

# **VIRGINIA PRACTITIONER SELF REFERRAL ACT ADVISORY OPINION**

## **Re: Application of Telomerix Stem Cell Biobank, L.L.C.**

### **REQUEST**

On August 13, 2019, Telomerix Stem Cell Biobank, L.L.C., a Virginia limited liability corporation (“Telomerix”), and its sole member, Christian Perez, M.D. (“Dr. Perez”), submitted an application for an advisory opinion to the Virginia Board of Health Professions (“the Board”), requesting a determination of whether their proposed business arrangement would violate the Virginia Practitioner Self-Referral Act (“the Act”), found at Va. Code §§ 54.1-2410-54.1-2414. The Act prohibits referrals from a practitioner to another entity with whom the practitioner, or immediate family member, has an investment interest. Va. Code §54.1-2411. Telomerix seeks to determine whether prospective physician-investors who inform patients that Telomerix is an option to provide stem cell related services would be giving a referral under the Act. Further, if the proposed arrangement constitutes a referral, Telomerix requests that the Board make a determination as to whether physician-investors would be sufficiently involved in the ongoing care of the patients to satisfy the “office practice” exception of the Act. The Board has jurisdiction to consider this request under Va. Code § 54.1-2412.

### **FACTS**

Dr. Perez is an obstetrician and gynecologist licensed by the Virginia Board of Medicine who specializes in reproductive endocrinology; he is the sole member of Telomerix, which has been established for the purpose of performing stem cell isolation, processing, cryopreservation, and storage of human stem cells. Telomerix asserts that it will be the first stem cell service provider of its kind in the Commonwealth of Virginia, and seeks to be owned and organized by

physician-investors, including Dr. Perez, who will collect specimens from patients in a safe clinical environment, and then provide them to Telomerix for processing and storage.

If a patient decides to seek stem cell related services, Telomerix proposes that physician-investors will provide the patient with a list of laboratories through which the services can be performed. This list will include laboratories across the country, including Telomerix. Physician-investors will not instruct or affirmatively direct their patients to choose Telomerix over any of the provided options.<sup>1</sup> Once stem cell samples are collected, and if the patient chooses Telomerix as the laboratory, then Telomerix will perform various laboratory and storage functions, including preprocessing to determine a sample's viability, processing good from bad stem cells, and the freezing and storage process.

At the informal conference, Dr. Perez indicated that any new physician-investors would be required to enter into an "operating agreement" that would specify how Telomerix would be offered as an option for processing and storage. The operating agreement would include the Board's advisory opinion as an attachment.

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Under the Act, a health care practitioner is prohibited from referring patients to an entity outside the referring practitioner's office or group practice if the practitioner, or an immediate family member, is an investor in such entity. Va. Code § 54.1-2411(A).

The following pertinent terms are defined at Va. Code §54.1-2410:

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<sup>1</sup> Although beyond the scope of this opinion, Telomerix represents that the investor disclosure required by Va. Code § 54.1-2964 will accompany the list of providers. Whether this notice complies with Va. Code §. 54.1-2964 is outside of the jurisdiction of the Board of Health Professions. This advisory opinion in no way addresses whether Telomerix's proposed disclosure complies with Va. Code § 54.1-2964.

"Investment interest" means the ownership or holding of an equity or debt security, including, but not limited to, shares of stock in a corporation, interests or units of a partnership, bonds, debentures, notes, or other equity or debt instruments, except investment interests in a hospital licensed pursuant to Article 1 (Section 32.1-123 et seq.) of Chapter 5 of Title 32.1.

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership interest, including an investment interest.

"Practitioner" means any individual certified or licensed by any of the health regulatory boards within the Department of Health Professions, except individuals regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Referral" means to send or direct a patient for health services to another health care practitioner or entity outside the referring practitioner's group practice or office practice or to establish a plan of care which requires the provision of any health services outside the referring practitioner's group practice or office practice.

### QUESTION

**Do the proposed actions of physician-investors in Telomerix meet the definition of “referral” under the Virginia Self-Referral Act if they provide patients seeking stem cell related services with a list of laboratories, including Telomerix, through which the services can be performed?**

As owners, physician-investors clearly are investors with an investment interest in Telomerix under Va. Code § 54.1-2410. Consequently, the Act prohibits them from referring their patients to Telomerix. Va. Code § 54.1-2411(A) (“a practitioner shall not refer a patient for health services to an entity outside the practitioner’s office or group practice if the practitioner . . . is an investor in such entity.”). Therefore, the Board must first determine whether Telomerix’s proposed actions constitute a referral under the Act. The definition of “referral” under the Act can be divided into two sections. In order to be a referral, a provider must “send or direct a patient for health services to another health care practitioner or entity.” Va. Code § 54.1-2410. Second, that practitioner, entity, or service must be outside the referring practitioner’s group or office practice. *Id.* Under the facts as laid out in its application and presented at its informal conference, Telomerix’s proposed business arrangement does not include a physician-investor

sending or directing a patient for health services to another health care practitioner or entity, and therefore is not a referral.

First, Merriam-Webster defines “send” as “to cause to go” or “to direct, order, or request to go.” MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/send> (last visited October 29, 2019). Similarly, “direct” is defined as “to cause to turn, move, or point undeviatingly or to follow a straight course” or “to regulate the activities or course of.” MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/direct> (last visited October 29, 2019). As such, the plain meaning of the Act indicates that in order to make a referral, a practitioner must take an affirmative action to persuade or otherwise instruct a patient to choose a specific service provider over another. That is not the case in this application.

The facts of the proposal do not demonstrate an instruction or direction to patients to use a particular stem cell service provider. Rather, the physician-investor will merely inform patients of several potential laboratories, including Telomerix, that offer the desired services. In addition, the business arrangement cannot be said to regulate the activity of patients by instructing them to use a particular stem cell service provider over another provider. Instead, the form that lists the laboratories advises patients of their many options, and it is the patient who chooses the laboratory of his own volition. All of the laboratories will be listed on the disclosure form in the same way, and Telomerix will not be highlighted, emphasized, or made to stand out from the other options. Likewise, Telomerix makes assurances that no physician-investor will affirmatively direct or pressure their patients to choose Telomerix. Therefore, merely including Telomerix on a list with other stem cell related service providers does not meet the definition of a “referral” under the Act.

In summary, Telomerix's proposed business arrangement does not "send" or direct" patients to a particular provider. Therefore, Telomerix's proposed actions do not amount to a referral and do not trigger the first section of the Act. Because there is not a referral in the application, it is not necessary for the Board to determine whether Telomerix is outside of the referring practitioner's group or office practice.

### **CONCLUSION**

For the reasons set forth above, the agency subordinate, pursuant to 18 VAC 75-20-60(E), recommends the following disposition to the Board of Health Professions:

If the physician-investors follow the procedures stated in the application, as well as in this Opinion, they will not make a referral to Telomerix within the meaning of the Act. These procedures are as follows:

1. Physician-investors will not affirmatively act in such a way as to direct or send their patients to use Telomerix's stem cell related services;
2. Physician-investors will provide their patients with a written list of stem cell related service providers, and such list will include Telomerix as one of several options;
3. Any effort by the physician-investors to provide patients with information about Telomerix will not outweigh their efforts to provide information about other stem cell related service providers, as all the options shared with the patients will be included on a single list.