

# HOUSE BILL No. 5655

April 2, 1990, Introduced by Reps. Leland, DeMars, Barns, Hart, Pitoniak, DeBeaussaert, Krause, Bandstra, Crandall, Middaugh, Gubow, Porreca, Profit, Perry Bullard, Spaniola, Berman, Saunders, Kilpatrick, Hollister, Sikkema, London, Hoffman, Bartnik, Jondahl, Wallace, Emerson, Hertel and Keith and referred to the Committee on Public Health.

A bill to amend Act No. 368 of the Public Acts of 1978, entitled as amended "Public health code," as amended, being sections 333.1101 to 333.25211 of the Michigan Compiled Laws, by adding part 95.

## THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Section 1. Act No. 368 of the Public Acts of 1978, as  
2 amended, being sections 333.1101 to 333.25211 of the Michigan  
3 Compiled Laws, is amended by adding part 95 to read as follows:

### 4 PART 95

5 CONTROLLED DIETARY PRODUCTS AND CONTROLLED WEIGHT LOSS PROGRAMS  
6 SEC. 9501. (1) AS USED IN THIS PART:

7 (A) "CONTROLLED DIETARY PRODUCT" MEANS A FOOD SUPPLEMENT OR  
8 PRODUCT INTENDED TO FACILITATE HUMAN WEIGHT LOSS WHICH, WHEN USED

1 AS DIRECTED, RESULTS IN, IS INTENDED TO RESULT IN, OR INCLUDES 1  
2 OR MORE OF THE FOLLOWING:

3 (i) A DAILY CALORIC CONSUMPTION OF 800 CALORIES OR LESS.

4 (ii) AN AVERAGE DAILY CONSUMPTION OF LESS THAN THE U.S. RDA  
5 LEVELS FOR PROTEIN, VITAMINS, AND MINERALS; LESS THAN 100 GRAMS  
6 OF CARBOHYDRATE; OR LESS THAN 25 GRAMS OF FAT.

7 (iii) THE USE OF A PRESCRIPTION DRUG IN THE REGIMEN.

8 (iv) EXCEPT FOR THE FIRST 7 DAYS, A WEIGHT LOSS OF 5 OR MORE  
9 POUNDS IN ANY 7-DAY PERIOD.

10 (B) "DIRECT MEDICAL SUPERVISION" MEANS THAT ALL OF THE FOL-  
11 LOWING ARE MET:

12 (i) EACH CLIENT WHO PARTICIPATES IN A CONTROLLED WEIGHT LOSS  
13 PROGRAM DOES SO ONLY ON THE ORDER OF A PHYSICIAN.

14 (ii) THE SPECIFIC COURSE OF TREATMENT OR INSTRUCTIONS FOR  
15 EACH CLIENT ARE ORDERED IN WRITING, SIGNED BY THE ADMITTING PHY-  
16 SICIAN, AND PLACED IN THE CLIENT'S MEDICAL RECORD.

17 (iii) A PHYSICIAN PARTICIPATES IN THE CLIENT'S TREATMENT ON  
18 A CONTINUING BASIS AT LEAST THROUGH COMPLETION OF ALL OF THE  
19 FOLLOWING:

20 (A) A COMPLETE MEDICAL HISTORY AND PHYSICAL ASSESSMENT UPON  
21 ENTERING THE PROGRAM.

22 (B) APPROPRIATE LABORATORY AND OTHER TESTS.

23 (C) INSTRUCTIONS TO THE CLIENT.

24 (D) PERIODIC REVIEW OF THE CLIENT'S MEDICAL STATUS, WHICH  
25 SHALL BE DOCUMENTED IN THE CLIENT'S MEDICAL RECORD.

26 (C) "PHYSICIAN" MEANS THAT TERM AS DEFINED IN SECTION 17001  
27 OR 17501.

1 (D) "PRESCRIPTION" MEANS THAT TERM AS DEFINED IN SECTION  
2 17708(3).

3 (E) "PRESCRIPTION DRUG" MEANS THAT TERM AS DEFINED IN SEC-  
4 TION 17708(4).

5 (F) "PROGRAM" MEANS A SERVICE OFFERED TO THE PUBLIC FOR A  
6 FEE BY A PERSON OR FACILITY WHICH SERVICE INCLUDES A PLAN OR PRO-  
7 CEDURE TO FACILITATE HUMAN WEIGHT LOSS THROUGH DIETARY MANIPULA-  
8 TION, MEDICATION, OR BOTH, AND WHICH, IF FOLLOWED AS DIRECTED,  
9 RESULTS IN, IS INTENDED TO RESULT IN, OR INCLUDES 1 OR MORE OF  
10 THE FOLLOWING:

11 (i) THE USE OF A CONTROLLED DIETARY PRODUCT.

12 (ii) A DAILY CALORIC CONSUMPTION OF 800 CALORIES OR LESS.

13 (iii) AN AVERAGE DAILY CONSUMPTION OF LESS THAN THE RECOM-  
14 MENDED DIETARY ALLOWANCE LEVELS FOR PROTEIN, VITAMINS, AND MINER-  
15 ALS; LESS THAN 100 GRAMS OF CARBOHYDRATE; OR LESS THAN 25 GRAMS  
16 OF FAT.

17 (iv) EXCEPT FOR THE FIRST 7 DAYS, A WEIGHT LOSS OF 5 OR MORE  
18 POUNDS IN ANY 7-DAY PERIOD.

19 (G) "RECOMMENDED DIETARY ALLOWANCE" MEANS THE STANDARDS FOR  
20 NUTRIENT INTAKE FOR THE UNITED STATES POPULATION AS DETERMINED BY  
21 THE NATIONAL RESEARCH COUNCIL UNDER THE NATIONAL ACADEMY OF  
22 SCIENCES.

23 (H) "U.S. RDA" MEANS UNITED STATES RECOMMENDED DAILY ALLOW-  
24 ANCES USED FOR THE NUTRIENT LABELING OF PRODUCTS AS DETERMINED BY  
25 THE NATIONAL RESEARCH COUNCIL UNDER THE NATIONAL ACADEMY OF  
26 SCIENCES.

1 (2) IN ADDITION, ARTICLE 1 CONTAINS GENERAL DEFINITIONS AND  
2 PRINCIPLES OF CONSTRUCTION APPLICABLE TO ALL ARTICLES IN THE  
3 CODE.

4 SEC. 9503. (1) A CONTROLLED DIETARY PRODUCT SHALL NOT BE  
5 SOLD, DISTRIBUTED, OR DISPENSED EXCEPT PURSUANT TO A PRESCRIPTION  
6 WRITTEN BY A PHYSICIAN IN THE SAME MANNER AS A PRESCRIPTION IS  
7 WRITTEN FOR A PRESCRIPTION DRUG UNDER PART 177.

8 (2) UNLESS A THIRD-PARTY PAYER PROVIDES A BENEFIT FOR WEIGHT  
9 LOSS:

10 (A) A PHYSICIAN SHALL NOT BILL A THIRD-PARTY PAYER FOR SERV-  
11 ICES RELATED SOLELY TO WEIGHT LOSS.

12 (B) A PERSON SHALL NOT ADVERTISE THAT SERVICES RELATED  
13 SOLELY TO WEIGHT LOSS ARE REIMBURSABLE BY THIRD-PARTY PAYERS.

14 SEC. 9505. (1) EXCEPT AS PROVIDED IN SECTION 9513, A PROGRAM  
15 SHALL NOT BE OWNED, OPERATED, OFFERED TO THE PUBLIC, OR MARKETING  
16 IN THIS STATE UNLESS IT HAS BEEN REGISTERED WITH THE DEPARTMENT.

17 (2) A PROGRAM MAY BECOME REGISTERED WITH THE DEPARTMENT BY  
18 SUBMITTING AN APPLICATION ON A FORM PRESCRIBED BY THE DEPARTMENT  
19 WHICH STATES THAT THE PROGRAM MEETS BOTH OF THE FOLLOWING:

20 (A) IS ADMINISTERED TO ALL CLIENTS UNDER DIRECT MEDICAL  
21 SUPERVISION.

22 (B) MAINTAINS A MEDICAL RECORD FOR EACH CLIENT WHICH  
23 INCLUDES A SIGNED DOCUMENT OF INFORMED CONSENT WHICH ADDRESSES  
24 ALTERNATIVES AND RISKS INVOLVED IN THE PROGRAM.

25 (3) REGISTRATION SHALL BE OBTAINED ON AN ANNUAL BASIS AND ON  
26 A FORM PROVIDED BY THE DEPARTMENT. THE FORM SHALL INCLUDE ALL OF  
27 THE FOLLOWING:

(A) THE NAME OF THE PROGRAM AND ITS LOCATION.

(B) THE NAME OF THE OWNER OR CORPORATE MEMBER, OR BOTH.

(C) A STATEMENT CERTIFYING COMPLIANCE WITH SUBSECTION (2).

(D) SUCH OTHER INFORMATION AS THE DEPARTMENT REASONABLY

REQUIRES TO PROTECT THE PUBLIC'S HEALTH.

(4) REGISTRATION SHALL BE RENEWED IF THE PROGRAM PAYS THE RENEWAL FEE AND CONTINUES TO COMPLY WITH THIS PART AND ANY RULES PROMULGATED UNDER THIS PART, AS DETERMINED BY THE DEPARTMENT.

(5) THE INITIAL REGISTRATION AND SUBSEQUENT ANNUAL RENEWAL FEE SHALL BE \$300.00.

(6) A CERTIFICATE OF REGISTRATION ISSUED BY THE DEPARTMENT SHALL BE EXHIBITED AT ALL TIMES IN A CONSPICUOUS PLACE LOCATED IN A CUSTOMER-FREQUENTED AREA OF THE PROGRAM LOCATION, OR SHALL BE SHOWN TO THE CUSTOMER PRIOR TO THE DELIVERY OF PROGRAM SERVICES. A SEPARATE CERTIFICATE OF REGISTRATION SHALL BE REQUIRED AT EACH LOCATION WHERE A PROGRAM IS PROVIDED.

(7) EACH PROGRAM REGISTERED UNDER THIS PART SHALL CONSPICUOUSLY DISPLAY A POSTER PROVIDED BY THE DEPARTMENT. THE POSTER SHALL CONTAIN ALL OF THE FOLLOWING INFORMATION:

(A) THAT THE PROGRAM IS REGISTERED WITH THE DEPARTMENT UNDER THIS PART.

(B) THAT THE PROGRAM IS REQUIRED TO PROVIDE DIRECT MEDICAL SUPERVISION FOR ALL PATIENTS.

(C) OTHER INFORMATION AS DETERMINED BY THE DEPARTMENT.

SEC. 9507. (1) A PERSON WHO HAS A REASONABLE BELIEF THAT THIS PART OR THE RULES PROMULGATED UNDER THIS PART HAVE BEEN VIOLATED MAY FILE A COMPLAINT WITH THE DEPARTMENT.

1       (2) THE DEPARTMENT SHALL INVESTIGATE A COMPLAINT MADE  
2 PURSUANT TO SUBSECTION (1) AND SHALL ENFORCE THIS PART AND THE  
3 RULES PROMULGATED UNDER THIS PART. PURSUANT TO SECTION 2235, THE  
4 DEPARTMENT MAY AUTHORIZE A LOCAL HEALTH DEPARTMENT TO FULFILL THE  
5 REQUIREMENTS OF THIS SUBSECTION.

6       (3) AN AUTHORIZED REPRESENTATIVE OF THE DEPARTMENT OR LOCAL  
7 HEALTH DEPARTMENT MAY INSPECT A PROGRAM IN ORDER TO DETERMINE  
8 COMPLIANCE WITH THIS PART. INSPECTIONS SHALL BE CONDUCTED ONLY  
9 DURING BUSINESS HOURS.

10       (4) IF THE DEPARTMENT DETERMINES THAT A PROGRAM IS NOT OPER-  
11 ATING IN COMPLIANCE WITH THIS PART OR RULES PROMULGATED UNDER  
12 THIS PART, THE DEPARTMENT SHALL ISSUE AN ORDER REQUIRING COMPLI-  
13 ANCE WITHIN A SPECIFIED PERIOD OF TIME. THE DEPARTMENT SHALL  
14 PROVIDE AN OPPORTUNITY FOR A HEARING WITHIN 10 WORKING DAYS AFTER  
15 THE ORDER IS ISSUED. THIS SECTION SHALL NOT LIMIT ANY OTHER  
16 ENFORCEMENT AUTHORITY VESTED IN THE DEPARTMENT.

17       (5) UPON A FINDING OF A DEFICIENCY OR VIOLATION OF THIS PART  
18 OR THE RULES PROMULGATED UNDER THIS PART WHICH SERIOUSLY AFFECTS  
19 THE HEALTH, SAFETY, OR WELFARE OF INDIVIDUALS RECEIVING SERVICES,  
20 THE DEPARTMENT SHALL ISSUE AN EMERGENCY ORDER DENYING, SUSPEND-  
21 ING, OR REVOKING THE REGISTRATION OF A PROGRAM. THE DEPARTMENT  
22 SHALL PROVIDE AN OPPORTUNITY FOR A HEARING WITHIN 5 WORKING DAYS  
23 AFTER ISSUANCE OF THE EMERGENCY ORDER. AN EMERGENCY ORDER SHALL  
24 INCORPORATE THE DEPARTMENT'S FINDINGS AND SHALL REMAIN IN EFFECT  
25 DURING A HEARING.

1 (6) THE REGISTRATION OF A PROGRAM MAY BE DENIED, SUSPENDED,  
2 OR REVOKED FOR VIOLATION OF THIS PART OR RULES PROMULGATED UNDER  
3 THIS PART.

4 (7) A PERSON WHO VIOLATES THIS PART OR RULES PROMULGATED  
5 UNDER THIS PART IS GUILTY OF A MISDEMEANOR.

6 (8) THIS PART DOES NOT PRECLUDE ANY OTHER REMEDIES AVAILABLE  
7 UNDER THE LAW.

8 SEC. 9509. (1) A PROGRAM SHALL NOT ENGAGE IN FALSE OR MIS-  
9 LEADING ADVERTISING.

10 (2) EXCEPT AS OTHERWISE PROVIDED IN SECTION 9505(6) AND (7),  
11 A PROGRAM SHALL NOT ADVERTISE THE FACT THAT IT IS REGISTERED  
12 UNDER THIS PART.

13 SEC. 9511. THE DEPARTMENT MAY PROMULGATE RULES NECESSARY TO  
14 IMPLEMENT THIS PART.

15 SEC. 9513. SECTIONS 9505 TO 9507 SHALL NOT APPLY TO EITHER  
16 OF THE FOLLOWING:

17 (A) A PROGRAM WHICH IS OPERATED BY A HOSPITAL OR HEALTH  
18 MAINTENANCE ORGANIZATION LICENSED UNDER ARTICLE 17.

19 (B) A PROGRAM WHICH IS PROVIDED IN A PHYSICIAN'S OFFICE,  
20 UNLESS BOTH OF THE FOLLOWING APPLY:

21 (i) THE PHYSICIAN HOLDS HIMSELF OR HERSELF OR HIS OR HER  
22 PRACTICE OUT OR ADVERTISES THAT HIS OR HER PRACTICE IS LIMITED  
23 TO, OR SPECIALIZES IN, WEIGHT LOSS OR THE TREATMENT OF OBESITY,  
24 OR BOTH.

25 (ii) THE PHYSICIAN'S PRACTICE IS CONDUCTED OUT OF MORE THAN  
26 1 OFFICE OR PRACTICE SETTING.