

# HMR at Home<sup>®</sup> Phone Program Informed Consent

Name \_\_\_\_\_

Phone \_\_\_\_\_

Address \_\_\_\_\_

This document contains important information about certain health risks associated with losing weight and any restrictions regarding participation in the HMR at Home Program with group phone support (the “Phone Program”). It also contains important information about the use and disclosure of personal information about you as a participant in the Phone Program. Please read this carefully.

The Phone Program is part of a system for weight management created by Health Management Resources<sup>®</sup> Corporation, (“HMR<sup>®</sup>”). The Phone Program at (the “Provider Program”) is offered under license from HMR. The Phone Program is designed to provide you with information on weight loss, physical activity, and healthy lifestyle behaviors. Phone Program staff and materials provide phone-based instruction and coaching that can help you reach a healthier weight and lifestyle. This is not considered a very low-calorie diet. The Phone Program does not provide medical screening, medical monitoring, or ongoing medical care and advice. Although some health coaches may be medical professionals or dietitians, such persons will not be practicing or otherwise functioning in such capacities when acting as a Phone Program health coach.

Medical studies indicate that people who are overweight or obese (with a BMI of 25 or greater) are at increased risk of many health problems and diseases including coronary heart disease and heart attacks, high blood pressure, strokes, increased cholesterol levels, diabetes, gallbladder disease, kidney disease, gout, osteoarthritis, neurological disorders, and certain types of cancer. Although no guarantees are made with regard to the results of the Phone Program, the likelihood that health risks associated with being overweight or obese will be reduced is statistically better with the achievement of an ideal body weight.

It is important to know that certain health risks have been associated with losing weight. Any weight-loss program may be associated with side effects including, but not limited to, the following: dizziness or light headedness, bowel changes, muscle cramps, fatigue, temporary anemia, cold sensation, menstrual irregularities, dry skin, temporary skin rash, and temporary hair loss. The following may also be associated with weight loss: the aggravation of pre-existing gallbladder disease, the development of gallbladder sludge or crystals, the appearance of previously undetected gallstones or the development of gallstones. The development of gallbladder disease could result in the need for surgical removal of the gallbladder. These conditions can also cause inflammation of the pancreas. Pancreatitis can be a serious condition and can become a chronic problem, lasting after any gallbladder disease has been resolved. A small percentage of people may develop symptoms related to gallbladder disease during any weight-reducing diet, including this diet using meal replacement products. A small percentage of people after a considerable weight loss (usually 50 or more pounds) may develop temporary neurological symptoms such as limb weakness or numbness. Avoiding activities that cause compression on nerves, such as prolonged crossing of legs, may prevent this.

## **Weight-Loss Phase (Phase 1):**

### **The Phone Program’s Phase I diet and associated weight loss may result in changes in medical conditions and/or the need to adjust medications.**

**YOU SHOULD CONSULT WITH YOUR PHYSICIAN PRIOR TO STARTING ANY WEIGHT-LOSS PROGRAM.** Your physician may recommend medical monitoring while on the Phase I diet for a number of medical conditions including, but not limited to, diabetes, high blood pressure, cardiac disease, and kidney disease.

I understand that the weight-loss phase of the Phone Program (Phase I) has the following restrictions:

- I cannot participate in the Phone Program if I am pregnant or lactating (nursing a baby) for less than twelve weeks. If I become pregnant or suspect that I am pregnant, I will immediately notify my health coach and understand that I will not be allowed to continue in the Phone Program.
- I cannot participate in the Phone Program if I am anorexic or bulimic.
- I cannot participate in the Phone Program if I am allergic to egg, milk, corn, or soy. (**Note:** Lactose sensitivity or intolerance does not constitute a milk allergy and can be managed by using the HMR 70 Plus lactose-free shakes.)

- I cannot participate in the Phone Program if I am 18 years of age or under, or over 70 years of age and have a history of dizziness, prior TIAs (transient ischemic attacks), or strokes.
- I cannot participate in the Phone Program if I am taking the anti-seizure medication Trileptal® (oxcarbazepine).
- I cannot participate in the Phone Program if I have had bariatric surgery.

**It is important to speak with your doctor about any medical conditions or medications that could be affected by diet or weight loss. In particular, please review the following important information:**

**Important Information for People Who Are Taking Medication to Treat Diabetes**

- If I am taking diabetes medications, I agree to contact my physician prior to the diet to arrange for medical monitoring during the Phone Program diet.
- I understand that if I am compliant with the Phone Program diet and lose weight, I may very likely see a reduction in blood sugar and may require medication adjustment. In addition, I understand that the use of insulin and/or oral agents, in combination with weight loss, can also increase the risk of low blood sugars (hypoglycemia) and may also require my physician to make medication adjustments.
- I agree to carefully monitor my blood sugars and review my self-monitored blood glucose (SMBG) log with my physician before starting the diet and continue to do so during the diet to prevent low blood sugar (hypoglycemia) and poor glycemic control while facilitating weight loss.

**Important Information for People Who Are Taking Diuretics (Water Pills) and Other Drugs for High Blood Pressure**

- If I am taking high blood pressure medications, including diuretics (water pills), I agree to contact my physician prior to beginning the Phone Program to arrange for medical monitoring during the Phone Program diet.
- I understand that being on high blood pressure medication or diuretics, while on a low-salt, weight-reducing diet, such as the Phone Program diet, may cause me to experience dizziness, fatigue, and low blood pressure. Therefore, I understand that my high blood pressure medication may need to be adjusted.

**Important Information for People Who Are Taking the Anticoagulant (Blood Thinner) Coumadin® (warfarin)**

- I understand that the HMR Shakes are fortified with vitamin K. (This information is located on the *Diet Information to Share with Your Primary Care Provider* sheet in your Phone Program materials). If I am taking the blood thinner Coumadin (warfarin) this may result in a need to have this medication adjusted.
- I agree to consult with my physician about the need for monitoring my PT/INR and any necessary medication adjustment.

I understand that the possibility always exists that the combination of any significant disease, such as obesity, with methods employed for its treatment, such as the Phone Program, may lead to previously unobserved or unexpected ill effects. Please consult with your physician if you have any concerns regarding these risks. We have provided a *Diet Information to Share with Your Primary Care Provider* sheet in your Phone Program materials for you to provide to your doctor or primary care provider.

**Maintenance Phase (Phase 2):**

I understand that after weight loss, there is a weight-maintenance phase of the Phone Program (Phase 2). I may decide to enter the maintenance phase of the Phone Program either after first participating in the weight-loss phase of the Phone Program, or after first attending the HMR Program for Weight Management™ in person in a clinic setting. The primary goal of maintenance is to learn how to better manage my weight by:

- a) incorporating higher levels of physical activity (PA) into my daily routine;
- b) reducing overall calorie intake through the use of HMR meal replacements, eating vegetables and fruits, and making healthy food choices.

The weight-maintenance phase of the Phone Program has the same restrictions as the weight-loss phase (Phase 1) and as set forth in that section. Also, as set forth in that section;

- I understand that current medications and medical conditions may be affected as a result of practicing the lifestyle changes promoted in Phase 2 (weight maintenance) of the Phone Program and any additional weight loss I may achieve while in Phase 2. As a result, I may require ongoing adjustments to medications

for, but not limited to:

- a) anti-coagulation therapy (Coumadin)
- b) blood pressure
- c) diabetes management
- I agree to contact my primary care provider for the management of these and any other medications or medical conditions that may be affected by participation in the weight-maintenance phase of the Phone Program.
- I accept the responsibility for consulting with my primary care provider about managing or monitoring any current or new medical conditions that may appear during my participation in the weight-maintenance phase of the Phone Program.

### **For Both Weight-Loss and Maintenance Phases – How Information about You May Be Used in the Phone Program and Outside of the Phone Program**

As a part of joining the Phone Program, you have provided or will provide the Provider Program with certain personal information, including: your name, date of birth, sex, initial weight, height, weight-loss goal, food order preference (lactose-free, vegetarian), credit card information, telephone number, email address, and mailing/billing address). Also as you participate in the Phone Program you will provide additional data including weight change, use of meal replacement products, physical activity levels, intake of fruit and vegetables, and other adherence measures of the diet. How this and other information about your participation in the Phone Program is used in the Provider Program and outside the Provider Program is described below.

#### *How the Provider Program may use your personal information during your participation in the Phone Program*

You will participate in weekly phone classes that will include other participants, and you will be sharing information about your experience in the Provider Program with these other participants (e.g., *some of these other participants may be co-workers, people from your community, etc.*). You will also be sharing this information with the health coach leading the group phone classes.

The Provider Program will use and disclose personal information about you to the extent reasonably necessary as the Provider Program staff determines to allow the Provider Program to effectively help you lose and maintain weight, adopt a healthier lifestyle and diet, obtain the agreed upon payment for Phone Program services and products, and help HMR and the Provider Program to operate and maintain a high quality, weight-management Phone Program. How personal information about you may be used may not be obvious. In addition to the telephone, use and disclosure of personal information about you may be made via mail, fax, email, and/or Internet as may be necessary for the Provider Program to offer you the Phone Program and achieve the objectives described above. Please note that communication with the Provider Program staff will occur via phone conferencing and electronic mail. Please use your best judgment in emailing personal information and note that phone communication is an alternative.

#### *How the Provider Program may share your information with HMR and how that information is used by HMR in training and other aspects of supporting the Phone Program and other HMR Weight-Loss Programs*

In order to ensure the highest quality weight management services, the Provider Program staff receives focused, ongoing training. This training occurs in a variety of ways. For example, training is sometimes done by recording weekly classes and individual phone calls and playing them back for the benefit of staff and their trainers – and this may include telephone calls or classes where some of your personal information is disclosed. This is an invaluable aid in training new staff as well as helping “veteran” staff sharpen their skills. These recordings have also been used at HMR national trainings as an effective educational tool. Sometimes, the Provider Program and/or HMR staff or third parties hired by the Provider Program or HMR will be on the call as part of their training as health coaches or other weight management specialists or in the role of trainers themselves. Sometimes persons outside the Provider Program or HMR doing research in the field of obesity treatment or third parties serving in a consulting capacity to the Provider Program or HMR will be permitted to listen and learn more about how a Phone Program operates. Sometimes a participant’s spouse, other family member, or close friend will also join the phone call to learn more about caring for that participant. Occasionally a person being considered as a new hire may listen to the call to help us and this person better assess whether this person is a good fit at the Provider Program. All of these activities positively impact the quality of the Provider Program and the Phone Program and help support overall operations of the Provider Program and the Phone Program.

*How HMR may use and disclose information as part of its national marketing and research efforts*

HMR may use “de-identified” information about you that is collected or developed from your participation in the Provider Program for promotion of the Phone Program and related weight-loss program marketing efforts. “De-identified” information is information that HMR reasonably believes does not contain any personally identifying information about you. Examples of personal information that HMR would not use in marketing and promoting the Phone Program include your name, address, telephone number, and the like. In most or all cases, de-identified information would also be aggregate information. HMR may also use de-identified information about you to publish or support publications for research and program development purposes. Again, none of the information HMR uses for marketing or research will personally identify you in any way.

The Provider Program will hold your personally identifiable information secure and will not share any personally identifiable information beyond those ways stated above except:

- When required by law (for example, subpoena, court or administrative order)
- For third party service providers and similar vendors performing necessary services who will be required to keep your information confidential. For example, the Provider Program may use data storage, shipping & billing vendors.

**Acknowledgement of the above and Consent to Terms of Participation, Including Use of Information**

I acknowledge responsibility for my own health, including the need to discuss this diet with my physician before beginning the Phone Program. I also confirm that I do not have any of the above conditions that would exclude participation in the Phone Program. I have read and understood the above information and consent to the use and disclosure of all information concerning my participation in the Phone Program as described above. This Informed Consent applies to both the weight-loss phase and the maintenance phase of the Phone Program unless I am participating in only one phase in which case this Informed Consent applies only to such phase. To the fullest extent permitted by law, I hereby assume all risks and hazards associated with, or which may arise from treatment through the Phone Program, hereby releasing the Provider Program and HMR and its affiliates, and all of their respective officers, directors, agents, and employees from any liability from said treatment or participation in the Phone Program, except where injury or damage therefrom is the proximate result of gross negligence on the part of the Provider Program, HMR, or related persons or entities.

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Participant’s Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Participant’s Name