

12. The proposed rule, despite its current legal status, offers us insights into the Board's analysis on the circumstances affected Ms. Simmons specifically in her inquiry regarding the administration of ketamine for sedation in intubated patients in intensive care beds. If the proposed rule were in effect, registered nurses would be permitted to administer ketamine, with an order from a qualified practitioner, if specific criteria are met. For deep sedation, it would be clearly permissible for an RN to administer anesthetic medications, like ketamine, to mechanically ventilated patients with a secured artificial airway. In addition, the RN would be required to 1) demonstrate competency, by a criteria based evaluation, in the physical assessment and monitoring of sedated patients, the pharmacodynamics and pharmacokinetics of the agents administered, airway management, mechanical ventilation, and be ACLS certified; 2) complete a patient assessment prior to administration of the medication; 3) ensure that the hospital has a quality assurance and performance improvement process in place; and 4) evaluate the patient for discharge readiness and obtain physician approval for discharge.

13. Ms. Simmons has been informed that Tampa General Hospital would develop policies and procedures whereby ketamine would be administered in the intensive care units (ICUs) like the six beds in the burn unit, by registered nurses pursuant to an order from a duly

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authorized practitioner to mechanically ventilated patients. These patients would have a secure artificial airway, would be assessed by trained registered nurses, monitored by trained nurses, and evaluated by trained nurses for discharge readiness prior to discharge, if applicable. The hospital has a quality assurance and performance improvement process in place.

14. Ms. Simmons has also been informed that Tampa General Hospital would develop policies and procedures whereby ketamine would be administered by RNs pursuant to an order from a duly authorized practitioner, to patients requiring analgesia for certain time limited procedures. These patients would be assessed by trained registered nurses, monitored by trained nurses who are ACLS certified, and evaluated by trained nurses for discharge readiness prior to discharge, if applicable.

15. The administration of ketamine by Ms. Simmons for the purposes of sedation in intubated patients would be via infusion, either continuous or intermittent. The administration will not be intended to include anesthetic level sedation, or suppress brain function (coma). The typical dose of ketamine which would be ordered in accordance with these procedures would be up to 50 mcg/kg/min, but would generally be 25 mcg/kg/min or less. The average amount of ketamine required to produce five to ten minutes of surgery anesthesia is 2mg/kg, after an induction dose of 1-4.5mg/kg.

16. On other occasions, like the burn unit, Ms. Simmons would administer extremely low doses of ketamine, 5 mcg/kg/hr, to patients undergoing time limited painful procedures like deep dressing changes.

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ARGUMENT

17. The Board of Nursing has discretion to determine if a particular set of facts, with respect to a specific licensee, results in actions which are within the scope of practice of the registered nurse.

18. The registered nurse may administer medication pursuant to an order of a duly authorized practitioner. In the facts presented here by Ms. Simmons, the registered nurse would be administering ketamine pursuant to the order of a duly authorized practitioner.

19. The registered nurse is also authorized to participate in the observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care. In both situations proposed here, Ms. Simmons would be observing how the patient reacts during the IV administration of ketamine, assessing the reactions, and intervening and evaluating the care as appropriate. The registered nurse has the critical thinking ability and the statutory authority to reach out to the ordering practitioner, or other practitioner as appropriate to ensure safe and effective patient care.

20. The registered nurse is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing. To this end Tampa General plans to offer and require nurses like Ms. Simmons to have specific education, training, and experience prior to participating in the administration of ketamine at non-anesthetic levels and would essentially require the standards set forth by the Board of Nursing in the proposed rule on conscious sedation for patients who are mechanically ventilated for sedating doses of ketamine.

21. In the case of purely analgesic doses, Ms. Simmons would be administering ketamine, in extremely low doses, to patients for pain relief, and who may not be intubated, but

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the nurse would be ACLS certified, acting pursuant to policies and procedures developed by the hospital, be area of the hospital where practitioners trained in anesthesia and airway management are readily available to support the ACLS certified RN. In addition, ketamine generally, is much less likely than other agents to cause respiratory depression, especially at such low doses.

22. While ketamine can be used as an anesthetic agent, in the case presented Ms. Simmons would be administering ketamine solely for sedation at sub-anesthesia levels or at extremely low doses for analgesia. This use is consistent with previously expressed opinions by the Board with different drugs of the same, or similar classification as in *In re Mashour-Smith* and *In re Schellhorn* where the Board agreed that with a mechanically ventilated patient, it is within the scope of practice of a registered nurse to administer diprivan for sedation.

23. Part of the Board's previous apparent concern with RN administered sedation is that a patient's airway be protected and that patients not slip into a respiratory depression when there is no qualified provider available to rescue the patient. Not only is ketamine significantly less likely to cause respiratory depression, but Ms. Simmons would only administer ketamine for sedation purposes to patients being mechanically ventilated, thus there would be no danger of an unsecured airway. In patients receiving analgesic doses of ketamine, there is essentially no concern of respiratory depression since the doses are so low. Regardless, Ms. Simmons is trained in airway management and other providers would be readily available to assist.

24. In the Board's previous declaratory statement which specifically addresses ketamine administration, in *In re Noelke*, there was no guaranteed protection of the patient's airway and there was no qualified provider available to rescue a patient who inadvertently slipped into a deeper level of sedation. In fact, for Ms. Simmons, the situation at TGH would be under totally different circumstances which address the concerns the Board had with Ms.

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Noelke's situation. Patients receiving ketamine for sedation will be mechanically ventilated, the ketamine will be used for sedation, not at anesthetic levels to render the patient insensible to pain, and there will be anesthesiologists and other providers available since the administration will only occur in the ICUs at TGH. Patients receiving ketamine for analgesia are extremely unlikely to experience respiratory depression due to the low doses which would be administered.

25. It is well within the scope of practice for a registered nurse to administer agents for sedation, particularly when the patient's airway is protected, the nurse is trained in ACLS and is practicing pursuant to policies and procedures of the hospital. Ms. Simmons, as an RN, is qualified to assess the patients before administration, and monitor and assess them during and after administration. Ms. Simmons would be practicing within her scope as a registered nurse as she administered ketamine for sedation in the specific circumstances set forth in this Petition.

26. It is well within the scope of practice for a registered nurse to administer agents for pain control during time limited procedures, particularly when the chance of any respiratory depression is remote, the nurse is trained in ACLS, and is practicing pursuant to policies and procedures of the hospital. Ms. Simmons, as an RN, is qualified to assess the patients before administration, and monitor and assess them during and after administration. Ms. Simmons would be practicing with her scope as a registered nurse as she administered analgesic doses of ketamine during time limited procedures in the specific circumstances set forth in this Petition.

WHEREFORE, Ms. Simmons respectfully requests that the Board issue a declaratory statement opining that the administration of ketamine by Ms. Simmons for sedation purposes, at non-anesthetic doses, to mechanically ventilated patients in ICU beds or for analgesic purposes to patients undergoing time limited procedures and who are assessed and monitored by Ms.

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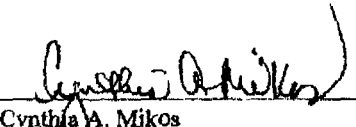
Simmons, practicing pursuant to established policies and procedures, is within the scope of practice of the registered nurse.

Respectfully submitted,


 ALLEN DELL, P.A.
 Cynthia A. Mikos
 Fla. Bar No.: 0984256
 Anna G. Small, Esq.,
 Fla. Bar. No.: 0017064
 202 S. Rome Ave., Suite 100
 Tampa, FL 33606-1854
 Tel: (813) 223-5351
 Fax: (813) 229-6682
 E-Mail: cmikos@allendell.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the fully executed foregoing instrument has been furnished via email (leeann.gustafson@oag.state.fl.us) and U.S. Mail to LeeAnn Gustafson, Office of the Attorney General, The Capitol, PL-01, Tallahassee, FL 32399 and via facsimile (850-410-1448) and U.S. Mail to the Florida Department of Health, Agency Clerk, 4052 Bald Cypress Way, Bin A02, Tallahassee, Florida 32399 on this 4th day of November, 2013.


 Cynthia A. Mikos