

CERTIFICATION OF ENROLLMENT

SUBSTITUTE HOUSE BILL 1205

Chapter 319, Laws of 1995

54th Legislature
1995 Regular Session

PHYSICIAN SELF-REFERRAL--LIMITATIONS ON

EFFECTIVE DATE: 7/23/95

Passed by the House April 20, 1995
Yeas 96 Nays 0

CLYDE BALLARD

**Speaker of the
House of Representatives**

Passed by the Senate April 11, 1995
Yeas 46 Nays 0

JOEL PRITCHARD

President of the Senate

Approved May 11, 1995

MIKE LOWRY

Governor of the State of Washington

CERTIFICATE

I, Timothy A. Martin, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 1205** as passed by the House of Representatives and the Senate on the dates hereon set forth.

TIMOTHY A. MARTIN

Chief Clerk

FILED

May 11, 1995 - 1:11 p.m.

**Secretary of State
State of Washington**

SUBSTITUTE HOUSE BILL 1205

AS AMENDED BY THE SENATE

Passed Legislature - 1995 Regular Session

State of Washington 54th Legislature 1995 Regular Session

By House Committee on Health Care (originally sponsored by Representative Dyer; by request of Department of Social and Health Services)

Read first time 02/14/95.

1 AN ACT Relating to physician referral; amending RCW 74.09.240,
2 18.64.011, and 18.64.255; reenacting and amending RCW 18.64.165; and
3 adding new sections to chapter 18.64 RCW.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 **Sec. 1.** RCW 74.09.240 and 1979 ex.s. c 152 s 5 are each amended to
6 read as follows:

7 (1) Any person, including any corporation, that solicits or
8 receives any remuneration (including any kickback, bribe, or rebate)
9 directly or indirectly, overtly or covertly, in cash or in kind

10 (a) in return for referring an individual to a person for the
11 furnishing or arranging for the furnishing of any item or service for
12 which payment may be made in whole or in part under this chapter, or

13 (b) in return for purchasing, leasing, ordering, or arranging for
14 or recommending purchasing, leasing, or ordering any goods, facility,
15 service, or item for which payment may be made in whole or in part
16 under this chapter,

17 shall be guilty of a class C felony(~~(:—PROVIDED, That)~~); however, the
18 fine, if imposed, shall not be in an amount more than twenty-five
19 thousand dollars, except as authorized by RCW 9A.20.030.

1 (2) Any person, including any corporation, that offers or pays any
2 remuneration (including any kickback, bribe, or rebate) directly or
3 indirectly, overtly or covertly, in cash or in kind to any person to
4 induce such person

5 (a) to refer an individual to a person for the furnishing or
6 arranging for the furnishing of any item or service for which payment
7 may be made, in whole or in part, under this chapter, or

8 (b) to purchase, lease, order, or arrange for or recommend
9 purchasing, leasing, or ordering any goods, facility, service, or item
10 for which payment may be made in whole or in part under this chapter,
11 shall be guilty of a class C felony(~~(:—PROVIDED, That))~~); however, the
12 fine, if imposed, shall not be in an amount more than twenty-five
13 thousand dollars, except as authorized by RCW 9A.20.030.

14 (3)(a) Except as provided in 42 U.S.C. 1395 nn, physicians are
15 prohibited from self-referring any client eligible under this chapter
16 for the following designated health services to a facility in which the
17 physician or an immediate family member has a financial relationship:

18 (i) Clinical laboratory services;

19 (ii) Physical therapy services;

20 (iii) Occupational therapy services;

21 (iv) Radiology including magnetic resonance imaging, computerized
22 axial tomography, and ultrasound services;

23 (v) Durable medical equipment and supplies;

24 (vi) Parenteral and enteral nutrients equipment and supplies;

25 (vii) Prosthetics, orthotics, and prosthetic devices;

26 (viii) Home health services;

27 (ix) Outpatient prescription drugs;

28 (x) Inpatient and outpatient hospital services;

29 (xi) Radiation therapy services and supplies.

30 (b) For purposes of this subsection, "financial relationship" means
31 the relationship between a physician and an entity that includes
32 either:

33 (i) An ownership or investment interest; or

34 (ii) A compensation arrangement.

35 For purposes of this subsection, "compensation arrangement" means
36 an arrangement involving remuneration between a physician, or an
37 immediate family member of a physician, and an entity.

38 (c) The department is authorized to adopt by rule amendments to 42
39 U.S.C. 1395 nn enacted after the effective date of this act.

1 (d) This section shall not apply in any case covered by a general
2 exception specified in 42 U.S.C. Sec. 1395 nn.

3 (4) Subsections (1) and (2) of this section shall not apply to

4 (a) a discount or other reduction in price obtained by a provider
5 of services or other entity under this chapter if the reduction in
6 price is properly disclosed and appropriately reflected in the costs
7 claimed or charges made by the provider or entity under this chapter,
8 and

9 (b) any amount paid by an employer to an employee (who has a bona
10 fide employment relationship with such employer) for employment in the
11 provision of covered items or services.

12 (~~(4)~~) (5) Subsections (1) and (2) of this section, if applicable
13 to the conduct involved, shall supersede the criminal provisions of
14 chapter 19.68 RCW, but shall not preclude administrative proceedings
15 authorized by chapter 19.68 RCW.

16 **Sec. 2.** RCW 18.64.011 and 1989 1st ex.s. c 9 s 412 are each
17 amended to read as follows:

18 Unless the context clearly requires otherwise, definitions of terms
19 shall be as indicated when used in this chapter.

20 (1) "Person" means an individual, corporation, government,
21 governmental subdivision or agency, business trust, estate, trust,
22 partnership or association, or any other legal entity.

23 (2) "Board" means the Washington state board of pharmacy.

24 (3) "Drugs" means:

25 (a) Articles recognized in the official United States pharmacopoeia
26 or the official homeopathic pharmacopoeia of the United States;

27 (b) Substances intended for use in the diagnosis, cure, mitigation,
28 treatment, or prevention of disease in man or other animals;

29 (c) Substances (other than food) intended to affect the structure
30 or any function of the body of man or other animals; or

31 (d) Substances intended for use as a component of any substances
32 specified in (a), (b), or (c) of this subsection, but not including
33 devices or their component parts or accessories.

34 (4) "Device" means instruments, apparatus, and contrivances,
35 including their components, parts, and accessories, intended (a) for
36 use in the diagnosis, cure, mitigation, treatment, or prevention of
37 disease in man or other animals, or (b) to affect the structure or any
38 function of the body of man or other animals.

1 (5) "Nonlegend" or "nonprescription" drugs means any drugs which
2 may be lawfully sold without a prescription.

3 (6) "Legend drugs" means any drugs which are required by any
4 applicable federal or state law or regulation to be dispensed on
5 prescription only or are restricted to use by practitioners only.

6 (7) "Controlled substance" means a drug or substance, or an
7 immediate precursor of such drug or substance, so designated under or
8 pursuant to the provisions of chapter 69.50 RCW.

9 (8) "Prescription" means an order for drugs or devices issued by a
10 practitioner duly authorized by law or rule in the state of Washington
11 to prescribe drugs or devices in the course of his or her professional
12 practice for a legitimate medical purpose.

13 (9) "Practitioner" means a physician, dentist, veterinarian, nurse,
14 or other person duly authorized by law or rule in the state of
15 Washington to prescribe drugs.

16 (10) "Pharmacist" means a person duly licensed by the Washington
17 state board of pharmacy to engage in the practice of pharmacy.

18 (11) "Practice of pharmacy" includes the practice of and
19 responsibility for: Interpreting prescription orders; the compounding,
20 dispensing, labeling, administering, and distributing of drugs and
21 devices; the monitoring of drug therapy and use; the initiating or
22 modifying of drug therapy in accordance with written guidelines or
23 protocols previously established and approved for his or her practice
24 by a practitioner authorized to prescribe drugs; the participating in
25 drug utilization reviews and drug product selection; the proper and
26 safe storing and distributing of drugs and devices and maintenance of
27 proper records thereof; the providing of information on legend drugs
28 which may include, but is not limited to, the advising of therapeutic
29 values, hazards, and the uses of drugs and devices.

30 (12) "Pharmacy" means every place properly licensed by the board of
31 pharmacy where the practice of pharmacy is conducted.

32 (13) The words "drug" and "devices" shall not include surgical or
33 dental instruments or laboratory materials, gas and oxygen, therapy
34 equipment, X-ray apparatus or therapeutic equipment, their component
35 parts or accessories, or equipment, instruments, apparatus, or
36 contrivances used to render such articles effective in medical,
37 surgical, or dental treatment, or for use or consumption in or for
38 mechanical, industrial, manufacturing, or scientific applications or
39 purposes, nor shall the word "drug" include any article or mixture

1 covered by the Washington pesticide control act (chapter 15.58 RCW), as
2 enacted or hereafter amended, nor medicated feed intended for and used
3 exclusively as a feed for animals other than man.

4 (14) The word "poison" shall not include any article or mixture
5 covered by the Washington pesticide control act (chapter 15.58 RCW), as
6 enacted or hereafter amended.

7 (15) "Deliver" or "delivery" means the actual, constructive, or
8 attempted transfer from one person to another of a drug or device,
9 whether or not there is an agency relationship.

10 (16) "Dispense" means the interpretation of a prescription or order
11 for a drug, biological, or device and, pursuant to that prescription or
12 order, the proper selection, measuring, compounding, labeling, or
13 packaging necessary to prepare that prescription or order for delivery.

14 (17) "Distribute" means the delivery of a drug or device other than
15 by administering or dispensing.

16 (18) "Compounding" shall be the act of combining two or more
17 ingredients in the preparation of a prescription.

18 (19) "Wholesaler" shall mean a corporation, individual, or other
19 entity which buys drugs or devices for resale and distribution to
20 corporations, individuals, or entities other than consumers.

21 (20) "Manufacture" means the production, preparation, propagation,
22 compounding, or processing of a drug or other substance or device or
23 the packaging or repackaging of such substance or device, or the
24 labeling or relabeling of the commercial container of such substance or
25 device, but does not include the activities of a practitioner who, as
26 an incident to his or her administration or dispensing such substance
27 or device in the course of his or her professional practice, prepares,
28 compounds, packages, or labels such substance or device.

29 (21) "Manufacturer" shall mean a person, corporation, or other
30 entity engaged in the manufacture of drugs or devices.

31 (22) "Labeling" shall mean the process of preparing and affixing a
32 label to any drug or device container. The label must include all
33 information required by current federal and state law and pharmacy
34 rules.

35 (23) "Administer" means the direct application of a drug or device,
36 whether by injection, inhalation, ingestion, or any other means, to the
37 body of a patient or research subject.

38 (24) "Master license system" means the mechanism established by
39 chapter 19.02 RCW by which master licenses, endorsed for individual

1 state-issued licenses, are issued and renewed utilizing a master
2 application and a master license expiration date common to each
3 renewable license endorsement.

4 (25) "Department" means the department of health.

5 (26) "Secretary" means the secretary of health or the secretary's
6 designee.

7 (27) "Health care entity" means an organization that provides
8 health care services in a setting that is not otherwise licensed by the
9 state. Health care entity includes a free-standing outpatient surgery
10 center, a free-standing cardiac care center, or a kidney dialysis
11 center. It does not include an individual practitioner's office or a
12 multipractitioner clinic.

13 NEW SECTION. Sec. 3. A new section is added to chapter 18.64 RCW
14 to read as follows:

15 (1) In order for a health care entity to purchase, administer,
16 dispense, and deliver legend drugs, the health care entity must be
17 licensed by the department.

18 (2) In order for a health care entity to purchase, administer,
19 dispense, and deliver controlled substances, the health care entity
20 must annually obtain a license from the department in accordance with
21 the board's rules.

22 (3) The receipt, administration, dispensing, and delivery of legend
23 drugs or controlled substances by a health care entity must be
24 performed under the supervision or at the direction of a pharmacist.

25 (4) A health care entity may only administer, dispense, or deliver
26 legend drugs and controlled substances to patients who receive care
27 within the health care entity and in compliance with rules of the
28 board. Nothing in this subsection shall prohibit a practitioner, in
29 carrying out his or her licensed responsibilities within a health care
30 entity, from dispensing or delivering to a patient of the health care
31 entity drugs for that patient's personal use in an amount not to exceed
32 seventy-two hours of usage.

33 NEW SECTION. Sec. 4. A new section is added to chapter 18.64 RCW
34 to read as follows:

35 (1) The owner of a health care entity shall pay an original license
36 fee to be determined by the secretary, and annually thereafter, on or
37 before a date to be determined by the secretary, a fee to be determined

1 by the secretary, for which he or she shall receive a license of
2 location, which shall entitle the owner to purchase legend drugs or
3 controlled substances at the location specified for the period ending
4 on a date to be determined by the secretary. A declaration of
5 ownership and location filed with the department under this section
6 shall be deemed presumptive evidence of ownership of the health care
7 entity.

8 (2) The owner shall immediately notify the department of any change
9 of location or ownership in which case a new application and fee shall
10 be submitted.

11 (3) It shall be the duty of the owner to keep the license of
12 location or the renewal license properly exhibited in the health care
13 entity.

14 (4) Failure to comply with this section is a misdemeanor and each
15 day that the failure continues is a separate offense.

16 (5) In the event that a license fee remains unpaid after the date
17 due, no renewal or new license may be issued except upon payment of the
18 license renewal fee and a penalty fee equal to the original license
19 fee.

20 **Sec. 5.** RCW 18.64.165 and 1989 1st ex.s. c 9 s 404 and 1989 c 352
21 s 4 are each reenacted and amended to read as follows:

22 The board shall have the power to refuse, suspend, or revoke the
23 license of any manufacturer, wholesaler, pharmacy, shopkeeper,
24 itinerant vendor, peddler, poison distributor, health care entity, or
25 precursor chemical distributor upon proof that:

26 (1) The license was procured through fraud, misrepresentation, or
27 deceit;

28 (2) The licensee has violated or has permitted any employee to
29 violate any of the laws of this state or the United States relating to
30 drugs, controlled substances, cosmetics, or nonprescription drugs, or
31 has violated any of the rules and regulations of the board of pharmacy
32 or has been convicted of a felony.

33 NEW SECTION. **Sec. 6.** A new section is added to chapter 18.64 RCW
34 to read as follows:

35 Every proprietor or manager of a health care entity shall keep
36 readily available a suitable record of drugs, which shall preserve for
37 a period of not less than two years the record of every drug used at

1 such health care entity. The record shall be maintained either
2 separately from all other records of the health care entity or in such
3 form that the information required is readily retrievable from ordinary
4 business records of the health care entity. All record-keeping
5 requirements for controlled substances must be complied with. Such
6 record of drugs shall be for confidential use in the health care
7 entity, only. The record of drugs shall be open for inspection by the
8 board of pharmacy, who is authorized to enforce chapter 18.64, 69.41,
9 or 69.50 RCW.

10 **Sec. 7.** RCW 18.64.255 and 1984 c 153 s 14 are each amended to read
11 as follows:

12 Nothing in this chapter shall operate in any manner:

13 (1) To restrict the scope of authorized practice of any
14 practitioner other than a pharmacist, duly licensed as such under the
15 laws of this state. However, a health care entity shall comply with
16 all state and federal laws and rules relating to the dispensing of
17 drugs and the practice of pharmacy; or

18 (2) In the absence of the pharmacist from the hospital pharmacy, to
19 prohibit a registered nurse designated by the hospital and the
20 responsible pharmacist from obtaining from the hospital pharmacy such
21 drugs as are needed in an emergency: PROVIDED, That proper record is
22 kept of such emergency, including the date, time, name of prescriber,
23 the name of the nurse obtaining the drugs, and a list of what drugs and
24 quantities of same were obtained; or

25 (3) To prevent shopkeepers, itinerant vendors, peddlers, or
26 salesmen from dealing in and selling nonprescription drugs, if such
27 drugs are sold in the original packages of the manufacturer, or in
28 packages put up by a licensed pharmacist in the manner provided by the
29 state board of pharmacy, if such shopkeeper, itinerant vendor,
30 salesman, or peddler shall have obtained a registration.

Passed the House April 20, 1995.

Passed the Senate April 11, 1995.

Approved by the Governor May 11, 1995.

Filed in Office of Secretary of State May 11, 1995.