

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 1967

To require providers of home infusion therapy services to be licensed.

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## IN THE SENATE OF THE UNITED STATES

MARCH 24 (legislative day, FEBRUARY 22), 1994

Mr. METZENBAUM introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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## A BILL

To require providers of home infusion therapy services to be licensed.

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  
10 in a State unless the person is licensed by the State in  
11 accordance with this section to provide (or arrange for the

1 provision of) such services. No State shall license such a  
2 person unless the State finds that the person meets the  
3 standards for licensing established under this section.

4 (b) STANDARDS.—

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

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

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

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

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

1 (C) adheres to written protocols and poli-  
2 cies with respect to the provision (or arrange-  
3 ment for the provision) of services;

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

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

8 (F) conducts a quality assessment and as-  
9 surance program, including drug regimen re-  
10 view and coordination of patient care;

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

15 (H) assumes responsibility for the quality  
16 of services provided by others under arrange-  
17 ments with such person;

18 (I) establishes appropriate protocols and  
19 explains such protocols clearly to patients be-  
20 fore the initiation of a treatment plan; and

21 (J) meets such other requirements as the  
22 Secretary may determine are necessary (A) to  
23 assure the safe and effective provision of home  
24 infusion therapy services, and (B) respecting

1           the quality of the provision of such services and  
2           the charges for such services.

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

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

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

1 retary shall have such procedural, investigative, and en-  
2 forcement powers in enforcing compliance with such re-  
3 quirements and may require the filing of reports, the pro-  
4 duction of documents, and the appearance of witnesses as  
5 though the applicable terms of such Act were part of this  
6 section.

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

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

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

23 (c) ADDITIONAL EXCEPTION FOR COMPENSATION  
24 ARRANGEMENT FOR MANAGEMENT OF PATIENT AND CO-  
25 ORDINATION OF CARE.—In applying subsection (b), in ad-

1 dition to the exceptions described in section 1877(e) of the  
2 Social Security Act, payment of reasonable compensation  
3 to a physician for the management of patient and coordi-  
4 nation of care shall not be considered to be a compensation  
5 arrangement described in section 1877(a)(2)(B) of such  
6 Act.

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

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

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

23 **SEC. 5. EFFECTIVE DATES.**

24 (a) LICENSING REQUIREMENT.—

1           (1) IN GENERAL.—Except as provided in para-  
2 graph (2), section 3(a) shall apply to home infusion  
3 therapy services provided on or after the first day of  
4 the first month that begins more than 90 days after  
5 the date of the enactment of this Act, without re-  
6 gard to whether or not the Secretary of Health and  
7 Human Services issues final regulations to carry out  
8 such section have been promulgated by such date.

9           (2) STATE LEGISLATION.—In the case of a  
10 State which the Secretary of Health and Human  
11 Services determines requires State legislation (other  
12 than legislation appropriating funds) in order for the  
13 State to provide for the licensing required under sec-  
14 tion 3(a), section 3(a) shall not apply in the State  
15 for home infusion therapy services provided before  
16 the first day of the first calendar quarter beginning  
17 after the close of the first regular session of the  
18 State legislature that begins after the date of the en-  
19 actment of this Act. For purposes of the previous  
20 sentence, in the case of a State that has a 2-year  
21 legislative session, each year of such session shall be  
22 deemed to be a separate regular session of the State  
23 legislature.

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

