

## **SELF-REFERRAL ACT ADVISORY OPINION**

**RE: Application of Center for Weight Loss Success, P.C.**

### **REQUEST**

On January 27, 2014, Center for Weight Loss Success, P.C. (“CFWLS”), a Virginia professional corporation, submitted an application for an advisory opinion to the Board of Health Professions (“Board”). The purpose of the application is to seek an advisory opinion in order to clarify whether its proposed arrangement with Weight Loss Practice Builder LLC (“WL Practice Builder”) and the referrals of patients from other medical practices to WL Practice Builder invoke the Virginia Practitioner Self-Referral Act (the “Act”) and, if so, whether the proposed arrangement would violate any of the provisions of the Act. As part of the inquiry, CFWLS also seeks an opinion as to whether the services provided to the referred patients by WL Practice Builder are “health services” under the Act. On February 27, 2014, CFWLS provided additional information regarding its arrangement with WL Practice Builder.

### **FACTS**

CFWLS is a professional corporation that is owned entirely by Thomas W. Clark, M.D. (“Dr. Clark”) and is organized to provide professional medical services, including bariatric surgery and other comprehensive weight loss services, to its patients in the Commonwealth of Virginia. These services are provided through Dr. Clark and other qualified health care providers and staff members. CFWLS primarily provides surgical weight loss services with ninety percent (90%) of its patients receiving some type of bariatric surgery. The other ten percent (10%) of CFWLS’s patients receive non-surgical medically-related weight loss services. The surgical patients and the non-surgical patients receive weight loss counseling from

CFWLS's team of professionals, which is comprised of a licensed registered nurse, a licensed weight loss counselor, and unlicensed weight loss coaches and personal trainers. CFWLS's team will provide the patient with a wide array of options to lose weight, including the lowest cost online program, "My Weight Loss Academy" (the "Academy"), which is offered through CFWLS's e-store and also through CFWLS's membership site as described below. The patient has total control over which option he or she chooses after taking into consideration Dr. Clark's and CFWLS's staff's recommendations and the patient's financial capabilities. It is anticipated that many patients will prefer the Academy over more costly in-person services offered by CFWLS given the lower cost and accessibility of the online-based Academy.

WL Practice Builder is a limited liability company that is owned entirely by Karol Clark, who is Dr. Clark's wife ("Ms. Clark"). WL Practice Builder operates out of office space in CFWLS' building that is leased to it by CFWLS. WL Practice Builder provides certain weight loss educational services to clients through its qualified staff members who are employed by CFWLS, but with limited personal involvement of Dr. Clark via interactive webinars and other similar means of communications. Ms. Clark will be the only employee of WL Practice Builder. Specifically, WL Practice Builder enrolls clients in the online-based weight loss education program called My Weight Loss Academy. The Academy is an online-based educational program that was created by Dr. and Ms. Clark. Clients who enroll in the Academy will receive access to fourteen (14) online video sessions that are led by Dr. Clark and accompanying written modules and action guides that were authored by Dr. and Ms. Clark. Through the video sessions and written action guide, Dr. Clark teaches clients about the fundamentals of living a healthy lifestyle. The video sessions include modules on motivation, accountability, a simplified eating plan, vitamins, fitness, carbohydrates, stress management, protein, metabolism, fat, and how to

make healthy habits last a lifetime. Clients enrolled in the Academy will also be able to receive other services from CFWLS, such as weekly habit modification “how to” classes hosted by CFWLS’s qualified weight loss management counselors online. Clients can also choose to enroll in fitness classes through CFWLS and/or receive individualized in-person counseling sessions from CFWLS staff for an additional fee.

WL Practice Builder will be paid a flat fee by the clients under a private-pay arrangement to enroll in the Academy. Any additional services offered by WL Practice Builder to clients enrolled in the Academy will also be paid by the clients under a private-pay arrangement. WL Practice Builder and Dr. Clark will not submit claims to Medicare, Medicaid, or any other government or private third party payor for any of the services provided by WL Practice Builder to the clients.

Ms. Clark oversees and supervises all services provided to the non-medical clients of CFWLS and WL Practice Builder by supervising the non-medical staff employed by CFWLS, while Dr. Clark writes and directs the video sessions, and authors the written materials provided to the clients. When a client’s medical condition dictates the need for the involvement of a physician, Dr. Clark is available for private consultation with clients through CFWLS.

Under the proposed arrangement, some of WL Practice Builder’s clients will be CFWLS patients because they are referred by Dr. Clark to WL Practice Builder for enrollment in the Academy. Clients will also be referred to WL Practice Builder by other physicians and healthcare professionals, as well as by fitness facilities and personal trainers. WL Practice Builder also expects to gain many self-referred clients through its own branding and marketing efforts via the internet and mass advertising. The goal is to have one hundred and twenty (120)

clients enrolled in the Academy at any one time (i.e., twenty (20) new clients per month in a six-month program). It is anticipated that the majority of these clients will be referred by referral sources outside of Dr. Clark's medical practice or will be self-referred.

With respect to the patients referred by physicians other than Dr. Clark, WL Practice Builder plans to pay the referring physician a "lead fee" in the amount of approximately twenty percent (20%) to thirty percent (30%) of the overall fixed fee for the Academy that is charged to a client. WL Practice Builder may also license the Academy program to the referring physicians so that the program is available to the patients of the referring physicians as part of their own group and/or office practice.

### **VIRGINIA PRACTITIONER SELF-REFERRAL ACT**

Under the Act, a health care practitioner is prohibited from referring a patient for health services to an entity outside his or her office or group practice if he or she or any immediate family member is an investor in such an entity, unless the Board of Health Professions grants an exception or unless certain other conditions are met. Pursuant to Section 54.1-2411(A) of the Code, if the entity to which the practitioner makes the referral provides "health services," the Act will apply. The following definitions, found in Section 54.1-2410 of the Code, are pertinent to this discussion:

"Entity" means any person, partnership, firm, corporation, or other business ... that delivers health services.

"Immediate family member" means the individual's spouse, child, child's spouse, stepchild, stepchild's spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling.

"Health services" means any procedures or services related to prevention, diagnosis, treatment, and care rendered by a health care worker, regardless of whether the worker is regulated by the Commonwealth.

“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.

“Office practice” means the facility or facilities at which a practitioner, on an ongoing basis, provides or supervises the provision of health services to consumers.

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

### **QUESTIONS**

- 1. Does the proposed arrangement between CFWLS and WL Practice Builder, a separate legal entity, implicate the Virginia Practitioner Self-Referral Act (the “Act”)?**

Based on the information contained in the application, since WL Practice Builder is a separate legal entity and is owned by Ms. Clark, an immediate family member of Dr. Clark, the owner of CFWLS, the Act will apply if CFWLS is making a referral under the Act. To be considered a referral, the referral must be for health services as defined by the Act. Therefore, whether WL Practice Builder is providing health services to its clients must be determined.

- 2. Does WL Practice Builder provide health services as defined by the Act?**

Health services are defined “as any procedures or services related to prevention, diagnosis, treatment, and care rendered by a health care worker, regardless of whether the worker is regulated by the Commonwealth.” Based on the information contained in the application, WL Practice Builder provides certain weight loss educational services to clients. Specifically, WL Practice Builder enrolls clients in a weight loss education program called My Weight Loss Academy, an online-based educational program created by Dr. and Ms. Clark. Clients who

enroll in the Academy will receive access to fourteen modules of training (written material, videos and PDF action guides) that are available via an online membership site. The video sessions and written action guide teach clients about the fundamentals of living a healthy lifestyle. The video sessions include modules on motivation, accountability, a simplified eating plan, vitamins, fitness, carbohydrates, stress management, protein, metabolism, fat, and how to make healthy habits last a lifetime. Although Dr. Clark presents the video portion of the Academy, there is limited personal involvement with Dr. Clark. Additionally, clients enrolled in the Academy will be able to receive other services from CFWLS, such as weekly habit modification “how to” classes hosted by CFWLS’s weight loss management counselors online. If a client’s medical condition dictates the need for the involvement of a physician, Dr. Clark is available for private consultation with clients through CFWLS.

Based on the description of the services provided by WL Practice Builder through My Weight Loss Academy, it appears that these services are health services as contemplated by the Act. The services related to “living a healthy lifestyle” provided by WL Practice Builder described above, to include materials on motivation, accountability, a simplified eating plan, vitamins, fitness, carbohydrates, stress management, protein, metabolism, fat, and how to make healthy habits last a lifetime relate directly to the prevention, diagnosis, and treatment of many common medical disorders and diseases treated by physicians. It appears that most patients will be directed or referred to WL Practice Builder primarily to address weight management. Patients also may have other medical conditions commonly associated with being overweight such as elevated blood pressure, blood sugar and cholesterol. All of the foregoing may result in medical diagnoses. The health services offered by WL Practice Builder are commonly recommended alternatives to or adjunctive strategies with medication or surgery to address the

treatment and medical management of these diagnoses. Further, the treatment and medical management of these conditions will help prevent or slow the advancement of conditions such as heart, renal and vascular disease. Although the services provided by WL Practice Builder through My Weight Loss Academy are available without physician referral, it appears that many patients will be directed or referred to WL Practice Builder by Dr. Clark or another physician as the result of one of these medical conditions that the physician is presently treating or has treated in the past. Since the information that WL Practice Builder provides to clients through the Academy are commonly recommended in the prevention, diagnosis and treatment of specific medical conditions, these types of services meet the definition of health services under the Act. Therefore, if CFWLS directs or sends patients to WL Practice Builder for these health services, a referral would occur under the Act.

**3. Since the Act is implicated by a referral for health services, does the proposed arrangement between CFWLS and WL Practice Builder meet an applicable exception set forth in the Act?**

Since a referral by CFWLS to WL Practice Builder for health services implicates the Act, the Board must determine whether the described arrangement between CFWLS and WL Practice Builder meets either the office or group practice exception as defined by the Act. Since the proposed arrangement establishes that WL Practice Builder will be a separate legal entity, the group practice exception does not apply.

For the WL Practice Builder services to be considered part of the office practice of CFWLS and meet the office practice exception of the Act, Dr. Clark must, “on an ongoing basis, provide or supervise the provision of” such health services. The Act does not define the terms “supervise” or “on an ongoing basis.” Such terms should be given their usual, commonly

understood meanings, in accordance with the rules of statutory construction. To “supervise” means to watch over a particular activity or task being carried out by other people and ensure that it is carried out correctly (Encarta World English Dictionary). “On an ongoing basis” has been defined as “consistent with the concept of services being available on ‘a continuing, day to day basis,’ ‘an exclusive, permanent and full time’ basis or a ‘regular or regularly’ scheduled basis.” (*Advisory Opinion of the Board of Health Professions in the Matter of InVision Healthcare, Inc.*, quoting *Advisory Opinion of the Board of Health Professions in the Matter of Vistar Eye Center, Inc.*, quoting *Tryc v. Michigan Veterans’ Facility*, 451 Mich. 129, 545 N.W.2d 642 (1996 Mich.)).

It is represented that clients that enroll in WL Practice Builder are provided certain weight loss educational services through qualified staff members who are employed by CFWLS, Dr. Clark’s medical practice. This staff is comprised of a licensed registered nurse, a weight loss counselor, and unlicensed weight loss coaches and personal trainers. Although Ms. Clark oversees the services provided to the non-medical clients of CFWLS and supervises the non-medical staff, Dr. Clark is required to supervise licensed nursing staff providing health services. These weight loss education services will be provided in the office of CFWLS. Additionally, Dr. Clark is available via interactive webinars and other similar means of communications to interact with clients/patients that are enrolled in My Weight Loss Academy. Further, Dr. Clark is available to provide medical treatment when a patient’s medical condition dictates the need for the involvement of a physician.

Based on this arrangement, it appears that Dr. Clark would be involved regularly, whether through his CFWLS staff providing weight loss educational services, his supervision of licensed nursing staff providing health services, his availability to interact with My Weight Loss

Academy clients via interactive webinars and other similar means of communications, and his availability to provide medical treatment when a client's medical condition dictates involvement of a physician.

Although neither the Act nor prior advisory opinions of the Board specifically requires that physicians be physically present in order to provide supervision of health services on an ongoing basis to meet the "office practice" exception, it is a factor that may be considered to establish supervision of care on an ongoing basis. The majority of the health services provided by WL Practice Builder through My Weight Loss Academy will take place at CFWLS, Dr. Clark's practice location. The representations of CFWLS imply that Dr. Clark will be continuously and regularly involved in the delivery of health services to the clients of WL Practice Builder.

Since Dr. Clark will be continuously and regularly involved in the delivery of the health services to the clients of WL Practice Builder, the facts establish that the office practice exception will be satisfied. Accordingly, as long as the arrangement between CFWLS and WL Practice Builder remains consistent with the representations in the application, the arrangement may be considered to meet the definition of "supervise on an ongoing basis," and therefore, this proposed level of involvement by Dr. Clark would meet the requirements of the Act. This interpretation would be consistent with prior Board opinions.

**4. Does the Act prevent a physician that is not an investor or does not have an immediate family member as an investor in WL Practice Builder from referring a patient to WL Practice Builder?**

The answer to a question such as this is dependent upon a fact-specific inquiry for each individual providing a referral, so an answer of general applicability may not be provided. Nonetheless, the Act is clear that it is invoked *only* if the referring physician is an investor or will have an immediate family member as an investor in WL Practice Builder. Further, a physician

or group of physicians purchasing a license to use the materials of WL Practice Builder, as described in the application, does not appear to implicate the Act, since a referral is not being made under those described circumstances.

Finally, CFWLS asks whether the Act prohibits the “lead fee” provided to other referring physicians. Fees for referrals that relate to individual physicians are controlled by the statutes and regulations of the Board of Medicine. Therefore, the Board of Health Professions will not address this question.

### CONCLUSION

For the reasons set forth above, the Board of Health Professions, pursuant to 18 VAC 75-20-60(E) of the Regulations Governing Practitioner Self-Referral, concludes the following:

(1) Since WL Practice Builder is a separate legal entity and is owned by Ms. Clark, an immediate family member of Dr. Clark, the owner of CFWLS, the Act applies if CFWLS makes a referral under the Act. Further, since WL Practice Builder provides health services, the Act applies to CFWLS making referrals of their patients to WL Practice Builder for My Weight Loss Academy services. As a result, referrals by CFWLS to WL Practice Builder are prohibited unless WL Practice Builder is considered part of the CFWLS’s office or group practice;

(2) If Dr. Clark is regularly involved on an ongoing basis in the care provided to his patients at WL Practice Builder consistent with the representations in the application, and, as represented, would be available to the clients of WL Practice Builder for weight loss consultations, and available as medical conditions warranted treatment, the referral of patients to WL Practice Builder for weight loss education services satisfies the “office practice” exception of Section 54.1-2411(A) of the Code; and

(3) The Act is invoked only if the referring physician is an investor or will have an immediate family member as an investor in WL Practice Builder. The purchase of a license to use the materials of WL Practice Builder by a physician or group of physicians as described in the application does not appear to implicate the Act, since a referral is not being made under the described circumstances.