Final Order No. DOII-14-0226-DS -MQA FILED DATEFEB 172014 Department of Health By Departy Agency Clerk

STATE OF FLORIDA BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY

STATEMENT OF

JOSE E. GARCIA, M.D.

FINAL ORDER ON PETIITIONS FOR DECLARATORY STATEMENT

This matter came before the Board of Medicine (hereinafter the "Board") on December 6, 2013, in Orlando, Florida, for consideration of two Petitions for Declaratory Statement (attached hereto as exhibits A and B). The Notices of Petition for Declaratory Statements were published on July 9, 2013, in the Vol. 39, No. 132, in the Florida Administrative Register.

The petitioner, Jose E. Garcia, M.D., originally filed two petitions that generally inquire as to whether his proposed telemedicine practice plans comply with Rule 64B8-9.014, Florida Administrative Code. The first petition (hereinafter referred to as Petition A) inquires as to the propriety of his telemedicine practice for after hour care. The second petition (hereinafter referred to as Petition B) addresses the propriety of his telemedicine practice for patients located in rural areas. On August 27, 2013, the Petitioner filed a consolidated Petition for Declaratory Statement (hereinafter referred to as Petition C) that addressed both issues and clarified some of the issues regarding the use of non-physician healthcare practitioners. This final order shall be responsive to Petition C.

FINDINGS OF FACTS

The facts set forth in Petitioner Garcia's Petition C 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.

2. The Petitions filed in this cause is are 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 individual Petitioner, an

allopathic physicians licensed pursuant to Chapter 458, Florida Statutes, is a substantially

affected person due to the fact that his failure to comply with Rule 64B8-9.014, Florida

Administrative Code, may result in disciplinary action by the Board.

4. Rule 64B8-9.014, Florida Administrative Code, reads as follows:

64B8-9.014 Standards for Telemedicine Prescribing Practice.

(1) Prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances, as well as prescribing legend drugs other than in the course of a physician's professional practice.

(2) Physicians and physician assistants shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met:

(a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.

(b) Discussion between the physician or the physician assistant and the patient regarding treatment options and the risks and benefits of treatment.

(c) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B8-9.003, F.A.C.

(3) The provisions of this rule are not applicable in an emergency situation. For purposes of this rule an emergency situation means those situations in which the prescribing physician or physician assistant determines that the immediate administration of the medication is necessary for the proper treatment of the patient, and that it is not reasonably possible for the prescribing physician or physician assistant to comply with the provision of this rule prior to providing such prescription.

(4) The provisions of this rule shall not be construed to prohibit patient care in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including the use of any prescribed medications, nor on-call or cross-coverage situations in which the physician has access to patient records.

(5) For purposes of this rule, the term "telemedicine" shall include, but is not limited to, prescribing legend drugs to patients through the following modes of communication:

(a) Internet;

(b) Telephone; and

(c) Facsimile.

5. The above-referenced rule clarifies that providing treatment recommendations, including the prescribing of legend drugs, based solely on electronic medical questionnaires is not in compliance with the standard of care and precluded by law. Rule 64B8-9.014 does not set forth a blanket prohibition on the use of telemedicine technology to provide medical care to patients.

6. Petitioner's proposed practice plan as set forth in Petition C does not reveal any practices that would violate Rule 64B8-9.014. It is important to note, however, that the standard of care remains the same regardless of whether the physician provides medical services in person or via telemedicine. It is the treating physician's responsibility to assure that the technology employed will provide him or her with sufficient data and information that will enable him or her to provide medical services within the current standard of care.¹

7. The Board's response to this Petition addresses solely the question propounded by the Petitioner and only addresses issues regarding the practice of medicine. 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 14th day of Abruary, 2014.

BOARD OF MEDICINE

Allison M. Dudley, J.D., Executive Director For Nabil El Sanadi, M.D., Ghair

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.

¹ The Board of Medicine believes that prescribing controlled substances via telemedine is precluded by the current standard of care.

CERTIFICATE OF SERVICE

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Deputy Agency Clerk

FILED
DEPARTMENT OF HEALTH DEPUTY CLERK
CLERK: Bridget Coalis
DATE: Aux 27, 2013

STATE OF FLORIDA DEPARTMENT OF HEALTH BOARD OF MEDICINE

IN RE:

Petition of Jose E. Garcia, M.D.

Case No.

PETITION FOR DECLARATORY STATEMENT

Jose E. Garcia, M.D. petitions pursuant to Section 120.565, Florida Statutes, for a Declaratory Statement seeking a determination as to the applicability of Florida Administrative Code Rule 64B8-9.014, implementing section 458.331(1)(q), (t), and (v), Florida Statutes, to a proposed telemedicine program, stating:

1. Petitioner is Jose E. Garcia., M.D., an internal medicine physician licensed in Florida. Dr. Garcia is the President and Chief Executive Officer of American Care, Inc. ("American Care"). American Care offers services to patients through employed physicians, nurse practitioners and other licensed professionals. The majority of American Care's patients are insured by Medicaid.

2. For the purposes of this Petition, Petitioner's address is that of his undersigned counsel.

PETITIONER'S STANDING

3. American care operates clinics in Florida, some of which operate in rural areas. At these locations, a medical care provider is available to see patients in the office one or two days per week. Petitioner is proposing to provide medical care in rural

areas through the telemedicine program outlined in this Petition five days per week during normal business hours and after normal clinic in other locations.

4. Petitioner seeks a declaration that Rule 64B8-9.014, Florida Administrative Code, does not prohibit him from utilizing telemedicine technology to provide medical care to patients in his clinics as set forth in this Petition. Rule 64B8-9.014 regulates the delivery of health care by physicians who utilize telemedicine technology. Accordingly, Petitioner has standing to seek a declaratory statement under Section 120.565, Florida Statutes.

STATEMENT OF FACTS AND LAW

5. Petitioner and American Care employ physicians and nurse practitioners to deliver health care to patients in a clinic setting. All American care providers must meet the credentialing requirements of American Care. Some American Care clinics operate in rural areas in the State of Florida that are not open to the public five days per week. Petitioner desires to implement a telemedicine program that will enable patients in these rural areas to access medical care five days per week, and after hours in other locations.

6. Telemedicine would only be available to existing clinic patients who have been seen personally by a clinic medical provider prior to the telemedicine visit. The telemedicine provider must be a member of the American Care practice or an American Care on-call covering practice physician who is licensed in Florida and resides in Florida. The provider, however, may be at another clinic location other than the telemedicine patient location. The provider will have access to the patient's electronic medical

record. The provider must document the patient encounter in accordance with Section 458.331(1)(m), Florida Statutes.

7. When a patient who meets criteria for a telemedicine visit arrives at the office, the front desk associates will check-in and check-out telemedicine patients. A Florida-licensed practical nurse will take the patient's vital signs, take the patient to the telemedicine exam room, and enter the vital signs information into the patient's electronic medical record.

8. All clinic locations using the telemedicine program will maintain an exam room for the telemedicine program.

9. A practical nurse, licensed in accordance with Chapter 464, Florida Statutes, will assist patients and prepare them to video conference with the telemedicine provider. Practical nurses are permitted by Florida law to administer treatments and medications in nursing homes, hospitals and home health care settings pursuant to lawful orders of a physician or a nurse practitioner even if the physician/nurse practitioner is not physically present at the time the treatment or medication is administered by the nurse. It is the intent to utilize the services of a licensed practical nurse in the same, lawful manner with the telemedicine program proposed in this Petition.

10. The video camera in the exam room will allow the on-call provider to see the patient and the patient will be able to see the provider. During the visit, the licensed practical nurse will be in the exam room at all times and assist when needed (the facilitator.) The licensed practical nurse will be permitted to perform and

administer the following tests and treatments under the direction of the provider (who will be either a Florida-licensed physician or a Florida-licensed Advanced Registered Nurse Practitioner) :

- a. Pulse oxymetry
- b. Spirometry
- c. EKG
- d. Fingerstick blood sugars
- e. Urine dipsticks
- f. Urine HCG
- g. Fingerstick hemoglobin
- h. Albuterol 0.083% nebulized $\times 1$
- i. Ipatropium 0.02% nebulized × 1

The telemedicine provider will review the patient's electronic medical record. The telemedicine provider will obtain a history of the patient's complaints, evaluate the general appearance of the patient, and evaluate the patient's vital signs and any testing done in the office. Based on the patient's medical record and present findings, the telemedicine provider will: 1) refer the patient to the hospital for treatment of an acute illness; 2) order treatment consistent with the current treatment the patient has received within the last year at American Care as documented in the patient's electronic medical record; or 3) schedule a follow-up appointment to see an American Care provider when the provider is physically present at the clinic. The telemedicine provider must document the patient's evaluation in accordance with Section 458.331(1)(m), Florida Statutes.

11. If the telemedicine provider determines that medication should be prescribed, such medications must be called to the pharmacy. Patients may wait until a provider is physically at the clinic location for an in-person evaluation by the provider to

obtain their medications under the dispensing practitioner program. If a patient is in need of medication, the licensed practical nurse may administer one dose of the required medications, under the direction of the telemedicine provider, if the patient has taken the medication before as documented in the patient's medical record. Medications which may be administered to a telemedicine patient are limited to the following:

Acetaminophen 325mg Amlodipine 10mg Amlodipine 2.5mg Amlodipine 5mg Ampicillin 500mg Aspirin 325mg Aspirin 81mg Bactrim DS Benazepril 10mg Benazepril 20mg Cipro 500mg Clonidine 0.1mg Clonidine 0.2mg Diphenhydramine 50 mg Furosemide 20mg Furosemide 40mg Hydrochlorothiazide 12.5mg Hydrochlorothiazide 25mg Lisinopril 10mg Lisinopril 20mg Lisinopril 40mg Lisinopril 5mg Losartan 50mg Metoprolol 25mg Metoprolol 50mg Nifedipine 10mg NTG 0.4mg

This formulary may be modified from time to time by American Care's pharmacy and therapeutic committee to reflect current therapeutic practices. The formulary will not, however, be amended to include controlled substances.

12. Rule 64B8-9.014 provides standards for telemedicine prescribing practices

as follows:

(1) Prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances, as well as prescribing legend drugs other than in the course of a physician's professional practice.

(2) Physicians and physician assistants shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met:

(a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.

(b) Discussion between the physician or the physician assistant and the patient regarding treatment options and the risks and benefits of treatment.

(c) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B8-9.003, F.A.C.

All of the elements of subsection (2) will be met under the telemedicine program

described above. The patient will have been seen in person previously by an American

Care practice physician. An evaluation, history, and physical examination will have

been performed; discussion about treatment options will occur; and contemporaneous

medical records will be maintained.

13. Moreover subsection (4) of Rule 64B8-9.014 provides:

The provisions of this rule shall not be construed to prohibit patient care in consultation with another physician who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications, nor on-call or cross-coverage situations in which the physician has access to patient records.

The telemedicine program set forth above provides the same type of care that is routinely provided on an on-call or cross-coverage basis. The patient must be a patient of a provider at an American Care clinic. The telemedicine provider must be a member of an American Care practice who has agreed to provide coverage to American Care patients. In the proposed telemedicine plan, however, the patient have the additional benefit of direct, and instantaneous, visualization through the videoconference telemedicine technology. Accordingly, subsection (4) of the Rule provides an additional and independent basis for the approval of this proposed telemedicine plan.

WHEREFORE, Petitioner, Jose E. Garcia, M.D., respectfully requests that the Board of Medicine issue a Declaratory Statement holding that the provisions of Chapter 458.331(1), Florida Statutes, as implemented by Rule 64B8-9.014, Florida Administrative Code, do not prohibit the telemedicine program described in this Petition.

RESPECTFULLY SUBMITTED this 27 day of August, 2013.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished, by Hand Delivery, to EDWARD A. TELLECHEA, ESQUIRE, Senior Assistant Attorney General, Chief, Administrative Law Bureau, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; and Crystal A. Sanford, CPM, Program Operations Administrator, Department of Health (DOH) | Division of Medical Quality Assurance (MQA), Board of Medicine, 4052 Bald Cypress Way, # C03, Tallahassee, FL. 32399-3256, this