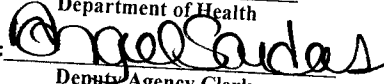


FILED DATE **OCT 20 2014**

Department of Health

By:   
Deputy Agency Clerk

STATE OF FLORIDA  
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY  
STATEMENT OF RICHARD A. DE LA CRUZ, M.D.,  
DIANA C. MACCARIO, M.D., AND J. MICHAEL  
BENFIELD, M.D.

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**FINAL ORDER ON PETITIONS FOR DECLARATORY STATEMENT**

This matter came before the Board of Medicine (hereinafter the "Board") on August 1, 2014, in Orlando, Florida, for consideration of the *Petition for Declaratory Statement re Florida Statute 456.44 and Certain Procedures for Prescribing Controlled Substances* (attached hereto as exhibit A). The Notice of Petition for Declaratory Statement was published on June 19, 2014, in Volume 40, No. 119, in the Florida Administrative Register.

The Petition filed by Richard de la Cruz, M.D., Diana C. Maccario, M.D., and J. Michael Benfield, M.D. (hereinafter the "Petitioners") inquires as to whether the proposed practice model that involves providing care to homebound patients and patients in skilled nursing facilities through the use of Advanced Registered Nurse Practitioners (ARNPs) violates Section 456.44, Florida Statutes.<sup>1</sup>

**FINDINGS OF FACTS**

The facts set forth in the Petition (exhibit A) and attachments are hereby adopted and incorporated herein by reference as the findings of fact by the Board.

**CONCLUSIONS OF LAW**

1. 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.

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<sup>1</sup> Dr. J. Michael Benfield is not currently licensed in Florida but is currently a Florida licensure applicant.

2. 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.

3. For purposes of determining standing in this matter, the Petitioners, allopathic physicians licensed pursuant to Chapter 458, Florida Statutes, are substantially affected persons due to the fact that their failure to comply with Section 456.44, Florida Statutes, may result in disciplinary action by the Board.

4. As set forth in their Petition, the Petitioners intend to provide primary care services to homebound patients and patients in skilled nursing facilities in Florida through the use of ARNPs. The ARNPs will actually see the patients and in some instances the patients will require the prescribing of controlled substances for the treatment of chronic nonmalignant pain. The ARNPs will conduct the face to face encounter with the patient and will do the following:

- Interview the patients in detail and develop the first draft of a complete medical history.
- Conduct a complete physical examination and document the examination in the medical record.
- Document in the medical record the nature and intensity of the pain.
- Document the presence of one or more recognized medical indications for the use of a controlled substance.
- Develop the first draft of a written plan for assessing the patient's risk of aberrant drug-related behavior.
- Develop the first draft of a written individualized treatment plan.
- Discuss the risk and benefits of the use of controlled substances.
- Obtain the patients signature on a written controlled substance agreement

- Seeing any patients for whom controlled substances are prescribed at regular intervals not to exceed 3 months.

The Petitioners, who will not see the patients at all, will prescribe the controlled substances in such instances after reviewing the ARNPs work.

5. Section 456.44, Florida Statutes, sets forth minimal standards of practice that apply to Florida physicians who prescribe controlled substances for the treatment of chronic non-malignant pain. Subsection (3) imposes specific requirements upon physicians who choose to prescribe controlled substances for the treatment of chronic non-malignant pain such as developing a written plan for assessing each patient's risk for aberrant drug-related behavior, developing a written individualized treatment plan for each patient and discussing with the patient the risks and benefits of the use of controlled substances. Throughout subsection (3) the legislature imposed these duties upon the "physician" or the "registrant" which by definition must be a "physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance...." Section 456.44(2), Florida Statutes (2013).

5. In Section 456.44(3)(a), however, where the statute requires a complete medical history and a physical examination prior to beginning any treatment, the legislature provides that "[t]he exact components of the physical examination shall be left to the judgment of the *clinician* who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment." (Emphasis Added)

6. While the Board acknowledges that ARNPs may perform medical acts pursuant to protocols and under the supervision of physicians licensed under chapters 458, 459, and 466, the Board believes that with one exception the duties set forth in Section 456.44 were placed upon the prescribing "physician" exclusively and are non-delegable. The one exception lies in

Section 456.44(3)(a) where the legislature allows the "clinician" to perform the requisite physical examination and determine its necessary components. The term "clinician" appears once in Section 456.44(3) and the terms "physician" or "registrant" are found throughout the rest of the subsection when referencing duties under the statute. This leads the Board to believe that the legislature intended for only physicians to perform the duties set forth in Section 456.44 with the one exception of the performance physical examinations. Otherwise if the legislature had intended to allow physicians to delegate other duties set forth in Section 456.44 it would have used the term "clinician" more often throughout the statute.

8. Based on the foregoing, the Board believes that the Petitioner's proposed practice model is precluded by Section 456.44 because the Petitioners delegate duties set forth in subsection (3) that are non-delegable. Under their plan the Petitioners may never even set eyes upon the patients even though Section 456.44(3)(d) explicitly provides that patients prescribed controlled substance must be seen by the physician at regular intervals. Section 456.44 clearly imposes specific duties upon physicians who prescribe controlled substances to patients with chronic non-malignant pain but the Petitioner's proposed practice model cuts the physician out of the process until the very end and delegates such important duties to nurse practitioners who are precluded by Florida law from prescribing controlled substances. Quite simply, the Petitioner's proposed practice model subverts Florida's regulatory scheme for the prescribing of controlled substances to patients with chronic non-malignant pain.

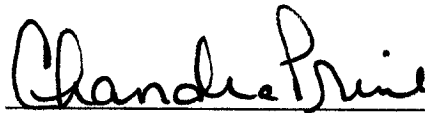
9. The Board's response to this Petition addresses solely the question propounded by the Petitioner and only addresses issues regarding the practice of medicine and not the practice of nursing or any other profession. The Board's conclusion is based solely on the

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 16 day of October, 2014.

**BOARD OF MEDICINE**



Chandra Prine, Acting Executive Director  
For Nabil El Sanadi, 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 by U. S. Mail and email transmission to: Joseph L. Ardery, Esq., Frost Brown Todd, LLC, 400 West Market Street, 32nd Floor, Louisville, Kentucky 40202-3363, [jardery@fbtlaw.com](mailto:jardery@fbtlaw.com); and by email transmission to Edward A. Tellechea, Chief Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050, [ed.tellechea@myfloridalegal.com](mailto:ed.tellechea@myfloridalegal.com); and Jennifer Tschetter, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, [jennifer.tschetter@doh.state.fl.us](mailto:jennifer.tschetter@doh.state.fl.us); on this 20<sup>th</sup> day of October, 2014.



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**Deputy Agency Clerk**

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

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**MEMORANDUM**

**Date:** October 14, 2014

**To:** Lucy C. Gee, M.S., Division Director  
Division of Medical Quality Assurance

**From:** Allison M. Dudley, J.D. Bureau Chief  
Bureau of Health Care Practitioner Regulation

**Subject:** Delegation of Authority

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Effective October 14, 2014, Chandra Prine, Program Operations Administrator will have delegated authority as the Acting Executive Director of the Board of Medicine until further notice.

Richard A. de la Cruz, M.D.  
Florida License Number: ME80275

Diana C. Maccario, M.D.  
Florida License Number: ME103566

J. Michael Benfield, M.D.  
Kentucky License Number: 38836  
President and Chief Executive Officer, MD2U

June 14, 2014

Florida Board of Medicine  
Attn: Ms. Crystal Sandford  
Programs Operations Administrator  
4052 Bald Cypress Way, Bin C-03  
Tallahassee, FL 32399-3253

**Petition for Declaratory Statement re Florida Statute 456.44 and  
Certain Procedures for Prescribing Controlled Substances**

Dear Members of the Board of Medicine:

We hereby request a Declaratory Statement from the Board of Medicine on the interpretation and application of Florida Statute 456.44, enacted in 2011 and amended in 2012. The Statute deals with the prescribing of controlled substances.

**The Petitioners and an Overview of the Issues for the Board's Consideration**

Two of us, Dr. de la Cruz and Dr. Maccario, are Florida licensed physicians whose separate practices are described on the separate signature pages at the end of this Petition. In addition to their regular patient services and other professional activities other work, Dr. de la Cruz and Dr. Maccario both supervise and collaborate with Florida licensed Advanced Registered Nurse Practitioners (Nurse Practitioners) who provide primary care services to homebound and home limited patients in the patients' residences and in skilled nursing facilities (SNFs). Dr. de la Cruz and Dr. Maccario provide these supervisory and collaborative services as independent contractors for MD2U Florida LLC, a company which employs the Florida licensed Nurse Practitioners. Dr. de la Cruz began providing these services in 2012, and Dr. Maccario began providing them in 2013.

Dr. Benfield is a Kentucky licensed physician who lives and works in Louisville, Kentucky. He is currently applying for a Florida license. Dr. Benfield founded MD2U in 2004. MD2U provides primary care services through Nurse Practitioners it employs. Dr. Benfield is MD2U's President and Chief Executive Officer. MD2U operates through several affiliated companies, including MD2U Florida LLC. MD2U's system of operations is described on its website: [www.md2u.com](http://www.md2u.com).

FILED  
DEPARTMENT OF HEALTH  
DEPUTY CLERK  
CLERK ANGEL SANDERS  
DATE JUN 17 2014



As part of their services in Florida for MD2U Florida LLC, Dr. de la Cruz and Dr. Maccario prescribe medications, including Schedule II – V controlled substances.<sup>1</sup>

This Petition describes the actions taken by Dr. de la Cruz and Dr. Maccario and by MD2U's Nurse Practitioners and Certified Pharmacy Technicians in MD2U's Medication Management Department in Louisville, Kentucky, before Dr. de la Cruz and Dr. Maccario prescribe a controlled substance for a Florida patient served by MD2U's Nurse Practitioners.

We seek a Declaratory Statement that Dr. de la Cruz and Dr. Maccario are acting in accordance with Florida Statute 456.44, even though they do not personally visit with the homebound and home limited patients, because they appropriately rely on actions taken by MD2U's Florida Nurse Practitioners, actions taken by MD2U's Certified Pharmacy Technicians in MD2U's Medication Management Department, and safeguards in the MD2U system of operations for some aspects of the fact-gathering, analysis, and documentation that relates to their independent professional decisions whether to prescribe controlled substances in each instance.

We believe that Dr. de la Cruz and Dr. Maccario are acting in accordance with Florida Statute 456.44 and that when Dr. Benfield is issued his Florida license he too will satisfy Florida Statute 456.44 when he engages in the same professional practices.

Copies of MD2U's Narcotic Prescribing Protocol and Florida Statute 456.44 and are attached to this Petition after the signature pages below.

#### **Procedures for Board Consideration of this Petition**

The three of us file this Petition pursuant to Florida Statute 120.565. That statute provides that any substantially affected person may seek a declaratory statement regarding a Florida State Agency's opinion as to the applicability of a statutory provision, or of any rule or order of the Agency, as it applies to the petitioner's particular set of circumstances.

Dr. de la Cruz and Dr. Maccario are "substantially affected persons" because their personal prescribing practices, working in conjunction with the Nurse Practitioners and the Certified Pharmacy Technicians, are the subject of this Petition. Dr. Benfield joins in this Petition to assist in explaining MD2U's system of operations and also as a prospective Florida licensed physician who intends to personally prescribe in Florida in accordance with the facts stated in this Petition after he is licensed in Florida. We request that the Board's Declaratory Statement extend to Dr. Benfield as well as to Dr. de la Cruz and Dr. Maccario.

Florida Statute 120.565 also states that a petition for a declaratory statement "shall state with particularity the petitioner's set of circumstances." Accordingly, we have attempted to set out in

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<sup>1</sup> As we believe the Board is aware, Florida is one of two States that do not allow Nurse Practitioners to prescribe Schedule II - V controlled substances. We believe that all of the other 48 States allow them to write such prescriptions, subject to various State statutes and regulations that vary from State to State.

detail below the relevant facts and circumstances for the Board's consideration and have attached a copy of MD2U's Narcotic Prescribing Protocol.

We have noted that Florida Statute 120.565 also states that:

The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Register. Agency disposition of petitions shall be final agency action.

We understand that the Board will consider this Petition at its meeting to be held on Friday, August 1, 2014, at Renaissance Orlando at SeaWorld, 6677 Sea Harbor Drive, Orlando, Florida 32821. Each of us will be present on August 1 in Orlando to answer questions the Board, its staff, or its advisors may have. We will also work together to answer before the Board's August 1 meeting any questions presented to us by the Board or any of its representatives.

We respectfully submit to the Board that this Petition addresses issues of great importance to a growing number of low and moderate income Florida residents who are elderly or chronically ill, or both, and who are homebound or home limited. This growing segment of Florida's population – and of the nation's population -- is best served by primary care practitioners who visit them where they live. Without primary care in the family residence or the SNF where these types of patients reside, the patients are very likely to overburden ambulance systems, hospital emergency rooms, and other services and facilities that are already struggling and that are best used for things other than the provision of primary care.

Many of these patients need prescriptions for controlled substances. Each of us believes, based on our professional experience, that the system for making decisions whether to prescribe controlled substances described in this Petition, and embodied in MD2U's attached Narcotic Prescribing Protocol, satisfies all applicable ethical, professional, and legal standards, including those set out in Florida Statute 456.44.

We respectfully submit to the Board that the prescribing practices described in this Petition are lawful, appropriate, and . . . in today's world . . . increasingly necessary.

#### **Detailed Statement of Facts and Circumstances**

##### **1. Dr. de la Cruz and Dr. Maccario**

Dr. de la Cruz and Dr. Maccario are both active Florida licensed physicians whose professional work and activities apart from their work with MD2U is described on their separate signature pages at the end of this Petition. They both have DEA numbers and prescribe for in their work apart from MD2U a broad range of medications as needed and appropriate, including Schedule II - V controlled substances. Dr. de la Cruz and Dr. Maccario are both in good standing with this Board. They both are registered as controlled substance prescribers under Florida Statute 456.44, Section 2.

Neither Dr. de la Cruz nor Dr. Maccario operates a pain-management clinic as defined in Florida Statute 458.3265. More specifically, neither of them advertises in any medium for any type of pain-management services, and there has never been a month in which either of them has prescribed for a majority of their regular office patients for the treatment of chronic nonmalignant pain opioids or the other controlled substances listed in Florida Statute 458.3265.

2. **Dr. Benfield, MD2U, the Nurse Practitioners, and the Special Population They Serve**

Dr. Benfield is board certified in family medicine and pediatric medicine. As noted above, he founded MD2U in 2004 in Louisville, Kentucky.

MD2U employs Nurse Practitioners who provide primary healthcare services to low and moderate income people in their homes and in SNFs. MD2U and its Nurse Practitioners currently provide primary care services in Kentucky, Indiana, Ohio, West Virginia, North Carolina, Louisiana, and Florida.

MD2U uses a team approach, with Nurse Practitioners on the front line dealing directly with the patients, and with physicians in the background providing supervision, collaboration, consultation and, where the particular patient's circumstances warrant and applicable State law requires, prescriptions for controlled substances.

MD2U's patients are all home-bound or home-limited. The majority of them fall into the recognized category of "frail and elderly." Many are chronically ill. MD2U's patients are not high income individuals. MD2U does not operate a concierge medical service. Most of its patients live in low-income urban neighborhoods or in rural or semi-rural areas. They are most efficiently served where they live. The payers for the services of MD2U's Nurse Practitioners in Florida are Medicare, Florida Medicaid, and, in some instances, private insurers, or the patients themselves.

Without home visits and SNF visits by MD2U's Nurse Practitioners, these patients may present inappropriate burdens for ambulance services, hospital emergency rooms, and other services and facilities. Everyone is interested in providing quality primary care at a reasonable cost to the overall health system. The MD2U model of Nurse Practitioner primary care is a compassionate, effective, and appropriate system of primary care.

Physicians play an important role in the MD2U system of operations. MD2U employs some Physicians, but for the most part it contracts them as independent contractors. It identifies and contracts with independent experienced, highly qualified primary care Board certified Physicians and emergency medicine Board certified Physicians who provide supervision and oversight to the Nurse Practitioners and collaborate with them using a team approach. The Physicians work with the Nurse Practitioners in a medically and professionally appropriate manner, for the patients' best interests, and in accordance with applicable Federal and State laws.

MD2U operates in Florida through MD2U Florida LLC, an entity it formed specifically for providing services here. MD2U Florida LLC employs all of the MD2U Nurse Practitioners who provide primary care services to Florida residents. MD2U Florida LLC has contracted with Dr.

de la Cruz and Dr. Maccario. It pays them for the services that they provide to the Nurse Practitioners and to MD2U Florida LLC. Dr. de la Cruz and Dr. Maccario do not bill the patients or the patients' insurance plans.

Neither Dr. Benfield nor any MD2U entity operates or has ever operated a pain-management clinic as defined in Florida Statute 458.3265.

### 3. Physician Prescribing Practices for MD2U Patients

Many, but by no means all, of MD2U's Florida patients suffer from chronic pain. The pain sometimes arises from nonmalignant conditions, but in many instances it is directly related to malignancies.<sup>2</sup> Proper medical treatment for some, but by no means all, of MD2U's Florida patients includes prescribing Schedule II – V controlled substances.

MD2U's Nurse Practitioners prescribe controlled substances in accordance with MD2U's Narcotic Prescribing Protocol in all States in which MD2U now operates, except for Florida. MD2U understands that Florida and Alabama are the only two States in which Nurse Practitioners may not prescribe any controlled substances.<sup>3</sup>

Dr. de la Cruz and Dr. Maccario prescribe controlled substances for MD2U's Florida patients only when all circumstances warrant. They are familiar with, and act in accordance with, MD2U's Narcotic Prescribing Protocol. They rely on MD2U's Nurse Practitioners for taking the actions that require face-to-face encounters with the patients. These actions include, but are not limited to, in the instance of patients complaining of chronic pain:

Interviewing the patient in detail and developing the first draft of a complete medical history.

Conducting a complete physical examination and documenting the examination in the medical record.

Documenting in the medical record the nature and intensity of the pain the patient is experiencing.

Documenting the presence of one or more recognized medical indications for the use of a controlled substance.

Developing the first draft of a written plan for assessing the patient's risk of aberrant drug-related behavior.

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<sup>2</sup> Please note that the standards of practice in Florida Statute 456.44(3) appear to relate to prescribing controlled substances for chronic nonmalignant pain, but not for other types of pain.

<sup>3</sup> Florida Statute 893.04(1) states that a pharmacist may dispense controlled substances on a written or oral prescription of a "practitioner" if various conditions are satisfied. The definition of "practitioner" in Florida Statute 893.02 does not include Nurse Practitioners.

Developing the first draft of a written individualized treatment plan that states objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

Discussing with the patient the risks and benefits of the use of controlled substances.

Obtaining the patient's signature of a written controlled substance agreement outlining the patient's responsibilities.

Seeing any patient for whom controlled substances are prescribed at regular intervals, not to exceed 3 months.

Dr. de la Cruz and Dr. Maccario review carefully the Nurse Practitioner's work in each instance before prescribing any controlled substance. They also rely on analysis performed by MD2U's Medication Management Department. Highly trained individuals in that Department screen all documents prepared by the Nurse Practitioners and return to them documents needing further work. Dr. de la Cruz and Dr. Maccario are always available to the Nurse Practitioners for consultation, and they reach out to the Nurse Practitioners for more information, if needed, as they make their independent professional decisions whether to prescribe controlled substances.

#### Other Factors

Many of the Florida patients served by MD2U's Nurse Practitioners receive no prescriptions for controlled substances at all. The MD2U system is set up to serve home-bound, home limited, and SNF resident patients needing primary care services where they live, whether or not they may require powerful controlled substances.

We also want to note to the Board that none of the three of us, nor any MD2U entity, nor any MD2U Nurse Practitioner ever dispenses any controlled substances directly to any patients. None of them owns any direct or indirect interest in any pharmacy. The patients are always free to choose which pharmacy will provide the controlled substances Dr. de la Cruz and Dr. Maccario prescribe.

Florida Statute 456.44, which we are asking the Board to construe, was enacted in 2011 and amended in 2012. Florida and other states enacted statutes during those years to fight "pill mills." Nothing in anything we do or in MD2U's system of operations presents any "pill mill" risks.

While Florida law does not allow Nurse Practitioners to prescribe controlled substances, it clearly gives them and the physicians with whom they collaborate broad authority to set the terms of their relationship. Florida Statute 458.348 is titled "Formal supervisory relationships, standing orders, and established protocols; notice; standards." Subsection (4) sets out fairly specific rules for the relationship between Physicians and Nurse Practitioner in some instances. For example, it deals with Physicians who supervise Nurse Practitioners "at a medical office other than the physician's primary practice location." But no portion of subsection (4) deals directly with Physicians who supervise Nurse Practitioners who serve patients in the patients'

homes and in SNFs. Moreover, subsection (4)(e) of 458.348 states that subsection 4 does not apply to:

. . . health care services provided in a nursing home licensed under part II of chapter 400, an assisted living facility licensed under part I of chapter 429, a continuing care facility licensed under chapter 651, or a retirement community consisting of independent living units and a licensed nursing home or assisted living facility . . . [or] health care services provided to persons enrolled in a program designed to maintain elderly persons and persons with disabilities in a home or community-based setting . . .

It appears to us that the Florida Legislature has chosen to allow Florida licensed Physicians and Nurse Practitioners a reasonably wide range of discretion in determining the details of their relationship when the Nurse Practitioners are serving patients who are home-bound, home-limited or residing in SNFs.

We have also noted that the Florida Legislature has stated in Florida Statute 464.012(3):

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the [Florida Board of Nursing] upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Monitor and alter drug therapies.

....

It appears to us that the Florida Legislature chose to allow Florida licensed Physicians and Nurse Practitioners a reasonably wide range of discretion in determining the power of Nurse Practitioners to monitor and alter drug therapies in any setting, and not just when the Nurse Practitioners are serving patients who are home-bound, home-limited or residing in SNFs.

The team approach in the MD2U system is consistent Florida Statute 464.012(3)(a). The Florida legislature encourages reasonable team approaches.

#### Specific Requests Regarding Declaratory Statement

We ask the Board to declare that the Physician prescribing activities described in this Petition do not violate Florida Statute 456.44. We know that the Board will decide on the wording of its Declaratory Statement, but we offer the following for the Board's consideration:

The Board declares that the prescribing practices currently used by Dr. Richard A. de la Cruz and Dr. Dianna C. Maccario, M.D. and proposed to be used by Dr. J. Michael Benfield, when and if he becomes licensed in Florida, as described in the three Physicians' Petition for Declaratory Statement dated June 13, 2014, including the MD2U Narcotic Prescribing Protocol to the Petition, do not violate Florida Statute 456.44(3), titled "Standards of practice", solely because of the fact that none of the Physicians has or will have any face to face encounter at any point with the particular patient for whom the Physician writes a prescription for a controlled substance.

We declare that Florida Statute 456.44(3) does not require one or more face to face encounters between the prescribing physician and the individual for whom the physician issues the prescription for the controlled substance as long as all actions described in Florida Statute 456.44(3) involving face to face encounters are performed by a Florida-licensed advanced registered nurse practitioner with whom the physician issuing the prescription has a supervisory relationship and the acts performed by the advanced registered nurse practitioner are within the framework of an established protocol that is filed with the Florida Board of Nursing, as provided in Florida State 464.012(3) or any applicable successor statute.

This Declaratory Statement deals only with the application of Florida Statute 456.44 and not to any other professional or medical standard and only with the facts described in the Petition, including MD2U's Narcotic Prescribing Protocol.

### Alternatives

We believe this Petition has merit, and we hope to receive the positive Declaratory Statement we seek. If the Board declines to issue the Declaratory Statement we seek, there could be disruptions for the Florida patients served by MD2U's Nurse Practitioners. They might lose their access to primary care where they live. These patients are sick and suffering and there could be significant patient hardships.

We respectfully request the Board to consider the alternatives we face if the Board declines to issue the Declaratory Statement we seek.

One alternative that might provide a continuum of patient care would be for MD2U to incur an added expense by working with physicians other than primary care physicians and emergency medicine to obtain the controlled substance prescriptions.

Subsection (3) of 456.44 is titled "Standards of Practice." Its final paragraph includes the following language:

This subsection does not apply to a board-eligible or board-certified anesthesiologist, psychiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the

Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes.

MD2U could enter into arrangements with one or more Florida physicians in one or more of the specified categories. This would drive up costs and cause an increase in prices. We believe that primary care physicians and emergency medicine physicians working with MD2U's well-trained Nurse Practitioners and working within MD2U's carefully designed system for the provision of safe, effective services in the homes and SNFs described in this Petition satisfies the standards of practice set out in 456.44(3). But in order to minimize any disruption in continuity of care to patients, we respectfully request the Board, if it declines to issue the Declaratory Statement we seek, to state in its Declaratory Statement that as long as the prescribing physician falls into any of the categories described in the language quoted above from the final paragraph of 456.44(3) then none of the standards of practice in 456.44(3) would apply.

We hope, of course, that the Board will issue the Declaratory Statement we seek.

Finally, we want to note again in closing that the system of medical services described in this Petition is limited to individuals who fall into the categories outlined above. They have serious medical problems. They are best served in their homes or in the SNFs where they reside. We respectfully submit that the Declaratory Statement we seek is consistent with Florida Statute 456.44 and with sound medical practice, patient safety, protections against prescription drug abuse, and the necessities of Florida's evolving healthcare system.

Thank you for your review of this Petition.

Attachments: Signature pages of the three Physicians

MD2U Narcotic Prescribing Protocol for Florida

Florida Statute 456.44 - Controlled Substance Prescribing

cc: Jessica Schmoll  
MD2U Chief Compliance Officer




**Petition for Declaratory Statement re Florida Statute 456.44 and  
Certain Procedures for Prescribing Controlled Substances**

**Signature page of Richard A. de la Cruz, M.D.**

I have reviewed and approved the foregoing Petition and respectfully request the Florida Board of Medicine to issue the Declaratory Statement described in the Petition.

I am Board certified in Emergency Medicine. My address of record with the Board with respect to my Florida license is my home address, 969 Lake Asbury Drive, Green Cove Springs, Florida, 32043. I perform emergency medicine services at Orange Park Medical Center, 2001 Kingsley Ave, Orange Park Florida, 32073. I am an independent contractor at the ER, contracting through EMCARE. I am credentialed at Memorial Hospital Jacksonville, Julington Creek free standing ED, and Capital Regional Medical Center in Tallahassee, in addition to Orange Park Medical Center, my principal place of service.

Respectfully submitted,



Richard A. de la Cruz, M.D.

Florida License Number: ME80275

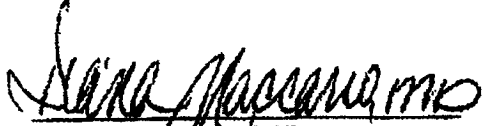
Petition for Declaratory Statement re Florida Statute 456.44 and  
Certain Procedures for Prescribing Controlled Substances

Signature page of Diana C. Maccario, M.D.

I have reviewed and approved the foregoing Petition and respectfully request the Florida Board of Medicine to issue the Declaratory Statement described in the Petition.

I am board certified in Family Medicine. My address of record with the Board with respect to my Florida license is my office address, 9191 RG Skinner Pkwy #603, Jacksonville, FL 32256. I perform office duties full time at First Coast Family Medicine at the above address. I am also credentialed at St. Vincent's Riverside and St. Vincent's Southside for admission purposes.

Respectfully submitted,

 6/13/14  
Diana C. Maccario, M.D.  
Florida License Number: ME103566

**Petition for Declaratory Statement re Florida Statute 456.44 and  
Certain Procedures for Prescribing Controlled Substances**

**Signature Page of J. Michael Benfield, M.D.**

I have reviewed and approved the foregoing Petition and respectfully request the Florida Board of Medicine to issue the Declaratory Statement described in the Petition.

As noted in the Petition, I am a Kentucky licensed physician who lives and works in Louisville, Kentucky. I am currently applying for a Florida license. I founded MD2U in 2004. MD2U provides primary care services through Nurse Practitioners it employs. I am MD2U's President and Chief Executive Officer.

MD2U operates through several affiliated companies, including MD2U Florida LLC. MD2U's system of operations is described on our website: [www.md2u.com](http://www.md2u.com).

Respectfully submitted,



J. Michael Benfield, M.D.

Kentucky License Number: 38836

MD2U, President & CEO

140 Whittington Parkway, Suite 100

Louisville, KY 40222

**MD2U Narcotic Prescribing Protocol**



## Narcotic Prescribing Protocol

Updated 6-13-14

1. The prescribing of narcotics for chronic pain is a challenge under the best of circumstances. This can be due to issues of substance abuse, addiction, legal requirements and other factors, including the historically high percentage of drug abusers intermingled with the chronic pain population. The goal of MD2U is to provide narcotics when deemed appropriate utilizing the guidelines of State Medical and State Nursing Licensure Boards. In order to continue prescribing narcotics to patients, it is necessary to have tight controls and rigid rules established to eliminate those who procure narcotics for illegal purposes or for substance abuse, to protect the privileges of our practice to prescribe, to maintain the health and welfare of the patients, and to obey the laws under which we operate, both federal and state.

Narcotics are but one avenue of pain therapy and **never** represent the sole method of pain control. Narcotics have potential for addiction and substance abuse, can be diverted for sale and/or for improper routes of administration, or shared with others. Narcotics may produce dependence, tolerance, and addiction. Side effects of narcotics include sedation, respiratory depression, swelling in the feet, dental decay acceleration, hives, itching, slurred speech, impaired thinking and function to the point a person may be dangerous when driving or operating machinery when taking narcotics, ICU admission, coma, and death. For these reasons, we reserve the right to change to a non-narcotic therapy at any time it is medically indicated. We also reserve the right to insist on an in or out patient treatment program for narcotic dependence. There is no implied or expressed patient right to narcotic therapy in a physician or nurse practitioner's practice, or in a hospital.

MD2U utilizes a team approach to prescribing narcotics within our practice, according to state and federal rules, regulations, and guidelines as determined by Nursing and Medical Licensing Boards. This is necessary to monitor prescriptive practices appropriately across the practice. The team consists of Nurse Practitioners in the field, the Medication Management Department in the home office, the Supervising, Collaborating or Delegating Physicians, the Compliance Department in the home office and patients who are receiving narcotic prescriptions. All of these individuals are dedicated to providing safe and effective care for a vulnerable homebound or home limited patient population.

## **2. EXPECTATIONS OF THE NURSE PRACTITIONER (NP) IN THE FIELD:**

- a. All Nurse Practitioners are expected to prescribe controlled substances within the framework of their scope of practice, as determined by state and federal guidelines.
- b. There must be a specific, valid medical reason for prescribing a scheduled drug and documentation in the patient medical record should support this. Any conditions, acute or chronic, as well as radiological tests, laboratory tests, physical exams, and consultations with a specialist must be documented prior to initiation and during treatment with a narcotic medication. NPs on the mental health team must document the components of a mental health exam.
- c. Queries should be made to the controlled substance monitoring system applicable to the state in which the NP is practicing, according to state law requirements, prior to initiation of narcotic therapy and as necessary for follow-up (See Appendix for state by state requirements and guidelines).
- d. Before initially prescribing or refilling narcotic prescriptions, the Nurse Practitioner will order a drug screen via urine, blood or saliva as clinically appropriate and review results (with the exception of palliative care patients). If there are circumstances that prevent this from taking place prior to initial prescribing, the NP will document the specific reason and situation in which prescribing was necessary prior to reviewing a drug screen. Examples include acute, one time narcotic uses, fear of withdraw symptoms, inability to obtain records in a timely manner, and clinical judgment based on patient assessment.
- e. The Nurse Practitioner will document a written treatment plan that states the objectives of treatment and any additional diagnostics that may be required. This should include an exit strategy, including potential discontinuation of controlled substances, when appropriate.
- f. Every Nurse Practitioner will discuss the risks and benefits of the use of a controlled substance with the patient, including the risk of tolerance and drug dependence and obtain written consent for the treatment with such medications. Discussion and consent should be obtained by the parent if the patient is a minor, or with the legal guardian or health care surrogate. Consent is addressed in the narcotic agreement used by MD2U.
- g. Ongoing management for chronic pain treated with narcotics should include updating the patient's medical record, modifying the treatment plan as necessary and querying the controlled substance monitoring system applicable to state of practice according to state law requirements. (See Appendix for state by state requirements and guidelines).

- h. Nurse Practitioners will complete the Narcotic Assessment in the patient's medical record on all patients who have controlled substances prescribed to them and will update the Assessment as changes are made in the patient's treatment plan.  
Completion of the Narcotic Assessment includes: Review of the most recent state-specific controlled substances history report, review of pain levels, history of diagnostic tests and other modalities employed in the management of pain, and the ordering of a drug screen at the onset of narcotic or opioid therapy and at least annually thereafter.
- i. All eligible Nurse Practitioners will be required to obtain their own DEA number when they are eligible to do so. This will allow for each Nurse Practitioner to prescribe narcotics for their patients, in accordance with state laws regarding prescriptive authority and the need for physician collaboration or supervision in this matter.
- j. All medications being prescribed, including narcotics, should be included on the medicine list in the patient's chart. Pharmacy information should be updated or changes relayed to the medication management department if they are discussed during a visit.
- k. Some MD2U patients are seeing other physicians for structured pain management programs and treatment. It is the responsibility of the MD2U Nurse Practitioner to record this information in the patient's medical record. There will be no overlapping in the treatment of chronic pain.
- l. When the Nurse Practitioner is the prescriber, they will be required to note on their prescriptions "must last 30 days" to prohibit pharmacies from allowing early refills whenever a month supply of narcotics are being prescribed.

**3. EXPECTATIONS OF THE SUPERVISING/ COLLABORATING PHYSICIAN:**

- a. Supervising/Collaborating Physicians are responsible for providing oversight, when necessary, regarding the prescription of controlled substances. In some states, the Nurse Practitioner may not be able to prescribe narcotics or there may be restrictions regarding this authority. In these instances, the Physician may be responsible for signing prescriptions, according to the regulations of their State Medical Licensing Board, as part of a comprehensive plan of care for the patient. (See Appendix for state by state requirements and guidelines).
- b. Discussion with the Nurse Practitioner about a treatment plan of care regarding narcotic therapy and documentation of such plan of care when warranted.
- c. Physicians will perform all duties required of them in regards to accessing and utilizing prescription monitoring information. This

requirement is determined by individual state statues and guidelines (See Appendix for state requirements and guidelines).

- d. When the Physician is the prescriber, they will be required to note on their prescriptions "must last 30 days" to prohibit pharmacies from allowing early refills whenever a month supply of narcotics is being prescribed.

#### **4. EXPECTATIONS OF THE MEDICATION MANAGEMENT DEPARTMENT:**

- a. The Medication Management Department consists of Certified Pharmacy Technicians. This department will field all refill requests from patients and pharmacies, including those for controlled substances.
- b. When a refill request for a controlled substance comes into the Medication Management Department, the medical record will be reviewed for substantiation. Requests will be forwarded to the appropriate Nurse Practitioner or Physician for review if there are questions regarding the refill request. (See Appendix for state by state requirements and guidelines).
- c. The Medication Management Department will assist the Nurse Practitioners and Physicians in querying prescription monitoring programs as needed and as indicated by state licensing agencies (See Appendix for state by state requirements and guidelines).
- d. The Medication Management Department will document instances in which patients request to change pharmacies and the reason for doing so, as well as update the pharmacy info as needed.

#### **5. EXPECTATIONS OF APPROPRIATE PATIENT BEHAVIOR AND RESPONSIBILITY:**

- a. MD2U will be the only entity prescribing narcotics for chronic pain unless the patient is seeing a pain medication physician and they are taking on this role for the patient. If there is acute pain for a new condition for which the patient seeks care elsewhere, MD2U must be notified. At that time, the MD2U provider may adjust chronic pain medications. If it is discovered patients are receiving narcotics from multiple physicians, MD2U will immediately discontinue medication prescribing and notify pharmacies and other treating physicians of the patient activity.
- b. In certain states, there may be laws prohibiting patients from obtaining narcotics under false pretenses, such as seeing multiple physicians for narcotics without notifying the other physicians. In all states, there are laws which prohibit sharing of prescription narcotics with others, changing or altering a



narcotic prescription in order to obtain early refills or an increased quantity of narcotics, or the selling or trading of narcotics. These events are felonies under federal law and are not protected by the patient-doctor professional relationship. Therefore, any information MD2U receives regarding the commission of a felony will be reported to the police or the U.S. Drug Enforcement Administration.

- c. One pharmacy must be used for scripts. If that pharmacy does not have the prescription, then we expect patients to go to another pharmacy rather than receive a partial refill on the narcotic. We will not write additional scripts to cover the balance of a shortfall from a pharmacy with insufficient supplies. Therefore, in advance, ask the pharmacist not to fill the script with a partial refill if the pharmacy lacks sufficient stocks to carry out the prescription filling. If a second pharmacy must be used to fill a script of narcotics, then our practice must be notified at that time regarding the situation. If MD2U does not have the pharmacy information on file, we will not refill the medication.
- d. Refills of scripts for narcotics are only performed during routine office hours. We will not call in narcotic prescriptions nor write prescriptions after hours.
- e. **There are no early refills for any reason.** The patient is expected to make the prescription quantity last until the next scheduled visit, and at least 30 days if receiving chronic narcotic therapy written at monthly intervals. We do not refill prescriptions that were lost, stolen, spilled, etc. The sole exception to this rule will be if the patient can produce a police report after the medication has been reported stolen. It will then be up the discretion of the prescriber whether or not to refill the medication at that time. The responsibility for safekeeping of these medications lies solely with the patient. Therefore, it is recommended that each patient keep a lock box or other location for safekeeping. MD2U does not routinely prescribe 90 day supplies of narcotic medication.
- f. Upon request of the MD2U Compliance Department or the Nurse Practitioner, a pill count may be necessary and the patient should have their medication available for count at each visit.
- g. There will be no alcohol or illicit drug use while taking narcotic medications. Discovery of such via internal or external sources may result in discontinuation of narcotics immediately.
- h. Patients will be required to submit a mandatory initial drug screening via urine, blood and/or saliva sampling when chronic narcotic therapy is initiated, at least yearly thereafter, and when deemed necessary by prescribing provider.
- i. It is the policy of our practice that driving or operating machinery while taking narcotics may have negative consequences, and if

the patient elects to operate machinery or equipment, they do so at their own risk of injury or death.

- j. Sudden cessation of narcotics can result in injury to the patient, including severe abdominal cramping, severe anxiety, rapid heart rate, elevated blood pressure, nausea, etc. Therefore, it is important that patients take medications as prescribed rather than running out early or violating MD2U policy, which will result in sudden cessation of narcotic prescribing.

#### **6. REASONS NARCOTICS MAY BE IMMEDIATELY DISCONTINUED:**

Reasons for which narcotics will be stopped immediately and without any withdrawal medications include but are not limited to:

- a. Evidence of prescription alteration or fraud.
- b. Solid evidence presented to our practice that the patient has been selling the narcotics, sharing narcotics with others or injecting oral or transdermal narcotics.
- c. Threats of legal action or violence made against any of our staff in order to obtain narcotics.
- d. A positive drug test for illicit drug use or narcotics not prescribed by MD2U, or a negative urine drug screen for narcotics we are prescribing will be met with discontinuation of narcotics.
- e. External source confirmation of "doctor shopping" or obtaining narcotics chronically from multiple physicians or other prescribers simultaneously will require sudden narcotic discontinuation.
- f. Impairment of the patient to such a degree, that in the opinion of our medical practice, the patient poses a risk to themselves or to others may require narcotic discontinuation.

#### **7. REASONS NARCOTIC THERAPY MAY BE MODIFIED OR REDUCED:**

Reasons for which narcotic therapy will be modified or discontinued with the possibility of a drug taper or non-narcotic withdrawal medication administration:

- a. Lost or stolen scripts, overuse of medications, failure of escalating doses of narcotics to provide relief in the absence of any demonstrable worsening findings on clinical examination including X-rays/MRI.
- b. Arrest for driving while impaired or arrest for any alcohol related offence.
- c. Excessively frequent calls to our office regarding chronic pain issues.
- d. Prevarication regarding prior treatment and substance abuse.
- e. Failure to participate in the integrated therapies of our practice.

## 8. CHRONIC PAIN IS JUST THAT.

It is a long standing problem which has been present for months or years. It is important that patients keep a long term perspective on the treatment of this condition. Frequent calls to our office for non-urgent issues, frequent requests of narcotics changes outside appointment times, or histrionic behavior in the absence of new conditions may make patients non-candidates for continued therapy in our practice. However, in the case of potentially life threatening emergencies such as severe respiratory depression and over sedation, our Nurse Practitioners may be contacted 24 hours a day by calling Emergency Line. Calls made for non-emergent issues or issues which should be handled during office hours may jeopardize continued treatment in our practice.

In such cases that it is warranted, the police will be called immediately to report a felony drug diversion or attempted extortion, and the patient will be immediately discharged from our practice. Committing a narcotics related crime is not protected by doctor-patient privilege and will not be tolerated by MD2U

## 9. Narcotic Prescription Guidelines- General

*The following summary comes from the Federation of State Medical Boards regarding Responsible Opioid Prescribing:*

**Evaluation of the Patient**—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

**Treatment Plan**—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the Nurse Practitioner and/or Physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

**Informed Consent and Agreement for Treatment**—The risks and benefits of the use of controlled substances should be discussed and

reviewed with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision making capacity. The patient should receive prescriptions from one prescriber and one pharmacy whenever possible.

***Consent for narcotic treatment by our practice is given on the initial visit as part of the new patient paperwork.***

**Periodic Review**—The Nurse Practitioner and/or Physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.

**Consultation**—The Nurse Practitioner and/or Physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

**Medical Records**—The Nurse Practitioner and/or Physician should keep accurate and complete records to include the medical history and physical examination, diagnostic, therapeutic and laboratory results, evaluations and consultations, treatment objectives, discussion of risks and benefits, informed consent, treatments, medications (including date, type, dosage and quantity prescribed), instructions and agreements and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

## **Appendix A**

### **Florida Specific Requirements and Guidelines**

#### **Prescription Monitoring Guidelines:**

The Florida Prescription Drug Monitoring Program (PDMP) is known as E-FORCSE (Electronic-Florida Online Reporting Controlled Substance Evaluation). It became operational on September 1, 2011.

The information collected in the database is available to registered health care practitioners to help guide their decisions in prescribing and dispensing certain highly-abused prescription drugs.

It may also assist health care practitioners in identifying patients who are "doctor shopping" or trying to obtain multiple prescriptions for the same controlled substance from multiple health care practitioners, which is a felony in the State of Florida.

E-FORCSE is a database that collects and stores schedule II, III, and IV controlled substance dispensing information

Health care practitioners are not required to access the database, as it is currently voluntary. MD2U's Florida Nurse Practitioners and Physicians will collaborate to use the database to provide effective and safe patient care.

The health care practitioner will use the report to supplement their patient evaluation, confirm the patient's prescription history, document compliance with a therapeutic regimen and identify potentially hazardous or fatal interactions. The report may also assist the health care practitioner to determine if a patient is "doctor shopping" or trying to obtain multiple prescriptions for controlled substances from multiple health care practitioners, which is a felony in the State of Florida.

#### **Additional Requirements in the State of Florida:**

A written protocol signed by all parties, representing the mutual agreement of the Physician and the Nurse Practitioner, shall include a Collaborative Practice Agreement. This agreement will provide a description of the duties of the Nurse Practitioner, a description of the duties of the Physician, and the drug therapies that the Nurse Practitioner may prescribe, initiate, monitor, alter, or order.

The Nurse Practitioner will be responsible for obtaining an Informed Consent and Controlled Substance Agreement for every patient taking narcotic medication at the initiation of treatment. This shall include risks and benefits of use of a controlled substance, including risks of abuse and addiction.

The Nurse Practitioner will be responsible for obtaining and documenting in the patient's medical record the following information, as taken from Florida Statute 456.44 regarding controlled substance prescribing:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.
9. Periodic reviews.
10. Results of any drug testing.
11. A photocopy of the patient's government-issued photo identification.
12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
13. The physician's full name presented in a legible manner.

Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

**REGISTRATION.**—Effective January 1, 2012, a Physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must: Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

The Medication Management Department will relay all requests for controlled substance refills to the Physician electronically, along with a copy of the last visit note from the Nurse Practitioner. The Physician and Nurse Practitioner will develop an individualized treatment plan, as necessary for each patient, according to Florida Statute 456.44: The treatment plan shall state objectives that will be used to determine treatment success,

such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the Nurse Practitioner and/or Physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

The Physician will review the last visit note, as well as the medication being requested to refill. They will then approve or deny the request accordingly. Prescription refills or denials will be called to the pharmacy by the Medication Management Department. Prescription requests that require a signature will be mailed to the prescribing Physician, along with an envelope that includes a mailing address of where the prescription needs to be delivered. The Physician will review and sign the prescription accordingly.

**Florida Statute 456.44**  
**Controlled Substance Prescribing**

**(1) Definitions.—**

(a) “Addiction medicine specialist” means a board-certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b) “Adverse incident” means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c) “Board-certified pain management physician” means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) “Board eligible” means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e) “Chronic nonmalignant pain” means pain unrelated to cancer 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.

(f) “Mental health addiction facility” means a facility licensed under chapter 394 or chapter 397.

**(2) Registration.--**Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV 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.

**(3) Standards of practice.--**The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.



(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.
2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.
9. Periodic reviews.
10. Results of any drug testing.
11. A photocopy of the patient's government-issued photo identification.
12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
13. The physician's full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the

consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Added by Laws 2011, c. 2011-141, § 3, eff. July 1, 2011. Amended by Laws 2012, c. 2012-160, § 31, eff. July 1, 2012.

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**Joseph L. Ardery**  
Member  
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jardery@fbtlaw.com

June 14, 2014

Florida Board of Medicine  
Attn: Ms. Crystal Sandford, Programs Operations Administrator  
4052 Bald Cypress Way  
Bin C-03  
Tallahassee, FL 32399-7017

Re: Petition for Declaratory Statement

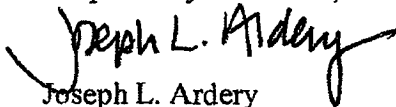
Dear Florida Board of Medicine:

Enclosed herewith is the Petition for Declaratory Statement re Florida Statute 456.44 and Certain Procedures for Prescribing Controlled Substances which we are filing on behalf of the three Physicians who have signed the Petition.

The Physicians understand that the Board will consider this Petition at its meeting to be held on Friday, August 1, 2014, at Renaissance Orlando at SeaWorld, 6677 Sea Harbor Drive, Orlando, Florida 32821. Each of them will be present on August 1 in Orlando to answer questions the Board, its staff, or its advisors may have. They will also work together to answer before the Board's August 1 meeting any questions presented to them by the Board or any of its representatives. I recommend that any such questions be directed to me so that I can coordinate communications.

I will contact Ms. Crystal Sandford during the week beginning Monday, June 16, to follow up on this filing and to answer any questions she may have.

Respectfully submitted,

  
Joseph L. Ardery

Enclosure

cc: Jessica Schmoll  
MD2U Chief Compliance Officer

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14 JUN 16 AM 3:00  
MEDICINE BOARD