Final Order No. DOH-08-FILED DATE -Department of Deputy Agency Clerk

STATE OF FLORIDA BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT OF MARK P. TROLICE, M.D.

FINAL ORDER

This matter came before the Board of Medicine (hereinafter the "Board") on February 2, 2008, in Jacksonville, Florida, for consideration of the referenced Petition for Declaratory Statement (attached hereto as exhibit A). The Notice of Petition for Declaratory Statement was published on December 28, 2007, in the Vol. 33, No. 52, in the Florida Administrative Weekly.

The petition filed by MARK P. TROLICE, M.D. (hereinafter the "Petitioner") inquired as to whether the proposed investment arrangement set forth below is precluded by Section 458.053, Florida Statutes (2007), "the Patient Self-Referral Act of 1992." ¹

FINDINGS OF FACTS

1. Petitioner Dr. Mark Trolice ("Petitioner") is a Florida licensed medical doctor (License Number ME78893) who is board certified in obstetrics and gynecology.

2. Petitioner owns and operates his medical practice through A&M Endeavors, LLC, a Delaware limited liability company, Series 1, d/b/a Fertility C.A.R.E (hereinafter "Fertility C.A.R.E") and a fertility lab through A&M Endeavors, LLC, a Delaware limited liability company, Series 2, d/b/a Fertility C.A.R.E. IVF Division (hereinafter "IVF").

¹ Unless indicated otherwise, all statutory references will be to the 2007 version of the Florida Statutes.

Fertility C.A.R.E. and IVF are series within A&M Endeavors, LLC. A&M Endeavors is wholly owned by Petitioner and his wife, as Tenants by the Entireties. Petitioner is the Managing Member of A&M Endeavors, LLC.

3. Petitioner seeks to invest in a new entity, likely a limited liability company ("Pharmacy LLC") to provide pharmaceutical products and related services to patients of Fertility C.A.R.E. and/or IVF. Pharmacy LLC will be owned 49% by Petitioner through a new Florida limited liability company, to be wholly owned by Petitioner and his wife, as Tenants by the Entireties and in which Petitioner will serve as Managing Member and 51% by LBG Holdings, LLC ("LBG Holdings").

4. LBG Holdings is owned by licensed pharmacists Larry B. Howard (License Number PS22661) and Ramena L. Howard (License Number PS32132). Larry Howard is the Managing Member of LBG Holdings. The Howards will be employed by Pharmacy LLC and will be responsible for directly managing and supervising the pharmacy's operations. The Howards are unrelated to Petitioner.

5. Pharmacy LLC will be located in a separate suite within the same building as Fertility C.A.R.E. and IVF. Pharmacy LLC will lease the suite from A&M Endeavors, LLC, a Delaware limited liability company, Series 3 ("A&M Series 3") the record owner of the building. A&M Series 3 is a series within A&M Endeavors, LLC. The lease between A&M Series 3 and Pharmacy LLC will be a written lease for a term at least one year in duration, the rent charged to Pharmacy LLC will not exceed fair market value and will not depend in any way upon the volume or profitability of Pharmacy LLC's

business. The rent further will not be adjusted to reflect any additional value Petitioner or Pharmacy LLC may attribute to the proximity of Pharmacy LLC to Fertility C.A.R.E.

6. Pharmacy LLC will employ the pharmacists and staff necessary to operate the pharmacy. The staff and physicians of Fertility C.A.R.E. or IVF will not be employed by Pharmacy LLC.

7. Petitioner and the other physicians and staff employed by Fertility C.A.R.E or IVF may refer Fertility C.A.R.E. and IVF patients to Pharmacy LLC. The other physicians employed by Fertility C.A.R.E. or IVF currently hold no investment interests in Fertility C.A.R.E., IVF, or A&M Series 3 and will not hold any investment interest in Pharmacy LLC. The compensation of the other physicians and staff employed by Fertility C.A.R.E. or IVF will in no way be dependent upon or influenced by the volume of referrals such physicians or staff may make to Pharmacy LLC.

8. In addition to patients referred by physicians employed by Fertility C.A.R.E. or IVF, Pharmacy LLC may also provide services to patients referred by physicians unrelated to Fertility C.A.R.E. or IVF. Such outside physicians also will not hold any investment interest in Pharmacy LLC.

9. Pharmacy LLC may also possibly fill on-line or internet prescriptions.

10. Prices charged by Pharmacy LLC will be competitive with those prices charged by other retail pharmacies. Pharmacy LLC will also stock and offer certain specialty items that may not be readily available through other retail pharmacies:

Pharmacy LLC will not be accepting payment from Medicare, Medicaid, or any federal, state, or local government health program.

11. Fertility C.A.R.E. and IVF will make all mandatory written disclosures to its patients, as described in Section 456.052, Florida Statutes, prior to making any referrals to Pharmacy LLC.

CONCLUSIONS OF LAW

12. 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.

13. 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.

14. The Board finds that the Petitioner, an allopathic physician licensed pursuant to Chapter 458, Florida Statutes, has demonstrated that he possesses the requisite standing to bring this action.

15. The Board is of the opinion that the proposed practice arrangement as presented by the Petitioner and set forth above complies with all the provisions of Section 458.053, Florida Statutes.

16. This Final Order is issued in response to the question propounded by the Petitioner as set forth in his Petition For Declaratory Statement. The Board's conclusion is based solely on the Board's application of the factual circumstances outlined in the Petition to the pertinent statutory provision set forth above and should not be interpreted as commenting on whether the facts in the petition may or may not

violate any other provision of Chapter 458 or 456, Florida Statutes, or any rules promulgated thereunder.

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

DONE AND ORDERED this _____ day of _____ ____, 2008.

BOARD OF MEDICINE

Larry McPherson, Jr., Executive Director for Robert Cline, 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 to: Gary A. Forster, Esquire, Pohl & Short, P.A., Post Office Box 3208, Winter Park, Florida 32790; and by interoffice mail to Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050; and Josefina Tamayo, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, on this _______ day of _______, 2008.

Ŵ **Deputy Agency Clerk**

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ERIC C. BOLKHMAN ALEX CHEIS COSTOPOULOS ALEXANDER S. DOUGLAS II MATT G. FIRESTONE GARY A. FORSTER MARK A. GRIMES RICHARD A. HEINLE KATHRYN P. JONES DAVID J. KOHS ROBERT S. MACDONALD TERESA N. PHILLIPS FRANK L. POHL JAMES E. SHEPHERD, V HOUSTON E. SHORT JOIN R. SUCESON, JR JAMES C. WASHBURN

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August 27, 2007

PETITION FOR DECLARATORY STATEMENT BEFORE THE STATE OF FLORIDA BOARD OF MEDICINE

<u>Via Certified Mail - Return Receipt Requested</u> State of Florida Board of Medicine Florida Department of Health Agency Clerk's Office 4052 Bald Cypress Way, Bin # A02 Tallahassee, Florida 32399-1703

> Re: Petition for Declaratory Statement/Dr. Mark P. Trolice Our File No.: 6081-24:

Dear Sir or Madam:

Pursuant to Section 120.565, Florida Statutes and Rule 28-105, Florida Administrative Code, Mark P. Trolice, M.D. (the "Petitioner"), of 593.1 Brick Court, Winter Park, Florida 32792 (Tel: 407-672-1378; Fax No.: 407-672-1106) requests a declaratory statement to confirm that the proposed arrangement described in detail below does not constitute a prohibited activity under Section 456.053, Florida Statutes (the "Patient Self-Referral Act of 1992") (enclosed).

Patient Self-Referral Act of 1992.

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Section 456.053(5)(b) generally prohibits a health care provider from referring a patient for the provision of a non-designated health care item or service to an entity in which the health care provider is an investor. However, Sections 456.053(b)(2)-(3) set forth an exception for certain investment interests that meet the following requirements:

(i) No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity;

(ii) The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals:

(iii) The terms under which an investment interest is offered to an investor which is in a position to make referrals to the entity are not related to the previous or expected volume of referrals from that investor to the entity;

(iv) There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining and investor;

(v) The entity does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest; and

(vi) The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market value of any preoperational services rendered, invested in the entity by that investor.

Proposed Arrangement.

Petitioner Dr. Mark Trolice ("Petitioner") is a licensed medical doctor (License Number-ME78893) who is board certified in obstetrics and gynecology. Petitioner owns and operates his medical practice through A&M Endeavors, LLC, a Delaware limited liability company, Series 1, d/b/a Fertility C.A.R.E (hereinafter "Fertility C.A.R.E") and a fertility lab through A&M Endeavors, LLC, a Delaware limited liability company, Series 2, d/b/a Fertility C.A.R.E. [VF Division (hereinafter "IVF"). Fertility C.A.R.E. and IVF are series within A&M Endeavors, LLC. A&M Endeavors is wholly owned by Petitioner and his wife, as Tenants by the Entireties. Petitioner is the Managing Member of A&M Endeavors, LLC.

Petitioner seeks to invest in a new entity, likely a limited liability company ('Pharmacy LLC") to provide pharmaceutical products and related services to patients of Fertility C.A.R.E. and/or IVF. Pharmacy LLC will be owned 49% by Petitioner (through a new Florida limited liability company, to be wholly owned by Petitioner and his wife, as Tenants by the Entireties and in which Petitioner will serve as Managing Member) and 51% by LBG Holdings, LLC ("LBG Holdings"). LBG Holdings, in turn, is owned by licensed pharmacists Larry B. Howard (License Number PS22661) and Ramena L. Howard (License Number PS32132). Larry Howard is the Managing Member of LBG Holdings. The Howards will be employed by Pharmacy LLC and will be responsible for directly managing and supervising the pharmacy's operations. The Howards are unrelated to Petitioner.

Pharmacy LLC will be located in a separate suite within the same building as Fertility C.A.R.E. and IVF. Pharmacy LLC will therefore lease the suite from A&M Endeavors, LLC, a Delaware limited liability company, Series 3 ("A&M Series 3") the record owner of the building.

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A&M Series 3 is a series within A&M Endcavors, LLC. The lease between A&M Series 3 and Pharmacy LLC will be a written lease for a term at least one year in duration and the rent charged to Pharmacy LLC will not exceed fair market value. The rent charged also will not depend in any way upon the volume or profitability of Pharmacy LLC's business. The rent further will not be adjusted to reflect any additional value Petitioner or Pharmacy LLC may attribute to the proximity of Pharmacy LLC to Fertility C.A.R.E.

Pharmacy LLC will employ the pharmacists and staff necessary to operate the pharmacy. The staff and physicians of Fertility C.A.R.E. or IVF will not be employed by Pharmacy LLC.

Petitioner and the other physicians and staff employed by Fertility C.A.R.E or IVF may, at times, refer Fertilitý C.A.R.E. and IVF patients to Pharmacy LLC. The other physicians employed by Fertility C.A.R.E. or IVF currently hold no investment interests in Fertility C.A.R.E., IVF, or A&M Series 3 and will not hold any investment interest in Pharmacy LLC. The compensation of the other physicians and staff employed by Fertility C.A.R.E. or IVF will in no way be dependent upon or influenced by the volume of referrals, if any, such physicians or staff may make to Pharmacy LLC. In addition to patients referred by physicians employed by Fertility C.A.R.E. or IVF, Pharmacy LLC may also provide services to patients referred by physicians unrelated to Fertility C.A.R.E. or IVF. Such outside physicians also will not hold any investment interest in Pharmacy LLC. Pharmacy LLC may also possibly fill on-line or internet: prescriptions.

Prices charged by Pharmacy LLC will be competitive with those prices charged by other retail pharmacies. Pharmacy LLC will also stock and offer certain specialty items that may not be readily available through other retail pharmacies. Pharmacy LLC will not be accepting payment from Medicare, Medicaid, or any federal, state, or local government health program.

Fertility C.A.R.E. and IVF will make all mandatory written disclosures to its patients, as described in Florida Statutes Section 456.052 prior to making any referrals to Pharmacy LLC.

Analysis.

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The Patient Self-Referral Act of 1992 substantially affects the Petitioner because Petitioner would not be permitted to lawfully refer any patients of Fertility C.A.R.E. or IVF to Pharmacy LLC, if the proposed arrangement were not in compliance with the Act. Pharmacy LLC further would not be permitted to lawfully bill for or collect payment for the products and services it provides and Petitioner would not be permitted to lawfully accept any financial return associated with Petitioner's intended investment in Pharmacy LLC. A declaratory statement confirming that the proposed arrangement is in compliance with the Patient Self-Referral Act of 1992 would eliminate regulatory instability and permit Petitioner to efficiently organize the formation of and investment in Pharmacy LLC.

Prior to making any investment in Pharmacy LLC, Petitioner therefore seeks the Board's determination that the following are permissible under the Act: (1) Petitioner's investment in and ownership of a 49% ownership interest in Pharmacy LLC, (2) referrals of Fertility C.A.R.E. and/or IVF patients by physicians employed by Fertility C.A.R.E. and IVF to Pharmacy LLC, (3) acceptance of referrals by Pharmacy LLC of patients referred to it by outside physicians and

those physicians employed by Fertility C.A.R.E. or IVF, and (4) billing to and collection of payment from patients so referred for services and products provided by Pharmacy LLC. Petitioner also requests that the declaratory statement confirm that (1) Petitioner's receipt of returns on his investment in Pharmacy LLC are not a "kickback" as defined in Florida Statutes Section 456.054 (enclosed), (2) the proposed leasing arrangement between Pharmacy LLC (as tenant) and A&M Series 3 (as landlord) is excluded from the term "investment interest" pursuant to Section 456.053(3)(k)(2), Florida Statutes and (3) the rent received by A&M Series 3 is not a "kickback" as defined in Florida Statutes Section 456.054.

For the reasons discussed below, the proposed arrangement is not prohibited by the Patient Sclf-Referral Act of 1992 because such arrangement will meet all of the requirements set forth in Sections 456.053(b)(2)-(3), Florida Statutes.

Petitioner will hold 49% ownership interest in Pharmacy LLC. Therefore, no more than 50% of the value of the investment interests in Pharmacy LLC will be held by investors in a position to make referrals to Pharmacy LLC. The terms under which an investment interest is offered to an investor who is in a position to make referrals to Pharmacy LLC will be no different than the terms offered to an investor who is not in a position to make such referrals. Also, the terms under which the investment interests are offered will not in any way be related to or influenced by the previous or expected volume of referrals, if any, made by such investors.

Moreover, there will be no requirement for an investor to make referrals as a condition for becoming or remaining an investor. Pharmacy LLC also will not loan to or guarantee funds for potential investors for the financing of an investor's acquisition of an ownership interest in Pharmacy LLC. The return on investment received by the investors will further be directly proportional to the amounts invested by each investor (including the amount of properational services rendered by the investor) and will in no-way be contingent upon the volume of referrals made by the investor to Pharmacy LLC.

The proposed leasing arrangement also is permissible under the Patient Self-Referral Act of 1992. As discussed above, the Act generally prohibits a physician from referring a patient to an entity for non-designated health care items or services if the referring physician holds an "investment interest" in such entity. Section 456.053(k) defines "investment interest" as an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes or other equity or debt instruments." However, excluded from the definition of "investment interest" is "an investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or exceeds fair market value." Section 456.053(k)(3), Florida Statues. The rent to be charged by A&M Series 3 to Pharmacy LLC will not exceed fair market value and will not be determined in any manner by the business volume or profitability of Pharmacy LLC. Therefore; Petitioner's interest in A&M Series 3 is not an "investment interest" for the purposes of the Patient Self Referral Act of 1992.

The return Petitioner will receive, if any, on his investment in Pharmacy LLC also is not a "kickback." Section 456.054 Florida statues defines a "kickback" as "a remuneration or payment back pursuant to an investment interest, compensation arrangements, or otherwise, by a provider

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of health care services or items, of a portion of the charges for services rendered to a referring health care provider as an incentive or inducement to refer patients for future services or items, when the payment is not tax deductible as an ordinary and necessary expense."

Returns Petitioner will receive, if any, associated with his ownership interest in Pharmacy LLC are not "kickbacks," as they will not be contingent upon or measured by the volume of referrals, if any, Petitioner may make to Pharmacy LLC. Pharmacy LLC's operating agreement will moreover establish that the members will receive distributions only in proportion to their membership interests. Petitioner will therefore receive a proportionate share of Pharmacy LLC's revenues, to the extent such amounts are available after payment of Pharmacy LLC's operating expenses and the establishment of sufficient reserves for capital expenditures and contingent liabilities. The returns that may be paid to Petitioner therefore will not constitute an incentive or inducement to make referrals to Pharmacy LLC.

Similarly, the rent that will be paid by Pharmacy LLC is not a kickback, as the amount of rent charged will bear no relationship to the profitability or volume of Pharmacy LLC's business. The rent will be consistent with fair market value and will not be adjusted to reflect any value Petitioner or Pharmacy LLC may attribute to Pharmacy LLC's proximity to Fertility C.A.R.E. of IVF. The rents that will be paid to A&M Series 3 therefore will not constitute an incentive or inducement to make referrals to Pharmacy LLC.

For the reasons set forth above, the proposed arrangement complies with the Patient Self-Referral Act of 1992. We seek a declaratory statement confirming such position, as is encouraged by Section 455.654(5)(b)(4), Florida Statutes.

Please advise as to any further information that may be needed for the Board to make its determination. We will also be available to attend any hearing as may be required by the Board.

Please do not hesitate to contact us with any questions or comments you may have.

Gary A. Forster

GAF/kj/bls Enclosures cc: Mark P. Trolice, M.D.