

103^D CONGRESS
2^D SESSION

H. R. 4128

To require providers of home infusion therapy services to be licensed and to limit physician referrals for services in which the physician has a financial interest.

IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 1994

Mr. BROWN of Ohio (for himself, Mr. DINGELL, Mr. WAXMAN, and Mr. STOKES) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Ways and Means

A BILL

To require providers of home infusion therapy services to be licensed and to limit physician referrals for services in which the physician has a financial interest.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Sarah Weber Home
5 Infusion Consumer Protection Act of 1994”.

6 **SEC. 2. LICENSING OF PROVIDERS OF HOME INFUSION**
7 **THERAPY SERVICES.**

8 (a) REQUIREMENT.—No person shall provide (or ar-
9 range for the provision of) home infusion therapy services

1 in a State unless the person is licensed by the State in
2 accordance with this section to provide (or arrange for the
3 provision of) such services. No State shall license such a
4 person unless the State finds that the person meets the
5 standards for licensing established under this section.

6 (b) STANDARDS.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services shall establish standards for the li-
9 censing of persons providing (or arranging for the
10 provision of) home infusion therapy services consist-
11 ent with this subsection.

12 (2) SUPERVISION.—A person licensed under
13 this section shall only provide (or arrange for the
14 provision of) home infusion therapy services to an
15 individual who is under the care of a physician and
16 under a plan established and periodically reviewed
17 by a physician.

18 (3) PROVIDER QUALIFICATIONS.—A person
19 shall not be licensed consistent with this section un-
20 less the person—

21 (A) has been determined to be capable of
22 providing, or arranging for the provision of,
23 home infusion therapy services;

1 (B) maintains clinical records on all indi-
2 viduals for whom the person provides (or ar-
3 ranges for the provision of) such services;

4 (C) adheres to written protocols and poli-
5 cies with respect to the provision (or arrange-
6 ment for the provision) of services;

7 (D) makes services available (as needed) 7
8 days a week on a 24-hour basis;

9 (E) coordinates all home infusion therapy
10 services with the patient's physician;

11 (F) conducts a quality assessment and as-
12 surance program, including drug regimen re-
13 view and coordination of patient care;

14 (G) assures that only trained (or licensed
15 if necessary) personnel provide infusion prod-
16 ucts (and any other service for which training
17 is required to safely provide the service);

18 (H) assumes responsibility for the quality
19 of services provided by others under arrange-
20 ments with such person;

21 (I) establishes appropriate protocols and
22 explains such protocols clearly to patients be-
23 fore the initiation of a treatment plan; and

24 (J) meets such other requirements as the
25 Secretary may determine are necessary (A) to

1 assure the safe and effective provision of home
2 infusion therapy services, and (B) respecting
3 the quality of the provision of such services and
4 the charges for such services.

5 A protocol referred to in subparagraph (I) shall in-
6 clude a provision for appropriate notification of indi-
7 viduals receiving home infusion therapy services in
8 the event of the cancellation of the provision of those
9 services.

10 (4) FEE.—A person shall not be licensed con-
11 sistent with this section unless the person assures
12 that charges for the provision of home infusion ther-
13 apy services by the person (or under arrangements
14 made by the person) shall not exceed such a fee as
15 the Secretary by regulation may establish to assure
16 that the charge for such services is reasonably
17 related to the services actually provided.

18 (c) ENFORCEMENT.—Compliance with the require-
19 ments of subsection (a) shall be enforced under the Fed-
20 eral Trade Commission Act by the Secretary of Health
21 and Human Services. A violation of any such requirement
22 shall constitute an unfair or deceptive act or practice in
23 commerce in violation of section 5(a) of the Federal Trade
24 Commission Act and shall be subject to enforcement under
25 section 5(b) of such Act irrespective of whether the person

1 who committed such violation is engaged in commerce or
2 meets any other jurisdictional test in such Act. The Sec-
3 retary shall have such procedural, investigative, and en-
4 forcement powers in enforcing compliance with such re-
5 quirements and may require the filing of reports, the pro-
6 duction of documents, and the appearance of witnesses as
7 though the applicable terms of such Act were part of this
8 section.

9 **SEC. 3. LIMITATION ON PHYSICIAN REFERRALS.**

10 (a) GENERAL RULE.—Except as provided in this sec-
11 tion, if a physician (or an immediate family member of
12 such physician) has a financial relationship with an entity
13 described in section 1877(a)(2) of the Social Security Act,
14 then the physician may not make a referral to the entity
15 for the furnishing of home infusion therapy services.

16 (b) INCORPORATION OF MEDICARE PHYSICIAN OWN-
17 ERSHIP AND REFERRAL PROVISIONS.—The provisions of
18 subsections (b) through (h) of section 1877 of the Social
19 Security Act (other than subsections (f) and (g)(1)) shall
20 apply with respect to subsection (a) of this section in the
21 same manner as they apply to section 1877(a) of such Act.
22 In applying the previous sentence, any reference to a “des-
23 ignated health service” is deemed to be a reference to
24 home infusion therapy services.

1 (c) TREATMENT OF PRESCRIPTION AS A REFER-
2 RAL.—In applying subsection (b) and in addition to sec-
3 tion 1877(h)(5) of the Social Security Act, the prescrip-
4 tion of a drug to be administered through home infusion
5 constitutes a “referral” by a “referring physician”.

6 **SEC. 4. HOME INFUSION THERAPY SERVICES DEFINED.**

7 For purposes of this Act, the term “home infusion
8 therapy services” means the nursing, pharmacy, and relat-
9 ed services, including medical supplies, intravenous fluids,
10 delivery, and equipment, required for the provision of
11 therapeutic agents to patients by parenteral administra-
12 tion, including intravenous, intra-arterial, subcutaneous,
13 epidural, intrathecal, intramuscular, and peritoneal infu-
14 sion, by an enteral feeding tube for the purpose of improv-
15 ing or maintaining an individual’s health condition in the
16 individual’s residence.

17 **SEC. 5. EFFECTIVE DATES.**

18 (a) LICENSING REQUIREMENT.—

19 (1) IN GENERAL.—Except as provided in para-
20 graph (2), section 3(a) shall apply to home infusion
21 therapy services provided on or after the first day of
22 the first month that begins more than 90 days after
23 the date of the enactment of this Act, without re-
24 gard to whether or not the Secretary of Health and

1 Human Services issues final regulations to carry out
2 such section have been promulgated by such date.

3 (2) In the case of a State which the Secretary
4 of Health and Human Services determines requires
5 State legislation (other than legislation appropriat-
6 ing funds) in order for the State to provide for the
7 licensing required under section 3(a), section 3(a)
8 shall not apply in the State for home infusion ther-
9 apy services provided before the first day of the first
10 calendar quarter beginning after the close of the
11 first regular session of the State legislature that be-
12 gins after the date of the enactment of this Act. For
13 purposes of the previous sentence, in the case of a
14 State that has a 2-year legislative session, each year
15 of such session shall be deemed to be a separate reg-
16 ular session of the State legislature.

17 (b) LIMITATION ON REFERRALS.—Section 4 shall
18 apply to referrals made after December 31, 1994.

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