

## **Informed Consent for Medically Management Weight Loss Therapy**

I acknowledge that I am voluntarily entering into a medically managed weight loss program with **ADAPS Healthcare, LLC** (henceforth referred to as "the practice"). I fully realize that entering any program involving weight reduction, which includes moderate calorie restriction, exercise, and medications, involves potential risks and side effects. The risks include, but may not be limited to the following:

1. **Cardiovascular (heart or blood pressure):** These problems may include heart palpitations, irregular beats, or rapid heartbeat. These effects are usually mild but can result in serious problems including heart attack or stroke. Also, these medications may increase blood pressure, which if left untreated can lead to heart attack or stroke. If you discontinue the weight loss medication, the elevated blood pressure usually resolves. For this reason, if you are on blood pressure medications you are required to monitor your blood pressure daily and discontinue medications if blood pressure rises, your heart rate increases, or you feel palpitations. (Please initial) \_\_\_\_\_
2. **Sudden Death:** Patients with morbid obesity, particularly those with hypertension, heart disease, or diabetes, have a statistically higher chance of suffering sudden death when compared to normal weight people without such medical problems. Rare instances of sudden death have occurred while obese patients were undergoing medically supervised weight reduction, though no cause and effect relationship with the diet has been established. The possibility cannot be excluded that some undefined or unknown factor in the treatment program could increase this risk in an already medically vulnerable patient. (Please initial) \_\_\_\_\_
3. **Reduced Potassium Levels:** The calorie level you will be consuming is 800 or more calories per day and it is important that you consume the calories which have been prescribed in your diet to minimize side effects. Failure to consume all of the food and fluids, nutritional supplements or taking a diuretic medication (water pill) may cause low blood potassium levels or deficiencies in other nutrients. Low potassium levels can cause serious heart irregularities. When someone has been on a reduced calorie diet, a rapid increase in calorie intake, especially overeating or binge-eating, can be associated with bloating, fluid retention, disturbances in electrolytes, or gallbladder attacks and abdominal pain. For these reasons, following the diet carefully and following the gradual increase in calories after weight loss is essential. (Please initial) \_\_\_\_\_

4. Gall Bladder Disease: Any program resulting in rapid weight loss may precipitate the formation of gallstones, which could lead to cholecystitis (inflammation of your gallbladder), which is a medical urgency or emergency and could require surgery. This is typically because of the rapid weight loss, not the medications you are taking. Symptoms include right upper abdominal pain, abdominal just below your ribs, nausea, and vomiting. (Please initial) \_\_\_\_\_
5. Pancreatitis: Pancreatitis, or an infection in the bile ducts, may be caused by gallstones or the development of sludge or obstruction in the bile ducts. The symptoms of pancreatitis include pain in the left upper abdominal area, nausea, and fever. Pancreatitis may be precipitated by binge-eating or consuming a large meal after a period of dieting. Also associated with pancreatitis is long-term abuse of alcohol and the use of certain medications and increased age. Pancreatitis may require surgery and may be associated with more serious complications and death. (Please initial) \_\_\_\_\_
6. Psychiatric: There are reported cases of “hysterical or psychotic reactions” associated with the use or discontinuation of some of the drugs utilized for weight-loss purposes. These reactions are extremely rare. (Please initial) \_\_\_\_\_
7. Men over 40 and post-menopausal women in general, and patients with risk factors for cardiovascular disease should have a cardiovascular evaluation before entering an medically managed weight loss program. This may include an ECG, a stress test, or other testing procedures, as per the discretion of a cardiologist. If you are over the age of 40, post-menopausal (female), smoke, have a history of high blood pressure, high cholesterol or you are diabetic, you acknowledge that you have had a cardiac evaluation and that you have been cleared medically prior to starting this weight loss program. (Please initial) \_\_\_\_\_
8. Common, but troublesome side effects may include but not be limited to dry mouth, palpitations, “speedy” feeling, headaches, sleeplessness, rash, fever, nausea, vomiting, allergic reactions, decreased insulin sensitivity, flushing, headache, fatigue, lightheadedness, abdominal cramping, joint pain, fluid retention, and additional side effects not listed that will be discussed during your evaluation with Rosemarie Spada, FNP or covering provider (henceforth referred to as "the practitioner"). These side effects are generally rare, and most patients tolerate treatment without an issue. Please initial) \_\_\_\_\_

9. Drug interactions may occur if other medications are taken. Therefore, I will check with my prescribing medical provider before starting the program if I am taking other medications. (Please initial) \_\_\_\_\_
10. Certain medical conditions may be worsened if on this program, including glaucoma, hypertension, and heart disease. (Please initial) \_\_\_\_\_
11. Pregnancy (Females Only). If you become pregnant, inform your physician immediately. Your diet must be changed promptly to avoid further weight loss because a restricted diet could be damaging for a developing fetus. You must take precautions to avoid becoming pregnant during the course of weight loss. (Please initial) \_\_\_\_\_
12. The use of medications for weight management is indicated for those patients who have a BMI of 30 or higher or a BMI of 27 or higher with other medical conditions such as high blood pressure, diabetes, or high cholesterol. Prescribing medications for patients not fitting these criteria, is considered “off label” and not “FDA approved.” Therefore, the potential risks vs. benefits may be great. For patients not fitting the BMI criteria for use of appetite suppression medication, you are acknowledging that: a. You have put forth a true effort to lose weight through diet and exercise over the past 6 months and have still not achieved your weight-loss goals. b. That your inability to lose weight is causing significant emotional distress. You are choosing to enter this medically managed weight loss program voluntarily and hold harmless the practice and the practitioner for use of such medications. (Please initial) \_\_\_\_\_
13. You acknowledge that alcohol and illicit drug use is prohibited in the program. Drugs like cocaine and amphetamines when used in conjunction with appetite suppressants and other medications prescribed could cause serious injury or death. The use of alcohol will also affect your results. (Please initial) \_\_\_\_\_
14. I understand that the provider and I will determine what my daily caloric intake will be at my initial visit. (Please initial) \_\_\_\_\_
15. I acknowledge that I understand that the amount of weight loss varies from patient to patient, and is, to a large extent, dependent on each patient’s personal motivation and commitment to their diet and exercise plan. No claims as to efficacy or specific amount of weight loss is either expressed or implied. I understand the importance of routinely following up with the practice to monitor my progress during treatment. I understand this is vital to the safety of the treatment program and certify that I will be returning monthly as prescribed. (Please initial) \_\_\_\_\_

16. I hereby authorize the practice, the practitioner and additional staff of the practice to evaluate me for admission into the practice weight management program and treat me accordingly. I consent to obtaining blood work before treatment if deemed necessary. I certify that I am signing this under my free will and am competent to make my own medical decisions. (Please initial) \_\_\_\_\_

17. I have reviewed the mentioned risks and have determined the benefits outweigh the possible risks associated with medically managed weight loss therapy with the practice. I release any claim in court or any type of complaint that could result from treatment with the practice, the practitioner and any other staff associated with the practice and will not hold liable any provider or staff of the practice. (Please initial) \_\_\_\_\_

18. I understand that treatment modalities utilized by the practice might not be supported by scientific/medical literature and could be seen as experimental or based on anecdotal claims. Many medical providers, including endocrinologists, surgeons, family practice doctors, etc., might see these types of treatments as not medically necessary. I also understand that many of the medications being utilized within the practice medically managed weight loss program are considered to be used "off label" and might not be FDA approved for weight loss purposes. (Please initial) \_\_\_\_\_

By signing below, I acknowledge that I have had an opportunity any concerns and the above information with the practice and the practitioner, either in person or by telephone conversation. I consent to the treatment being offered to me by the practice and I am satisfied with the explanation. I acknowledge that I have read or have had read to me the above consent and understand the information presented.

Print: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Risks and Benefits

Acknowledgment I recognize the potential risks of this treatment program, and I also understand the potential benefits of weight loss, which may include:

1. Decreased risk of heart attack.
2. Decreased risk of adult onset diabetes mellitus.
3. Decrease risk to developing arthritis or developing musculoskeletal conditions that are caused by excessive weight.
4. Increased emotional and psychological well-being.
5. Decreased risk of developing certain types of cancer.

I acknowledge that the medically managed weight loss program recommended to me by the practice is just one of multiple strategies to reduce weight. Alternative treatment options include:

1. Diet and exercise alone without medications.
2. The use of other kinds of medications to achieve appetite suppression.
3. Non-medical weight loss programs like Weight Watchers.
4. Bariatric Surgery.

Print: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### My Obligations and Representations

Any questions I have regarding this treatment have been answered to my satisfaction. I understand that I will be responsible for administering the medications prescribed to me if I do not have them administered to me in clinic. I also promise to comply with the dosages and frequency of medications prescribed to me. I certify that I am under the regular care of a primary care provider for any other conditions I might have or am found to have. I will consult with my primary care provider or specialist regarding any other condition I might have. I understand that if I do not have a primary care provider, that I will be encouraged to seek one out. I acknowledge that I am seeking care at the practice for medically managed

weight loss services the practice offers. I acknowledge I am not wanting to establish primary care with the practice, and I am here for specialized care including weight loss therapy, diet counseling, exercising counseling, etc.

Print: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### Regaining Weight Acknowledgement:

There is a Risk of Regaining the Weight you have lost... Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some of it back over time. Factors which favor maintaining weight loss include exercise, adherence to a diet that is low-calorie, nutritious, and full of lean proteins and vegetables, and planning a strategy for coping with weight regain before it occurs. Successful treatment may take months or even years. Utilizing medications to assist you in your weight-loss goals in addition to diet and exercise could result in the weight coming back if you do not maintain eating a healthy diet and exercising. Additionally, if you have had fluctuations in your weight in the past, it may be more difficult to maintain the weight you lose.