## Disclaimer on use of compounded and off-label medications for weight loss and wellness.

At Optimal Sleep And Weight Loss clinic, the health and safety of our patients are our top priority.

Obesity Medicine as a specialty on its own is a new field in medical practice and a lot of research is being done to find safe and effective anti-obesity medications. Based on data available at the moment, the GLP-1 receptor agonist such as Wegovy and Zepbound have been shown to be very effective and safe and are FDA-approved for weight loss. Pills such as Phentermine/Topiramate (Qysmia), Bupropion/Naltrexone (Contrave) are also FDA-approved for weight loss. Supply shortage and insurance coverage and high out-of-pocket costs have limited access to anti-obesity medications.

Compounded formulations of anti-obesity medications including the GLP-1 receptor agonists have gained popularity in recent years given these shortcomings. It is worth noting that compounded formulations of medications are manufactured by 503 A or 503 B compounding pharmacies which do not necessarily adhere to the same safety standards set by the FDA and their effectiveness may be different from the brand formulation. 503B compounding pharmacies are outsourcing pharmacies registered with the FDA, overseen and inspected by the FDA according to a risk-based schedule. 503A compounding pharmacies are not registered with the FDA. State board of pharmacies have primary responsibility of the day-to-day oversight of state-licensed pharmacies that are not registered with the FDA.

To meet patient-specific needs and unique circumstances, we might use compounded formulations of anti-obesity medications and weight loss supplements from state-licensed compounding pharmacies with our patient's informed consent after discussing treatment options with them.

For more information about compounded medication, visit <u>Compounding and the FDA: Questions and Answers | FDA.</u>