Partnership for Healthy Weight Management

# Voluntary Guidelines for Providers of Weight Loss Products or Services

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# The Partnership for Healthy Weight Management

## The Partnership:

A coalition composed of representatives from science, academia, the health care professions, government, commercial enterprises, and organizations promoting the public interest.

#### Mission:

To promote sound guidance to the general public on strategies for achieving and maintaining a healthy weight.<sup>1</sup>

### Principles:

- G Following sensible and healthy guidelines for eating and physical activity is important for healthy weight management.
- Obesity<sup>2</sup> is a serious, chronic disease that is known to reduce life span, increase disability and lead to many serious illnesses including diabetes, heart disease, and stroke.
- Excess weight is caused by an interaction of genetic (inherited) and environmental (social and cultural) factors, which include metabolic (physical and chemical) and behavioral (psychological and emotional) components. Because of the complexity of weight loss, gain, and maintenance, promises of quick and effortless weight loss are worthless.
- A sedentary lifestyle is a significant barrier to successfully maintaining weight loss and preventing further weight gain.
- Losing weight requires burning more calories than the body takes in, by either reducing caloric intake or increasing caloric expenditure, or preferably, both.
- Achieving and maintaining even a modest amount of weight loss can reduce the severity of illnesses associated with obesity.

- Effective weight management involves behavior modification which is a lifelong commitment and includes at least two components:
  - healthful eating in accordance with the Dietary Guidelines for Americans, emphasizing a reduction in total calories, a lowered fat consumption, and an increase in vegetables, fruits and whole grains, and
  - increased frequent and regular physical activity of at least moderate intensity.
- Medical, pharmacological and surgical interventions may be options for individuals with more serious cases of overweight and obesity. These interventions, used in conjunction with a plan for healthy eating and physical activity, should be utilized in conformance with applicable treatment guidelines.
- The consumer is entitled to accurate, reliable, and non-deceptive information about methods for weight management. The Partnership encourages weight loss providers to adopt the Partnership's Voluntary Disclosure Guidelines for Providers of Weight Loss Products and Programs.
- The Partnership opposes discrimination, including discrimination based upon size or weight.
- The Partnership does not endorse any particular product or program for weight loss or weight management.

<sup>&</sup>lt;sup>1</sup> Healthy weight is defined as a body mass index (BMI) equal to or greater than 19 and less than 25 among all people aged 20 or over. To determine body mass index, divide weight in kilograms (2.2 lbs. = 1 kg) by height in meters squared (39.4 ins. = 1 m). See the table (p.9) for quick conversion from height and weight to BMI.

<sup>&</sup>lt;sup>2</sup> For the purposes of this document, "obesity" is defined as a body mass index (BMI) equal to or greater than 30, which approximates 30 pounds of excess weight. Excess weight also places people at risk of developing serious health problems.

## VOLUNTARY GUIDELINES FOR PROVIDERS OF WEIGHT LOSS PRODUCTS OR SERVICES

## I. FORMAT AND DISTRIBUTION

These Voluntary Guidelines represent a consensus of voluntary consumer disclosure practices reached by a panel of weight management companies, weight loss professionals, and consumer protection groups. They are not binding, do not represent legal standards or interpretation of any legal requirements, and are not sponsored or issued by any government agency. Providers<sup>1</sup> should only make these disclosures to the extent that they are permissible under applicable state and federal law.<sup>2</sup> Providers that subscribe to these Voluntary Guidelines may be flexible in tailoring the Guidelines to the structure and needs of their own programs. Different programs will comply in different ways with various portions of the Guidelines. However, providers should not represent, directly or indirectly, in advertising or otherwise, that they subscribe to their particular program or product.

The examples set forth in the Voluntary Guidelines are provided for the purpose of illustration, and are not intended to represent a required or preferred form or format. Different providers and types of providers may utilize varying formats for disclosure.

Providers following these guidelines should make all disclosures clearly and prominently. Providers that obligate purchasers to make payments in the future or that collect non refundable payments in advance for products or services to be consumed or provided in the future, should make all disclosures in a single document that is given to all prospective clients/patients on their first visit to the center and prior to purchase.<sup>3</sup> Providers that charge for products and services as they are used by the purchaser — "pay-as-you-go programs" — or that collect refundable payments in advance of delivery of the services,<sup>4</sup> should also include all disclosures covered by these guidelines in a single document except that cost information may be provided either as part of the document or on clear and prominent postings at each center. Providers who post notices of costs should do so in a manner that renders them consistently viewable by consumers during their visit and permits consumers to notice and read the contents upon first entering the area occupied by the provider's customer representatives or recruiters.

Providers should instruct their staff to encourage prospective clients/patients to read all disclosures prior to enrolling in the program.

Services actually provided should not be inconsistent with the content of these disclosures. (For example, a provider should not offer advice of a medical nature if the disclosures state that medical advice is not provided.) In addition, written or oral representations contained in advertising or any other materials or presentations should not be inconsistent with or contradict these disclosures.

## **II. INFORMATION CONTENT**

Providers of weight management services should, at a minimum, voluntarily provide to prospective patients/clients the following information:<sup>5</sup>

**A.** Information concerning **staff qualifications and central components of the program**. This includes a description of the program content and goals<sup>6</sup> and pertinent information about the weight management training, experience, certification and education of the customer service personnel where the service, including distribution of products, is being provided, and which is appropriate to the program. The disclosure should include wording that encourages prospective patients/clients to ask additional questions about the qualifications of the provider and should not be deceptive or misleading.

Example 1

#### Our Staff

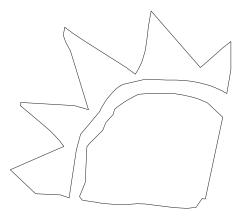
The "Weight Away Diet Center" program consists of diet, exercise, and behavioral modification. Program leaders who have successfully used the Weight Away program to lose weight monitor your weekly progress. Staff is required to have completed Weight Away program as well as a six-week in-house staff training program covering nutrition, weight-loss dynamics, customer service, and presentation. One or more Weight Away counselors will see you on an individual or group basis at each meeting. Our staff does not offer medical or psychological counseling. Please feel free to ask for more details about any particular leader's training or experience.

#### Example 2

#### Our Staff

The "Community Hospital Obesity Clinic" provides a medically supervised weight loss program for patients with severe disorders related to obesity or whose obesity places them at risk of developing such disorders. The program consists of optional low or very low-calorie diet plans, exercise, and lifestyle education. During this program, patients following a very-low-calorie diet will receive a protein supplement diet formula to substitute for regular meals and a multi-vitamin supplement. Our staff is comprised of one physician who is board-certified in endocrinology, two registered nurses (RNs), three registered dietitians (RDs), one masters level exercise physiologist and one clinical psychologist (Ph.D.) Usually, patients will visit with the dietitians and exercise physiologist. Other professional staff are available for consultation if professional intervention is indicated. Prospective patients are encouraged to ask about staff experience and training and how much time various staff members spend with individual patients.

- **B**. Information about the **risks associated with overweight and obesity**, and the benefits to be derived from modest weight loss, *e.g.*:
  - That obesity and overweight are associated with increased risk of heart disease, diabetes, some forms of cancer, gall bladder disease, osteoarthritis, stroke, and sleep apnea, among other illnesses, and that moderate amounts of weight loss (five to ten percent of total body weight) can reduce many of the risks.<sup>7</sup>
- **C.** Information about the **risks associated with the provider's product or program**. This includes for programs, the risks associated with any drugs, devices, dietary supplements, or exercise plans that are provided in the course of the program or treatment. In addition to program/product—specific risks, the information provided should indicate:
  - That consultation with a medical professional is advisable for people who are under treatment for specific medical conditions or taking prescribed medications.
  - That unless medically indicated, weight loss after the first two or three weeks of dieting should not exceed a rate of three pounds or approximately one and one-half percent of body weight per week. More rapid weight loss may cause an increased risk of developing gallbladder disease, risk which is believed to be higher than the risk of developing gallbladder disease as a result of staying overweight/obese. People who are considered medically appropriate for more rapid weight loss should have their progress monitored by a physician.
  - That very-low-calorie diets (< 800 kcal per day) are designed to promote rapid weight loss in people whose obesity has resulted in, or has put them at medical risk of, developing serious health complications. Rapid weight loss may also be associated with some medical problems. This program provides medical supervision to minimize risks associated with rapid weight loss.<sup>8</sup>
  - That people undergoing weight loss can experience physical changes in the body (dizziness, interruptions in the menstrual cycle, hair loss, for example) that may indicate more serious conditions. People noticing such changes should be advised to talk immediately to their primary care physician.



Example 3: For providers whose programs are designed to produce weight loss at a rate of approximately two pounds per week.

What You Need To Know About the Safety of the "Healthy Weight Loss Clinic" Diet

This diet has been designed to promote weight loss of no more than two pounds — or one percent of total body weight — a week. Medical authorities recommend that losing weight at such a rate reduces risk of health problems that have been associated with more rapid weight loss (greater than three pounds per week). Some people may lose weight at a slightly higher rate. However, we will monitor your progress and modify your diet if your rate of weight loss after the first two or three weeks exceeds a rate of three pounds — or one and one-half percent of body weight — a week.

Children and adolescents, pregnant or breast feeding women, and people with significant health problems such as bulimia, heart disease, kidney disease, diabetes or psychiatric disorder, should not begin this program without written authorization by their primary care provider.

People under treatment for other conditions or taking medications prescribed by their health care provider should tell their providers that they have begun this diet because, in some cases, adjustments to medications or modifications to the weight loss program may be appropriate.

Weight loss can produce physical changes in the body such as interruptions in the menstrual cycle, temporary hair loss, and dizziness. Such changes may indicate more serious health complications. Report any such changes that you notice to your primary care provider.

Remember, people who are overweight or obese are at increased risk of developing heart disease, diabetes, some forms of cancer, gall bladder disease, osteoarthritis and sleep apnea. Losing even small amounts of weight (five to ten percent of body weight), may reduce these risks. The side effects and complications that some people may experience while losing weight by following a healthy eating plan and exercise program are usually minor compared to the risks of overweight and obesity. **D.** Information about **program costs.** This includes (1) total program costs, including all fixed costs (administrative fees, entry fees, renewal fees, as appropriate), (2) periodic costs such as weekly attendance fees or mandatory food purchases (expressed for food purchases at the option of the provider as either average approximate costs or a high/low range of costs per scheduled payment unit or per week), (3) optional costs (such as fees charged for reentering the program or for any optional maintenance program), and (4) discretionary costs (medical tests, for example). Providers should also identify, clearly and prominently, any non-refundable costs. If practicable, providers should disclose total approximate program costs averaged across all dieters.

Example 4

| "BYE-BYE BMI Weight Loss Centers" Cost Schedule:             |         |
|--|---------|
| <u>Mandatory Charges</u> :                                   |         |
| One-Time Entry Fee   | \$xx.xx |
| Each Weekly Meeting (attended)                               | \$xx.xx |
| Average (approximate) cost of food per week                  | \$xx.xx |
| Nutritional Supplements (30 day supply)                      | \$xx.xx |
| Discretionary Additional Charges (if Center deems necessary) |         |
| Blood tests, Physician Exam, EKG                             | \$xx.xx |
| <u>Optional Additional Charges</u> (if client chooses)       |         |
| Re-entry fee (after absence of at least consecutive visits)  | \$xx.xx |
| Optional Maintenance Program                                 | \$xx.xx |
| ALL COSTS NON DEFUNDABLE                                     |         |

- ALL COSTS NON-REFUNDABLE
- **E**. Consumers of weight loss products and services are entitled to receive **outcome information** that would allow people to make informed choices among weight loss products and services. Providers are encouraged to collect data, e.g., how much weight consumers of a particular product or program have lost and how long they kept off all or part of their weight loss, and disclose weight loss and maintenance information to prospective clients/patients before they enroll.<sup>9</sup>

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Providers subscribing to these guidelines should include within the document containing the other disclosures:

- the statement, "Most people who lose weight are likely to find it difficult to keep the weight off. They can improve their chances by adopting a lifelong commitment that includes:
  - increased frequent and regular physical activity of at least moderate intensity, and
  - healthy eating in accordance with the Dietary Guidelines for Americans, emphasizing a reduction in total calories, a lowered fat consumption, and an increase in vegetables, fruits and whole grains," and
  - information about the health benefits of modest amounts of weight loss (5 10 percent of body weight, 10 20 pounds).

Example 5: For providers that make specific disclosures

Patients under Dr. Doe's weight loss treatment lost, on average, 17.5 pounds, and after 18 months, they kept off 55 percent of their weight loss. This measurement includes all patients who remained in active weight loss for at least three weeks.

Most people who lose weight are likely to find it difficult to keep the weight off. They can improve their chances by adopting a lifelong commitment that includes:

- increased frequent and regular physical activity of at least moderate intensity, and
- healthy eating in accordance with the Dietary Guidelines for Americans, emphasizing a reduction in total calories, a lowered fat consumption, and an increase in vegetables, fruits and whole grains.

Moreover, maintaining a modest amount of weight loss over time has been shown to have health benefits.

## Example 6: For providers that choose not to make specific disclosures

Most people who lose weight are likely to find it difficult to keep the weight off. They can improve their chances by adopting a lifelong commitment that includes:

- increased frequent and regular physical activity of at least moderate intensity, and
- healthy eating in accordance with the Dietary Guidelines for Americans, emphasizing a reduction in total calories, a lowered fat consumption, and an increase in vegetables, fruits and whole grains.

Moreover, even weight loss of as little as ten percent of body weight, if maintained over time, has been shown to be beneficial.

#### **Body Mass Index (BMI)**

Body mass index, or BMI, is a new term to most people. However, it is the measurement of choice for many physicians and researchers studying obesity. BMI uses a mathematical formula that takes into account both a person's height and weight. BMI equals a person's weight in kilograms divided by height in meters squared. (BMI=kg/m<sup>2</sup>). The table printed here has already done the math and metric conversions. To use the table, find the appropriate height in the left-hand column. Move across the row to the given weight. The number at the top of the column is the BMI for that height and weight.

| BMI<br>(kg/m²)  | 19           | 20  | 21  | 22  | 23  | 24  | 25  | 26  | 27  | 28  | 29  | 30  | 35  | 40  |
|-----------------|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Height<br>(in.) | Weight (lb.) |     |     |     |     |     |     |     |     |     |     |     |     |     |
| 58              | 91           | 96  | 100 | 105 | 110 | 115 | 119 | 124 | 129 | 134 | 138 | 143 | 167 | 191 |
| 59              | 94           | 99  | 104 | 109 | 114 | 119 | 124 | 128 | 133 | 138 | 143 | 148 | 173 | 198 |
| 60              | 97           | 102 | 107 | 112 | 118 | 123 | 128 | 133 | 138 | 143 | 148 | 153 | 179 | 204 |
| 61              | 100          | 106 | 111 | 116 | 122 | 127 | 132 | 137 | 143 | 148 | 153 | 158 | 185 | 211 |
| 62              | 104          | 109 | 115 | 120 | 126 | 131 | 136 | 142 | 147 | 153 | 158 | 164 | 191 | 218 |
| 63              | 107          | 113 | 118 | 124 | 130 | 135 | 141 | 146 | 152 | 158 | 163 | 169 | 197 | 225 |
| 64              | 110          | 116 | 122 | 128 | 134 | 140 | 145 | 151 | 157 | 163 | 169 | 174 | 204 | 232 |
| 65              | 114          | 120 | 126 | 132 | 138 | 144 | 150 | 156 | 162 | 168 | 174 | 180 | 210 | 240 |
| 66              | 118          | 124 | 130 | 136 | 142 | 148 | 155 | 161 | 167 | 173 | 179 | 186 | 216 | 247 |
| 67              | 121          | 127 | 134 | 140 | 146 | 153 | 159 | 166 | 172 | 178 | 185 | 191 | 223 | 255 |
| 68              | 125          | 131 | 138 | 144 | 151 | 158 | 164 | 171 | 177 | 184 | 190 | 197 | 230 | 262 |
| 69              | 128          | 135 | 142 | 149 | 155 | 162 | 169 | 176 | 182 | 189 | 196 | 203 | 236 | 270 |
| 70              | 132          | 139 | 146 | 153 | 160 | 167 | 174 | 181 | 188 | 195 | 202 | 207 | 243 | 278 |
| 71              | 136          | 143 | 150 | 157 | 165 | 172 | 179 | 186 | 193 | 200 | 208 | 215 | 250 | 286 |
| 72              | 140          | 147 | 154 | 162 | 169 | 177 | 184 | 191 | 199 | 206 | 213 | 221 | 258 | 294 |
| 73              | 144          | 151 | 159 | 166 | 174 | 182 | 189 | 197 | 204 | 212 | 219 | 227 | 265 | 302 |
| 74              | 148          | 155 | 163 | 171 | 179 | 186 | 194 | 202 | 210 | 218 | 225 | 233 | 272 | 311 |
| 75              | 152          | 160 | 168 | 176 | 184 | 192 | 200 | 208 | 216 | 224 | 232 | 240 | 279 | 319 |
| 76              | 156          | 164 | 172 | 180 | 189 | 197 | 205 | 213 | 221 | 230 | 238 | 246 | 287 | 328 |

#### Body weight in pounds according to height and body mass index.

Adapted with permission from Bray, G.A., Gray, D.S. Obesity, Part I, Pathogenesis, West J. Med. 1988: 149: 429-41.

## <u>Endnotes</u>

- <sup>1</sup> "Providers" includes any individual or organization involved in providing weight loss services or products to the public, including, but not limited to, physicians, clinical psychologists, dieticians, nutritionists, and commercial programs, as well as any one else selling products or publications designed to cause weight loss or result in weight maintenance.
- <sup>2</sup> Providers of a weight loss *product* should note that use of statements about the risks associated with overweight and obesity, the risks associated with the product, or about outcomes may render the product adulterated, misbranded, or unapproved under the Federal Food, Drug, and Cosmetic Act and relevant regulations promulgated by the Food and Drug Administration.
- <sup>3</sup> In the case of telephone sales, inasmuch as providers cannot give written disclosures to prospective patients/clients until they visit a center, sales should not be considered final until the prospective patient/client has received the disclosures and had a chance to read them. Alternatively, providers may include with the disclosures, a clear and conspicuous notice of their right to rescind such a sale within at least five days.
- <sup>4</sup> A single, non refundable entry fee or registration fee that does not exceed 150 percent of the fee charged for a single visit or session in an otherwise pay-as-you-go program does not remove the program from pay-as-you-go status.
- <sup>5</sup> In order to assure compliance, these guidelines should be placed in the program/procedures policy manual or such other written guidance provided to program staff.
- <sup>6</sup> The description of the program should include information about any products (drugs, devices, dietary supplements, herbals products, food substitutes, foods, etc.), whether required or optional, that are provided in the course of the program.
- <sup>7</sup> While most providers will likely want to include information about the risks of obesity and the benefits of weight loss, any such disclosure is optional, and the failure to provide such a statement will not be considered inconsistent with the guidelines.
- <sup>8</sup> This guideline is only applicable to providers who offer very-low-calorie diet plans.
- <sup>9</sup> These guidelines encourage but do not mandate outcome disclosures in terms of weight loss and weight maintenance. Weight loss programs differ, and at the current time, there is no consensus on what the content and the format of such disclosures should be. Research is lacking as to what consumers need and how they interpret or use such information. The Partnership for Healthy Weight Management has resolved to pursue means to develop such research and to encourage the development of consumer education materials that provide guidance on outcome information and how consumers can use it.

Federal Trade Commission www.ftc.gov