

ILLINOIS REGISTER

HEALTH FACILITIES AND SERVICES REVIEW BOARD

NOTICE OF ADOPTED AMENDMENTS

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SUBCHAPTER b: OTHER BOARD RULES

PART 1235
HEALTH CARE WORKER SELF-REFERRAL

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AUTHORITY: Implementing and authorized by the Health Care Self-Referral Act (Public Act

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87-1207, effective January 1, 1993.)

SOURCE: Emergency rule adopted 17 Ill. Reg. 402, effective January 4, 1993, for a maximum of 150 days; adopted at 17 Ill. Reg. 8498, effective June 4, 1993; amended at 41 Ill. Reg. _____, effective _____.

SUBPART A: AUTHORITY, PUBLIC HEARINGS, PURPOSE AND DEFINITIONS

Section 1235.10 Statutory Authority

This Part is promulgated by authority granted to the Illinois Health Facilities [and Services Review](#)~~Planning~~ Board (State Board or Board) under the Illinois Health Facilities Planning Act (Planning Act) (~~Ill. Rev. Stat. 1991, ch. 111½, pars. 1151 et seq.~~)[20 ILCS 3960] and under ~~Public Act 87-1207~~, the Health Care Worker Self-Referral Act [[225 ILCS 47](#)].

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.20 Public Hearings ([Repealed](#))

~~In accordance with the provisions of Section 12 of the Health Facilities Planning Act, public hearings on this Part were held on February 17, 1993. Copies of the public hearing record are available for inspection at the headquarters of the State Board at 525 West Jefferson Street, Springfield, Illinois 62761.~~

(Source: Repealed at 41 Ill. Reg. _____, effective _____)

Section 1235.30 Purpose

The General Assembly recognizes that patient referrals by health care workers for health services to an entity in which the referring health care worker has an investment interest may present a potential conflict of interest. ~~It...it~~ is the intent of the General Assembly to provide guidance to health care workers regarding acceptable patient referrals, to prohibit patient referrals to entities providing health services in which the referring health care worker has an investment interest, and to protect the citizens of Illinois from unnecessary and costly health care expenditures. ~~It...it~~ is not the intent of the General Assembly to limit appropriate delivery of care, nor force unnecessary changes in the structures created by workers for the health and convenience of their patients. [[225 ILCS 47/5](#)](~~Section 5 of the Act~~)

(Source: Amended at 41 Ill. Reg. _____, effective _____)

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Section 1235.40 Applicability

The [Health Care Worker Self-Referral Act](#) applies to referrals for health services made on or after January 1, 1993. However, if a health care worker acquired an investment interest before July 1, 1992, ~~the~~^{this} Act shall not apply to referrals made for health services before January 1, 1996. [\[225 ILCS 47/10\]](#)~~(Section 10 of the Act)~~

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.50 Definitions

The following definitions shall apply to the terms used in this Part:

"Act" means the [Health Care Worker Self-Referral Act](#). [\[225 ILCS 47\]](#)

"Board" or "State Board" means the Health Facilities [and Services Review](#)~~Planning~~ Board. [\[224 ILCS 47/15\(a\)\]](#)~~(Section 15(a) of the Act)~~

"Community" means a metropolitan area for a city, and a county for a rural area. [\[225 ILCS 47/20\(b\)\]](#)~~(Section 20(b) of the Act)~~

"Entity" means any individual, partnership, firm, corporation, or other business that provides health services but does not include an individual who is a health care worker who provides professional services to an individual. [\[225 ILCS 47/15\(b\)\]](#)~~(Section 15(b) of the Act)~~

"Group Practice" means a group of 2 or more health care workers legally organized as a partnership, professional corporation, not-for-profit corporation, faculty practice plan or a similar association in which occurs:

each health care worker who is a member or employee or an independent contractor of the group provides substantially the full range of services that the health care worker routinely provides, including consultation, diagnosis, or treatment, through the use of office space, facilities, equipment, or personnel of the group;

the services of the health care workers are provided through the group, and payments received for health services are treated as receipts of the group; [and](#)

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*the overhead expenses and the income from the practice are distributed by methods previously determined by the group. [\[225 ILCS 47/15\(c\)\]](#)
~~(Section 15(c) of the Act)~~*

"Health Care Worker" means any individual licensed under the laws of this State to provide health services, including but not limited to: dentists licensed under the Illinois Dental Practice Act [\[225 ILCS 25\]](#); dental hygienists licensed under the Illinois Dental Practice Act; nurses and advanced practice nurses licensed under the Illinois ~~Nurse Practice~~Nursing Act [\[225 ILCS 65\]](#)~~of 1987~~; occupational therapists licensed under the Illinois Occupational Therapy Practice Act [\[225 ILCS 75\]](#); optometrists licensed under the Illinois Optometric Practice Act of 1987 [\[225 ILCS 80\]](#); pharmacists licensed under the Pharmacy Practice Act [\[225 ILCS 85\]](#)~~of 1987~~; physical therapists licensed under the Illinois Physical Therapy Act [\[225 ILCS 90\]](#); physicians licensed under the Medical Practice Act of 1987 [\[225 ILCS 60\]](#); physician assistants licensed under the Physician Assistant Practice Act of 1987 [\[225 ILCS 95\]](#); podiatrists licensed under the Podiatric Medical Practice Act of 1987 [\[225 ILCS 100\]](#); clinical psychologists licensed under the Clinical Psychologist Licensing Act [\[225 ILCS 15\]](#); clinical social workers licensed under the Clinical Social Work and Social Work Practice Act [\[225 ILCS 20\]](#); speech-language pathologists and audiologists licensed under the Illinois Speech-Language Pathology and Audiology Practice Act [\[225 ILCS 110\]](#); or hearing aid dispensers licensed under the Hearing ~~Instrument~~Aid Consumer Protection Act [\[225 ILCS 50\]](#) or any of their successor Acts. [\[225 ILCS 47/15\(d\)\]](#)~~(Section 15(d) of the Act)~~

"Health Services" means health care procedures and services provided by or through a health care worker. [\[225 ILCS 47/15\(e\)\]](#)~~(Section 15(e) of the Act)~~

"Immediate Family Member" means a health care worker's spouse, child, child's spouse, or a parent. [\[225 ILCS 47/15\(f\)\]](#)~~(Section 15(f) of the Act)~~

"Investment Interest" means an equity or debt security issued by an entity, including, without limitation, shares ~~of~~ stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments except that investment interest does not include interest in a hospital licensed under the laws of the State of Illinois. [\[225 ILCS 47/15\(g\)\]](#)~~(Section 15(g) of the Act)~~

"Investor" means an individual or entity directly or indirectly owning a legal or beneficial ownership or investment interest; (such as through an immediate family

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member, trust, or another entity related to the investor). [\[225 ILCS 47/15\(h\)\]](#)~~(Section 15(h) of the Act)~~

"Metropolitan Area" means a geographically identified area consisting of community areas or townships (as applicable) not to exceed a population of 50,000 people.

"Office Practice" includes the facility or facilities at which a health care worker, on an ongoing basis, provides or supervises the provision of professional health services to individuals. [\[225 ILCS 47/15\(i\)\]](#)~~(Section 15(i) of the Act)~~

"Referral" means any referral of a patient for health services, including, without limitation:

The forwarding of a patient by one health care worker to another health care worker or to an entity outside the health care worker's office practice or group practice that provides health services. ~~(Section 15(j) of the Act)~~

The request or establishment by a health care worker of a plan of care outside the health care worker's office practice or group practice that includes the provision of any health services. [\[225 ILCS 47/15\(j\)\]](#)~~(Section 15(j) of the Act)~~

"Rural Area" means any geographic area located outside a metropolitan statistical area as defined by the U.S. Census Bureau.

(Source: Amended at 41 Ill. Reg. _____, effective _____)

SUBPART B: REFERRALS

Section 1235.100 Prohibited Referrals

The following patient referrals are prohibited under the Act:

- a) patient referrals *to an entity outside the health care worker's office or group practice in which the health care worker is an investor, unless:*
 - 1) *the health care worker directly provides health services within the entity and will be personally involved with the provision of care to the referred patient* [\[225 ILCS 47/20\(a\)\]](#)~~(Section 20(a) of the Act)~~, or

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- 2) the State Board approves an exception pursuant to Section 1235.200;
- b) patient referrals to another health care worker or entity based upon the condition that the health care worker or entity will make referrals with an intent to evade the prohibitions of the ~~Self-Referral Act~~ by inducing patient referrals ~~that~~~~which~~ would be prohibited if the health care worker or entity made the referral directly [\[225 ILCS 47/20\(e\)\]](#)~~(Section 20(e) of the Act)~~;
- c) patient referrals to a publicly traded entity in which the health care worker has an investment interest that does not comply with the following provisions:
 - 1) *The entity is listed for trading on the New York Stock Exchange or on the American Stock Exchange, or is a national market system security traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers* [\[225 ILCS 47/20\(c\)\(1\)\]](#)~~(Section 20(e)(1) of the Act)~~; and
 - 2) *The entity had, at the end of the corporation's most recent fiscal year, total net assets of at least \$30,000,000 related to the furnishing of health services* [\[225 ILCS 47/20\(c\)\(2\)\]](#)~~(Section 20(e)(2) of the Act)~~; and
 - 3) *Any investment interest obtained after January 1, 1993 is traded on the exchanges listed in ~~subsection~~~~Section 1235.100(c)(1)-above~~ after the entity became a publicly traded corporation* [\[225 ILCS 47/20\(c\)\(3\)\]](#)~~(Section 20(e)(3) of the Act)~~; and
 - 4) *The entity markets or furnishes its services to referring health care worker investors and other health care workers on equal terms* [\[225 ILCS 47/20\(c\)\(4\)\]](#)~~(Section 20(e)(4) of the Act)~~; and
 - 5) *All stock held in such publicly traded companies, including stock held in the predecessor privately held company, shall be of one class without preferential treatment as to status or remuneration* [\[225 ILCS 47/20\(c\)\(5\)\]](#)~~(Section 20(e)(5) of the Act)~~; and
 - 6) *The entity does not loan funds or guarantee any loans for health care workers who are in a position to be referred to an entity* [\[225 ILCS 47/20\(c\)\(6\)\]](#)~~(Section 20(e)(6) of the Act)~~; and

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- 7) *The income on the health care worker's investment is tied to the health care worker's equity in the entity rather than to the volume of referrals made [\[225 ILCS 47/20\(c\)\(7\)\]](#) ~~(Section 20(c)(7) of the Act)~~; and*
- 8) *The investment interest does not exceed 1/2 of 1% of the entity's total equity. [\[225 ILCS 47/20\(c\)\(8\)\]](#) ~~(Section 20(c)(8) of the Act)~~*

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.110 Allowable Referrals

All patient referrals other than those prohibited by Section 1235.100 are allowable under the Act. In addition, *a health care worker may refer a patient, who is a member of a health maintenance organization ("~~HMO~~") licensed in this State, for health services to ~~an~~any entity, outside the health care worker's office or group practice, in which the health care worker is an investor, provided that any such referral is made pursuant to a contract with the HMO. [\[225 ILCS 47/20\(h\)\]](#) ~~(Section 20(h) of the Act)~~*

(Source: Amended at 41 Ill. Reg. _____, effective _____)

SUBPART C: COMMUNITY NEED EXCEPTION

Section 1235.200 Introduction

One of the stated goals of the ~~Health Care Worker Self-Referral~~ Act is to *"prohibit patient referrals to entities providing health services in which the referring health care worker has an investment interest"*. [\[225 ILCS 47/5\]](#) ~~(Section 5 of the Act)~~ This provision can be tempered through the use of an exception for community need. ~~As a concept~~ community need can be segmented into two principal components: need for a particular service and the existence and availability of alternative financing. An applicant for a community need exception must document compliance with both principal components.

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.210 Community Need

- a) A health care worker may invest in, and refer to, an entity if the State Board determines that:
 - 1) in a referral arrangement, alternative financing does not exist; and

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- 2) ~~that~~ a demonstrated need for the service is present in the community.
- b) The health care worker must document any of the following to demonstrate community need:
- 1) there is no other entity within the community that provides the medical service proposed; ~~or~~
- 2) if the health service currently exists within the community, the use of these facilities can be shown to be a hardship for patients due to factors such as excessive (over 45 minutes) travel time to obtain service, existing admission or treatment policies of other entities ~~that~~which restrict the availability of the service, or perceived quality concerns by the general public involving existing providers ~~that~~which restrict the use of ~~the~~such services; or
- 3) *the entity is formed to own or lease medical equipment ~~that~~which will replace obsolete or otherwise inadequate equipment that is in or under the control of a hospital located in a federally designated health manpower shortage area [\[225 ILCS 47/20\(b\)\(3\)\]](#) ~~(Section 20(b)(3) of the Act)~~ as documented by:*
- A) excessive downtime and high maintenance costs; or
- B) the equipment representing an advancement in technology ~~that~~which will make available medical procedures not possible on existing equipment.

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.220 Alternative Financing

- a) A health care worker may invest in and refer to an entity if the State Board determines a demonstrated community need exists and ~~that~~ alternative financing is not₁ or was not₁ available.
- b) The health care worker must document that:
- 1) *individuals who are not in a position to refer patients to an entity are or*

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were given a bona fide opportunity to also invest in the entity on the same terms as those offered a referring health care worker [\[225 ILCS 47/20\(b\)\(1\)\]](#)~~(Section 20(b)(1) of the Act)~~; and ~~that~~

- 2) ~~the~~[such](#) investment was not forthcoming.
- c) Documentation shall consist of copies of all information that supports this position.

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.230 Assurances

In addition to documenting compliance with [Sections](#) 1235.210 and 1235.220, a health care worker must document compliance with the assurances and conditions of this Section. Documentation shall consist of a written profile ~~demonstrating as to~~ how compliance will occur and copies of all supporting documentation. Assurances and conditions are [that](#):

- a) ~~That~~ no health care worker who invests shall be required or encouraged to make referrals to the entity or otherwise generate business as a condition of becoming or remaining an investor; ~~and~~
- b) ~~That~~ the entity shall market or furnish its services to referring health care worker investors and other investors on equal terms; ~~and~~
- c) ~~That~~ the entity shall not loan funds or guarantee any loans for health care workers who are in a position to refer to an entity; ~~and~~
- d) ~~That~~ the income on the health care worker's investment shall be tied to the health care worker's equity in the facility, rather than to the volume of referrals made; ~~and~~
- e) ~~That~~ any investment contract between the entity and the health care worker shall not include any covenant or non-competition clause that prevents a health care worker from investing in other entities; ~~and~~
- f) ~~That~~ when making a referral, a health care worker must disclose his [or her](#) investment interest in an entity to the patient being referred to ~~that~~[such](#) entity. If alternative facilities are reasonably available, the health care worker must provide the patient with a list of alternative facilities. The health care worker

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shall inform patients that they have the option to use an alternative facility other than one in which the health care worker has an investment interest. ~~The and the~~ patient will not be treated differently by the health care worker if the patient chooses to use another entity. This shall be applicable to all health care worker investors, including those who provide direct care or services for their patients in entities outside their office practices; ~~and~~

- g) ~~That~~ *if a third party payer requests information with regard to a health care worker's investment interest, the same shall be disclosed; ~~and~~*
- h) ~~That~~ *the entity shall establish an internal utilization review program to ensure that investing health care workers provided appropriate or necessary utilization; ~~and~~*
- i) ~~That~~ *if a health care worker's financial interest in an entity is incompatible with a referred patient's interest, the health care worker shall make alternative arrangements for the patient's care [\[225 ILCS 47/20\(b\)\(2\) through \(10\)\]](#) ~~(Section 20(b) of the Act)~~; and*
- j) ~~That~~ *all documentation required by the State Board to confirm that all assurances have been met will be provided upon request for a period of two years following exception issuance.*

(Source: Amended at 41 Ill. Reg. _____, effective _____)

Section 1235.240 Application for Exception – Completeness Review

- a) Each application for exception must be submitted to the State Board in writing at ~~the offices of the Executive Secretary~~, 525 W. Jefferson Street, [2nd Floor](#), Springfield IL 62761.
- b) The application must contain the following information in order to be complete:
 - 1) The name and identifying information of the health care worker requesting the exception;
 - 2) The information and documentation regarding community need required in Section 1235.210;
 - 3) The information and documentation regarding alternative financing

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required in Section 1235.220;

- 4) Documentation of the assurances required in Section 1235.230;
 - 5) Certification and notarized signature of the applicant health care worker that the information and documentation contained in the application for exception is true and correct to the best of his or her information and belief.
- c) ~~Board staff~~~~The Executive Secretary~~ shall review the application to determine if all required information ~~of completion~~ has been submitted. ~~Board staff~~~~The Executive Secretary~~ may request the health care worker to submit additional information regarding completion.
 - d) ~~The Executive Secretary shall provide to the State Board a copy of the application and any additional information received from the health care worker for a determination of completeness. The State Board staff shall determine whether the request is substantially complete within 10~~~~have no more than 45~~ days from ~~receiving~~~~the date of receipt of~~ the application for exception ~~to determine completeness. A determination of completeness requires seven affirmative votes and shall be based on a finding by the State Board that the health care worker has provided the required information. Failure to obtain seven affirmative votes results in a finding that the application is incomplete.~~
 - e) A health care worker may submit additional information to the State Board for an application for exception ~~that~~~~which~~ has been deemed incomplete. ~~The State Board staff~~ shall re-evaluate the application for completeness based upon the additional information received. Any application for exception ~~that~~~~which~~ is not complete within ~~30~~~~60~~ days ~~after~~~~of~~ a State Board finding of incompleteness shall be null and void and considered withdrawn.
 - f) All information submitted in conjunction with an application for exception shall be considered public information and shall be subject to disclosure ~~in the course of the State Board deliberations in conformance with the provisions of the Open Meetings Act [5 ILCS 120). Such information may be further disclosed in~~ conformance with the provisions of the Freedom of Information Act [5 ILCS 140]) and ~~2 Ill. Adm. Code 1925~~~~the rules and regulations promulgated thereunder.~~

(Source: Amended at 41 Ill. Reg. _____, effective _____)

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Section 1235.250 Application for Exception – State Board Review

- a) The State Board shall approve or deny an application for exception within 90 days from the date on which the application was deemed complete. Failure to act on an application within the 90 day review period, *shall mean that no alternative is practical based upon the ~~facts~~ factors set forth in the completed application and shall constitute approval of the application.* [225 ILCS 47/20(b)] (~~Section 20(b) of the Act~~)
- b) During the course of review, the State Board may request supplemental information from the health care worker. The State Board may, within the 90 day review period, defer action on the application until ~~such time as~~ the supplemental information has been received.
- ~~e) Approval of an application for exception requires seven affirmative votes and shall be based on a finding by the State Board that the health care worker has documented compliance with the provisions of this Subpart and the Act. Failure to obtain seven affirmative votes shall constitute denial of the application for exception.~~
- ~~c~~d) Action taken by the State Board on an application for exception shall constitute a final administrative decision ~~and shall be~~ subject to the provisions of the Administrative Review Law [735 ILCS 5/Art. III].
- ~~d~~e) Pursuant to an approved application for exception, a health care worker may invest in, and refer patients to, the specific entity identified in the application, whether or not the health care worker provides direct services within ~~that said~~ entity, based upon his or her having demonstrated community need for the entity and the unavailability of alternative financing.

(Source: Amended at 41 Ill. Reg. _____, effective _____)

SUBPART D: STATE BOARD ADVISORY OPINIONS

Section 1235.310 Request for Opinion – Completeness Review

- a) A request for an advisory opinion must be made by a health care worker, in writing, on forms ~~as may be~~ prescribed by the State Board and submitted to the State Board at Office of the Executive Secretary, 525-535 West Jefferson Street, 2nd Floor, Springfield IL, Illinois 62761.

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- b) The request must contain the following information in order to be complete:
- 1) The name and identifying information of the health care worker requesting the opinion;
 - 2) Identification of the entity and description of the health care services being provided or proposed by or through the entity;
 - 3) The type and amount of existing or proposed investment interest in the entity;
 - 4) A description of the nature of the investment interest and copies of any existing or proposed documents between the health care worker and the entity, including ~~but not limited to~~ leases, contracts, organizational documents, etc.
 - 5) Certification and notarized signature of the health care worker requesting the opinion that the information contained in the request for opinion and supporting documentation is true and correct to the best of his or her information and belief.
- c) ~~Board staff~~Board staff~~The Executive Secretary~~ shall review the request to determine whether all required information has been submitted. ~~Board staff~~Board staff~~The Executive Secretary~~ may request the health care worker to submit additional information.
- d) ~~Board staff~~Board staff~~The Executive Secretary~~ shall submit a copy of the request for advisory opinion and any additional information received from the health care worker to the State Board. ~~The State Board~~ shall determine whether the request is substantially complete within ~~10~~45 days ~~after receiving~~ after receiving ~~from the date of receipt of~~ the request for advisory opinion. ~~A determination of completeness requires seven affirmative votes and shall be based on a finding by the State Board that the health care worker has provided the required information. A request which fails to receive seven affirmative votes shall be deemed incomplete.~~
- e) A health care worker may submit additional information to the State Board for a request for advisory opinion ~~that~~which has been deemed incomplete. ~~The State Board~~ staff shall re-evaluate the request for completeness based upon the additional information received. Any incomplete request for advisory opinion ~~that~~which is not complete within ~~30~~60 days ~~after~~of a State Board determination

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shall be considered withdrawn.

- f) All information submitted in conjunction with a request for advisory opinion shall be considered public information and shall be subject to disclosure ~~in the course of the State Board deliberations in conformance with the provisions of the Open Meetings Act [5 ILCS 120]. Such information may be further disclosed in~~ conformance with the provisions of the Freedom of Information Act [5 ILCS 140] and [2 Ill. Adm. Code 1925](#) ~~the rules and regulations promulgated thereunder.~~

(Source: Amended at 41 Ill. Reg. _____, effective _____)