Bv·	Delegates	Bromwell	Pena-Melnyk,	Barron	Cullison	
J2,	J1					6lr2017 CF SB 739

Kelly, Kipke, Krebs, Luedtke, McDonough, Miele, Morgan, Oaks, Platt, Rose, Saab, and Sample–Hughes Introduced and read first time: February 12, 2016

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Integrated Community Oncology Reporting Program

3 FOR the purpose of establishing the integrated community oncology reporting program; 4 establishing the purpose of the program; requiring the program to be administered $\mathbf{5}$ by the Secretary of Health and Mental Hygiene, in consultation with the Maryland 6 Health Care Commission; requiring the Secretary, in consultation with the 7 Commission, to adopt regulations to implement the program; establishing 8 requirements for the regulations; requiring the Secretary, in consultation with the 9 Commission, to establish a competitive process to select participants for the program 10 under certain circumstances; requiring the competitive selection process to give 11 weight to certain applicants; requiring the Secretary, in consultation with the 12Commission, to report on certain dates to the Governor and certain legislative 13 committees on the performance of each integrated community oncology center 14participating in the program; requiring the Secretary, in consultation with the 15Commission, on or before a certain date, to conduct a certain evaluation, make a 16 certain recommendation, and report on the evaluation and recommendation to the 17Governor and certain legislative committees; establishing a certain exception to a 18 certain prohibition against self-referrals by certain health care practitioners; 19 defining certain terms; providing for the termination of this Act; and generally 20relating to the integrated community oncology reporting program.

- 21 BY repealing and reenacting, without amendments,
- 22 Article Health Occupations
- 23 Section 1–301(a), (b), (f), (g), (h), and (i) and 1–302(a), (b), (c), and (e)
- 24 Annotated Code of Maryland
- 25 (2014 Replacement Volume and 2015 Supplement)

26 BY adding to

27 Article – Health Occupations

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.



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$egin{array}{c} 1 \\ 2 \\ 3 \end{array}$	Section 1–301(l), (m), (n), and (o), 1–302(d)(12), and 1–302.1 Annotated Code of Maryland (2014 Replacement Volume and 2015 Supplement)					
4 5 6 7 8	BY repealing and reenacting, with amendments, Article – Health Occupations Section 1–301(l) and 1–302(d)(10) and (11) Annotated Code of Maryland (2014 Replacement Volume and 2015 Supplement)					
9 10	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:					
11	Article – Health Occupations					
12	1–301.					
13	(a) In this subtitle the following words have the meanings indicated.					
$14\\15$	(b) (1) "Beneficial interest" means ownership, through equity, debt, or other means, of any financial interest.					
16 17 18	(2) "Beneficial interest" does not include ownership, through equity, debt, or other means, of securities, including shares or bonds, debentures, or other debt instruments:					
$\frac{19}{20}$	(i) In a corporation that is traded on a national exchange or over the counter on the national market system;					
$\begin{array}{c} 21 \\ 22 \end{array}$	(ii) That at the time of acquisition, were purchased at the same price and on the same terms generally available to the public;					
$23 \\ 24 \\ 25$	(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;					
$\frac{26}{27}$	(iv) That are unrelated to the past or expected volume of referrals from the health care practitioner to the health care entity; and					
$\frac{28}{29}$	(v) That are not marketed differently to health care practitioners that may make referrals than they are marketed to other individuals.					
$30 \\ 31 \\ 32$	(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:					

1 (1) In which each health care practitioner who is a member of the group 2 provides substantially the full range of services which the practitioner routinely provides 3 through the joint use of shared office space, facilities, equipment, and personnel;

4 (2) For which substantially all of the services of the health care 5 practitioners who are members of the group are provided through the group and are billed 6 in the name of the group and amounts so received are treated as receipts of the group; and

7 (3) In which the overhead expenses of and the income from the practice are 8 distributed in accordance with methods previously determined on an annual basis by 9 members of the group.

10 (g) "Health care entity" means a business entity that provides health care 11 services for the:

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(1) Testing, diagnosis, or treatment of human disease or dysfunction; or

13 (2) Dispensing of drugs, medical devices, medical appliances, or medical 14 goods for the treatment of human disease or dysfunction.

15 (h) "Health care practitioner" means a person who is licensed, certified, or 16 otherwise authorized under this article to provide health care services in the ordinary 17 course of business or practice of a profession.

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

20 (L) "INTEGRATED COMMUNITY ONCOLOGY CENTER" MEANS A HEALTH 21 CARE ENTITY THAT:

(1) TO ENSURE THAT THE HEALTH CARE ENTITY IS REPORTING ON
THE EFFECT OF INTEGRATION BY COMMUNITY ONCOLOGISTS, IS AT LEAST 50%
OWNED BY AN ONCOLOGY GROUP PRACTICE; AND

- 25 (2) OFFERS MEDICAL ONCOLOGY SERVICES AND RADIATION 26 ONCOLOGY SERVICES IN THE SAME GROUP PRACTICE.
- 27 (M) "ONCOLOGIST" MEANS A PHYSICIAN WHO IS:

(1) BOARD-CERTIFIED OR BOARD-ELIGIBLE IN MEDICAL ONCOLOGY,
 RADIATION ONCOLOGY, HEMATOLOGY, OR ANOTHER ONCOLOGY SPECIALTY
 RECOGNIZED BY THE AMERICAN BOARD OF MEDICAL SPECIALTIES; OR

31(2) A SURGEON WHO CONSULTS PREDOMINANTLY WITH PATIENTS32WHO HAVE A CANCER DIAGNOSIS.

1 (N) "ONCOLOGY GROUP PRACTICE" MEANS A GROUP PRACTICE THAT, AS OF 2 JANUARY 1, 2017:

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(1) IS COMPOSED SOLELY OF ONCOLOGISTS, AT LEAST 50% OF WHOM:

- 4
- (I) ARE OWNERS OF THE PRACTICE; AND

5 (II) PRACTICE MEDICINE IN THE STATE UNDER A LICENSE 6 ISSUED BY THE STATE BOARD OF PHYSICIANS.

7 (2) RECEIVED MORE THAN 50,000 PHYSICIAN ENCOUNTERS PER 8 YEAR IN THE STATE FOR THE PREVIOUS 3 CALENDAR YEARS;

9 (3) PARTICIPATED IN MEDICARE AND THE MARYLAND MEDICAL 10 ASSISTANCE PROGRAM FOR THE PREVIOUS 3 CALENDAR YEARS;

11 (4) HAS TREATED PATIENTS IN THE STATE FOR AT LEAST THE 12 PREVIOUS 10 YEARS; AND

13(5)CAN DEMONSTRATE THAT THE PRACTICE HAS THE EXPERTISE14AND TECHNICAL CAPABILITIES SUFFICIENT TO:

15 (I) SUPPORT THE COLLECTION AND REPORTING OF 16 INFORMATION REQUIRED UNDER § 1–302.1(E)(6) OF THIS SUBTITLE;

17(II)SUPPORT THE PRACTICE'S USE OF EVIDENCE-BASED18CLINICAL PATHWAYS THROUGH ELECTRONIC MEDICAL RECORDS;

19(III) CONDUCT INNOVATIVE ONCOLOGY PAYMENT MODEL20STUDIES WITH HEALTH INSURANCE CARRIERS IN THE STATE; AND

21 (IV) ENROLL CANCER PATIENTS IN CLINICAL TRIALS IN AT 22 LEAST ONE OF THE PRACTICE'S LOCATIONS IN THE STATE.

23 (O) "PROGRAM" MEANS THE INTEGRATED COMMUNITY ONCOLOGY 24 REPORTING PROGRAM ESTABLISHED UNDER § 1–302.1 OF THIS SUBTITLE.

25 [(l)] (P) (1) "Referral" means any referral of a patient for health care 26 services.

27 (2) "Referral" includes:

1 (i) The forwarding of a patient by one health care practitioner to 2 another health care practitioner or to a health care entity outside the health care 3 practitioner's office or group practice; or

4 (ii) The request or establishment by a health care practitioner of a 5 plan of care for the provision of health care services outside the health care practitioner's 6 office or group practice.

7 1-302.

8 (a) Except as provided in subsection (d) of this section, a health care practitioner 9 may not refer a patient, or direct an employee of or person under contract with the health 10 care practitioner to refer a patient to a health care entity:

11 (1) In which the health care practitioner or the practitioner in combination 12 with the practitioner's immediate family owns a beneficial interest;

13 (2) In which the practitioner's immediate family owns a beneficial interest 14 of 3 percent or greater; or

15 (3) With which the health care practitioner, the practitioner's immediate 16 family, or the practitioner in combination with the practitioner's immediate family has a 17 compensation arrangement.

18 (b) A health care entity or a referring health care practitioner may not present or 19 cause to be presented to any individual, third party payor, or other person a claim, bill, or 20 other demand for payment for health care services provided as a result of a referral 21 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.

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

(10) A health care practitioner who refers a patient to a dialysis facility, if
the patient has been diagnosed with end stage renal disease as defined in the Medicare
regulations pursuant to the Social Security Act; [or]

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

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1 (ii) The ownership or investment interest is in the hospital itself and 2 not solely in a subdivision of the hospital; **OR**

3 (12) A HEALTH CARE PRACTITIONER WHO HAS A BENEFICIAL 4 INTEREST IN AND PRACTICES MEDICINE AT AN INTEGRATED COMMUNITY 5 ONCOLOGY CENTER THAT PARTICIPATES IN THE PROGRAM.

6 (e) A health care practitioner exempted from the provisions of this section in 7 accordance with subsection (d) shall be subject to the disclosure provisions of § 1–303 of 8 this subtitle.

9 **1–302.1.**

10 (A) THERE IS AN INTEGRATED COMMUNITY ONCOLOGY REPORTING 11 PROGRAM.

12 **(B)** THE PURPOSE OF THE PROGRAM IS TO DETERMINE THE ABILITY OF 13 INTEGRATED COMMUNITY ONCOLOGY CENTERS TO SAFELY AND APPROPRIATELY 14 DELIVER RADIATION THERAPY TO PATIENTS UNDER AN EXEMPTION FROM THE 15 PROHIBITION AGAINST SELF-REFERRAL UNDER § 1–302(D)(12) OF THIS SUBTITLE.

16 (C) THE PROGRAM SHALL BE ADMINISTERED BY THE SECRETARY, IN 17 CONSULTATION WITH THE MARYLAND HEALTH CARE COMMISSION.

18 (D) ON OR BEFORE JANUARY 1, 2017, THE SECRETARY, IN CONSULTATION 19 WITH THE MARYLAND HEALTH CARE COMMISSION, SHALL ADOPT REGULATIONS TO 20 IMPLEMENT THE PROGRAM.

21 (E) THE REGULATIONS SHALL:

22 (1) ALLOW NOT MORE THAN FIVE INTEGRATED COMMUNITY 23 ONCOLOGY CENTERS TO PARTICIPATE IN THE PROGRAM;

24 (2) ESTABLISH AN APPLICATION PROCESS FOR INTEGRATED 25 COMMUNITY ONCOLOGY CENTERS THAT SEEK TO PARTICIPATE IN THE PROGRAM;

26 (3) REQUIRE AN INTEGRATED COMMUNITY ONCOLOGY CENTER TO BE
 27 AT LEAST 50% OWNED BY AN ONCOLOGY GROUP PRACTICE THROUGHOUT THE
 28 DURATION OF THE INTEGRATED COMMUNITY ONCOLOGY CENTER'S PARTICIPATION
 29 IN THE PROGRAM;

30(4) REQUIRE AN INTEGRATED COMMUNITY ONCOLOGY CENTER THAT31IS PARTICIPATING IN THE PROGRAM TO PARTICIPATE IN MEDICARE, THE32MARYLAND MEDICAL ASSISTANCE PROGRAM, AND, IF THE INTEGRATED

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1 COMMUNITY ONCOLOGY CENTER INCLUDES ONCOLOGISTS SPECIALIZING IN 2 PEDIATRIC ONCOLOGY OR PEDIATRIC HEMATOLOGY SERVICES, THE MARYLAND 3 CHILDREN'S HEALTH PROGRAM;

4 (5) ALLOW AN INTEGRATED COMMUNITY ONCOLOGY CENTER TO 5 PARTICIPATE IN THE PROGRAM FOR AT LEAST 10 YEARS, AS LONG AS THE 6 INTEGRATED COMMUNITY ONCOLOGY CENTER CONTINUES TO MEET PROGRAM 7 REQUIREMENTS; AND

8 (6) REQUIRE AN ONCOLOGY GROUP PRACTICE THAT OWNS AN 9 INTEGRATED COMMUNITY ONCOLOGY CENTER AND EACH HEALTH INSURANCE 10 CARRIER WITH WHICH THE INTEGRATED COMMUNITY ONCOLOGY CENTER 11 CONTRACTS TO REPORT QUARTERLY TO THE SECRETARY INFORMATION THAT IS 12 REQUIRED TO DETERMINE:

13(I) REFERRAL RATES FOR RADIATION ONCOLOGY14CONSULTATIONS AND UTILIZATION RATES FOR RADIATION THERAPY SERVICES BY15THE ONCOLOGY GROUP PRACTICE'S PHYSICIANS;

16 (II) THE PERCENTAGE OF REFERRALS FOR RADIATION 17 THERAPY BY THE ONCOLOGY GROUP PRACTICE'S PHYSICIANS THAT COMPLY WITH 18 CLINICAL GUIDELINES ESTABLISHED BY THE NATIONAL COMPREHENSIVE CANCER 19 NETWORK;

(III) RELATIVE TO THE EQUIVALENT OUTPATIENT SERVICES
 PROVIDED IN OTHER CARE SETTINGS AND THE EQUIVALENT OUTPATIENT SERVICES
 AND REFERRALS PROVIDED BY THE PHYSICIANS IN THE ONCOLOGY GROUP
 PRACTICE BEFORE THEIR PARTICIPATION IN THE PROGRAM, THE EFFECT OF EACH
 INTEGRATED COMMUNITY ONCOLOGY CENTER ON:

251. **AVERAGE PATIENT OUT-OF-POCKET COSTS;** 262. **EMERGENCY ROOM AND HOSPITAL INPATIENT** 27**UTILIZATION BY PATIENTS;** 283. **OVERALL RADIATION UTILIZATION RATES;** 294. HEALTH CARE COSTS IN THE STATE; AND 30 5. THE MARYLAND ALL-PAYER MODEL CONTRACT; AND 31(IV) HEALTH OUTCOMES AND SATISFACTION LEVELS OF 32 PATIENTS TREATED BY INTEGRATED COMMUNITY ONCOLOGY CENTERS RELATIVE

1 TO STATEWIDE AVERAGES ACROSS OTHER CARE SETTINGS FOR COMPARABLE 2 PATIENT POPULATIONS.

3 (F) (1) IF MORE THAN FIVE INTEGRATED COMMUNITY ONCOLOGY
4 CENTERS APPLY AND QUALIFY TO PARTICIPATE IN THE PROGRAM, THE SECRETARY,
5 IN CONSULTATION WITH THE MARYLAND HEALTH CARE COMMISSION, SHALL
6 ESTABLISH A COMPETITIVE PROCESS TO SELECT PARTICIPANTS.

7 (2) THE COMPETITIVE SELECTION PROCESS SHALL GIVE WEIGHT TO 8 APPLICANTS THAT:

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(I) TREAT A LARGER NUMBER OF PATIENTS;

10 (II) DEMONSTRATE A COMMITMENT TO ACCEPTING PATIENTS 11 WHO ARE COVERED BY MEDICARE AND THE MARYLAND MEDICAL ASSISTANCE 12 PROGRAM;

13(III) DEMONSTRATE THE ABILITY TO PURSUE INNOVATIVE14ONCOLOGY PAYMENT MODELS WITH HEALTH INSURANCE CARRIERS; AND

15(IV) ENROLL A LARGER NUMBER OF PATIENTS IN CLINICAL16TRIALS.

ON OR BEFORE JANUARY 1, 2018, AND ON OR BEFORE JANUARY 1 OF 17(G) EACH SUBSEQUENT YEAR, THE SECRETARY, IN CONSULTATION WITH THE 18 MARYLAND HEALTH CARE COMMISSION, SHALL REPORT TO THE GOVERNOR AND, 19 SUBJECT TO § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE SENATE 20EDUCATION, HEALTH, AND ENVIRONMENTAL AFFAIRS COMMITTEE AND THE 21HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE ON THE 2223PERFORMANCE OF EACH INTEGRATED COMMUNITY ONCOLOGY CENTER 24PARTICIPATING IN THE PROGRAM.

25 (H) ON OR BEFORE JANUARY 1, 2028, THE SECRETARY, IN CONSULTATION 26 WITH THE MARYLAND HEALTH CARE COMMISSION, SHALL:

(1) CONDUCT AN EVALUATION OF THE PERFORMANCE OF EACH
INTEGRATED COMMUNITY ONCOLOGY CENTER PARTICIPATING IN THE PROGRAM
BASED ON THE INFORMATION REPORTED UNDER SUBSECTION (E)(6) OF THIS
SECTION;

31 (2) RECOMMEND WHETHER, BASED ON THE EVALUATION, THE 32 EXEMPTION UNDER § 1–302(D)(12) OF THIS SECTION SHOULD BE MADE 33 PERMANENT; AND

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1 (3) REPORT ON THE EVALUATION AND RECOMMENDATION TO THE 2 GOVERNOR AND, SUBJECT TO § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE 3 SENATE EDUCATION, HEALTH, AND ENVIRONMENTAL AFFAIRS COMMITTEE AND 4 THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE.

5 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 6 October 1, 2016. It shall remain effective for a period of 12 years and, at the end of 7 September 30, 2028, with no further action required by the General Assembly, this Act 8 shall be abrogated and of no further force and effect.