Feel Like Oh Yeah, LLC 29 Stevensville Road Underhill, VT 05489

June 16, 2021

Green Mountain Care Board c/o Donna Jerry, Senior Health Policy Analyst 144 State Street Montpelier, VT 05620

Delivered Electronically to: GMCB.CON@vermont.gov

Request for Jurisdictional Determination and Exclusion Under 18 V.S.A. § 9435(a) for Practitioners of the Healing Arts

Dear Green Mountain Care Board,

I am writing to request a Jurisdictional Determination by the Board for the following project described in greater detail below; the purchase and opening of two QC Kinetix franchise outlets to provide non-surgical and non-pharmaceutical pain management services within Vermont

Our first planned QC Kinetix outlet, will be in Chittenden County with the exact location yet to be determined. We will use existing medical office space, with a projected opening date of January 1st, 2022. The project will have a second location in Windsor County expected to open by July 1st, 2022, similarly using an existing medical office space. Each location will be approximately 1800-2000 square feet. The planned service area will be the Burlington DMA (designated market area) of 17 counties including 12 in Vermont, 3 in New York and 2 in New Hampshire.

QC Kinetix outlets are concierge medicine pain clinics, with twenty-two clinics currently operating in six states. QC Kinetix outlets treat patients for damaged joints, muscles, tendons, ligaments, cartilage, and tissue, where that damage is due to arthritis or injury. QC Kinetix has developed a proprietary system using non-surgical injections to restore damaged tissue, decrease pain, and increase quality of life. All procedures are provided on an outpatient basis. The QC Kinetix system begins with a blood draw from the patient, performed by an on-staff phlebotomist, or Certified Medical Assistant. The patient's blood is then processed using the QC Kinetix system and returned to the patient's body by an injection to the region requiring treatment. These treatments can be used locally for musculoskeletal injections, but are not used for systemic diseases or administered intravenously. These services will be provided by an on-staff licensed Nurse Practitioner, (under Rule 8.2 of the Vermont Board of Nursing Administrative Rules, effective January 15, 2015, the Board may license an individual to practice as an APRN in the role of a

Nurse Practitioner). As a franchise of the QC Kinetix brand, we will have committed national leadership providing timely updates regarding FDA regulations and medical techniques.

Each patient receives a plan tailored to their specific needs by our on-staff nurse who will assess the patient's needs, plan a strategy in collaboration with other medical professionals as needed, and implement the patient plan to address the patient's pain. Our on-staff nurse will evaluate the patient's treatment and revise the plan as appropriate, and shall delegate such nursing interventions as are appropriate. In our therapeutic treatments we draw the patient's blood, filter it, concentrate it and inject it into the patient's joints. We also aspirate bone marrow, filter it, concentrate it and then inject it into the patient's joints. We use a non-ablative class IV laser for tissue heating, not destruction or alteration, so the laser we use is not surgical.

These procedures may also rely on the use of plasma, platelet rich plasma, A2M (Alpha 2 Macroglobulin), placental tissue, and bone marrow stem cells, administered through musculoskeletal injections.

We believe the project falls within the exclusion from Certificate of Need jurisdiction under 18 V.S.A. § 9435(a) for offices of practitioners of the healing arts regularly occupied by health care providers in which they perform a range of services "usually performed by such providers on an outpatient basis." Under Vermont law, "registered nursing" means the practice of nursing, which includes in relevant part: assessing the health status of individuals and groups; establishing a nursing diagnosis; establishing goals to meet identified health care needs; planning a strategy of medical or health care; prescribing nursing interventions to implement the strategy of care; implementing the strategy of care; delegating nursing interventions that may be performed by others and that do not conflict with this subchapter; maintaining safe and effective nursing care rendered directly or indirectly; evaluating responses to interventions; managing and supervising the practice of nursing; collaborating with other health professionals in the management of health care; and, addressing patient pain. 26 V.S.A. § 1572 (A) – (J), (K) – (M) (emphasis added).

Additionally, under 26 V.S.A. § 1572(4), "Advanced practice registered nurse" or "APRN" means "a licensed registered nurse authorized to practice in this State who, because of specialized education and experience, is licensed and authorized to perform acts of medical diagnosis and to prescribe medical, therapeutic, or corrective measures under administrative rules adopted by the Board." We plan to hire a Nurse Practitioner, which is an authorized role for an APRN under Rule 8.2 of the Vermont Board of Nursing Administrative Rules (the "Board of Nursing Rules"). Rule 8.5 of the Board of Nursing Rules states that the scope of practice for an APRN includes the scope of a registered nurse (discussed above) and is expanded to include acts of medical diagnoses including ordering and interpreting diagnostic tests and procedures, and prescribing medical, therapeutic, or corrective measures. We intend for the nurse practitioner to serve as our medical director for both locations, though there is a possibility of hiring a licensed physician as medical director depending on the labor market at the time of hiring. As an APRN, our Nurse Practitioner will have the training and Board approvals necessary to develop the treatment plans discussed above and to prescribe the therapeutic measures used in the QC Kinetix system.

Comparing this list of the statutory scope of a registered nurse's and an APRN's typical scope of services shows that the services to be provided by our QC Kinetix franchise are

quintessentially within the statutory framework of services to be provided by a Nurse Practitioner in Vermont, and therefore the exclusion from jurisdiction is appropriate.

There is demand for non-surgical and non-pharmaceutical pain management within Vermont. Vermont is working hard to overcome the opioid abuse problem that has affected the nation, and is making progress in this area; as a non-pharmaceutical pain management option, our treatments will be another tool to assist in this statewide effort. However, at this time, there are a very limited number of regenerative therapy clinics operating within Vermont. Currently, we believe that similar services are only offered by two other companies in Vermont, and with our facility in Windsor, QC Kinetix will be the first regenerative therapy clinic operating outside of the Burlington-Montpelier corridor. The total project start-up costs are estimated to be approximately \$433,000 (not including expected operating costs) and will be financed through a combination of a small business loan by Community Bank NA to Feel Like Oh Yeah, LLC and personal contributions by Tom and Stacy Lee. Equipment purchased will include a Class IV laser, centrifuge, ultrasound, computers and various office equipment. These startup costs demonstrate our commitment to this project, and our personal belief in the demand for these services.

QC Kinetix franchises operate with cash only billing, and do not bill any insurance as our services are not covered by Medicare or any private payor. This is a concierge model that allows the patients to be involved in the non-invasive treatment methods that only elite athletes once had access to. We do not anticipate many referrals from other medical professionals, typically QC Kinetix clients learn about the services provided by QC Kinetix through online, radio, and print advertising. Our advertising may include representations that our procedures can improve patients' quality of life with no surgery or steroids, and that regenerative treatments provide long term results by addressing the root cause of pain. QC Kinetix has been endorsed by pro football hall of famer, Emmett Smith, who has stated, "During my 15 seasons in the NFL and then transitioning to my very active life after football, taking care of my body and joints has always been a primary focus for me ... When I think about the longevity of my joints, it all starts with what I do today. QC Kinetix provides several different therapies that are state-of-the-art, cutting-edge treatments, which complement and promote the body's natural healing process so well. It's always exciting to partner with a company when you've experienced first-hand the quality and effectiveness of their products." More information from QC Kinetix is available at https://qckinetix.com/press/.

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¹ A Google search of the terms "regenerative therapy clinic Vermont" provides a list of two service providers in Vermont for similar treatments, with offices located in Winooski, Stowe, and Colchester. A listing is provided for UVMMC, but this appears to be a blog post on stem cell treatments only and not an indication that said treatment is provided.

The following table details the anticipated medical staffing for our QC Kinetix outlet:

Service provided	Provider	Staffing time	On or Off Site
	qualification	planned	
Blood Draw	Phlebotomist, or	Part Time	All services are
	Certified medical		outpatient care on
	assistant (CMA)		site.
Develop patient plan; process	Nurse Practitioner	Part Time	All services are
blood according to QC Kinetix	(Advance Practice		outpatient care on
system; administer processed	Registered Nurse)		site.
blood to patient according to			
plan.			

We anticipate having two administrative staff as well, for a total of four staff members. Each location will be open one day a week, and we hope to employ the same staff at the two facilities on different days of each week.

We currently anticipate the following operating costs for both locations combined:

	Year 1	Year 2	Year 3
Total Project Costs	\$433,160.00	\$0.00	\$0.00
Operating Costs	\$586,500.00	\$1,108,500.00	\$1,108,500.00

Please note that, due to the structure of the business, a significant portion of these annual operating costs are related to advertising as discussed above.

We thank the Board for your consideration and look forward to providing Vermonters with this service.

Kind Regards,

Tom Lee

Manager

Feel Like Oh Yeah, LLC