

By: Melissa [Signature]  
Deputy Agency Clerk

STATE OF FLORIDA  
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT

FLORIDA HOSPICES AND PALLIATIVE  
CARE, INC.

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**FINAL ORDER**

This matter came before the Board of Medicine (hereinafter the "Board") on August 5, 2011, in Jacksonville, Florida, for consideration of the referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on July 22, 2011, in the Vol. 37 , No. 29, in the Florida Administrative Weekly.

The petition filed by Florida Hospice and Palliative Care, Inc. (hereinafter the "Petitioner") inquires as to whether the provisions of Section 456.44 (Ch. 2011-141, § 3, Laws of Fla.) are applicable to the prescribing of controlled substances by physicians licensed under Chapter 458, Florida Statutes, in connection with the provision of palliative care to patients that are served by a hospice or an entity that is controlled by or is under common control with a hospice.

**FINDINGS OF FACTS**

1. The Petitioner is a not-for-profit, IRS Section 501(c)(3) organization representing Florida's hospice programs.
2. A hospice is defined under Florida law as a centrally administered corporation providing a continuum of palliative and supportive care for the terminally ill patient and his or her family. § 400.601(3), Fla. Stat. (2010).
3. "Palliative Care" is defined under Florida law as services or interventions which are not curative but are provided for the reduction or abatement of pain and human suffering.

§ 400.601(7), Fla. Stat. (2010).

4. A hospice patient is a terminally ill individual receiving hospice services. § 400.601(8), Fla. Stat. (2010).

5. A patient is considered terminally ill if such patient has a medical prognosis that his or her life expectancy is one year or less if the illness runs its normal course. § 400.601(10), Fla. Stat. (2010).

6. The hospice services include the administration of and the prescribing of controlled substance for the treatment of terminally ill hospice patients.

7. Hospices employ medical directors licensed pursuant to Chapters 458 or 459, who shall have the responsibility for directing the medical care and treatment of hospice patients and may appoint additional hospice physicians who shall perform all duties prescribed by law. All appointed hospice physicians, licensed pursuant to Chapters 458 or 459, who are subject to the same licensing qualifications as the hospice medical director. § 400.6105(1), Fla. Stat. (2010).

8. Physicians not employed by a hospice may provide hospice services to hospice patients.

#### **CONCLUSIONS OF LAW**

9. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

10. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

11. The 2011 Florida Legislature enacted CS/CS/HB 7095 which was signed into law by the Governor and is now referenced as Chapter 2011-141, Laws of Florida. Section

456.44(1)(d), (Ch. 2011-141, § 3, Laws of Fla.), requires among other things that physicians licensed pursuant to Chapter 458 who prescribe any controlled substance for the treatment of chronic nonmalignant pain designate themselves as controlled substance prescribing practitioners on their practitioner profiles; require such registered physicians to meet certain standards of practice, including requiring all patients undergo a physical examination and enter into a written controlled substance agreement, a written protocol, an assessment of risk for aberrant behavior, a treatment plan, specified informed consent, consultation and referral in certain circumstances, and medical records meeting certain criteria.

12. More specifically, Section 456.44(2), (Ch. 2011-141, § 3, Laws of Fla.) reads as follows:

(2) REGISTRATION. - Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

13. In turn, Section 456.44(3), (Ch. 2011-141, § 3, Laws of Fla.), provides for specific Standards of Practice that must be followed by all registrants subject to the provisions of that section.

14. If a physician subject to Section 456.44(2) and (3) fails to comply with the requirements of Section 456.44, he or she may be disciplined by the Board of Medicine pursuant to Section 456.072(2), Florida Statutes.

15. Petitioner has inquired as to whether physicians licensed pursuant to Chapter 458, Florida Statutes, who provide palliative care through the prescribing of controlled

substances to patients that are served by a hospice or an entity that is controlled by or is under common control with a hospice, must comply with Section 456.44(2) and (3) as currently found in Chapter 2011, § 3, Laws of Florida.

16. The answer to the Petitioner's inquiry turns on the definition of the term "chronic nonmalignant pain" as set forth in Section 456.44(1)(d), (Ch. 2011-141, § 3, Laws of Fla.) .

Section 456.44(1)(d), defines the term as:

pain unrelated to cancer or rheumatoid arthritis ***which persists beyond the usual course of disease*** or the injury that is the cause of the pain or more than 90 days after surgery.  
(emphasis supplied.)

17. Under the clear terms of Section 456.44(2), (Ch. 2011-141, § 3, Laws of Fla.), only those physicians who prescribe patients controlled substances for the treatment of chronic nonmalignant pain, must designate themselves as controlled substance prescribing practitioner on their practitioner profile and must comply with the standards of practice set forth in Section 456.44(3), (Ch. 2011-141, § 3, Laws of Fla.).

18. The Board is of the opinion that when a physician provides palliative care through the prescribing of controlled substances to a patient served by a hospice or an entity controlled by or under common control with a hospice, the patient is being treated for pain that is **within** the usual course of his or her disease and comorbidities, including related secondary conditions. This being the case, such patient is not being treated for chronic nonmalignant pain, and therefore, the treating physician, under such circumstances, is not subject to the provisions of Section 456.44(2) and (3), (Ch. 2011-141, § 3, Laws of Fla.).

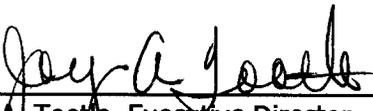
19. This Final Order is issued in response to the question propounded by the Petitioner as set forth in its Petition For Declaratory Statement. The Board's conclusion is based

solely on the Board's application of the factual circumstances outlined in the Petition to the pertinent statutory and rule provisions set forth above.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

**DONE AND ORDERED** this 10th day of October, 2011.

**BOARD OF MEDICINE**

  
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Joy A. Tootle, Executive Director  
for George Thomas, M.D., Chair

**NOTICE OF APPEAL RIGHTS**

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished via email to: R. Terry Rigsby, Pennington, Moore, Wilkinson, Bell & Dunbar, P.A., Post Office Box 10095, 215 South Monroe Street, 2<sup>nd</sup> Floor (32301), Tallahassee, Florida 32302-2095, trigsby@penningtonlaw.com; and by interoffice mail to Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050; and Nicholas Romanello, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, on this 7<sup>th</sup> day of October, 2011.

*Melissa Tellechea*

**Deputy Agency Clerk**

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STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BOARD OF MEDICINE

IN RE:

PETITION OF FLORIDA HOSPICES  
AND PALLIATIVE CARE, INC.

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**PETITION FOR DECLARATORY STATEMENT BEFORE  
THE DEPARTMENT OF HEALTH, BOARD OF MEDICINE**

Petitioner, FLORIDA HOSPICES AND PALLIATIVE CARE, INC., by and through its undersigned counsel, petitions pursuant to §120.565, Florida Statutes, and Rule Chapter 28-105, Florida Administrative Code, for a Declaratory Statement and states as follows:

1. Petitioner, FLORIDA HOSPICES AND PALLIATIVE CARE, INC. (FHPC), is a Florida non profit corporation. Its address and contact numbers are: 2000 Apalachee Parkway, Suite 200, Tallahassee, Florida 32301; telephone 850-878-2632; and facsimile 850-878-5688.

2. For purposes of this Petition, FHPC's authorized representative is R. Terry Rigsby, with the law firm Pennington, Moore, Wilkinson, Bell & Dunbar, P.A., 215 South Monroe Street, Second Floor, Tallahassee, Florida 32301; telephone 850-222-3533; and facsimile 850-222-2126.

3. FHPC is a statewide association which represents 41 of the 42 licensed hospice programs. FHPC's member hospice programs serve patients in all 67 Florida counties. FHPC has standing to initiate this Petition by virtue of the fact all of FHPC's members employ and/or contract with Florida physicians licensed pursuant to chapter 458,

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Florida Statutes, in order to provide necessary medical care and treatment to patients requiring palliative care for the reduction or abatement of pain.

4. The issue involved in this request for Declaratory Statement affects the substantial interests of all FHPC member hospice programs as they desire their physician employees, agents and programs to be fully compliant with all provisions of state law.

5. In particular, FHPC seeks a determination that the provisions of § 456.44, as created in § 3 of Ch. 2011-141, Laws of Florida, are not applicable to the prescribing of controlled substances by physicians licensed under chapter 458, Florida Statutes, in connection with the provision of palliative care to patients served by a hospice or an entity that is controlled by or under common control with a hospice.

#### **Statement of Facts and Law**

6. A hospice is defined under Florida law as a centrally administered corporation providing a continuum of palliative and supportive care for the terminally ill patient and his or her family. § 400.601(3), Fla. Stat. (2010).

7. "Palliative Care" is defined under Florida law as services or interventions which are not curative but are provided for the reduction or abatement of pain and human suffering. § 400.601(7), Fla. Stat. (2010).

8. A hospice patient is a terminally ill individual receiving hospice services. § 400.601(8), Fla. Stat. (2010).

9. A patient is considered terminally ill if such patient has a medical prognosis that his or her life expectancy is one year or less if the illness runs its normal course. § 400.601(10), Fla. Stat. (2010).

10. Admission to a hospice program shall be made upon a diagnosis and

prognosis of terminal illness by a physician licensed pursuant to chapter 458 or chapter 459, Florida Statutes. § 400.6095(2), Fla. Stat. (2010).

11. Every Florida hospice is required by law to employ a medical director licensed pursuant to chapter 458 or chapter 459, who shall have the responsibility for directing the medical care and treatment of hospice patients. § 400.6105(1), Fla. Stat. (2010).

12. Each hospice must provide a continuum of hospice services which afford the patient and the family of the patient a range of service delivery which can be tailored to specific needs and preferences of the patient and family at any point in time throughout the length of care of the terminally ill patient. § 400.609, Fla. Stat. (2010). Each hospice must provide certain statutorily mandated core services, as well as provide physician services directly or through contract. § 400.609(1)(a), Fla. Stat. (2010). In addition to the designated hospice medical director noted above, a hospice may appoint additional hospice physicians who shall perform all duties prescribed by law. All appointed hospice physicians are subject to the same licensing qualifications as the hospice medical director. Fla. Admin. Code R. 58A-2.014(4).

#### **The Controlled Substance Prescribing Law**

13. The 2011 Florida Legislature enacted CS/CS/HB 7095, requiring, among other things, *certain* physicians to designate themselves as controlled substance prescribing practitioners on their practitioner profiles; requiring such registered physicians to meet certain standards of practice, including requiring all patients undergo a physical examination and enter into a written controlled substance agreement, a written protocol, an assessment of risk for aberrant behavior, a treatment plan, specified informed consent, consultation and referral in certain circumstances, and medical records meeting certain

criteria.

14. CS/CS/HB 7095 has since been signed into law by Governor Scott and is now referenced as Ch. 2011-141, Laws of Florida.

15. While it is recognized that additional regulatory controls over the prescribing of controlled substances are necessary to address a serious threat to the public health and welfare, in enacting Ch. 2011-141 the Legislature did not intend to regulate all physicians or the prescribing of controlled substances for all patients. In addition to certain express exemptions carved out as to specified categories of board-certified physicians, the controlled substance prescribing legislation was drafted so as not to regulate the treatment of patients with certain diseases, including patients with cancer, rheumatoid arthritis, and diseases involving pain occurring in the usual or normal course of the disease.

16. For reasons set forth herein, FHPC seeks confirmation from the Board of Medicine, on behalf of its members and their physician employees and agents, that acknowledges the provisions of the controlled substance prescribing law do not apply to the prescribing of controlled substances in connection with the provision of palliative care to patients that are served by a hospice or an entity that is controlled by, or is under common control with a hospice.

17. For purposes of this Petition, the relevant provisions of the controlled substance prescribing law are the following:

(a.) Section 456.44(1)(d), (Ch. 2011-141, § 3, Laws of Fla.) defines the term “[c]hronic nonmalignant pain” to mean:

pain unrelated to cancer or rheumatoid arthritis **which persists beyond the usual course of disease** or the injury that is the cause of the pain or more than 90 days after surgery.  
(emphasis supplied.)

(b.) Subsection 456.44(2), (Ch. 2011-141, § 3, Laws of Fla.) provides:

REGISTRATION. - Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

- (a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.
- (b) Comply with the requirements of this section and applicable board rules.

(c.) Subsection 456.44(3), (Ch. 2011-141, § 3, Laws of Fla.), provides for specific Standards of Practice that must be followed by all registrants subject to the provisions of that section.

18. Failure to comply with the requirements of § 456.44 when otherwise subject to the law is grounds for the Board of Medicine to take those disciplinary actions specified in § 456.072(2), Florida Statutes. (See Ch. 2011, § 1, Laws of Fla.)

#### **Application of Facts to Controlled Substance Prescribing Law**

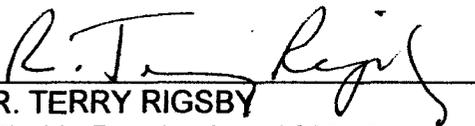
19. The mandates of § 3 of Ch. 2011-141 are only intended to apply to the prescribing of controlled substances for the medical care and treatment of certain categories of pain. The operative term in the new "controlled substance prescribing" law is "chronic nonmalignant pain". Chronic nonmalignant pain is pain unrelated to cancer or rheumatoid arthritis *which persists beyond the usual or normal course of a disease*. When a physician provides palliative care to a patient served by a hospice or an entity controlled by or under common control with a hospice, the patient is by definition experiencing pain that is within the usual and normal course of his or her disease and comorbidities, including any related secondary conditions.

20. Because patients provided palliative care by a hospice, or an entity

controlled by or under common control with a hospice, are not treated for chronic nonmalignant pain, as that term is defined in § 3 of Ch. 2011-141, Laws of Florida, the requirements of § 456.44 (Ch. 2011-141, § 3, Laws of Fla.) are not applicable to the prescribing of controlled substances by duly licensed Florida physicians for such patients.

WHEREFORE, FHPC respectfully requests that the Board of Medicine issue a Declaratory Statement that holds that the provisions of § 456.44 Controlled substance prescribing (Ch. 2011-141, § 3, Laws of Fla.), are not applicable to the prescribing of controlled substances by physicians licensed under chapter 458, Florida Statutes, in connection with the provision of palliative care to patients that are served by a hospice or an entity that is controlled by, or is under common control with a hospice.

Respectfully submitted this 12<sup>th</sup> day of July, 2011.



R. TERRY RIGSBY  
Florida Bar Number: 202045  
Pennington, Moore, Wilkinson,  
Bell & Dunbar, P.A.  
Post Office Box 10095  
215 South Monroe Street, 2<sup>nd</sup> Floor (32301)  
Tallahassee, Florida 32302-2095  
Telephone: 850-222-3533  
Facsimile: 850-222-2126

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Petition for Declaratory Statement has been served by hand delivery on the Department of Health, ATTN.: Joy Tootle, Executive Director, Board of Medicine, 4052 Bald Cypress Way, Tallahassee, Florida 32399, this 12<sup>th</sup> day of July, 2011.

  
R. TERRY RIGSBY