



**House
Legislative
Analysis
Section**

Washington Square Building, Suite 1025
Lansing Michigan 48909
Phone 517/373-6466

House Bill 4159 (Substitute H-2)
First Analysis (6-23-87)

RECEIVED

Sponsor: Rep. Burton Leland
Committee: Public Health

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THE APPARENT PROBLEM:

According to the Department of Public Health, medically unsound weight reduction regimens which place users at potentially serious health risk are being promoted in Michigan by individuals with no health training and who have made no provision for medical assessment and supervision of their clients. Almost anyone can go into the business of helping people to lose weight; there is little or no regulation of weight-loss businesses or weight-loss products. Although there are many reputable programs that offer safe and effective methods of weight reduction, some businesses operate with little regard for the interests of their clientele. Employees of weight loss clinics have testified that customers were put on drastic, unproven diet regimens with virtually no medical supervision and without regard to past health problems. Some clinics appear to be mainly interested in performing lucrative laboratory tests. Not only do such enterprises perpetrate consumer fraud but they pose serious health hazards to the public. Much of the public is simply unaware of the dangers that exist in undertaking a drastic weight reduction effort. Semi-starvation diets are dangerous even to otherwise healthy people, but the dangers increase dramatically for the obese, since health officials say obesity is often associated with other health problems, such as diabetes, hypertension, and coronary heart disease. Similar problems exist with the marketing of some kinds of diet products. Several years ago health officials attributed some 60 deaths nationwide (including half a dozen in Michigan) to the use of very low calorie diet products. Some people think that the state should monitor weight loss programs and products that involve drastic diet regimens to make sure that there is sufficient medical supervision to protect the public health.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to require the annual registration of some weight loss programs, which would then have to provide direct medical supervision of service to clients.

Exemptions

Weight loss programs provided in a physician's office by a physician and programs operated by hospitals and health maintenance organizations would be specifically exempted by the bill. However, if a physician's practice were advertised as limited to or specializing in weight loss or the treatment of obesity and were also conducted out of more than one office or practice setting, then it would not be exempt. Any program that does not fall under the bill's definition of "weight loss program" would be exempt from registration requirements. The bill also would specifically exempt books which set forth weight loss plans but which are not intended to be used in conjunction with a weight loss service.

Program Registration

No program that met the bill's definition of weight loss program could be owned, marketed, offered to the public,

or operated without first being registered with the Department of Public Health. There would be an annual registration fee of \$400. To qualify for registration, an applicant would have to state that the program was administered to all clients under direct medical supervision and that it maintained the required medical record for each client, including a signed document of informed consent.

By "direct medical supervision," the bill would mean that each client who participated in a controlled weight loss program did so only on the order of a licensed physician or certified nurse practitioner; that the specific course of treatment or the instructions for each client were ordered in writing, signed by the admitting physician or certified nurse practitioner, and kept in the client's medical record; and that a licensed physician or certified nurse practitioner participated in each client's treatment on a continuing basis, including completion of a medical history and physical assessment when a client entered the program, appropriate laboratory tests, instructions to the client, and a periodic review of a client's medical status which would have to be documented in the client's medical record.

Definition of Programs

The bill would apply only to weight loss programs offered to the public for a fee that had as part of their regimens one or more of the following:

- a daily caloric intake of 800 calories or less;
- an average daily consumption of less than the federally recommended levels for protein, vitamins, and minerals, less than 100 grams of carbohydrates or less than 25 grams of fat;
- the intended loss of five or more pounds in any seven-day period (except for the first seven days).

Enforcement

The Department of Public Health would have the responsibility of enforcing the act and investigating complaints, although it could delegate responsibilities to local health departments. The department would be able to deny, suspend, or revoke a registration for a violation of the bill or of the rules promulgated by the department to carry out the provisions of the bill, or for false or misleading advertising. A violation of the bill's provisions would be a misdemeanor. The department could also issue orders requiring compliance with the law or rules if a program was found not to be in compliance. The department would have to provide a hearing within ten days after any compliance order or within five days after issuing an emergency order denying, revoking, or suspending a registration. The Department of Public Health or a local health department would have access to a program during business hours for the purpose of inspection for compliance.

Third-Party Payments

The bill would prohibit physicians from billing a third-party payer for services related solely to weight loss and would

H.B. 4159 (6-23-87)

prohibit anyone from advertising that weight loss services were reimbursable by third parties. The prohibitions would not apply in cases where someone had a benefit for weight loss services from a third party payer. (This provision means that unless a customer had specific coverage for the weight loss services a physician could not bill the customer's insurer. Similarly, weight loss programs could not advertise that their services were covered by third-party payers.)

Posting and Advertising

A certificate of registration would have to be exhibited conspicuously in all program locations or could be shown to customers before they received any services. Further, each program would have to conspicuously display a poster provided by the Department of Public Health saying that program was registered with the department and that direct medical supervision was required. A program, however, could not in any other way advertise that it was registered.

MCL 333.9501 et al.

FISCAL IMPLICATIONS:

The Department of Public Health estimates that implementation of the bill would cost \$96,000 a year, which would be covered by registration fees of \$400 a year by participating weight loss programs. The fees would be deposited in the general fund and an appropriation would be required for the implementation and administration of the bill. (4-30-87)

ARGUMENTS:

For:

The bill would offer the public some measure of protection against the marketing of high-risk weight loss regimens. The public health is endangered now, health officials say, by weight reduction plans promoted by people with no health training and no knowledge of nutrition who make no serious attempt to provide customers with the kind of medical supervision that is essential if drastic diets are to be both safe and effective. This bill will address that problem by requiring that all programs with a specified level of risk be registered with the Department of Public Health. To be registered, a weight loss program would have to agree to provide its clients with the benefits of ongoing medical supervision. Programs that did not do so would not be able to operate in Michigan. Furthermore, people would only be able to embark on such drastic programs on the written order of a physician or certified nurse practitioner, who would have to specify the course of treatment for each client.

The bill would apply to clinics and other businesses that promote to the public extreme dietary practices as a way to lose weight. The bill would not affect those business operations that promote what health officials call "scientifically and medically sound regimens." Many clinics will not have to meet the bill's registration requirements. For example, Weight Watchers will not fall under this bill, according to health officials, because they do not advocate regimens severe enough to meet the bill's definition of "weight loss program."

Against:

It should be noted that the approach employed by the bill has limitations. For one thing, the registration program is a "paper" registration; that is, those registering merely have to claim they are meeting departmental standards and pay a fee. The enforcement of standards will only occur when complaints are investigated. Second, a high-risk program might escape regulation by adopting a

regimen just slightly less drastic than the one the bill specifies as the threshold regimen for the registration program.

Response: At the very least, the bill will let state health officials know who is engaged in this business and where to find them. But more than that, the bill does provide standards of medical supervision that potentially hazardous weight loss programs and products will have to meet to be marketed in the state. The expectation is that once the registration is in place, the market will contribute to enforcing the bill's standards: not only will dissatisfied customers lodge complaints but program operators will probably lodge complaints against competitors who are not meeting the requirements of the registration program.

Against:

Some people are concerned that registration efforts will have the effect of granting respectability to those programs that must comply at the expense of those who need not. For people to get the impression that registered programs were superior to unregistered ones would be an unhappy consequence.

Response: The bill addresses that problem by prohibiting registered weight loss programs from advertising the fact that they are registered.

Against:

The bill represents another example of unnecessary government regulation. People should be free to live their own lives as they see fit, and if they choose to take the risk involved in engaging in a rapid weight loss program then that is their business.

Response: There is a public expectation of consumer protection regulation in public health areas. People have the attitude that if a public health service is available, then it must be safe.

Against:

The requirement that physicians or certified nurse practitioners, rather than registered nurses, participate in these programs will effectively put out of business some currently operating reputable clinics. There are only 200 certified nurse practitioners licensed in Michigan, so to require supervision by certified nurse practitioners is unrealistic and unfair to those programs currently operating safely and responsibly with registered nurses providing supervision of clients.

Response: Although currently only about 200 certified nurse practitioners are licensed in Michigan, the Michigan Nurses Association estimates that there currently are about 1,000 certified nurse practitioners in the state who have successfully passed their national certifying examinations and who would only have to go through the relatively simple state licensing requirements in order to become fully licensed in Michigan. A representative from the Michigan Nurses Association further testified that in the opinion of the association registered nurses are not qualified to provide the kind of supervision necessary for these extremely low calorie diets.

Reply: The experience of Weight Loss Clinic International, which has 110 locations in the United States and Canada, including 24 in Michigan, has been that registered nurses provide extremely competent supervision of weight loss programs designed by WLC's physicians. More than 18,000 clients are participating in WLC programs now, with over 500,000 having participated since WLC was founded over 12 years ago. Not a single client has died or suffered medical complications from the program, which should indicate the competency of

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registered nurses to administer and supervise such programs.

Against:

The present version of the bill omits regulation of weight loss products, which greatly weakens the amount of consumer protection afforded by the bill. The bill should be amended to include regulation of weight loss products as well as programs, as the original bill did.

POSITIONS:

The Department of Public Health supports the bill. (6-22-87)

The Department of Licensing and Regulation does not have a position on the bill at this time. (6-22-87)

The Michigan State Medical Society supports the bill. (6-22-87)

The Michigan Nurses Association supports the bill. (6-22-87)

The Michigan Dietetic Association supports the bill. (6-22-87)

The Michigan Council Against Health Fraud supported the original bill, but does not support the present bill. (6-22-87)

Blue Cross Blue Shield of Michigan supports the bill. (6-22-87)

The Weight Loss Clinic International, Inc., opposes the bill. (6-22-87)