

ASSEMBLY, No. 3477

STATE OF NEW JERSEY 213th LEGISLATURE

INTRODUCED NOVEMBER 17, 2008

Sponsored by:

Assemblywoman ELEASE EVANS

District 35 (Bergen and Passaic)

Assemblywoman CLEOPATRA G. TUCKER

District 28 (Essex)

Co-Sponsored by:

**Assemblyman Prieto, Assemblywoman Rodriguez, Assemblyman Green
and Assemblywoman Jasey**

SYNOPSIS

Restricts sale or lease of certain ultrasound equipment.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 5/22/2009)

1 AN ACT concerning ultrasound equipment and supplementing Title
2 26 of the Revised Statutes.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

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7 1. a. A person shall not sell, offer to sell, offer for promotional
8 purposes, lease, or otherwise distribute in this State an obstetric-
9 gynecologic ultrasonic imager, except to any of the following:

10 (1) a health care professional licensed pursuant to Title 45 of the
11 Revised Statutes;

12 (2) a health care facility licensed pursuant to P.L.1971, c.136
13 (C.26:2H-1 et seq.);

14 (3) a dealer, distributor, manufacturer's representative, or sales
15 agent that purchases an obstetric-gynecologic ultrasonic imager for
16 the sole purpose of selling, leasing, or otherwise distributing the
17 equipment in accordance with this act;

18 (4) a bank, leasing company, or financial institution that
19 purchases an obstetric-gynecologic ultrasonic imager from a
20 manufacturer or other person for the sole purpose of leasing the
21 system in accordance with this act; or

22 (5) an educational or research facility that purchases an
23 obstetric-gynecologic ultrasonic imager for training or research
24 purposes.

25 b. Nothing in this section shall be construed to permit a person
26 who is not so authorized under federal law or regulations to buy,
27 lease, or use an obstetric-gynecologic ultrasonic imager.

28 c. For the purposes of this section, "obstetric-gynecologic
29 ultrasonic imager" means a prescription medical device defined by
30 the federal Food and Drug Administration in 21 CFR 884.2225, the
31 use of which is regulated by the federal Food and Drug
32 Administration in the Department of Health and Human Services.

33

34 2. a. A person who violates the provisions of this act shall be
35 subject to a penalty of not less than \$500 nor more than \$1,000 for
36 each offense, to be collected by the Commissioner of Health and
37 Senior Services in a civil action through a summary proceeding
38 under the "Penalty Enforcement Law of 1999," P.L.1999, c.274
39 (C.2A:58-10 et seq.). The municipal court and the Superior Court
40 shall have jurisdiction of proceedings for the enforcement of the
41 penalty provided by this section.

42 If the violation is of a continuing nature, each day during which
43 it continues constitutes an additional, separate, and distinct offense.

44 b. The Commissioner of Health and Senior Services may
45 institute a civil action for injunctive relief to enforce this act and to
46 prohibit and prevent a violation of this act, and the court may
47 proceed in the action in a summary manner.

1 3. This act shall take effect on the 30th day after enactment.

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STATEMENT

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6 This bill prohibits the sale, lease, or distribution of an obstetric-
7 gynecologic ultrasonic imager in the State to any person other than
8 the following:

9 1. a licensed health care professional;

10 2. a licensed health care facility;

11 3. a dealer, distributor, manufacturer's representative, or sales
12 agent that purchases an obstetric-gynecologic ultrasonic imager for
13 the sole purpose of selling, leasing, or otherwise distributing the
14 equipment to a person pursuant to this act;

15 4. a bank, leasing company, or financial institution that
16 purchases an obstetric-gynecologic ultrasonic imager from a
17 manufacturer or other person for the sole purpose of leasing the
18 system to a person pursuant to this act; or

19 5. an educational or research facility that purchases an
20 obstetric-gynecologic ultrasonic imager for training or research
21 purposes.

22 A person violating the provisions of this bill is subject to a civil
23 penalty of not less than \$500 and not more than \$1,000 for each
24 offense, to be collected by the Commissioner of Health and Senior
25 Services.

26 This bill is in response to the situation in which persons are
27 acquiring and using ultrasound equipment for nonmedical purposes
28 without a physician's prescription or the proper training.
29 Ultrasound equipment is designated by the federal Food and Drug
30 Administration as a prescription medical device and should be used
31 to monitor the growth and development of a fetus only by trained
32 personnel.