

STATE OF FLORIDA
BOARD OF NURSING

IN RE: PETITION FOR DECLARATORY STATEMENT OF
BETTERHUMANS, INC. and JAMES CLEMENT

FINAL ORDER

THIS MATTER came before the Board of Nursing (Board) pursuant to Section 120.565, Florida Statutes, at a duly-noticed public teleconference meeting held on June 3, 2021. Petitioner, Mr. Clement was present with counsel, Geoffrey D. Smith, Attorney at Law. The Board was represented by Deborah Bartholow Loucks, Senior Assistant Attorney General.

The Petition was filed with the Department of Health on April 9, 2021. Petitioner is requesting that the Board issue a Declaratory Statement answering questions related to the proposed employment of an Advanced Practice Registered Nurse (APRN) and the authorized scope of practice, if employment is permitted.

Having considered the Petition and relevant statutes and rules, the Board issues the following:

FINDINGS OF FACT

1. The Petition was duly filed and noticed in the Florida Administrative Register; Volume 47 Number 76 published on April 20, 2021.
2. The Petition is attached hereto and incorporated herein by reference.
3. Petitioner is asking three specific questions concerning the proposed employment of an APRN. The questions are:
 - a. Is it within the general scope of practice for a registered autonomous practice APRN to serve as the clinical supervisor of operations of the proposed clinic in providing primary care services to patients related to their participation in IRB approved clinical trials?

b. Is it within the scope of practice for an APRN not registered as an autonomous APRN to be supervised remotely by a medical board consisting of four physicians, under a supervisory protocol with at least one physician licensed and practicing in another state (e.g., New York)?

c. If the answer to “a” above is in the negative, is it within the general scope of practice for an APRN to be the supervisor of clinic operations if the APRN establishes a supervisory protocol with a Florida physician, who will not be on-site at the clinic location?

4. Petitioner is not licensed as a nurse in the State of Florida.

CONCLUSIONS OF LAW

5. The Board has jurisdiction over this matter pursuant to section 120.565, and Chapter 464, Florida Statutes.

6. After discussion, the Board voted to answer the above-listed questions in the following manner.

a. Yes.

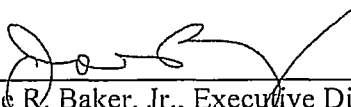
b. Please refer to Section 464.012(3), Florida Statutes.

c. Yes.

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

DONE AND ORDERED this 23rd day of June, 2021.

BOARD OF NURSING



Joe R. Baker, Jr., Executive Director
for Deborah McKeen, CD-LPN, BS, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided to **Betterhumans, Inc.** and **James Clement**, by sending same by electronic mail to their counsel of record, Geoffrey D, Smith, geoff@smithlawtlh.com; **Deborah Loucks**, Senior Assistant Attorney General, Deborah.Loucks@myfloridalegal.com; and **Angela Southwell**, Paralegal Specialist, Office of the Attorney General, angela.southwell@myfloridalegal.com; on June 23, 2021.



Deputy Agency Clerk

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Florida Appellate District where the party resides. The Notice of Appeal must be filed within thirty (30) days of rendition of the order to be reviewed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

IN RE:

Case No.: _____

PETITION FOR DECLARATORY
STATEMENT BEFORE THE BOARD
OF NURSING,

BETTERHUMANS, INC. and
JAMES CLEMENT, Petitioners.

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PETITION FOR DECLARATORY STATEMENT

Petitioners, Betterhumans, Inc. and James Clement, petition pursuant to Section 120.565, Florida Statutes, for a Declaratory Statement seeking a determination as to the interpretation of sections 464.012 and 464.0123 Florida Statutes, stating:

1. Petitioners are Betterhumans, Inc., a Florida non-profit corporation, which is registered as a 501(c)(3) with the Internal Revenue Service and which operates as a biomedical research organization, and James Clement, the president and director of Betterhumans, Inc.

2. The Petitioners are in the process of establishing a planned health care clinic in Florida for the purpose of implementing clinical trials approved by a federal Institutional Review Board ("IRB") at a location in Sumter County, Florida. Petitioners propose to recruit and employ an Advanced Practice Registered Nurse ("APRN") or a registered autonomous APRN to serve as the clinical supervisor of operations and to see and treat patients participating in the clinical trials at the clinic location.

3. The purpose of this Petition is to obtain clarification from the Board of Nursing ("the Board") that the proposed employment of an APRN will be within the authorized scope of practice for such practitioner.

4. The Petitioners' address is 3563 Northeast 77 Avenue Gainesville, FL 32609 and the telephone number is (888) 311-6711. For purposes of this petition, Petitioners' contact information is that of undersigned counsel.

STATEMENT OF HOW PETITIONERS ARE SUBSTANTIALLY AFFECTED

5. Pursuant to section 120.565 Florida Statutes, any substantially affected person may seek a declaratory statement from the board as to the applicability of a statutory provision, or of any rule or order of the board, as it applies to the Petitioner's particular set of circumstances.

6. The Petitioners seek to open a health care clinic in Sumter County, Florida to conduct clinical trials approved by a federal IRB that may include trials on biologics, off-label repurposed prescription drugs, and various over the counter ("OTC") supplements. Additionally, the interventional clinical trials will involve physical and mental exams, numerous blood tests, and DEXA Scan measurements that will be performed before, sometimes during, and after the treatments are concluded. The Petitioners propose to recruit and employ an APRN or a registered autonomous APRN to serve as supervisor of clinical operations and to see, treat, and monitor patients who are participating in clinical trials at the clinic.

7. Petitioners are substantially affected by the scope of practice provisions for APRNs set forth in sections 464.012 and 464.0123 Florida Statutes. These provisions will determine whether or not Petitioners may employ an APRN within the authorized scope of practice to manage the duties of clinical supervisor of operations. Petitioners will spend substantial amounts of money and time procuring a health care clinic location, obtaining numerous licenses, certificates, policies, and registrations that are required to open and operate a health care clinic, and recruitment and employing of the necessary staff to operate the clinic. In the event that the proposed employment of an APRN to serve as clinical supervisor of operations is not authorized by applicable statutes

and rules of the Board, the Petitioners will be required to amend the business model or terminate the proposed clinic project altogether. Since the Petitioners operate as a non-profit corporation, they are limited in operating funds and cannot expend money on a project that is not authorized by statutes and rules.

8. Petitioners seek a declaration pursuant to sections 464.012 and 464.0123, Florida Statutes, to determine if it is within the scope of practice for an APRN, or autonomous APRN to be the clinical supervisor of operations for the proposed clinic.

STATEMENT OF LAWS

9. The Health Care Clinic Act ("the Act"), section 400.9905(4)(e), Florida Statutes provides an exemption from the Act for entities that are exempt from federal taxation under 26 U.S.C. § 501(c)(3). It provides in pertinent part as follows:

(4) "Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. As used in this part, the term does not include and the licensure requirements of this part do not apply to:

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees at least two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

Emphasis added.

10. Betterhumans, Inc. is a 501(c)(3) Florida non-profit corporation that qualifies as exempt under section 400.9905(4)(e), Florida Statutes, and would therefore be exempt from the Act. Thus, the clinic will be operated as an exempt health care clinic engaged in patient care and treatment in the area of primary care for participants in IRB approved clinical trials.

11. The proposed duties and responsibilities of the APRN supervisor of clinical operation are more particularly described herein, but importantly do not include any office surgical procedures, or other procedures beyond the scope of primary care activities for patients electing to participate in the IRB approved clinical trial undertaken at the clinic location.

12. It is not clear from review of the scope of practice provisions of the Nurse Practice Act as to whether an APRN can serve as the supervisor of clinical operations in an exempt health care clinic that is conducting IRB approved clinical trials.

13. Section 464.012, Florida Statutes, delineates the general functions for the APRN and provides as follows:

(3) An advanced practice registered nurse shall perform those functions authorized in this section within the framework of an established protocol that must be maintained on site at the location or locations at which an advanced practice registered nurse practices, unless the advanced practice registered nurse is registered and practicing under s. 464.0123. In the case of multiple supervising physicians in the same group, an advanced practice registered nurse must enter into a supervisory protocol with at least one physician within the physician group practice. 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 practice registered nurse may:

(a) Prescribe, dispense, administer, or order any drug; however, an advanced practice registered nurse may prescribe or dispense a controlled substance as defined in s. 893.03 only if the advanced practice registered nurse has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(e) Order any medication for administration to a patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893.

14. The above allowable general functions require that the APRN practice under a supervisory protocol with a physician currently licensed under chapter 458, chapter 459, or chapter 466.

15. Pursuant to section 464.0123, Florida Statutes, the registered autonomous APRN may provide the above services without physician supervision, in addition to the following provided in pertinent sections:

...
 (3) PRACTICE REQUIREMENTS.—

(a) An advanced practice registered nurse who is registered under this section may:

1. Engage in autonomous practice only in primary care practice, including family medicine, general pediatrics, and general internal medicine, as defined by board rule.

3. Perform the general functions of an advanced practice registered nurse under s. 464.012(3) related to primary care.

5. Provide a signature, certification, stamp, verification, affidavit, or endorsement that is otherwise required by law to be provided by a physician, except an advanced practice registered nurse registered under this section may not issue a physician certification under s. 381.986.

(c) An advanced practice registered nurse engaging in autonomous practice under this section may not perform any surgical procedure other than a subcutaneous procedure.

(d) The board shall adopt rules, in consultation with the council created in subsection (4), establishing standards of practice for an advanced practice registered nurse registered under this section.

16. Pursuant to the above authority, the Board has adopted the Rules set forth at 64B9-4 F.A.C. regarding the autonomous practice of an APRN. Under Rule 64B9-4.001 (12), F.A.C., the Board has defined the term primary care practice as follows:

Primary care practice – includes physical and mental health promotion, assessment, evaluation, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses, inclusive of behavioral and mental health conditions.

STATEMENT OF FACTS APPLICABLE TO DETERMINATION

17. As stated above, the purpose of the proposed clinic is for Betterhumans, Inc. to conduct IRB-approved clinical trials.

18. Betterhumans, Inc. has historically conducted numerous similar types of IRB approved clinical trials. The clinical trials are regulated by the FDA and are therefore monitored by an IRB Committee.

19. Every clinical study is led by a principal investigator. The Betterhumans, Inc. clinical studies' principal investigator is the petitioner, James Clement. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals. Betterhumans, Inc. has a Medical Advisory Board consisting of five medical doctors, four of whom live in the United States and one of whom lives in the United Kingdom.

20. Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to federal agencies such as the National Institutes of Health, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Doctors, other health care providers, and other individuals can also sponsor clinical research.

21. Clinical studies can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators and approved by the IRB committee.

22. Examples of clinical trial interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials may compare a new medical approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other.

23. Specific Betterhumans, Inc. clinical trials have included the following:

- a. NAD+ IV Infusions (these require prescriptions), generally performed by a nurse (pursuant to physician's Rx) or Study Physician;
- b. NAD+ precursors (nicotinamide riboside and nicotinamide mononucleotide OTC supplements), provided for subjects to take home and take orally as instructed;
- c. CD38 inhibitor (Apigenin, an OTC supplement) provided for subjects to take home and take orally as instructed;
- d. Dasatinib (an FDA approved drug) and Quercetin (an OTC supplement), given to the patient in-office by a nurse as directed by Study Physician;
- e. Exosomes (produced by an IRB Committee approved cGMP facility); given by IV infusion or injection, pursuant to Study Physician's instructions; and
- f. Rapamycin/Sildenafil (an FDA approved drug), Rx or shipped to patients to take according to Study Physician's instructions.

24. Betterhumans, Inc. intends to seek IRB Committee approval for additional clinical trials once the COVID-19 pandemic allows in various areas that will include biologicals (cell-based products), off-label repurposed prescription drugs, and various OTC supplements. The interventional clinical trials intended at the clinic will involve physical and (often) mental exams, numerous blood tests, and DEXA Scan measurements, both before, sometimes during, and after the treatments are concluded.

25. The employed APRN would conduct the following activities:

- a. Initial clinical trial participant visit, to include, but will not be limited to, collecting health history information, taking of vital signs, conducting a physical examination, DEXA Scan, blood tests, providing an explanation of the clinical trial and protocols, and if necessary, prescribing dietary supplements, medications, IV therapies, or injections.
- b. Follow up visits, to include, but will not be limited to, taking of vital signs, conducting a physical examination, DEXA Scan, blood tests, participant interview on effect of treatments, and if necessary, prescribing dietary supplements, medications, IV therapies, or injections.
- c. As clinic supervisor, the APRN will be responsible for managing the clinic's daily operations by completing the following duties: recruiting and hiring staff;

managing facilities, solving staff complaints, and establishing clinic specific policies.

26. The APRN will not:
- a. Perform any surgical procedure other than a subcutaneous procedure.
 - b. Aside from overseeing the patient's care related specifically to participation in the clinical trial protocols, will not diagnose participants with a medical condition or sickness.
 - c. Aside from overseeing the patient's care related specifically to participation in the clinical trial protocols, will not medically treat participants for sickness.
 - d. Will not create medical records on participants for any reason other than their participation in the clinical trial.

SPECIFIC REQUESTS FOR DETERMINATION

27. The determinations requested are as follows:
- a. Is it within the general scope of practice for a registered autonomous practice APRN to serve as the clinical supervisor of operations of the proposed clinic in providing primary care services to patients related to their participation in IRB approved clinical trials?
 - b. Is it within the scope of practice for an APRN not registered as an autonomous APRN to be supervised remotely by a medical board consisting of four physicians, under a supervisory protocol with at least one physician licensed and practicing in another state (e.g., New York)?
 - c. If the answer to "a" above is in the negative, is it within the general scope of practice for an APRN to be the supervisor of clinic operations if the APRN establishes a supervisory protocol with a Florida physician, who will not be on-site at the clinic location?

WHEREFORE, Petitioners, Betterhumans, Inc. and James Clement, respectfully request that the Board of Nursing issue a Declaratory Statement under sections 464.012 and 464.0123, Florida Statutes, regarding the above issues.

Respectfully submitted this 9th day of April 2021.

/s/ Geoffrey D. Smith
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 Counsel for Petitioners

CERTIFICATE OF SERVICE

I certify that copies of the foregoing have been filed with the Department of Health's Agency Clerk's Office, 4052 Bald Cypress Way, Bin #A02, Tallahassee, Florida 32399-1703 by facsimile to 850-413-8743, this 9th day of April 2021.

/s/ Geoffrey D. Smith
 GEOFFREY D. SMITH

SMITH & ASSOCIATES
 ATTORNEYS AND COUNSELORS AT LAW

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TO: Agency Clerk
 Department of Health
 (850) 413-8743

FROM: Geoffrey D. Smith
 Sabrina B. Dieguez

DATE: April 9, 2021

PAGES: 10 (including cover sheet)

CASE NAME: In Re: Petition for Declaratory Statement Before the Board
 of Nursing
 Betterhumans, Inc. and James Clement, Petitioners

CLIENT NO.: 948.000

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