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By: **Senators Dyson, Colburn, Lenett, Middleton, and Zirkin** Introduced and read first time: February 1, 2008 Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 Patient Referrals – Imaging and Radiation Therapy Services – Accreditation

- 3 FOR the purpose of altering the definition of "in-office ancillary services" as it relates 4 to certain referrals by certain health care practitioners so as to include magnetic resonance imaging services, radiation therapy services, and computed 5 6 tomography scan services; altering certain exceptions to certain patient referral 7 prohibitions; requiring health care entities that furnish magnetic resonance 8 imaging services, radiation therapy services, and computed tomography scan 9 services to receive accreditation from certain organizations by certain dates; 10 authorizing the provisional accreditation of certain health care entities; requiring certain health care entities to maintain certain standards and make 11 available evidence of accreditation; defining a certain term; and generally 12 relating to the referral of patients for resonance imaging services, radiation 13 14 therapy services, and computed tomography scan services.
- 15 BY repealing and reenacting, with amendments,
- 16 Article Health Occupations
- 17 Section 1–301, 1–302, 1–303
- 18 Annotated Code of Maryland
- 19 (2005 Replacement Volume and 2007 Supplement)
- 20 BY adding to
- 21 Article Health Occupations
- Section 1–701 to be under the new subtitle "Subtitle 7. Accreditation of
 Business Entities that Furnish Magnetic Resonance Imaging Services,
 Computer Tomography Scan Services, and Radiation Therapy Services"
- 25 Annotated Code of Maryland
- 26 (2005 Replacement Volume and 2007 Supplement)



²⁷ SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF 28 MARYLAND, That the Laws of Maryland read as follows:

	2 SENATE BILL 708					
1	Article – Health Occupations					
2	1–301.					
3	(a) In this subtitle the following words have the meanings indicated.					
4 5	(b) (1) "Beneficial interest" means ownership, through equity, debt, or other means, of any financial interest.					
6 7 8	debt, or other means, of securities, including shares or bonds, debentures, or other					
9 10	(i) In a corporation that is traded on a national exchange or over the counter on the national market system;					
$\begin{array}{c} 11 \\ 12 \end{array}$	(ii) That at the time of acquisition, were purchased at the same price and on the same terms generally available to the public;					
$13 \\ 14 \\ 15$	refer patients to the health care entity on the same terms that are offered to health					
$\begin{array}{c} 16 \\ 17 \end{array}$	(iv) $$ That are unrelated to the past or expected volume of referrals from the health care practitioner to the health care entity; and					
18 19	(v) That are not marketed differently to health care practitioners that may make referrals than they are marketed to other individuals.					
$20 \\ 21 \\ 22$	(c) (1) "Compensation arrangement" means any agreement or system involving any remuneration between a health care practitioner or the immediate family member of the health care practitioner and a health care entity.					
23	(2) "Compensation arrangement" does not include:					
$24 \\ 25 \\ 26$	(i) Compensation or shares under a faculty practice plan or a professional corporation affiliated with a teaching hospital and comprised of health care practitioners who are members of the faculty of a university;					
27 28 29	(ii) Amounts paid under a bona fide employment agreement between a health care entity and a health care practitioner or an immediate family member of the health care practitioner;					
$30 \\ 31 \\ 32$	(iii) An arrangement between a health care entity and a health care practitioner or the immediate family member of a health care practitioner for the provision of any services, as an independent contractor, if:					

1			1.	The arrangement is for identifiable services;	
$2 \\ 3 \\ 4 \\ 5$	2. The amount of the remuneration under the arrangement is consistent with the fair market value of the service and is not determined in a manner that takes into account, directly or indirectly, the volume or value of any referrals by the referring health care practitioner; and				
6 7 8	3. The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the health care provider;				
9 10 11 12	(iv) Compensation for health care services pursuant to a referral from a health care practitioner and rendered by a health care entity, that employs or contracts with an immediate family member of the health care practitioner, in which the immediate family member's compensation is not based on the referral;				
13 14 15 16 17	(v) An arrangement for compensation which is provided by a health care entity to a health care practitioner or the immediate family member of the health care practitioner to induce the health care practitioner or the immediate family member of the health care practitioner to relocate to the geographic area served by the health care entity in order to be a member of the medical staff of a hospital, if:				
18 19 20	1. The health care practitioner or the immediate family member of the health care practitioner is not required to refer patients to the health care entity;				
21 22 23 24	0			The amount of the compensation under the ed in a manner that takes into account, directly or lue of any referrals by the referring health care	
25 26 27	practitioner to me a practitioner;	et com	3. munity	The health care entity needs the services of the health care needs and has had difficulty in recruiting	
28 29	payments are:	(vi)	Paym	ents made for the rental or lease of office space if the	
30			1.	At fair market value; and	
31			2.	In accordance with an arm's length transaction;	
32 33	payments are:	(vii)	Paym	ents made for the rental or lease of equipment if the	
34			1.	At fair market value; and	
35			2.	In accordance with an arm's length transaction; or	

$egin{array}{c} 1 \ 2 \end{array}$	(viii) Payments made for the sale of property or a health care practice if the payments are:
3	1. At fair market value;
4	2. In accordance with an arm's length transaction; and
5 6	3. The remuneration is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made.
7 8 9	(d) "Direct supervision" means a health care practitioner is present on the premises where the health care services or tests are provided and is available for consultation within the treatment area.
$10 \\ 11 \\ 12$	(e) "Faculty practice plan" means a tax exempt organization established under Maryland law by or at the direction of a university to accommodate the professional practice of members of the faculty who are health care practitioners.
$13 \\ 14 \\ 15$	(f) "Group practice" means a group of two or more health care practitioners legally organized as a partnership, professional corporation, foundation, not–for–profit corporation, faculty practice plan, or similar association:
16 17 18 19	(1) In which each health care practitioner who is a member of the group provides substantially the full range of services which the practitioner routinely provides through the joint use of shared office space, facilities, equipment, and personnel;
20 21 22 23	(2) For which substantially all of the services of the health care practitioners who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and
$24 \\ 25 \\ 26$	(3) In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined on an annual basis by members of the group.
$\begin{array}{c} 27 \\ 28 \end{array}$	(g) "Health care entity" means a business entity that provides health care services for the:
29 30	(1) Testing, diagnosis, or treatment of human disease or dysfunction; or
$\frac{31}{32}$	(2) Dispensing of drugs, medical devices, medical appliances, or medical goods for the treatment of human disease or dysfunction.

1 (h) "Health care practitioner" means a person who is licensed, certified, or 2 otherwise authorized under this article to provide health care services in the ordinary 3 course of business or practice of a profession.

4 (i) "Health care service" means medical procedures, tests and services 5 provided to a patient by or through a health care entity.

- 6 (j) "Immediate family member" means a health care practitioner's:
- 7 (1) Spouse;
- 8 (2) Child;
- 9 (3) Child's spouse;
- 10 (4) Parent;
- 11 (5) Spouse's parent;
- 12 (6) Sibling; or
- 13 (7) Sibling's spouse.

(k) (1) "In-office ancillary services" means those basic health care services
 and tests routinely performed in the office of one or more health care practitioners.

16 (2) (I) [Except for a radiologist group practice or an office 17 consisting solely of one or more radiologists, "in-office ancillary services" does not 18 include:

19 (i) Magnetic] "IN-OFFICE ANCILLARY SERVICES" INCLUDES
 20 MAGNETIC resonance imaging services [;

21

(ii) Radiation], **RADIATION** therapy services [;], or

[(iii) Computer] COMPUTER tomography scan services, IF THE
 HEALTH CARE ENTITY FURNISHING THE SERVICES MEETS THE ACCREDITATION
 REQUIREMENTS SET FORTH IN TITLE 1, SUBTITLE 6 OF THIS ARTICLE; AND

(II) THE HEALTH CARE ENTITY FURNISHING THE SERVICES
 IS A RADIOLOGIST GROUP PRACTICE OR AN OFFICE CONSISTING SOLELY OF ONE
 OR MORE RADIOLOGISTS; OR

(III) THE SERVICES ARE PROVIDED IN COMPLIANCE WITH §
 1-302(D)(4)(I)4 AND (II)2 OF THIS SUBTITLE.

1 "PERSONALLY SUPERVISED" MEANS THE RESPONSIBILITY OF A (L) $\mathbf{2}$ HEALTH CARE PRACTITIONER TO EXERCISE **ON-SITE SUPERVISION OR** 3 IMMEDIATELY **AVAILABLE** DIRECTION **EMPLOYEES** FOR PERFORMING 4 IN-OFFICE ANCILLARY SERVICES OR TESTS AS A RESULT OF A REFERRAL TO $\mathbf{5}$ THE HEALTH CARE PRACTITIONER.

6 [(1)] (M) (1) "Referral" means any referral of a patient for health care 7 services.

- 8
- (2) "Referral" includes:

9 (i) The forwarding of a patient by one health care practitioner 10 to another health care practitioner or to a health care entity outside the health care 11 practitioner's office or group practice; or

12 (ii) The request or establishment by a health care practitioner of 13 a plan of care for the provision of health care services outside the health care 14 practitioner's office or group practice.

15 1–302.

16 (a) Except as provided in subsection (d) of this section, a health care 17 practitioner may not refer a patient, or direct an employee of or person under contract 18 with the health care practitioner to refer a patient to a health care entity:

19 (1) In which the health care practitioner or the practitioner in 20 combination with the practitioner's immediate family owns a beneficial interest;

21 (2) In which the practitioner's immediate family owns a beneficial 22 interest of 3 percent or greater; or

(3) With which the health care practitioner, the practitioner's
immediate family, or the practitioner in combination with the practitioner's immediate
family has a compensation arrangement.

(b) A health care entity or a referring health care practitioner may not
present or cause to be presented to any individual, third party payor, or other person a
claim, bill, or other demand for payment for health care services provided as a result of
a referral prohibited by this subtitle.

30 (c) Subsection (a) of this section applies to any arrangement or scheme, 31 including a cross-referral arrangement, which the health care practitioner knows or 32 should know has a principal purpose of assuring indirect referrals that would be in 33 violation of subsection (a) of this section if made directly.

34 (d) The provisions of this section do not apply to:

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$\begin{array}{c}1\\2\\3\end{array}$	(1) A health care practitioner when treating a member of a health maintenance organization as defined in § 19–701 of the Health – General Article if the health care practitioner does not have a beneficial interest in the health care entity;
4 5	(2) A health care practitioner who refers a patient to another health care practitioner in the same group practice as the referring health care practitioner;
6 7 8 9	(3) A health care practitioner with a beneficial interest in a health care entity who refers a patient to that health care entity for health care services or tests, if the services or tests are personally performed by or under the direct supervision of the referring health care practitioner;
10 11	(4) A health care practitioner who refers in-office ancillary services or tests that are:
12	(i) 1. Personally furnished by:
13	[1.] A. The referring health care practitioner;
$\begin{array}{c} 14 \\ 15 \end{array}$	[2.] B. A health care practitioner in the same group practice as the referring health care practitioner; or
16 17 18	[3.] C. An individual who is employed and personally supervised by the qualified referring health care practitioner or a health care practitioner in the same group practice as the referring health care practitioner; OR
19 20 21 22 23 24	2. FOR MAGNETIC RESONANCE IMAGING SERVICES, RADIATION THERAPY SERVICES, AND COMPUTER TOMOGRAPHY SCAN SERVICES, PERSONALLY FURNISHED BY AN INDIVIDUAL WHO IS EMPLOYED AND PERSONALLY SUPERVISED BY THE QUALIFIED REFERRING HEALTH CARE PRACTITIONER OR A HEALTH CARE PRACTITIONER IN THE SAME GROUP PRACTICE AS THE REFERRING HEALTH CARE PRACTITIONER;
25	(ii) Provided [in]:
26 27 28	1. IN the same building where the referring health care practitioner or a health care practitioner in the same group practice as the referring health care practitioner furnishes services; [and] OR
29 30 31 32 33 34	2. FOR MAGNETIC RESONANCE IMAGING SERVICES, RADIATION THERAPY SERVICES, AND COMPUTER TOMOGRAPHY SCAN SERVICES, DURING THE REGULAR OFFICE HOURS MAINTAINED BY THE QUALIFIED REFERRING HEALTH CARE PRACTITIONER OR A HEALTH CARE PRACTITIONER IN THE SAME GROUP PRACTICE AS THE REFERRING HEALTH CARE PRACTITIONER IN THE SAME BUILDING WHERE THE REFERRING HEALTH CARE

1PRACTITIONER OR A HEALTH CARE PRACTITIONER IN THE SAME GROUP2PRACTICE FURNISHES SERVICES; AND

3 (iii) Billed by:

4 1. The health care practitioner performing or 5 supervising the services; or

6 2. A group practice of which the health care practitioner 7 performing or supervising the services is a member;

8 (5) A health care practitioner who has a beneficial interest in a health 9 care entity if, in accordance with regulations adopted by the Secretary:

(i) The Secretary determines that the health care practitioner's
 beneficial interest is essential to finance and to provide the health care entity; and

12 (ii) The Secretary, in conjunction with the Maryland Health 13 Care Commission, determines that the health care entity is needed to ensure 14 appropriate access for the community to the services provided at the health care 15 entity;

16 (6) A health care practitioner employed or affiliated with a hospital, 17 who refers a patient to a health care entity that is owned or controlled by a hospital or 18 under common ownership or control with a hospital if the health care practitioner does 19 not have a direct beneficial interest in the health care entity;

20 (7) A health care practitioner or member of a single specialty group 21 practice, including any person employed or affiliated with a hospital, who has a 22 beneficial interest in a health care entity that is owned or controlled by a hospital or 23 under common ownership or control with a hospital if:

(i) The health care practitioner or other member of that single
specialty group practice provides the health care services to a patient pursuant to a
referral or in accordance with a consultation requested by another health care
practitioner who does not have a beneficial interest in the health care entity; or

(ii) The health care practitioner or other member of that single
specialty group practice referring a patient to the facility, service, or entity personally
performs or supervises the health care service or procedure;

31 (8) A health care practitioner with a beneficial interest in, or 32 compensation arrangement with, a hospital or related institution as defined in § 33 19–301 of the Health – General Article or a facility, service, or other entity that is 34 owned or controlled by a hospital or related institution or under common ownership or 35 control with a hospital or related institution if:

1 (i) The beneficial interest was held or the compensation $\mathbf{2}$ arrangement was in existence on January 1, 1993; and 3 (ii) Thereafter the beneficial interest compensation or 4 arrangement of the health care practitioner does not increase; 5 A health care practitioner when treating an enrollee of a (9) provider-sponsored organization as defined in § 19-7A-01 of the Health - General 6 7 Article if the health care practitioner is referring enrollees to an affiliated health care 8 provider of the provider-sponsored organization; 9 A health care practitioner who refers a patient to a dialysis facility, (10)10 if the patient has been diagnosed with end stage renal disease as defined in the Medicare regulations pursuant to the Social Security Act; or 11 12A health care practitioner who refers a patient to a hospital in (11)13which the health care practitioner has a beneficial interest if: 14 The health care practitioner is authorized to perform (i) 15services at the hospital; and 16 The ownership or investment interest is in the hospital itself (ii) 17and not solely in a subdivision of the hospital. 18 (e)A health care practitioner exempted from the provisions of this section in 19 accordance with subsection (d) shall be subject to the disclosure provisions of § 1–303 of this subtitle. 20 211 - 303.22Except as provided in subsection (c) of this section and Title 12 of this (a) article, a health care practitioner making a lawful referral shall disclose the existence 23 $\mathbf{24}$ of the beneficial interest in accordance with provisions of this section. 25Prior to referring a patient to a health care entity in which the (b) 26 practitioner, the practitioner's immediate family, or the practitioner in combination 27with the practitioner's immediate family owns a beneficial interest, the health care practitioner shall: 2829 Except if an oral referral is made by telephone, provide the patient (1)30 with a written statement that: 31Discloses the existence of the ownership of the beneficial (i) interest or compensation arrangement; 3233 States that the patient may choose to obtain the health care (ii) 34service from another health care entity; and

$rac{1}{2}$	(iii) Requires the patient to acknowledge in writing receipt of the statement;
$\frac{3}{4}$	(2) Except if an oral referral is made by telephone, insert in the medical record of the patient a copy of the written acknowledgement;
5 6 7 8	(3) Place on permanent display a written notice that is in a typeface that is large enough to be easily legible to the average person from a distance of 8 feet and that is in a location that is plainly visible to the patients of the health care practitioner disclosing all of the health care entities:
9 10 11	(i) In which the practitioner, the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family owns a beneficial interest; and
12	(ii) To which the practitioner refers patients; and
13	(4) Documents in the medical record of the patient that:
14	(i) A valid medical need exists for the referral; and
$\begin{array}{c} 15\\ 16\end{array}$	(ii) The practitioner has disclosed the existence of the beneficial interest to the patient.
17	(c) The provisions of this section do not apply to:
18 19 20 21	(1) A health care practitioner when treating a member of a health maintenance organization as defined in § 19–701 of the Health – General Article and the health care practitioner does not have a beneficial interest in the health care entity; or
22	(2) A health care practitioner who refers a patient:
$\begin{array}{c} 23\\ 24 \end{array}$	$(i) \qquad \mbox{To another health care practitioner in the same group} \label{eq:integration} practice as the referring health care practitioner;}$
25 26	(ii) For in-office ancillary services, EXCEPT IN-OFFICE ANCILLARY SERVICES AS DEFINED UNDER § 1-301(K)(2); or
27 28	(iii) For health care services provided through or by a health care entity owned or controlled by a hospital.
29 30 31	(d) A health care practitioner who fails to comply with any provision of this section is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$5,000.

SUBTITLE 7. ACCREDITATION OF BUSINESS ENTITIES THAT FURNISH MAGNETIC RESONANCE IMAGING SERVICES, COMPUTER TOMOGRAPHY SCAN SERVICES, AND RADIATION THERAPY SERVICES.

4 **1–701.**

5 (A) IN THIS SECTION, "HEALTH CARE ENTITY" HAS THE MEANING 6 STATED IN § 1–301(G) OF THIS TITLE.

7 **(B)** EXCEPT AS OTHERWISE PROVIDED IN SUBSECTIONS (C) AND (D) OF 8 THIS SECTION, A HEALTH CARE ENTITY THAT FURNISHES MAGNETIC 9 **RESONANCE IMAGING SERVICES, COMPUTER TOMOGRAPHY SCAN SERVICES, OR** RADIATION THERAPY SERVICES SHALL BE ACCREDITED TO PROVIDE THE 10 SERVICES BY THE AMERICAN COLLEGE OF RADIOLOGY, THE AMERICAN 11 12**COLLEGE OF RADIATION ONCOLOGY, THE INTERSOCIETAL ACCREDITATION** 13COMMISSION, OR ANOTHER NATIONALLY RECOGNIZED ACCREDITATION 14 ORGANIZATION, AS APPROPRIATE, WHOSE ACCREDITATION STANDARDS HAVE 15BEEN REVIEWED AND DEEMED ADEQUATE BY THE DEPARTMENT FOR MAGNETIC 16 RESONANCE IMAGING, COMPUTER TOMOGRAPHY SCAN SERVICES, OR 17 **RADIATION THERAPY SERVICES.**

18 (1) **(C)** ANY HEALTH CARE ENTITY THAT BEGINS FURNISHING 19 MAGNETIC RESONANCE IMAGING SERVICES, COMPUTER TOMOGRAPHY SCAN 20SERVICES, OR RADIATION THERAPY SERVICES AFTER OCTOBER 1, 2008, SHALL 21FILE AN APPLICATION FOR ACCREDITATION WITH ONE OF THE APPROPRIATE 22ACCREDITING ORGANIZATIONS SET FORTH IN SUBSECTION (B) OF THIS SECTION 23BY APRIL 1, 2010, OR WITHIN 12 MONTHS OF THE DATE ON WHICH THE HEALTH 24CARE ENTITY BEGINS FURNISHING THE SERVICES, WHICHEVER PERIOD 25EXPIRES LATER.

(2) ANY HEALTH CARE ENTITY THAT FURNISHED MAGNETIC
RESONANCE IMAGINE SERVICES, COMPUTER TOMOGRAPHY SCAN SERVICES, OR
RADIATION THERAPY SERVICES ON OR BEFORE OCTOBER 1, 2008, THAT IS NOT
ACCREDITED TO PROVIDE THE SERVICES BY ONE OF THE ACCREDITING
ORGANIZATIONS SET FORTH IN SUBSECTION (B) OF THIS SECTION SHALL FILE
AN APPLICATION FOR ACCREDITATION TO PROVIDE THE SERVICES BY APRIL 1,
2010.

(D) (1) NOTWITHSTANDING ANY PROVISION OF THIS SECTION, A
 HEALTH CARE ENTITY THAT FURNISHES MAGNETIC RESONANCE IMAGING
 SERVICES, COMPUTER TOMOGRAPHY SCAN SERVICES, OR RADIATION THERAPY
 SERVICES SHALL BE DEEMED PROVISIONALLY ACCREDITED UNDER THIS
 SECTION UNTIL APRIL 1, 2010, OR FOR A PERIOD OF 12 MONTHS DATING FROM

THE DATE ON WHICH THE HEALTH CARE ENTITY BEGAN PROVIDING SERVICES,
 WHICHEVER PERIOD EXPIRES LATER.

3 (2) A HEALTH CARE ENTITY THAT HAS FILED AN APPLICATION
4 FOR ACCREDITATION AS PROVIDED UNDER SUBSECTION (C) OF THIS SECTION
5 AND HAS NOT BEEN REFUSED ACCREDITATION OR WITHDRAWN ITS
6 APPLICATION SHALL BE DEEMED PROVISIONALLY ACCREDITED FOR AN
7 ADDITIONAL 12-MONTH PERIOD BEGINNING ON THE DATE OF THE FILING OF
8 THE APPLICATION.

9 (E) (1) AFTER A HEALTH CARE ENTITY BECOMES ACCREDITED AS 10 PROVIDED UNDER SUBSECTION (B) OF THIS SECTION, THE ENTITY SHALL AT ALL 11 TIMES MAINTAIN THE ACCREDITATION AND CONFORM THE MANNER IN WHICH 12 IT FURNISHES THE SERVICES TO THE STANDARDS SET BY THE APPROPRIATE 13 ACCREDITING BODY.

14 (2) EVIDENCE OF THE ACCREDITATION SHALL BE MAINTAINED AT
 15 EVERY LOCATION IN WHICH ANY MAGNETIC RESONANCE IMAGING SERVICES,
 16 RADIATION THERAPY SERVICES, AND COMPUTER TOMOGRAPHY SCAN SERVICES
 17 ARE FURNISHED AND SHALL BE MADE AVAILABLE FOR INSPECTION ON
 18 REQUEST OF THE DEPARTMENT.

19 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect20 October 1, 2008.