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8lr3365 CF SB 1024

By: Delegates Pena-Melnyk, Bromwell, West, Angel, Barron, Cullison, Kipke, Krebs, McDonough, Metzgar, Miele, Morgan, Saab, Szeliga, and K. Young

Introduced and read first time: February 9, 2018 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Self-Referrals - Oncology Group Practices - Exemption

FOR the purpose of requiring the Maryland Health Care Commission to establish a process to exempt one oncology group practice in certain geographic regions from a certain prohibition against self-referral; requiring the Commission to adopt regulations on or before a certain date that include a certain application process and certain authorization for a certain oncology group practice to obtain a certain exemption; requiring an oncology group practice applying for the exemption to submit an application to the Commission on the form the Commission requires; requiring certain applicants to demonstrate, to the satisfaction of the Commission, that the applicant meets certain requirements; requiring the Commission to review a certain application and notify the applicant as to whether the applicant is approved as an integrated community oncology group practice within a certain period of time; requiring a certain integrated community oncology group practice to participate in certain programs, file a certain performance report, and comply with any other requirements established by the Commission; prohibiting a certain health care practitioner from collecting or attempting to collect certain money under certain circumstances, reducing or withholding certain care, or ordering or delivering certain care; requiring a certain health care practitioner to comply with certain requirements when making a certain referral; requiring an integrated community oncology group practice to file a certain performance report with the Commission on or before a certain date for certain years; requiring the Commission to review a certain performance report and make a certain determination within a certain period of time; requiring the Commission to make a certain report to the General Assembly under certain circumstances; defining certain terms and altering certain definitions; making conforming changes; and generally relating to self-referrals and oncology group practices.

BY repealing and reenacting, with amendments,

Article – Health Occupations

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 2 3	Section 1–301 and 1–302(d)(11) and (12) Annotated Code of Maryland (2014 Replacement Volume and 2017 Supplement)					
4 5 6 7 8	BY repealing and reenacting, without amendments, Article – Health Occupations Section 1–302(a), (b), (c), and (e) and 1–303 Annotated Code of Maryland (2014 Replacement Volume and 2017 Supplement)					
9 10 11 12	BY adding to Article – Health Occupations Section 1–302(d)(13) and 1–302.1 Annotated Code of Maryland (2014 Replacement Volume and 2017 Supplement)					
4 5	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND. That the Laws of Maryland read as follows:					
6	Article - Health Occupations					
17	1–301.					
18	(a) In this subtitle the following words have the meanings indicated.					
19 20	(b) (1) "Beneficial interest" means ownership, through equity, debt, or other means, of any financial interest.					
21 22 23	(2) "Beneficial interest" does not include ownership, through equity, debt, or other means, of securities, including shares or bonds, debentures, or other debt instruments:					
24 25	(i) In a corporation that is traded on a national exchange or over the counter on the national market system;					
26 27	(ii) That at the time of acquisition, were purchased at the same price and on the same terms generally available to the public;					
28 29 30	(iii) That are available to individuals who are not in a position to refer patients to the health care entity on the same terms that are offered to health care practitioners who may refer patients to the health care entity;					
31 32	(iv) That are unrelated to the past or expected volume of referrals from the health care practitioner to the health care entity; and					

(v) That are not marketed differently to health care practitioners that may make referrals than they are marketed to other individuals.

1 (C) "COMMISSION" MEANS THE MARYLAND HEALTH CARE COMMISSION.

- 2 **[(c)] (D)** (1) "Compensation arrangement" means any agreement or system 3 involving any remuneration between a health care practitioner or the immediate family member of the health care practitioner and a health care entity.
 - (2) "Compensation arrangement" does not include:

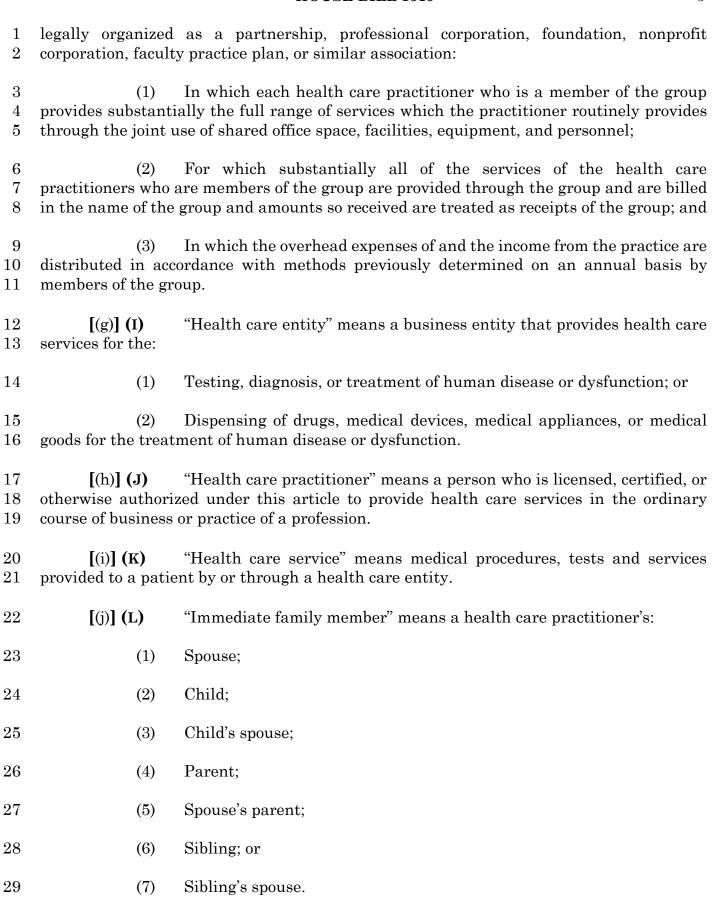
- 6 (i) Compensation or shares under a faculty practice plan or a 7 professional corporation affiliated with a teaching hospital and comprised of health care 8 practitioners who are members of the faculty of a university;
- 9 (ii) Amounts paid under a bona fide employment agreement between 10 a health care entity and a health care practitioner or an immediate family member of the 11 health care practitioner;
- 12 (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:
- 15 1. The arrangement is for identifiable services;
- 16 2. The amount of the remuneration under the arrangement 17 is consistent with the fair market value of the service and is not determined in a manner 18 that takes into account, directly or indirectly, the volume or value of any referrals by the 19 referring health care practitioner; and
- 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;
- 23 (iv) Compensation for health care services pursuant to a referral 24 from a health care practitioner and rendered by a health care entity, that employs or 25 contracts with an immediate family member of the health care practitioner, in which the 26 immediate family member's compensation is not based on the referral;
- (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:
- 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;

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1 2 3			The amount of the compensation under the arrangement that takes into account, directly or indirectly, the volume or ferring health care practitioner; and		
4 5 6	practitioner to meet corpractitioner;	3. nmunit	The health care entity needs the services of the ty health care needs and has had difficulty in recruiting a		
7 8	(vi) payments are:	Payn	nents made for the rental or lease of office space if the		
9		1.	At fair market value; and		
10		2.	In accordance with an arm's length transaction;		
11 12	(vii) payments are:	Payn	nents made for the rental or lease of equipment if the		
13		1.	At fair market value; and		
14		2.	In accordance with an arm's length transaction; or		
15 16	(viii) if the payments are:	Payn	nents made for the sale of property or a health care practice		
17		1.	At fair market value;		
18		2.	In accordance with an arm's length transaction; and		
19 20	agreement that would b	3. e comn	The remuneration is provided in accordance with an nercially reasonable even if no referrals were made.		
21 22 23	premises where the health care services or tests are provided and is available for				
24252627	COUNTY, DORCHEST	ER C	ORE REGION" MEANS CAROLINE COUNTY, CECIL OUNTY, KENT COUNTY, QUEEN ANNE'S COUNTY, OT COUNTY, WICOMICO COUNTY, AND WORCESTER		
28 29	- 1 / - 1 /	-	ractice plan" means a tax-exempt organization established ne direction of a university to accommodate the professional		

[(f)] (H) "Group practice" means a group of two or more health care practitioners

practice of members of the faculty who are health care practitioners.



"In-office ancillary services" means those basic health care

[(k)] **(M)**

(1)

1	services and tests routinely performed in the office of one or more health care practitioners.
2 3 4 5 6 7	(2) Except for a radiologist group practice [or], an office consisting solely of one or more radiologists, OR AN ONCOLOGY GROUP PRACTICE OR AN OFFICE CONSISTING SOLELY OF ONE OR MORE ONCOLOGISTS THAT PROVIDES RADIATION THERAPY SERVICES OR NONDIAGNOSTIC COMPUTER TOMOGRAPHY SCAN SERVICES TO PLAN AND DELIVER RADIATION THERAPY, "in—office ancillary services" does not include:
8	(i) Magnetic resonance imaging services;
9	(ii) Radiation therapy services; or
0	(iii) Computer tomography scan services.
$\frac{1}{2}$	(N) "INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE" MEANS AN ONCOLOGY GROUP PRACTICE THAT:
13	(1) IS LOCATED IN A TARGET REGION; AND
14 15	(2) HAS RECEIVED AN EXEMPTION UNDER § $1-302.1$ OF THIS SUBTITLE.
16 17 18	(O) "ONCOLOGY GROUP PRACTICE" MEANS A GROUP PRACTICE THAT, ON JANUARY 1, 2018, AND FOR THE DURATION OF TIME THE ONCOLOGY GROUP PRACTICE IS PRACTICING UNDER AN EXEMPTION UNDER § 1–302.1 OF THIS SUBTITLE, IS COMPOSED SOLELY OF ONCOLOGISTS WHO:
20	(1) ARE OWNERS OF THE PRACTICE; AND
21 22	(2) PRACTICE MEDICINE IN THE STATE UNDER A LICENSE ISSUED BY THE STATE BOARD OF PHYSICIANS.
23 24	(P) "PERFORMANCE REPORT" MEANS A REPORT TO THE COMMISSION UNDER § 1–302.1 OF THIS SUBTITLE.
25 26	[(l)] (Q) (1) "Referral" means any referral of a patient for health care services.
27	(2) "Referral" includes:
28 29	(i) The forwarding of a patient by one health care practitioner to another health care practitioner or to a health care entity outside the health care

practitioner's office or group practice; or

- 1 (ii) The request or establishment by a health care practitioner of a 2 plan of care for the provision of health care services outside the health care practitioner's 3 office or group practice.
 - (R) "SOUTHERN MARYLAND REGION" MEANS CALVERT COUNTY, CHARLES COUNTY, AND ST. MARY'S COUNTY.
- 6 (S) "TARGET REGION" MEANS A COUNTY IN THE WESTERN MARYLAND 7 REGION, THE SOUTHERN MARYLAND REGION, OR THE EASTERN SHORE REGION.
- 8 (T) "WESTERN MARYLAND REGION" MEANS ALLEGANY COUNTY, CARROLL 9 COUNTY, FREDERICK COUNTY, GARRETT COUNTY, AND WASHINGTON COUNTY.
- 10 1–302.

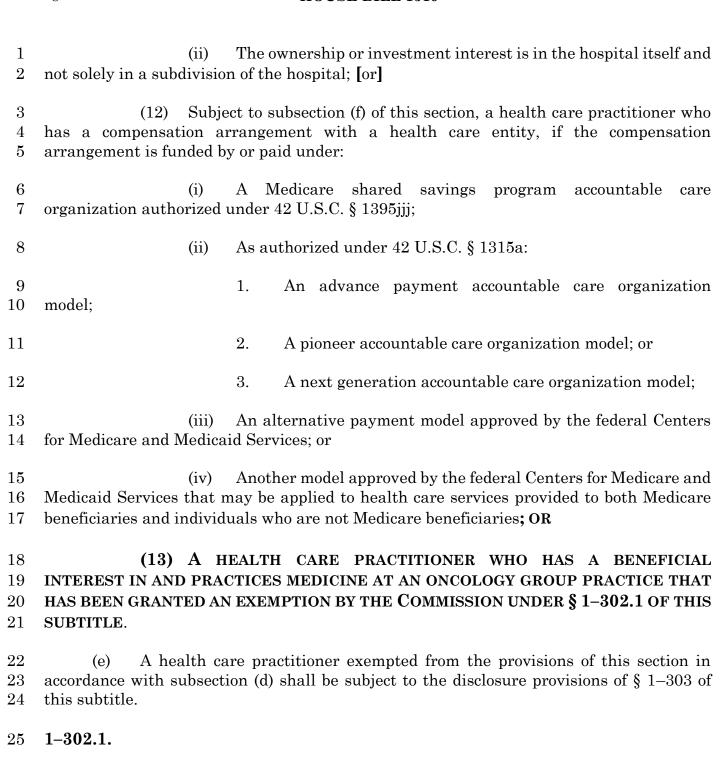
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- 11 (a) Except as provided in subsection (d) of this section, a health care practitioner 12 may not refer a patient, or direct an employee of or person under contract with the health 13 care practitioner to refer a patient to a health care entity:
- 14 (1) In which the health care practitioner or the practitioner in combination with the practitioner's immediate family owns a beneficial interest;
- 16 (2) In which the practitioner's immediate family owns a beneficial interest 17 of 3 percent or greater; or
- 18 (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.
- 21 (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.
 - (c) Subsection (a) of this section applies to any arrangement or scheme, including a cross—referral arrangement, which the health care practitioner knows or should know has a principal purpose of assuring indirect referrals that would be in violation of subsection (a) of this section if made directly.
- 29 (d) The provisions of this section do not apply to:
- 30 (11) A health care practitioner who refers a patient to a hospital in which 31 the health care practitioner has a beneficial interest if:
- 32 (i) The health care practitioner is authorized to perform services at 33 the hospital; and



- 26 (A) (1) THE COMMISSION SHALL ESTABLISH A PROCESS TO EXEMPT ONE
- 27 ONCOLOGY GROUP PRACTICE FROM EACH TARGET REGION FROM THE PROHIBITION
- 28 AGAINST SELF-REFERRAL UNDER § 1-302 OF THIS SUBTITLE.
- 29 (2) ON OR BEFORE DECEMBER 1, 2018, THE COMMISSION SHALL 30 ADOPT REGULATIONS TO CARRY OUT THIS SECTION, INCLUDING:
 - (I) AN APPLICATION PROCESS FOR THE COMMISSION TO BEGIN

- 1 ACCEPTING APPLICATIONS FOR THE EXEMPTION UNDER PARAGRAPH (1) OF THIS
- 2 SUBSECTION ON OR BEFORE APRIL 1, 2019; AND
- 3 (II) AUTHORIZING AN ONCOLOGY GROUP PRACTICE WITH MORE
- 4 THAN ONE PRACTICE LOCATION TO OBTAIN AN EXEMPTION UNDER PARAGRAPH (1)
- 5 OF THIS SUBSECTION FOR MORE THAN ONE LOCATION, BUT NOT MORE THAN ONE
- 6 EXEMPTION FOR EACH TARGET REGION.
- 7 (B) AN ONCOLOGY GROUP PRACTICE APPLYING FOR AN EXEMPTION UNDER
- 8 SUBSECTION (A) OF THIS SECTION SHALL SUBMIT AN APPLICATION TO THE
- 9 COMMISSION ON THE FORM THAT THE COMMISSION REQUIRES.
- 10 (C) EACH APPLICANT SHALL DEMONSTRATE, TO THE SATISFACTION OF THE
- 11 COMMISSION, THAT THE APPLICANT:
- 12 (1) (I) HAS PARTICIPATED IN MEDICARE AND THE MARYLAND
- 13 MEDICAL ASSISTANCE PROGRAM, AND, IF THE APPLICANT SPECIALIZES IN
- 14 PEDIATRIC ONCOLOGY OR PEDIATRIC HEMATOLOGY SERVICES, THE MARYLAND
- 15 CHILDREN'S HEALTH PROGRAM, FOR THE IMMEDIATELY PRECEDING 3 CALENDAR
- 16 YEARS; AND
- 17 (II) COMMITS TO ACCEPTING PATIENTS ENROLLED IN
- 18 MEDICARE AND THE MARYLAND MEDICAL ASSISTANCE PROGRAM, AND, IF THE
- 19 APPLICANT SPECIALIZES IN PEDIATRIC ONCOLOGY OR PEDIATRIC HEMATOLOGY
- 20 SERVICES, THE MARYLAND CHILDREN'S HEALTH PROGRAM, FOR THE DURATION
- 21 **OF THE EXEMPTION**;
- 22 (2) HAS SUFFICIENT EXPERTISE AND TECHNICAL CAPABILITIES TO:
- 23 (I) CONDUCT INNOVATIVE ONCOLOGY PAYMENT MODEL
- 24 STUDIES;
- 25 (II) ENROLL PATIENTS IN CLINICAL TRIALS; AND
- 26 (III) SUPPORT THE COLLECTION AND REPORTING OF
- 27 INFORMATION AS REQUIRED BY THE COMMISSION IN ACCORDANCE WITH
- 28 SUBSECTION (H) OF THIS SECTION;
- 29 (3) HAS THE ABILITY TO MEET A MINIMUM NUMBER OF PATIENT
- 30 ENCOUNTERS PER YEAR IN THE STATE, AS ESTABLISHED BY THE COMMISSION;
- 31 (4) PLANS TO PARTICIPATE IN EVIDENCE-BASED QUALITY AND
- 32 STANDARDIZED CARE PROGRAMS TO:

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PROGRAM;

1	(I) ACHIEVE THE GOALS OF MARYLAND'S ALL-PAYER MODEL
2	CONTRACT; AND
3	(II) PREVENT POSSIBLE REDUCTION OR WITHHOLDING OF
4	MEDICALLY NECESSARY ONCOLOGY OR HEMATOLOGY CARE OR THE ORDERING OR
5	
9	THE DELIVERY OF CARE THAT IS NOT MEDICALLY NECESSARY;
6	(5) IS ACCREDITED TO PROVIDE RADIATION THERAPY OR
7	NONDIAGNOSTIC COMPUTER TOMOGRAPHY SCAN SERVICES BY:
8	(I) THE AMERICAN COLLEGE OF RADIOLOGY;
O	(i) THE AMERICAN COLLEGE OF RADIOLOGI,
9	(II) THE AMERICAN COLLEGE OF RADIATION ONCOLOGY;
10	(TT) The Interpret of the Accompany of the Conference of the Confe
10	(III) THE INTERSOCIETAL ACCREDITATION COMMISSION;
11	(IV) THE JOINT COMMISSION'S AMBULATORY CARE
12	ACCREDITATION PROGRAM; OR
13	(V) ANY OTHER NATIONALLY RECOGNIZED ACCREDITATION
14	ORGANIZATION; AND
15	(6) IS ABLE TO:
16	(I) SAFELY AND APPROPRIATELY DELIVER RADIATION
17	THERAPY TO PATIENTS; AND
10	(II) ACHIEVE THE COALC AND MILECTONES OF THE CHATES
18	(II) ACHIEVE THE GOALS AND MILESTONES OF THE STATE'S
19	ALL-PAYER MODEL CONTRACT.
20	(D) THE COMMISSION SHALL REVIEW AN APPLICATION AND NOTIFY THE
21	ONCOLOGY GROUP PRACTICE WITHIN 60 DAYS AFTER RECEIVING THE APPLICATION
22	AS TO WHETHER THE ONCOLOGY GROUP PRACTICE IS APPROVED AS AN INTEGRATED
23	COMMUNITY ONCOLOGY GROUP PRACTICE.
24	(E) AN INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE SHALL:
25	(1) PARTICIPATE IN MEDICARE, THE MARYLAND MEDICAL
26	ASSISTANCE PROGRAM, AND, IF THE INTEGRATED COMMUNITY ONCOLOGY GROUP

PRACTICE INCLUDES ONCOLOGISTS SPECIALIZING IN PEDIATRIC ONCOLOGY OR

PEDIATRIC HEMATOLOGY SERVICES, THE MARYLAND CHILDREN'S HEALTH

- 1 (2) FILE AN ANNUAL PERFORMANCE REPORT WITH THE COMMISSION 2 AS REQUIRED UNDER SUBSECTION (H) OF THIS SECTION; AND
- 3 (3) COMPLY WITH ANY OTHER REQUIREMENTS ESTABLISHED BY THE 4 COMMISSION.
- 5 (F) (1) A HEALTH CARE PRACTITIONER MAY NOT COLLECT OR ATTEMPT
 6 TO COLLECT ANY MONEY FROM A PATIENT FOR A SERVICE PROVIDED IN AN
 7 INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE IF:
- 8 (I) THE PAYOR ISSUES AN ADVERSE DECISION THAT THE CARE 9 PROVIDED IS OR WAS NOT MEDICALLY NECESSARY, APPROPRIATE, OR EFFICIENT; 10 AND
- 11 (II) THE HEALTH CARE PRACTITIONER, AS AUTHORIZED BY THE 12 PATIENT, HAS EXHAUSTED ALL AVAILABLE APPEALS.
- 13 (2) A HEALTH CARE PRACTITIONER MAY NOT COLLECT OR ATTEMPT
 14 TO COLLECT AN AMOUNT OF MONEY FROM A PATIENT FOR A COVERED SERVICE
 15 PROVIDED IN AN INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE THAT IS
 16 GREATER THAN ANY DEDUCTIBLE, COPAYMENT, OR COINSURANCE AMOUNT
 17 PAYABLE BY THE PATIENT FOR COVERED SERVICES, TO BE CALCULATED AS IF THE
 18 SERVICE WERE PROVIDED BY AN IN-NETWORK PROVIDER OR FACILITY.
- 19 (3) A HEALTH CARE PRACTITIONER WHO PROVIDES SERVICES AT AN 20 INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE MAY NOT:
- 21 (I) REDUCE OR WITHHOLD MEDICALLY NECESSARY CARE; OR
- 22 (II) ORDER OR DELIVER CARE THAT IS NOT MEDICALLY 23 NECESSARY.
- 24 (G) AT THE TIME A HEALTH CARE PRACTITIONER IN AN INTEGRATED 25 COMMUNITY ONCOLOGY GROUP PRACTICE MAKES A LAWFUL REFERRAL, THE 26 HEALTH CARE PRACTITIONER SHALL COMPLY WITH THE REQUIREMENTS OF § 1–303 27 OF THIS SUBTITLE.
- 28 (H) (1) ON OR BEFORE DECEMBER 31 OF THE YEAR IN WHICH AN EXEMPTION IS GRANTED TO AN INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE AND ON OR BEFORE DECEMBER 31 FOR EACH OF THE IMMEDIATELY FOLLOWING 3 YEARS, THE INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE SHALL FILE A PERFORMANCE REPORT WITH THE COMMISSION.

(2) THE PERFORMANCE REPORT SHALL CONTAIN INFORMATION

- 1 REQUIRED BY THE COMMISSION TO EVALUATE THE PERFORMANCE OF THE
- 2 INTEGRATED ONCOLOGY GROUP PRACTICE.
- 3 (3) WITHIN 60 DAYS AFTER RECEIVING A PERFORMANCE REPORT,
- 4 THE COMMISSION SHALL REVIEW THE PERFORMANCE REPORT AND DETERMINE
- 5 WHETHER THE INTEGRATED COMMUNITY ONCOLOGY GROUP PRACTICE SHALL:
- 6 (I) RETAIN ITS EXEMPTION; OR
- 7 (II) RETAIN ITS EXEMPTION SUBJECT TO A CORRECTIVE
- 8 ACTION PLAN.
- 9 (4) WITHIN 60 DAYS AFTER RECEIVING AN INTEGRATED COMMUNITY
- 10 ONCOLOGY GROUP PRACTICE'S FOURTH PERFORMANCE REPORT, THE COMMISSION
- 11 SHALL SUBMIT A REPORT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH
- 12 § 2–1246 OF THE STATE GOVERNMENT ARTICLE, ON WHETHER THE INTEGRATED
- 13 COMMUNITY ONCOLOGY GROUP PRACTICE HAS ACHIEVED THE GOALS AND
- 14 MILESTONES OF THE STATE'S ALL-PAYER MODEL CONTRACT.
- 15 1–303.
- 16 (a) Except as provided in subsection (c) of this section and Title 12 of this article,
- 17 a health care practitioner making a lawful referral shall disclose the existence of the
- 18 beneficial interest in accordance with provisions of this section.
- 19 (b) Prior to referring a patient to a health care entity in which the practitioner,
- 20 the practitioner's immediate family, or the practitioner in combination with the
- 21 practitioner's immediate family owns a beneficial interest, the health care practitioner
- 22 shall:
- 23 (1) Except if an oral referral is made by telephone, provide the patient with
- 24 a written statement that:
- 25 (i) Discloses the existence of the ownership of the beneficial interest
- 26 or compensation arrangement;
- 27 (ii) States that the patient may choose to obtain the health care
- 28 service from another health care entity; and
- 29 (iii) Requires the patient to acknowledge in writing receipt of the
- 30 statement;
- 31 (2) Except if an oral referral is made by telephone, insert in the medical
- 32 record of the patient a copy of the written acknowledgement;

1 2 3 4	is in a location that is plainly visible to the patients of the health care practitioner disclosing				
5 6 7	(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				
8	(ii) To which the practitioner refers patients; and				
9	(4) Documents in the medical record of the patient that:				
10	(i) A valid medical need exists for the referral; and				
11 12	(ii) The practitioner has disclosed the existence of the beneficial interest to the patient.				
13	(c) The provisions of this section do not apply to:				
14 15 16	maintenance organization as defined in § 19-701 of the Health - General Article and the				
17	(2) A health care practitioner who refers a patient:				
18 19	(i) To another health care practitioner in the same group practice as the referring health care practitioner;				
20	(ii) For in-office ancillary services; or				
21 22	(iii) For health care services provided through or by a health care entity owned or controlled by a hospital.				
23 24 25	(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.				
26 27	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2018.				