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June 29, 2018

The Honorable Thomas “Mac” Middleton  
Chairman, Senate Finance Committee  
3 East Miller Senate Building  
Annapolis, MD 21401

Dear Chairman Middleton:

In response to your letter dated October 17, 2017, the Health Services Cost Review Commission (“Commission,” or “HSCRC”) is pleased to submit the study requested by the Finance Committee on the implications of the Maryland Patient Referral Law and oncology services on the newly announced Total Cost of Care Model in Maryland.

Under the new “Total Cost of Care Model,” Maryland will be expected to progressively transform care delivery across the health care system with the objective of improving health and quality of care. At the same time, State growth in Medicare spending must be maintained lower than the national growth rate. As a State, we must thoughtfully consider the policies and incentives that are available in order to drive value-based care and improved outcomes under the new Model. Fortunately, the Total Cost of Care Model gives the State flexibility to tailor initiatives to the Maryland health care context, and encourages providers to drive health care innovation. Care redesign initiatives provides new tools and resources for providers to better meet the needs of patients with complex and chronic conditions and help Marylanders achieve better health status overall. These are the driving forces that we should consider as we move toward a value-based system of care delivery that promotes better outcomes and reduced costs for Marylanders.

If you have any additional questions, please contact Katie Wunderlich at [katie.wunderlich@maryland.gov](mailto:katie.wunderlich@maryland.gov).

Sincerely,

A handwritten signature in blue ink that reads "Donna Kinzer". The signature is written in a cursive style.

Donna Kinzer  
Executive Director

Cc: Chair Shane Pendergrass  
Nelson Sabatini  
David Smulski  
Lisa Simpson

# **Implications of the Maryland Patient Referral Law and Oncology Services on Total Cost of Care**

## **HSCRC Response to Legislative Inquiry**

June 29, 2018

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## Executive Summary

This study and report emanates from a legislative request that the HSCRC look into whether legislation that had been recently proposed to provide safe harbors under the Maryland in-office ancillary provisions of the Maryland self-referral would have an impact on Maryland's new Total Cost of Care All-Payer Model. We reviewed materials including numerous national studies on self-referral, and the state of oncology and radiation therapy in the United States to understand the landscape and trends. We also met with stakeholders, toured facilities, and conducted data analysis on costs and volume in Maryland.

Based on the legislative request, the study has been limited to those services that are prohibited under the in-office ancillary provisions of the Maryland Patient Referral Law – radiation therapy, computed tomography (CT), and magnetic resonance imaging (MRI). We also limited the study to Medicare data since a primary concentration of the requirements of the Total Cost of Care All-Payer Model agreement with the Centers for Medicare & Medicaid Services (CMS) is on Medicare costs.

The scope of this study is also limited to the subject of the recent bills that addressed oncological radiation therapy and therapeutic CT. Since many of the national studies have expressed continued caution about the use of CT and MRI for diagnostic purposes, this study did not consider options for these types of services, although they could be the subject of further study if desired. Therefore, since MRI is a diagnostic tool, we have limited our approach to radiation therapy and CT used in conjunction with therapeutic oncology. Finally, since self-referral is currently permitted within hospital-owned facilities, we compared the costs and volume of these services at hospital outpatient facilities, freestanding facilities owned by hospitals, and freestanding facilities not owned by hospitals.

A review of the oncology workforce and related studies nationally show that there has been a continued shift of oncology services from physician offices to hospital outpatient facilities. Limited Maryland data on workforce trends demonstrate a similar picture. Shifts of services in general from physician practices to hospitals contribute to the growing financial losses at Maryland hospitals associated with unregulated physician services, and the concentration of the physician market at hospitals. For years, HSCRC staff has maintained that a healthy provider market is one that has both hospital-based, and non-hospital community-based physicians and providers working together for better patient care, and that it makes financial sense for hospitals to collaborate (not acquire) with community providers to the greatest extent practicable.

Several studies find that the trend is expected to continue and that radiation oncology is expected to continue to grow by about 19% between 2015 and 2025. The number of radiation oncologists per 100,000 population in 2015 is substantially similar in Maryland compared to the nation, 1.43 per 100,000 and 1.38 per 100,000, respectively.

Maryland radiation oncology centers serve about the average number of cancer cases per center compared to surrounding states - 738 per cancer center compared to the regional average of 728. Maryland also has among the fewest number of centers per 100,000 population compared to surrounding states, with 0.69 centers per 100,000 in population. This indicates that while there is a concentration of centers in central-Maryland, there could be a need for centers in rural and surrounding areas of the State.

Based on the available information summarized in this report, HSCRC staff concludes that it would be imprudent and potentially damaging to the Maryland Total Cost of Care All-Payer Model if self-referral of radiation therapy, CT, and MRI services were permitted under the self-referral law in the current fee-for-service environment. As shown in the Maryland data, radiation therapy is a high cost service; therefore, fluctuations in volume and cost from the base year for the total cost of care calculation can impact the total cost of care calculation, and create strain on the requirements of the Total Cost of Care All-Payer Model. However, under the auspices of value-based alternative payment models, this discussion could also lead to positive opportunities for total cost of care savings in Maryland.

Heretofore, Maryland has not been permitted by CMS to participate in national models such as the Oncology Care Model (OCM) and the Bundled Care for Performance Improvement Advanced (BPCIA), limiting Maryland's options in allowing physicians to participate in MACRA eligible programs that are not hospital-based. Currently only hospitals can be a convener under a care redesign alternative payment model in Maryland. Even if approved by Medicare, the existing self-referral law would prohibit radiation therapy providers from being conveners, or a medical oncology practice from being a convener, if it wishes to collaborate with a radiation therapy practice that it owns. Under a value-based Advanced Alternative Payment Model (Advanced APM), the volume incentives are removed, mitigating the risks of altering the self-referral law under a fee-for-service model.

It is in the best interests of the Maryland Total Cost of Care All-Payer Model for as many physicians as possible, particularly those who provide high cost services, to participate in an alternative payment model based on value (not volume) that uses the same incentives under which hospitals operate, regardless of the ownership arrangement. Therefore, as outlined in this study, serious consideration should be given to altering the Maryland Patient Referral Law in a very limited way so that providers of oncological radiation therapy and therapeutic CT services may participate, and/or be conveners, in an Advanced Alternative Payment Model regardless of the ownership arrangement in Maryland.

## Abbreviations

AAPM – Advanced Alternative Payment Model

APM – Alternative Payment Model

BCPIA – Bundled Payment for Care Improvement Advanced

CCW - Medicare Chronic Condition Warehouse

CMS - Centers for Medicare & Medicaid Services

CRT - Conformal Radiation Therapy

CT - Computed Tomography

HHS – U.S. Department of Health and Human Services

HSCRC – Health Services Cost Review Commission

IGRT – Image Guided Radiation Therapy

IMRT - Intensity-Modulated Radiation Therapy

MACRA - Medicare Access and CHIP Reauthorization Act

MEOS Payment - Monthly Enhanced Oncology Services Payment

MHCC – Maryland Health Care Commission

MPRL – Maryland Patient Referral Law

MRI - Magnetic Resonance Imaging

OCM – Oncology Care Model

RT – Radiation Therapy

SBRT - Stereotactic Body Radiation Therapy

SRS - Stereotactic Radiosurgery

TCOC – Total Cost of Care



# Implications of the Maryland Patient Referral Law and Oncology Services on the Total Cost of Care

## Background

### Legislative Letter and request

This study has been conducted pursuant to a legislative request (Appendix I) for the Health Services Cost Review Commission (HSCRC) to assess the impact that recently proposed changes to the Maryland self-referral law (MPRL) could have on the Maryland Total Cost of Care All-Payer Model. In order to better understand the environment both nationally and in Maryland, the HSCRC has utilized available data and previous studies on the cost variation of Radiation Therapy (RT) and therapeutic Computed Tomography (CT) services by the type of cancer, the therapeutic procedure used, facility type, and by episode length.

The legislative request expressed concern that establishing safe harbors in the existing self-referral law could increase volume for exempt services and, therefore, be counter-productive to the work that has been done to reduce cost and improve quality at hospitals and throughout the health care system. This concern is validated given the structure under which Maryland will be held accountable for - increases in the total cost of care, not just hospital costs.

### HSCRC and move to Total Cost of Care Model

The State of Maryland is leading a transformative effort to improve care and reduce the growth in health care spending. Effective January 1, 2014, the State of Maryland and the Centers for Medicare & Medicaid Services (CMS) entered into a new initiative to modernize Maryland's unique all-payer rate-setting system for hospital services. As the State's hospital rate-setting authority, the HSCRC plays a vital role in the implementation of this innovative approach to health reform.

This initiative, replacing Maryland's 36-year-old Medicare waiver, allows Maryland to adopt new and innovative policies aimed at reducing per capita hospital expenditures and improving patient health outcomes. Maryland strives to transform its health care system into one that enhances patient care, improves health, and lowers costs. The All-Payer Model aims to promote better care, better health, and lower costs for all Maryland patients. In contrast to Maryland's previous Medicare waiver that focused on controlling increases in Medicare inpatient payments per case, the All-Payer Model (Model) focuses on controlling increases in total hospital revenue per capita. The Model established a cumulative annual limit on per capita revenue growth of 3.58 percent and a Medicare savings target of \$330 million over the initial five-year period of the Model. This Model, in essence, shifted the hospital payment system from one that included volume-based financial incentives to one that was value-based.

Success of the New All-Payer Model will reduce costs to purchasers of care—businesses, patients, insurers, Medicare, and Medicaid—and improve the quality of the care that patients receive both inside and outside of the hospital. Since 2014, the State, in close partnership with providers, payers, and consumers, has made significant progress toward this modernization effort.

For more than 40 years, the HSCRC has been responsible for developing, refining, and implementing policy geared toward achieving its mandate of providing maximum efficiency and effectiveness at Maryland hospitals and achieving the goals of the Maryland All-Payer Model. In recent years, however, its role has been expanded by the creation of, first of its kind, value-based models to improve care more broadly.

The Commission is an independent agency of Maryland government and is unique in the U.S. because it sets hospital rates for self-pay and commercial patients as well as for Medicaid and Medicare patients as a result of its waiver from Medicare's Prospective Payment System. Maryland is the only state in the country with such rate setting authority and consequently is able to develop and implement cutting edge policies that have been emulated in other parts of the country.

Beginning in 2019, Maryland is embarking on an even newer, upgraded effort to transform care delivery across the healthcare system with the objective of improving health and the quality of care of Marylanders, not just patients who go to Maryland hospitals. The newer version of the Model, known as the Total Cost of Care Model All-Payer Model, will move beyond hospitals to address patient care across the entire spectrum of care to include post-acute providers, nursing homes, and physicians, with the goal of improving the patient experience and controlling total cost of care. This new model is seen as one of the most leading edge tools for potential future changes to health care delivery and health payment policies nationally and will help drive value-based incentives beyond hospitals and into the broader provider environment.

This Total Cost of Care All-Payer Model was made official on May 14, 2018, when the federal government announced its approval of the new Model. The value-based incentives that over the past 4 years have been placed primarily on hospitals will now be expanded to total cost of care. This means that effective care coordination, quality and cost incentives, consumer-driven health care, and value-based models across the entire health care system in Maryland are essential and must involve all providers in the quest for better care at reasonable cost. The current All-Payer Model achieved overall health care savings of \$586 million since 2014, far above the required \$330 million. At the same time, Maryland hospitals reduced their readmissions rate to below the nation and met various other quality-related requirements of the former model. The new Model requires that total cost of care savings (Medicare Part A and Part B) be ramped up to \$300 million annually by the fifth year (2023). The new model will continue for 10 years so long as the State meets the requirements of its agreement with CMS.

## Federal Stark Laws

Self-referral occurs when a physician asks a patient to return for an appointment, refers the patient to another colleague within the physician's own medical group, or refers a patient for a service like a laboratory test, imaging study, or surgical procedure in a facility with which the physician has a financial interest.<sup>1</sup> The focus of self-referral laws has been on those referrals where there is a financial interest.

In response to growing evidence of significantly higher utilization rates when physicians who owned physical therapy or laboratory facilities referred patients to those facilities, Congress passed the "Stark Law" in 1989 to regulate these types of self-referrals.<sup>2</sup> The statute imposed limitations on such referrals when there is an ownership interest or compensation arrangement. Since 1989, the federal Stark Law has been broadened to include a wider range of services. Today the Stark law prohibits a physician or the physician's immediate family member from referring Medicare patients for designated health services to an entity in which the physician has a financial relationship. The law also prohibits a physician or health care entity from billing for services where an improper referral has been made. For the purposes of the Stark law, designated health services are considered to be the following:

- (A) Clinical laboratory services.
- (B) Physical therapy services.
- (C) Occupational therapy services.
- (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- (E) Radiation therapy services and supplies.
- (F) Durable medical equipment and supplies.
- (G) Parenteral and enteral nutrients, equipment, and supplies.
- (H) Prosthetics, orthotics, and prosthetic devices and supplies.
- (I) Home health services.
- (J) Outpatient prescription drugs.
- (K) Inpatient and outpatient hospital services.
- (L) Outpatient speech-language pathology services.

While there are various exemptions to this law (See Appendix II for list of exemptions), the most notable one for the purpose of this report is that physicians are permitted to self-refer for designated health services that are performed within their own office. This is known as the "in-office ancillary service" exemption. The Stark law also states that if there is an ownership or investment interest in an in-office ancillary referral for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography, and any other similar services designated by the Secretary of the U.S. Department of Health and Human Services (HHS), the referring physician is required to inform the patient in writing of the relationship at the time of

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<sup>1</sup> Casalino, Lawrence, "Physician self-referral and physician-owned specialty facilities", Research Synthesis Report No. 15, Robert Wood Johnson Foundation, June, 2008.

<sup>2</sup> Section 1877 of the Social Security Act (42 U.S.C. 1395nn)

referral. In addition, for certain imaging and radiology services, physicians are required to include with the notice a list of at least 5 other suppliers within a 25-mile radius and their location and contact information.

Maryland's law takes a different approach to the in-office ancillary exemption which will be described below. In recognition of the potential dichotomy between Stark and other federal fraud and abuse laws with the goal of moving from a fee-for-service payment system to a value-based payment system, the Patient Protection and Affordable Care Act of 2010 (ACA) requires the HHS Secretary, in consultation with the Office of the Inspector General, to study whether changes need to be made to the fraud laws, including Stark, to ensure that these laws do not interfere with the shift to alternative payment models (APMs) and bona fide value-based payment structures. A 2016 report by the Secretary of Health and Human Services in conjunction with Office of the Inspector General noted that fraud and abuse laws "may serve as an impediment to robust innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings and reduce waste"; and that the Stark Law is a "particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws."<sup>3</sup>

A Health Care Leadership Council (HLC)<sup>4</sup> February 2017 report highlighted the need to consider further changes to Stark and fraud and abuse laws and regulation under a value-based system. One of the many options HLC proposed was to "issue safe harbors, exceptions, or guidance that effectively extend existing Anti-Kickback Statute and Physician Self-Referral (Stark) Law waivers for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) to all ACOs and to other organizations implementing alternative payment models that meet certain conditions, regardless of whether or not they are participating in the MSSP or other Medicare-specific program."<sup>5</sup>

Specific to the in-office ancillary services exception, which is the focus of this report, the ACA added a provision to require physicians to disclose financial interests to patients for the self-referral of imaging services, as described above.<sup>6</sup> This further explains the continuing caution of Medicare in the self-referral of imaging services.

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<sup>3</sup> Thorpe, J., Gray, E., "Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models", for Health Care Leadership Council, February, 2017, pgs, 12 and 13.

<sup>4</sup> The Healthcare Leadership Council (HLC), is a coalition of chief executives from all disciplines within American healthcare and is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. Members of HLC include hospitals, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and academic health centers.

<sup>5</sup> Thorpe, J., pg. 16.

<sup>6</sup> Thorpe, J., pg.13.

One of the recommendations of HLC was to issue safe harbors for “activities or initiatives that involve the integration of care, items, services, and payment across stakeholders (i.e., industry, providers, and payers), that meet certain established value-based health care criteria and that are designed to improve patient outcomes and reduce the overall cost of providing care.”<sup>7</sup>

### Maryland Self-referral Law

The Maryland Patient Referral Law (MPRL - Health Occupations Article § 1-301, *et seq.*) was passed by the General Assembly in 1993 when fee-for-service (FFS) was the predominant method of payment. The original law addressed the rising costs of health insurance and medical care. The MPRL is a broad statute and goes beyond the federal Stark law, in that it applies to all health care practitioners licensed under the Maryland Health Occupations Article who deliver services to patients covered by Medicare, Medicaid, and the commercial insurance market. The Stark law focuses primarily on Medicare. Moreover, the MPRL is not limited to “designated health services” as defined in Stark and shown above, but instead extends to all health care services.

Under the MPRL, any physician or health care practitioner is prohibited from referring a patient, or directing an employee or contractor of the practitioner to refer a patient, to a health care entity in which the practitioner, or the practitioner in combination with his or her immediate family, owns a beneficial interest in the entity or where the practitioner, the practitioner’s immediate family, or the practitioner in combination with the practitioner’s immediate family, has a compensation arrangement with the entity.<sup>8</sup> The MPRL prohibits a health care entity or a referring health care practitioner from presenting to any individual, third party payer, or other person a claim, bill, or other demand for payment for health care services provided as a result of a prohibited referral. A health care practitioner who fails to comply with provisions of the statute is subject to disciplinary action by the health occupation board that licenses the health care practitioner. Payers are afforded remedies to recover payments that result from a prohibited referral under Maryland Health Insurance Article § 15-110(c)-(f) for insurance products and under Maryland Health-General Article § 19-712.4 (a)-(e) for HMO plans.

The MPRL contains 12 exemptions from the prohibitions on self-referral in the MPRL. Of particular note, exemptions in Health Occupations §1-302(d)(2)-(4) permit referrals that would otherwise be prohibited if the referral of the patient is from one health care practitioner to another health care practitioner in the same group practice [(d)(2)], if the referring physician refers the patient to a health care entity for services or tests and either personally performs or

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<sup>7</sup> Thorpe, pg. 15

<sup>8</sup> Under § 1-301(c)(2), a compensation arrangement is defined as not including certain arrangements such as (i) compensation or shares under a faculty practice plan or a professional corporation affiliated with a teaching hospital; (ii) bona fide employment agreements between a health care entity and a health care practitioner or an immediate family member of the health care practitioner; and (iii) certain independent contractor relationships between a health care entity and health care practitioner or immediate family member of the health care practitioner. These types of arrangements are excluded from the MPRL’s general prohibition on referrals set forth in § 1-302(a).

directly supervises the services or tests [(d)(3)], or if the health care practitioner refers for in-office ancillary services or tests under certain conditions [(d)(4)]. Also of note, the exemption in §1-302(d)(5) allows the Secretary of the Department of Health (MDH) to grant an exception if a health care practitioner's beneficial interest is essential to finance the health care entity and the service is needed to ensure appropriate access for the community to the services provided at the health care entity.

The law also provides an exemption from the general prohibition against self-referral for the referrals of end-stage renal disease patients to dialysis facilities as well as for health care practitioners who refer patients to hospitals in which the practitioner has a beneficial interest and who are authorized to provide services at the hospital and whose ownership or investment interest is in the hospital itself and not solely in a subdivision of the hospital.

The provision of the MPRL that has been the subject of the most attention, particularly over the last decade, is the definition of "in-office ancillary services." The MPRL defines permitted in-office ancillary services in Health Occupations §1-301(k) by expressly excluding MRI, radiation therapy, and CT services from the definition of "in-office ancillary services" for all physician groups or offices except for those consisting solely of one or more radiologists. A 2004 Attorney General's Opinion stated that the law barred self-referral for advanced imaging, the target of repeated efforts at reform.<sup>9 10 11 12 13 14 15</sup>

The question of whether non-radiology practices were permitted to self-refer for advanced imaging was resolved in 2011 when the Maryland Court of Appeals, in *Potomac Valley Orthopaedic Associates (PVOA), et al. v. Maryland Board of Physicians (MBP)*, affirmed the declaratory ruling by the Maryland Board of Physicians that the prohibition against physician self-referrals applies to an orthopedic surgeon's referral of a patient to another health care provider in the same group practice for a MRI or a CT scan.<sup>16</sup> In affirming the MBP's declaratory ruling, the Court of Appeals also rejected the appellants' claims that the self-referrals at issue were permitted under the exemptions in Health Occupations §1-302(d)(2)-(3) referenced above.

Related to cancer care, since 2011 there have been several complaints to the MBP regarding urology services. In one case, the Board issued a "Consent Agreement" with a three year monitoring of required information. During the interview process for this study, this case was cited by several stakeholders. It is not the purpose of this paper to explore these complaints,

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<sup>9</sup> 89 Op. Att'y Gen. 10, 17 n.8 (Jan. 2004).

<sup>10</sup> H.B. 849, 424th Gen. Assem., Reg. Sess. (Md. 2007).

<sup>11</sup> S.B. 708, 425th Gen. Assem., Reg. Sess. (Md. 2008).

<sup>12</sup> H.B. 673, 426th Gen. Assem., Reg. Sess. (Md. 2009)

<sup>13</sup> H.B. 324, 427th Gen. Assem., Reg. Sess. (Md. 2010)

<sup>14</sup> H.B. 782, 428th Gen. Assem., Reg. Sess. (Md. 2011)

<sup>15</sup> H.B. 408, 429th Gen. Assem., Reg. Sess. (Md 2012)

<sup>16</sup> 417 Md. 622 (2011)

but it does highlight that as changes to the self-referral laws are contemplated, it is essential that the Maryland Board of Physicians has the adequate resources and authority to ensure that physicians are operating within the confines of law and regulation.

### MHCC Report

In 2015, The Maryland Health Care Commission (MHCC) convened a workgroup to examine possible changes to the MPRL. While the workgroup did not make specific recommendations, it did achieve consensus on the need to modernize the law to (1) allow for the development of additional bona fide value-based payment models, risk-sharing arrangements, and alignment models; and (2) ensure emerging compensation arrangements are permissible.

During the 2016 interim session of the Maryland General Assembly, the chair of the House Health and Government Operations Committee requested that the Maryland Hospital Association and the Patient Care and Access Coalition convene a workgroup to attempt to achieve consensus on legislation to exempt collaborations to promote provider alignment from the prohibition on self-referral. The workgroup, comprising representatives of hospitals, physician groups, commercial payers, and government agencies, met six times. While the workgroup found some areas of agreement, it was unable to reach consensus on legislation.

According to the report of the workgroup, there was general consensus that the MPRL should not impede current or future Medicare payment models, and that Maryland law should protect and encourage these models. Despite this consensus, workgroup members differed on the precise method by which referrals for health care services made within the context of financial relationships under any new federally created models should be protected.

Extension of MPRL protection for referrals made by health care practitioners in commercial models that are structured consistent with the approved federal models was another area of controversy. Some workgroup members favored stronger consumer protections, such as notice to patients and protection from balance billing by health care practitioners participating in these commercial models.

Modifications to the MPRL have assumed greater urgency due to the State's All-Payer Model contract with the federal Center for Medicare and Medicaid Innovation (CMMI). During the 2015 MPRL report, the HSCRC advised that shared savings compensation arrangements between hospitals and physicians approved by CMMI could violate State law unless the MPRL is modified. The Work Group established eight principles and points of consensus for future conversation on the topic. The report stated that, "These principles affirm the importance of modernizing the MPRL within the statute's current framework, while aligning the statute with new value-based payment models and risk-sharing arrangements that are fostered by the Affordable Care Act and the new hospital payment model. The eight principles reflect the

Workgroup’s agreement that greater clarity is needed to promote greater innovation and experimentation around the new payment models.”

### 2017 Legislation

The MHCC Work Group report culminated in legislation that passed during the 2017 Legislative Session. Senate Bill 369/Chapter 226 (Appendix III), was signed into law and permits exemptions to the Maryland self-referral law for certain compensation arrangements under federally approved programs or models.

A health care practitioner who has a compensation arrangement with a health care entity is exempt from the prohibition against self-referral if the compensation arrangement is funded by or paid under:

- (1) A Medicare Shared Savings Program accountable care organization (ACO);
- (2) An advance payment ACO model, a pioneer ACO model, or a next generation ACO model, as authorized under federal law;
- (3) An alternative payment model approved by the federal Centers for Medicare and Medicaid Services (CMS); or
- (4) Another model approved by CMS that may be applied to health care services provided to both Medicare and non-Medicare beneficiaries.

These exemptions may not be construed to;

- (1) permit an individual or entity to engage in the insurance business without obtaining a certificate of authority and satisfying all other applicable requirements;
- (2) impose additional obligations on a carrier providing incentive-based compensation to a health care practitioner or require the disclosure of information regarding the incentive-based compensation;
- (3) authorize a health care entity to knowingly make a direct or indirect payment to a health care practitioner as an inducement to reduce or limit medically necessary services to individuals who are under the direct care of the health care practitioner;
- (4) permit an arrangement that violates other specified provisions of law;
- (5) narrow, expand, or otherwise modify specified definitions; or
- (6) require another permitted compensation arrangement to comply with the bill’s provisions.

For exempt payment models that apply to individuals covered under health insurance under which there is cash compensation, at least 60 days before an exemption is implemented, the

participation agreement and other documents relevant to the payment model under which a compensation arrangement is funded or paid must be filed with the Insurance Commissioner. The filing is not required if the compensation arrangement is funded fully by or paid fully under the Medicare or Medicaid program. The filing is subject to a \$125 filing fee.

Within 60 days after the participation agreement and other relevant documents are filed, the Commissioner must determine if any compensation arrangement is insurance business and violates the Insurance Article or a related regulation. If the Commissioner determines that a compensation arrangement is insurance business and violates the Insurance Article or a regulation, the Commissioner must issue an order to the filer that specifies the ways in which the compensation arrangement is in violation. The Commissioner must hold a hearing before issuing an order and must give written notice of the hearing to the filer at least 10 days before the hearing. The notice must specify the matters to be considered at the hearing.

If the Commissioner issues an order that a compensation arrangement funded by or paid under such a payment model violates the Insurance Article or related regulations, the exemption is null and void.

If the compensation arrangement changes during its term, the filer must submit a revised filing to the Commissioner for review of the changes, and the Commissioner must determine anew as to whether the compensation arrangement is the business of insurance or violates the Insurance Article or a regulation.

This bill did not change the in-office ancillary provisions of the Maryland Statute, therefore, even if radiation oncology, CT or MRI were approved under a federal model, the MPRL would still prohibit self-referral for these services.

#### [Recent Proposed Legislation to Alter the In-Office Ancillary Provision of MPRL](#)

During the each of the 2016, 2017 and 2019 sessions, legislation was introduced to alter the in-office ancillary provisions as they related to Oncology services.<sup>17 18 19</sup> Each of these bills proposed to implement a limited test or pilot for providing certain MPRL safe harbors for integrated community oncology services for compensation arrangements for therapeutic CT and Radiation Therapy services. Below is a summary of each of the approaches proposed in these bills:

##### [House Bill 1422 \(2016\)](#)

This bill would have established an integrated community oncology reporting program in the then Department of Health and Mental Hygiene (DHMH). The bill exempted a health care practitioner who has a beneficial interest in and practices medicine at an integrated community oncology center that participates in the program from general prohibitions against self-referrals

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<sup>17</sup> H.B. 1422, 433<sup>th</sup> Gen. Assem., Reg. Sess. (Md 2016)

<sup>18</sup> H.B. 1053, 434<sup>th</sup> Gen. Assem., Reg. Sess. (Md 2017)

<sup>19</sup> H.B. 1519/S.B. 1024 , 435<sup>th</sup> Gen. Assem., Reg. Sess. (Md 2018)

by health care practitioners. The Secretary of Health and Mental Hygiene, in consultation with the MHCC, would have administered the program. The Secretary and MHCC would have been required to:

- (1) adopt implementing regulations by January 1, 2017;
- (2) report on the performance of each participating integrated community oncology center by January 1, 2018, and by January 1 of each year thereafter; and
- (3) conduct a performance evaluation of each participating center and recommend whether the exemption established under the bill should become permanent by January 1, 2028.

The provisions of the bill would then have terminated September 30, 2028.

The Bill was withdrawn toward the end of the 2016 Legislative Session.

#### [House Bill 1053 \(2017\)](#)

House Bill 1053 would have established an integrated community oncology reporting program in DHMH. The bill would have exempted a health care practitioner who has a beneficial interest in and practices medicine at an integrated community oncology center in the program from general prohibitions against self-referrals by health care practitioners. MHCC was required to administer the program and:

- (1) establish a specified clinical advisory workgroup to advise on the development of regulations and monitoring of participating centers;
- (2) adopt implementing regulations by November 1, 2017;
- (3) establish an application process, set application and participation fees, begin accepting applications on January 1, 2018, and monitor the performance of participating centers;
- (4) report on the performance of each center by December 1, 2019, and by December 1 annually through 2024; and
- (5) conduct a performance evaluation of each center and the impact of the program on Maryland's all-payer model contract by December 1, 2024.

MHCC was to select a consultant to serve as the program review manager to collect clinical, administrative, and patient satisfaction information and conduct required studies and reports. The provisions of the bill would have terminated June 30, 2025

This legislation passed the House of Delegates but did not receive a vote in the Senate.

#### [House Bill 1519/Senate Bill 1024 \(2018\)](#)

House Bill 1519 and Senate Bill 1024 required the MHCC to develop a process to establish "integrated community oncology group practices" that are located in specified "target regions" of the State and are exempt from the general prohibitions against self-referrals by health care practitioners. MHCC would have been required to adopt implementing regulations by December 1, 2018, and begin accepting applications by April 1, 2019. "Integrated community oncology group practices" would have been required to submit an annual performance report

to MHCC for four years. After receipt of the fourth performance report, MHCC would have submitted a report to the General Assembly on whether the “integrated community oncology group practice” has achieved the goals and milestones of the State’s all-payer model contract.

House Bill 1519 was withdrawn toward the end of the 2018 Legislative Session, while Senate Bill 1024 did not receive a vote.

## Scope of this Study

As indicated in the background section of this report, the issue of self-referral both nationally and in Maryland is broad and frequently controversial. For the purpose of this study, we take a limited scope based on the concerns expressed in the legislative letter for which this report has been undertaken. The letter specifically expresses concerns regarding the potential total cost of care implications of proposed bills during recent Maryland legislative sessions, particularly related to the implementation of an “integrated community oncology program.” As discussed above, these bills specifically focus on self-referral as it relates to oncology services and the in-office ancillary provisions of the MPRL.

The focus here is also on the implications that existing or potential future referral or payment practices would have on the total cost of care under Maryland’s recently approved enhancement to the Maryland All-Payer Model. Since the total cost of care cost metric is focused on Medicare, the analysis and focus of this study relates primarily to Medicare cost and quality. Though Maryland’s system is all-payer, the primary metrics for continuation of the Total Cost of Care All-Payer Model in Maryland relate to Medicare costs. Of course, quality metrics under Maryland’s agreement with Medicare apply across all-payers, so continued attention from a quality stand-point shall be extended to both Medicare and other payers.

In addition, the recent integrated community oncology bills addressed the self-referral law from a therapeutic perspective and did not proposed safe-harbors for diagnostic imaging such as MRI and CT used for diagnostic purposes. Thus, the approach in this report is to review literature and analyze data for Radiation Therapy and CT used for therapeutic purposes primarily. It is possible that some of the approaches discussed in the conclusions of this report could establish appropriate incentives for some diagnostic oncology services as well, however, experts have warned that creating episodes around diagnostic services can be problematic.

Therefore, this study is tailored to these concerns and issues and does not address self-referral as it relates to other types of services or beyond the in-office ancillary provisions of the law. Without analysis in those areas, it would be imprudent to assume that the conclusions of this report apply to other types of services or self-referral in a broader sense.

The purpose of this study, therefore, is to assess the potential implications that changes to the in-office ancillary provisions of the MPRL for oncology-related radiation therapy and therapeutic CT could have on the State’s total cast of care, and consider potential policy options based on those implications.

The HSCRC has taken a multifaceted approach to understanding, analyzing and opining on this issue. We have conducted an extensive literature review, met with various stakeholders, toured oncology centers, interviewed physicians, and performed data analytics.

The HSCRC has analyzed data from the Medicare Chronic Condition Warehouse (CCW) data set to better understand variations in cost for radiation therapy and therapeutic CT among hospital outpatient facilities, freestanding facilities owned by hospitals, and freestanding facilities not owned by hospitals in Maryland. The freestanding facility category is disaggregated in this way since under the self-referral law physicians may refer services to other hospital-owned practices or within a hospital-owned practice. This analysis will help to understand whether there are differences in cost and volume based on the ownership relationship. The HSCRC data team has also analyzed those costs by cancer type and procedure type under each type of cancer (modality), reflecting the different protocols and practice patterns of radiation therapy for each of these types of cancers.

We will also look at these services using episodes of 90-days since this episode length typically captures all of the services that occur after radiation therapy is complete.

Below is an example of the types of ancillary services that are typically associated with a radiation therapy episode:

- **Clinical Treatment Plan:** Process of the Radiation Oncologist designing the treatment of the patient.
- **Initial Set-up Simulation and Guidance:** Computerized simulation to map the actual treatment and positioning for the particular patient.
- **Devices:** Set of materials used to shield and immobilize the patient during radiation treatment.
- **Dosimetry:** Calculation of the amount of radiation the target and nearby structures would be exposed to during radiation treatment.
- **Delivery:** Delivery of the actual radiation therapy to the patient.
- **Guidance:** Imaging tests used to help the Radiation Oncologist place the radioactive source appropriately during treatment.
- **Physics:** Medical physicist services to support the Radiation Oncologist during treatment in delivering safe and effective treatment.
- **Management:** Radiation Oncologist's management and evaluation of the patient throughout treatment.

We will also analyze out-of-pocket costs in each of the sites of services, to assess the impact on patient expenditures for services; however, approximately 75% to 80% of Medicare patients have secondary insurance to cover some or all of these costs. The same does not hold true for commercial patients, which is not addressed in this study.

## Oncology and Radiation Oncology Landscape

In order to make policy decisions regarding Maryland's self-referral law, it is important to better understand the work force environment and prevalence of medical oncology, radiation oncology, and urology treatment both in Maryland and nationally.

The National Cancer Institute and the American Cancer Society (ACS) estimate that there were 1,688,780 new cancer cases and 600,920 cancer deaths in 2017.<sup>20</sup> The American Cancer Society also reported that the lifetime probability for developing cancer from 2010 to 2012 was 42.1% for males and 37.6% for females, while the probability of cancer death for this period was 22.6% for males and 19.1% for females.<sup>21</sup>

The National Cancer Institute also estimates that the costs for cancer therapy in 2010 in the United States reached more than \$124 billion, representing 5% of total health care spending; the figure is projected to reach \$157 billion by 2020.<sup>22</sup> In 2010, the most expensive cancers to treat were breast (\$16.5 billion), colorectal (\$14.1 billion), lymphoma (\$12.1 billion), lung (\$12.1 billion), and prostate (\$11.9 billion).<sup>23</sup>

The particular focus of this report is on radiation therapy. Radiation oncology represents one of the three pillars of cancer treatment – surgery, chemotherapy, and radiation. Radiation therapy is used in four primary circumstances: to reduce the size of a tumor prior to surgery (neoadjuvant therapy), as primary therapy (definitive therapy), post-operatively (adjuvant therapy), and for palliative treatment.<sup>24</sup> It is often a primary therapy for prostate, lung, breast, brain and brain metastases, head and neck, gynecological, skin, and other types of cancer as well as non-malignant conditions.<sup>25</sup> Radiation therapy is sometimes used in conjunction with chemotherapy, surgery, or other treatment modalities.

Nationally, radiation therapy services in a hospital outpatient facility covered by Medicare are paid under the Hospital Outpatient Prospective Payment System (OPPS). In Maryland, the HSCRC established the relative value units for this service. Freestanding radiation therapy centers nationally and in Maryland are paid under the Medicare Physician Schedule.

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<sup>20</sup> NCI: <https://seer.cancer.gov/statfacts/html/all.html> and American Cancer Society. (n.d.) Cancer Statistics Center. <https://cancerstatisticscenter.cancer.org/#/>.

<sup>21</sup> American Cancer Society Surveillance Research. (2016). Lifetime Probability of Developing and Dying from Cancer for 23 Sites, 2010-2012. Retrieved from <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2016/lifelong-probability-of-developing-and-dying-from-cancer-for-23-sites-2010-2012.pdf>.

<sup>22</sup> Sullivan, R., Peppercorn, J., Sikora, K., Zalberg, J., Meropol, N. J., Amir, E., & Fojo, T. (2011). Delivering affordable cancer care in high-income countries. *The lancet oncology*, 12(10), 933-980.

<sup>23</sup> Sullivan, R.

<sup>24</sup> Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services, November 2017

<sup>25</sup> Ibid.

## Nationally

In April 2017, The American Society of Clinical Oncology released a report entitled “*The State of Cancer Care in America 2017, A report by the American Society of Clinical Oncology*”.<sup>26</sup> This report summarized the landscape and issues for oncology in America and included data on the work force and the types and sizes of oncology practices. The table below shows the distribution of the types of physicians in the United States dedicated to direct oncology care. Oncology care is typically conducted by a team, frequently led by a Medical Oncologist, or for prostate cancer care it is typically led by an Urologist. The radiological team typically includes a radiation oncologist, radiation oncology nurses, dosimetrists, and a medical physicist.

Since care options are numerous and dependent on the cancer type, many oncology practices include physicians from various specialties such as those shown in Table 1. Care may also be provided by other providers which may or may not be part of an oncology practice such as “primary care providers, surgeons, pathologists, nurses, nurse practitioners, physician assistants, medical technicians, genetic counselors, social workers, mental health specialists, pharmacists, and pain and palliative care specialists.”<sup>27</sup>

**Table 1. National Number of Direct Care Oncology Physicians by Specialty**

Oncology Specialty	Physicians in Direct Patient Care
Medical Oncology/Hematology	12,166
Gynecologic Oncology	455
Pediatric hematology/Oncology	1853
Radiation Oncology	4457
Surgical Oncology	429

Various studies have observed the shift of oncology services from physician offices to hospital outpatient facilities, as well as the continued acquisition of oncology practices by hospitals. A 2015 report on community integrated oncology services conducted by Berkeley Research Group (BRG) showed that in 2008, 82% of chemotherapy services were performed in a physician office versus a hospital outpatient setting compared to 66% in 2013.<sup>28</sup> The report projected that in 2018 about half of all chemotherapy services will be provided at a hospital outpatient facility.<sup>29</sup> A CMS analysis showed that roughly 62% of radiation therapy episodes between January 1, 2013 and December 31, 2015 were furnished in a hospital outpatient

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<sup>26</sup> Kirkwood, M. , “The State of Cancer Care in America 2017, A report by the American Society of Clinical Oncology”, *Journal of Oncology Practice*, Volume 13, Issue 4, April 2017.

<sup>27</sup> Ibid, pg e370

<sup>28</sup> Younts, J., Vanervelde, A., “A Detailed Diagnosis of Integrated Community Oncology”, BRG Healthcare, 2015, pg. 16

<sup>29</sup> Ibid.

department.<sup>30</sup> At the same time, 38% of the Medicare episodes during that time period were provided in a freestanding radiation therapy center.

The BRG report explains that this trend is exacerbated by the hospital acquisition of community oncology practices. The BRG report states that the main pressures on physicians to move into the hospital setting are:

- Employment of oncologists and/or acquisition of community oncology practices to compete with other community-based practices;
- Growing costs to operate a private physician practice;
- Control of referral networks; and
- 340B drug pricing available to eligible hospitals.<sup>31</sup>

The in-office ancillary exception in the Stark law has been an important protection for integrated community oncology practices that has helped to insulate further shifting to hospitals. The BRG report states that the demise of the in-office ancillary exemption nationally would accelerate the trend toward hospital acquisitions.<sup>32</sup> This is the situation for Radiation Oncology in the Maryland self-referral law and, therefore, one could assume from the BRG conclusion that this adds additional pressure for medical and radiation oncology to be further consolidated at hospitals in Maryland.

A 2012 study by Avalere Health utilized 3 years of commercial health plan data on radiation therapy and found that roughly half of all radiation therapy treatment episode were provided in a hospital outpatient facility versus an office-managed practice.<sup>33</sup>

A study in the International Journal of Radiation Oncology in 2016 isolated workforce trends for radiation therapy and conducted a supply and demand analysis for 2015 to 2025. The Table below, highlights the expected growth in radiation oncology over the next 10 years showing a projected increase in treatment by 19%. The most prominent episodes are for the treatment of breast, lung, and prostate cancers.

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<sup>30</sup> <https://www.ccwdata.org/web/guest/home>.

<sup>31</sup> Younts, J. pg. 15.

<sup>32</sup> Ibid, pg. 14.

<sup>33</sup> Avalere Health, LLC, "Total Cost of Cancer Care by Site of Service: Physician Office vs Outpatient Hospital", March 2012, pg. 11.

**Table 2.<sup>34</sup> Projected estimates of patients receiving radiation therapy during their first treatment course, 2015 and 2025**

Cancer Type	2015	2025	Projected % increase
Breast (invasive)	110,000	130,000	14
Lung	81,000	100,000	24
Prostate	81,000	100,000	30
Oral	25,000	28,000	13
Breast (in situ)	23,000	26,000	13
Thyroid	22,000	23,000	9
Colorectal	19,000	23,000	18
Central Nervous System	14,000	15,000	13
Uterus	13,000	15,000	18
Non-Hodgkin Lymphoma	11,000	13,000	21
Larynx	9,300	11,000	20
Esophagus	8,900	11,000	23
Cervix	6,800	7,700	13
Other	61,890	75,220	18
All	490,000	580,000	19

Note: All numbers are rounded

Source: Pan, International Journal of Radiation Oncology

This supply and demand study also projected that the number of full-time equivalent radiation oncologists in the nation will increase by 27% between 2015 and 2025. For this period of time demand for radiation oncology services is expected to increase by 19%, indicating that the supply is expected to grow faster than the demand for these services. The study, however, stopped short of determining whether this expected growth would result in an over or under supply for these services due to limitations in the data set. They suggested further review.

From a regulatory standpoint, only Maryland and New Jersey have specific prohibitions in their statutes regarding self-referral of radiation therapy services. However, 18 states have Certificate of Need (CON) laws that restrict magnetic resonance imaging (MRI), and 23 have CON provisions with restrictions on radiation therapy.

### Maryland

In attempt to understand the market for oncology services in Maryland, the Maryland Health Care Commission shared data from the Board of Physician Licensure renewal files for 2013-2014, 2014-2015, and 2015-2016 (licensure takes place every 2 years). While it would be

<sup>34</sup> Pan, H., Haffty, B., Falit, B., et al., "Supply and Demand of Radiation Oncology in the United State: Updated Projections for 2015 and 2025", International Journal of Radiation Oncology, Vol. 96, No. 3, Feb. 2016, pg. 486.

preferable to go back further than 2014 to discern patterns of shift from facility types, 2014 was the earliest period where the data comparisons were considered reliable and from this source. Nonetheless, the limited data do show some recent trends.

### Oncology Physicians

Table 3 below shows the number of oncology physicians in Maryland in 2014 through 2016 regardless of whether they self-selected a site of service or not (approximately 13% of all Oncologists and Urologists did not select a site of service). As indicated in this report, a medical oncologist tends to be the leader of an oncology team, except for prostate cancer where the urologist tends (although not always) to oversee the care of those patients. Therefore, not surprisingly, of the 374 oncology physicians, 225 are medical oncologists in Maryland

Since Urologist play an important role in prostate care, we have included the number of urologists in the State as well. There were 213 Urologist in the state in 2016, and that represents an increase of 3.9% over the past 2 years.

**Table 3. Oncology and Urology Physicians Counts, 2014-2016**

<b>All Oncology and Urology Doctors, Maryland, 2014-2016</b>				
<b>Primary Concentration</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>% Change</b>
<b>Oncology</b>	<b>#</b>	<b>#</b>	<b>#</b>	<b>2014-2016</b>
Oncology Medical	225	228	229	-1.75
Oncology Radiation	86	84	82	4.88
Hematology/Oncology, Pediatric	22	25	24	-8.33
Oncology, Gynecological	19	17	16	18.75
Oncology, Musculoskeletal	6	5	3	100.00
Surgery, Complex General Surgical Oncology	16	11	9	77.78
<b>Subtotal</b>	<b>374</b>	<b>370</b>	<b>363</b>	<b>3.03</b>
<b>Urology</b>				
Urology	178	182	177	0.56
Urology, Female Pelvic Medicine and Reconstructive	7	6	3	133.33
Urology, Pediatric	7	7	7	0.00
Surgery, Urological	21	18	18	16.67
<b>Subtotal</b>	<b>213</b>	<b>213</b>	<b>205</b>	<b>3.90</b>
<b>Total</b>	<b>587</b>	<b>583</b>	<b>568</b>	<b>3.35</b>

\*Sources: Board of Physician Licensure Renewal File, 2015-2016, 2014-2015, 2013-2014

Note: All numbers are unofficial physician counts derived from information provided to the Maryland Board of Physicians during licensure renewal.

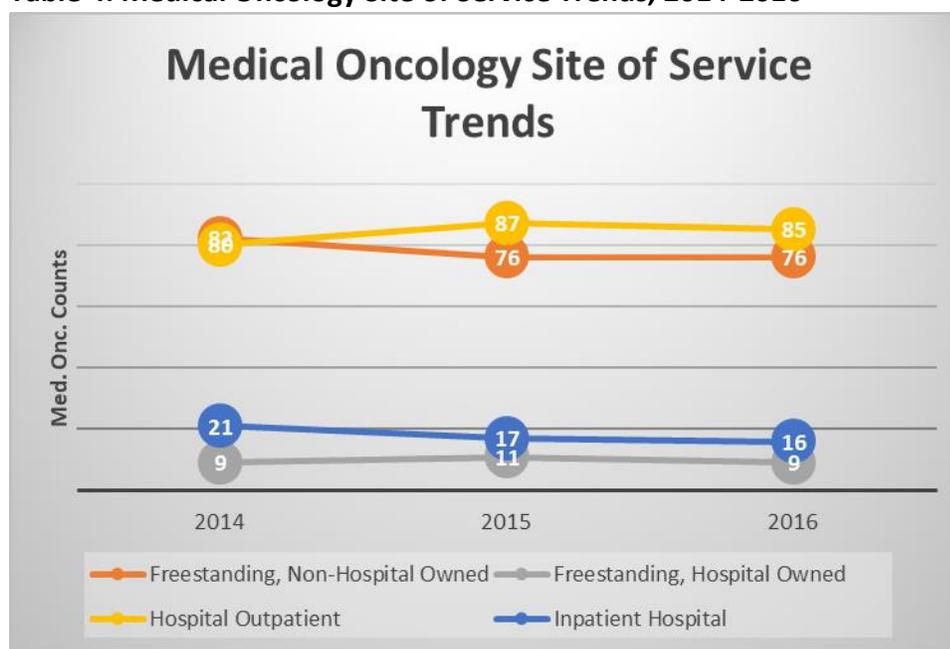
\*\*This Table includes all Oncology and Urology Physicians, including those who did not select a site of service

The Tables below illustrate the trends in the oncology work force by the site of service using the following categories: hospital inpatient, hospital outpatient, hospital owned freestanding facility, and non-hospital owned freestanding facility. Approximately 13% of all Oncologists and

Urologists in State did not self-select a site of service, so the totals in Table 3 above will not match the totals in Tables 4 through 6 below. Many national studies have illustrated shifts of physician services from physician offices to hospital outpatient facilities. The data below, will help to discern any such shifts for medical oncology, radiation therapy, and urology in Maryland.

Table 4 below shows a reduction in the number of medical oncologists practicing in non-hospital owned freestanding facilities, and an increase in those practicing at hospital outpatient centers during the past 2 years. The trends here are consistent with the trends discussed in many of the national studies, although a longer time series would be more helpful in realizing this trend over time.

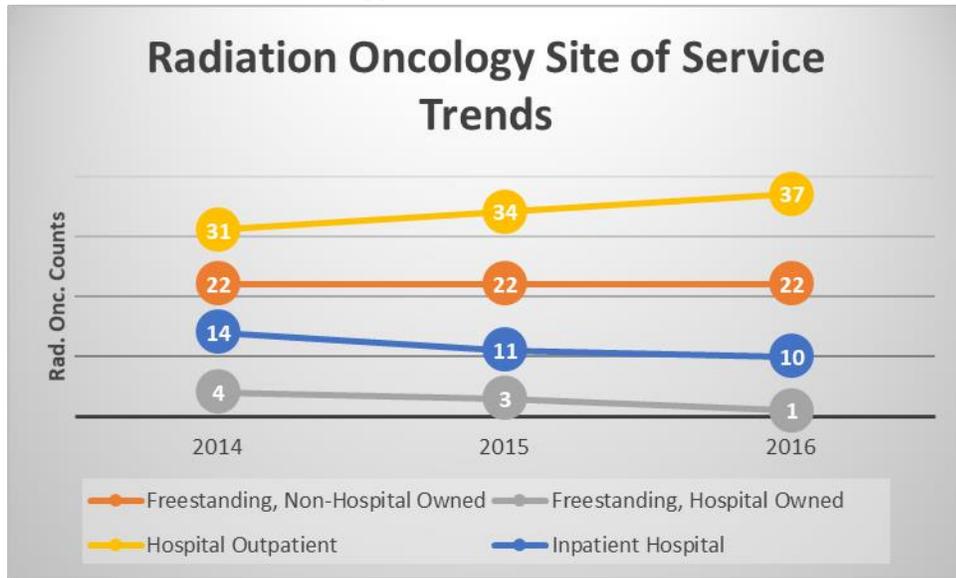
**Table 4. Medical Oncology Site of Service Trends, 2014-2016**



\*Sources: Board of Physician Licensure Renewal File, 2015-2016, 2014-2015, 2013-2014  
 Note: All numbers are unofficial physician counts derived from information provided to the Maryland Board of Physicians during licensure renewal.

Likewise, Table 5 shows a growth in the number of radiation oncologists practicing at hospital outpatient departments; however, the number of radiation oncologists in non-hospital owned freestanding facilities has remained the same over this period.

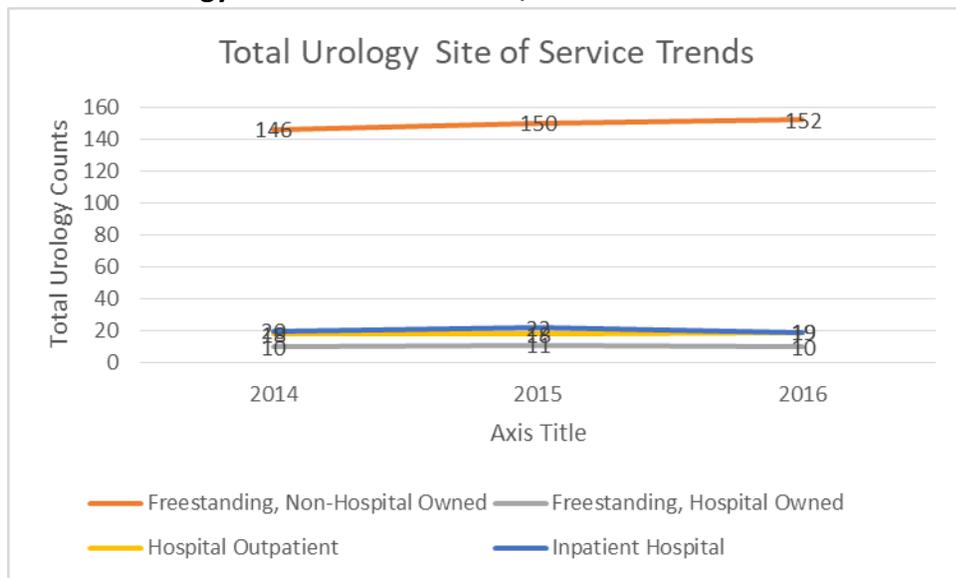
**Table 5. Radiation Oncology Site of Service Trends, 2014-2016**



\*Sources: Board of Physician Licensure Renewal File, 2015-2016, 2014-2015, 2013-2014  
 Note: All numbers are unofficial physician counts derived from information provided to the Maryland Board of Physicians during licensure renewal.

As for Urology, Table 6 below shows that a great majority of urologists practice in non-hospital owned freestanding facilities around the State. The number of Urologists in non-hospital owned freestanding settings has increased, while the number of Urologists serving in other settings has declined slightly during the period.

**Table 6. Urology Site of Service Trends, 2014-2016**



\*Sources: Board of Physician Licensure Renewal File, 2015-2016, 2014-2015, 2013-2014  
 Note: All numbers are unofficial physician counts derived from information provided to the Maryland Board of Physicians during licensure renewal.

Table 7 utilizes the available supply data for radiation oncologists nationally displayed in Table 1 above and compares that to data available in Maryland from the Board of Physician licensure files for the same year. While these are different data sets, it can help to draw comparisons in the prevalence of radiation oncology and the supply of radiation oncologists in Maryland compared to the nation. Table 7 shows that the number of radiation oncologists per 100,000 population in 2015 is substantially similar in Maryland compared to the nation, 1.43 per 100,000 and 1.38 per 100,000, respectively.

**Table 7. 2016 Radiation Oncologist per 100,000 population Maryland vs. Nation**

	# Radiation Oncologists	Population	Per 100,000 population
<b>United States</b>	4,457	322,762,018	1.3809
<b>Maryland</b>	86	6,024,752	1.4274

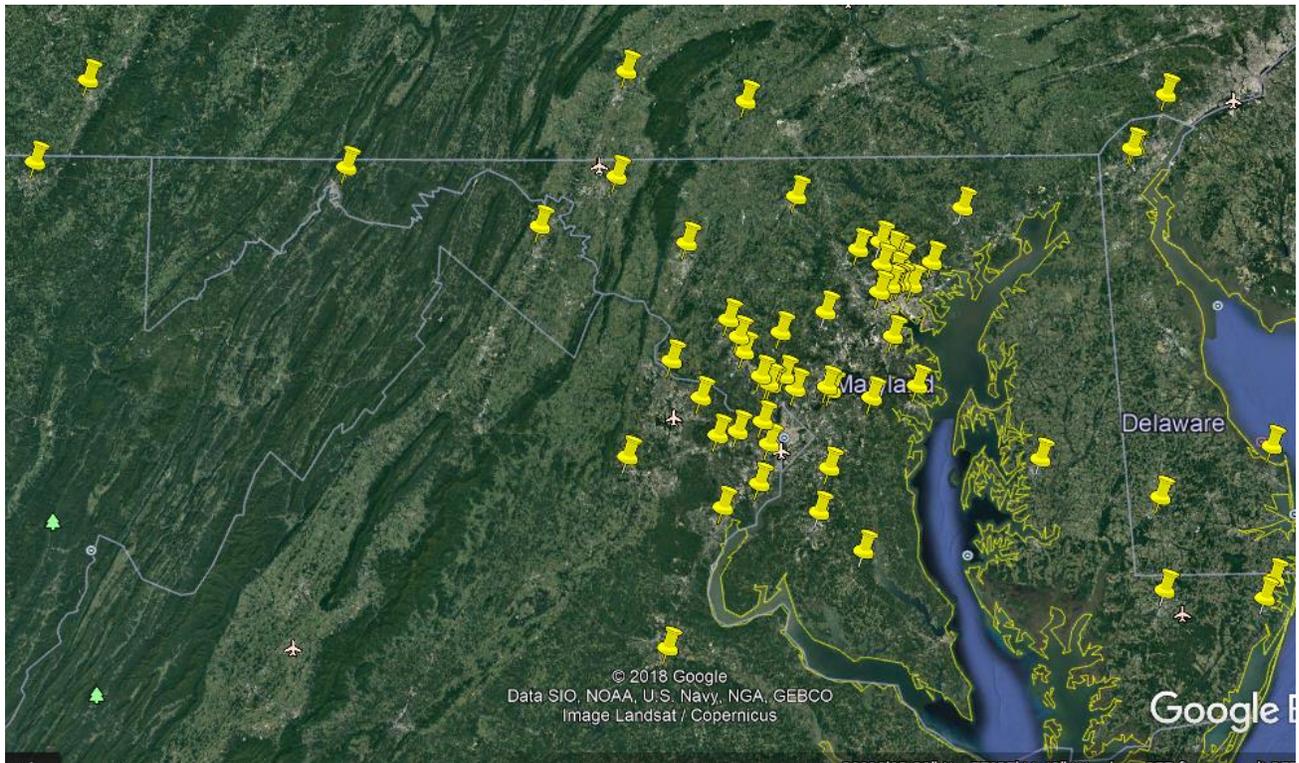
\*Sources: Board of Physician Licensure Renewal File, 2015-2016

#### Radiation Oncology Centers

There are 42 radiation oncology centers in Maryland. Exhibit 1 below displays where hospitals are located in Maryland and along its borders. The bulk of the centers are concentrated around central Maryland, where the majority of the State’s population resides. Many of these centers are co-located with private medical oncology practices or at least within proximity to medical oncology practices.

Of the 42 centers, 38 are owned by hospitals and 4 are owned by physicians. The 4 owned by physicians are located in Berlin, Gaithersburg, Greenbelt and Owings Mills.

**Exhibit 1. – Location of Radiation Oncology Centers in Maryland and On Borders**



Certification of radiation oncology centers by an accrediting entity is voluntary in Maryland. The 3 primary certification organizations are the American Society of Radiation Oncology (ASTRO), the American College of Radiology (ACR), and the American College of Radiation Oncology (ACRO). Some centers are certified by multiple accrediting organizations. Separate recognition is provided by The Commission on Cancer, which certifies centers based on meeting certain practice protocols and requirements. Of Maryland’s 42 centers, 35 are accredited by either ASTRO, ACR, or ACRO. In addition, 25 centers have obtained recognition from the Commission on Cancer (CoC). The number of centers certified by each organization appear in Table 8.

**Table 8. Number of Maryland Radiation Oncology Centers Certified by Entity**

Certification Entity	Radiation Oncology Centers Certified
American Society of Radiation Oncology (ASTRO)	4
American College of Radiology (ACR)	28
American College of Radiation Oncology (ACRO)	3
<b>Total</b>	<b>35</b>

\* Source: Maryland Radiological Society, 2017

To compare the density of radiation oncology centers in Maryland, we have obtained data on the number of oncology centers, number of cancer cases, and population for Maryland and the surrounding states.

**Table 9. 2017 Radiation Centers and Demographics by Surrounding States**

	MD	PA**	VA	DE	WV	DC	Mean of Border States
# of Radiation Therapy Centers*	42	118	58	6	17	5	41
2017 Estimated Cancer Cases (non-skin)	30,990	77,710	42,770	5,660	11,690	3,070	28,180
Invasive Cancer Cases /Radiation Oncology	738	659	737	943	688	614	728
Population of State 2017 Estimated	6,052,177	12,805,537	8,470,020	961,930	1,815,857	693,972	4,949,463
Radiation Oncology Centers per 100,000	0.69	0.92	0.68	0.62	0.94	0.72	0.78
Radiation Oncology Centers per 1,000	1.36	1.52	1.36	1.06	1.45	1.63	1.40

\* Source: *Radiation Therapy Facilities in the United States, Int. J. Radiation Oncology Biol. Phys, (2006)*, adjusted by recent survey of State Regulatory Agencies

\*\* The number of centers in PA is unadjusted from the 2006 report

Maryland radiation oncology centers serve about the average number of cancer cases per center compared to surrounding states - 738 per cancer center compared to the regional average of 728. Maryland also has among the fewest number of centers per 100,000 population, with 0.69 centers per 100,000 in population. The regional average is 0.78 per 100,000 population. Maryland has an average number of radiation oncology centers per 1,000 cancer cases in the region with 1.36 centers per 1,000 cases compared to 1.40 across the region.

The fact that Maryland is among the lowest of surrounding states in the number of radiation oncology centers per 100,000 population indicates that while there is a concentration of centers in central-Maryland, there could be a need for centers in rural and surrounding areas of the State. However, further study would be required to determine the actual need in those and other areas.

### Studies on Self-referral of Oncology Services

There have been various studies and reports over the years related to the issue of self-referral of oncology services. Some studies/reports were generated over the concern that self-referral of diagnostic oncology, such as imaging, may create incentives for over utilization of such

services. Others suggest that the lower cost of care at freestanding facilities could reduce the cost of oncology services.

Appendix IV summarizes the studies that have been frequently used during discussions on the issue of altering the in-office ancillary provision in the Maryland self-referral law. The culmination of all of these and other studies provide the following impressions that should be considered when making policy decisions related to Maryland's self-referral law, and are used in drawing conclusions in this report:

### Costs of Radiation Therapy

From 2000 to 2010, the volume of physician billing for radiation treatment increased 8.2%, while Medicare Part B payments for radiation treatment increased 216%.<sup>35</sup> Researchers indicate this increase in payments for radiation during this period was primarily due to significant uptake in a certain type of radiation therapy (Intensity-Modulated Radiation Therapy, or "IMRT").<sup>36</sup> In another study, researchers predicted that, "from 2010 to 2020, the demand for radiation therapy during the initial treatment course is expected to increase by 22% (from 470,000 patients receiving radiation therapy in 2010 to 575,000 patients receiving radiation therapy in 2020) as a result of the aging and diversification of the US population."<sup>37</sup>

For the same period (2010–2020), the number of adults age 65 and older requiring radiation therapy during the initial treatment course is projected to increase 38% (from 282,000 to 388,000) compared with a 1.7% increase (from 188,000 to 191,000) for individuals younger than age 65 treated with radiation therapy.<sup>38</sup>

### Payment, Self-Referral, and Utilization

There is clear evidence that under a fee-for service payment structure, reimbursement has played a role in clinical decisions for patient care. Various studies have shown that self-referring for diagnostic imaging services and IMRT services has driven increases in utilization and overall cost of these services. Some of the incentives may have been mitigated due to changes in reimbursement by Medicare for IMRT and other types of services. Nonetheless, the concern continues to be raised in a fee-for-service environment where the more physicians do, the more they get paid. It is clear that the Maryland Total Cost of Care All Payer Model is moving away from these types of incentives. Certainly, the governmental payers are as well. Also, greater concerns have been expressed for diagnostic imaging services rather than for radiation therapy services and CT scans when done as part of a therapy regimen. While there

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<sup>35</sup> Shen, X., Showalter, T. N., Mishra, M. V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. *Journal of Oncology Practice*, 10(4), e201-e207.

<sup>36</sup> Ibid

<sup>37</sup> Smith, B. D., Haffty, B. G., Wilson, L. D., Smith, G. L., Patel, A. N., & Buchholz, T. A. (2010). The Future of Radiation Oncology in the United States from 2010 to 2020: Will Supply Keep Pace with Demand? *Journal of Clinical Oncology*, 28(35), 5160-5165.

<sup>38</sup> Ibid.

are options for treatment of different types of cancer, there are clear protocols for each of the options, and physicians are well aware of the risks of over-radiation of patients.

Therefore, policy considerations should put emphasis on value-based models for self-referred imaging and radiation therapy services with a focus on therapeutic services. As stated in a study by Cureus, “while improper variation in IMRT utilization can increase costs without improving outcome, appropriate use of IMRT can be highly beneficial.”<sup>39</sup>

### Site of Service Cost Differences

Various studies have looked at the cost of chemotherapy services in hospital outpatient settings versus physician offices. Studies have shown that chemotherapy services provided in physician offices can be less expensive with either similar or fewer emergency department visits. Some studies factored in reduced prices for drugs at 340B hospitals; others did not.

These studies however, do not focus on Radiation Therapy, which is the subject of this study. Costs of radiation therapy services by site of service may or may not comport with the findings for chemotherapy services. Below, we will provide an analysis comparing the cost of Radiation Therapy services conducted at hospital outpatient facilities in Maryland versus freestanding facilities - both those owned by hospital and those not owned by hospitals.

An Avalere Study, however, conducted a radiation therapy site of service analysis from commercial health plan data.<sup>40</sup> The study analyzed data on 19,025 patients who received all of their radiation therapy for a single episode in either a freestanding radiation therapy center (office-managed) or a hospital outpatient department. The study found that the average cost of an office-managed radiation therapy episode was about \$16,300, while the average cost of a hospital outpatient facility-managed radiation therapy episode was \$16,000, a 2 percent difference.<sup>41</sup> The average radiation therapy episode lasted 2.1 months for office-managed patients versus 1.9 months for hospital outpatient facility-managed patients.<sup>42</sup> Interestingly, hospital outpatient radiation therapy episodes of one or two months were between 7 and 17 percent more expensive than similar-length freestanding office-managed episodes, while hospital outpatient episodes of three months were 4 percent less expensive.<sup>43</sup> The study does caution, however, that the risk adjustment model adjusts for some factors but not all relevant factors that could influence this outcome. They also did not control for modality (the procedure type) used during the episode. The HSCRC analysis below will differentiate between modality to provide a more refined analysis.

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<sup>39</sup> Kao J, Zucker A, Mauer E L, et al. (April 25, 2017) Radiation Oncology Physician Practice in the Modern Era: A Statewide Analysis of Medicare Reimbursement. *Cureus* 9(4): e1192. DOI 10.7759/cureus.1192

<sup>40</sup> Avalere Health, LLC

<sup>41</sup> Avalere, Health LLC, pg. 15.

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

Related to the site of service, many of the identified studies highlight the shift of oncology practice from physician offices to hospitals. This has clearly been a trend across most sub-specialties. Factors for this shift include competition, the desire for hospitals to establish coordinated care among hospital services, reimbursement, MACRA, and 340B drug pricing at hospitals. Participation of Maryland hospitals in the 340B program continues to expand.

The 340B Drug Pricing Program allows certain hospitals and other health care providers (“covered entities”) to obtain discounted prices on “covered outpatient drugs” (prescription drugs and biologics other than vaccines) from drug manufacturers. Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid. The discounts are substantial. Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid. Currently 25 of Maryland’s 47 hospitals participate in 340B (Appendix V).

If, in fact, non-hospital freestanding oncology practices were permitted to refer for radiation therapy, CT and MRI services, proponents argue that this would allow for integrated community oncology services to be provided in Maryland, as in other states. A BRG study states, and as confirmed by many of the studies reviewed here, integrated community oncology can provide three primary benefits to patients:

1. Lower costs relative to hospital outpatient care;
2. Efficient care delivery, particularly through medical home models; and
3. Personalized delivery of care.<sup>44</sup>

Maryland hospitals today can and do provide integrated oncology care throughout the State today. However, this report provides an opportunity to encourage collaboration between hospital owned and non-hospital owned oncology centers to utilize their assets to provide the best care for patients, at the most appropriate setting, and at reasonable cost. Under the new Total Cost of Care All-Payer Model, it is in the best interests of the State for providers to work together to improve quality, reduce total cost of care, and provide care that is patient-centered (not site of service centered). However this opportunity must be measured and controlled, like all other Medicare value-based models.

Also, HSCRC staff has long held the position that the Maryland health care system is most healthy when there are both hospital-based and community-based non-hospital owned options for care across the State, provided that the supply does not exceed demand for those services. It is not appropriate for all health care services to be consolidated at the hospital. The trends, however, continue to move in that direction. Maryland hospitals’ physician losses continue to grow, placing financial pressure on hospitals as they invest in practice transformation. Collaboration of services with non-hospital providers in most cases is less expensive, prudent,

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<sup>44</sup> Younts, J., pg. 6

and can be more patient convenience oriented, provided those community physicians are operating under the same or similar value-based incentives under which Maryland hospitals now operate.

Under the new Total Cost of Care All-Payer Model, it is essential that physicians in the community are under similar incentives as the hospital system. It would be in the best interests of the system to encourage physicians, whether their practices are owned by hospitals or not, to join value-based models, Advanced APMs, and other non-volume based payment structures.

## Maryland Analysis: Cost Differences between Sites of Services

The previous section highlights studies and data analysis conducted nationally. The HSCRC has utilized data available from CMS on the cost and volume of radiation therapy services as well as the cost by cancer type, modality, and the site of service.

We used hospital outpatient and physician fee schedule claims, accessed through CMS' Chronic Conditions Data Warehouse (CCW). The radiation treatment delivery services included various types of external beam radiation therapy such as 3-dimensional conformal radiation therapy (3DCRT), intensity-modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT), and brachytherapy. We identified an episode which starts at the first planning code for radiation therapy services and lasted for 90 days. Based on a national analysis of Medicare claims, roughly 99% of beneficiaries receiving radiation therapy completed their course of radiation within 90 days of when their radiation treatment was planned.

The number and dosages vary for types and acuity of the cancer but in most cases, the radiation therapy treatments are completed within 9 weeks, which allows for enough time to include the planning phase and any immediate follow-up.

National Medicare claims data show that roughly 55% of radiation therapy episodes between January 1, 2013 and December 31, 2015 were to treat breast cancer (20.4%), lung cancer (20.0%), or prostate cancer (15.0%). Non-melanoma skin cancer (6.3%), head and neck cancer (5.5%), and lower gastrointestinal (GI) cancer (4.3%) were also commonly treated with radiation.<sup>45</sup> This is consistent with the selection of the most frequent cancers types in the Maryland-specific CCW Data:

- Breast
- Prostate
- Lung
- Head and Neck
- Bone Metastasis

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<sup>45</sup> Centers for Medicare & Medicaid Services (CMS), "Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services", pg. 5.

- Brain Metastasis

As for the modality of treatment for each cancer, there are three primary types of radiation therapy: external beam radiation therapy (EBRT), internal radiation therapy (brachytherapy), and infused radiopharmaceuticals.<sup>46</sup>

External-beam radiation therapy is commonly furnished by a linear accelerator (LINAC) machine from outside the body in the form of photon beams (either x-rays or gamma rays). Proton therapy is a type of EBRT that uses protons generated by a cyclotron or synchrotron. Patients usually receive EBRT in daily treatment sessions, Monday to Friday, over the course of several weeks. The number of treatment sessions and total radiation dose depend on many factors, including the specific cancer treated, individual patient characteristics, and available clinical evidence. The techniques for furnishing EBRT include CRT, IMRT, IGRT, Tomotherapy, SRS, SBRT, proton beam therapy, and electron beam therapy.<sup>47</sup>

Another type of radiation therapy treatment is internal radiation therapy or brachytherapy, which entails placing a radioactive isotope sealed inside a tiny seed (pellet) in the patient's body next to the cancer cells. These isotopes naturally decay and emit radiation that damages nearby cancer cells. Interstitial brachytherapy uses a radiation source placed within tumor tissue such as within a prostate tumor. Intra-cavity brachytherapy uses a radiation source placed within a surgical cavity or body cavity near the tumor such as a chest cavity. Brachytherapy techniques include high dose rate brachytherapy (HDR) and low dose rate (LDR) brachytherapy.<sup>48</sup>

A third major type of radiation therapy treatment is radiopharmaceutical therapy, which uses a radioactive substance given by mouth or into a vein, which can target cancer throughout the body. For example, radioactive iodine is often used to treat certain types of thyroid cancer, because thyroid cells naturally take up iodine.<sup>49</sup>

Since one of the purposes of this study was to compare costs between sites of service, we narrowed this population down further to create a better comparison:

1. Focused on the top 6 cancers by diagnosis where volumes were more likely to create valid comparisons;
2. Focused only on cases where a beneficiary only had one episode of treatment for a single cancer type. As multi-episode, multi-cancer cases are likely more complex, excluding them from the studied cost increases the comparability across places of service.

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<sup>46</sup> National Cancer Institute Radiation (2013) Therapy for Cancer. Available at: <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet#q8>.

<sup>47</sup> CMS, "Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services", pg. 6.

<sup>48</sup> Ibid, pg. 7.

<sup>49</sup> Ibid. pg. 7.

3. There are a number of situations where a beneficiary can begin the radiation oncology process and have a planning session with a Radiation Oncologist but never receive any radiation oncology treatment. These cases were excluded as they are comparatively low cost and can distort cost per case comparisons.
4. As the comparison was done at a cancer type and modality level (eg. IMRT, CRT, etc.), certain small volume combinations were lost due to CMS restrictions on the data source. As these are by definition small volume cells, they were not useful for the site of service comparison anyway.

Table 10 below displays the types of cancers by highest cost. For this analysis we chose the top 6 cancers below.

**Table 10. Maryland Radiation Oncology Cost by Cancer Type**

<b>Cancer Type</b>	<b>Radiation oncology costs</b>
PROSTATE	\$ 47,438,513
BREAST	\$ 32,634,628
LUNG	\$ 32,306,918
HEAD AND NECK	\$ 12,201,650
BONE METASTASIS	\$ 7,498,053
BRAIN METASTASIS	\$ 6,358,000
SKIN	\$ 4,935,857
UTERUS	\$ 4,387,299
ESOPHAGUS	\$ 4,192,823
COLORECTAL - RECTAL	\$ 3,948,049

Table 11 presents a summary of the Medicare beneficiary spending on radiation Oncology in 2016 and 2017.

**Table 11. Radiation Oncology Spending for Maryland MC FFS Beneficiaries, 2016 and 2017 (1)**

	Unique Beneficiaries	Episodes (2)	Medicare Spending (in 000's) (5)	Cost per Unique Beneficiary	% of Radiation Oncology Spend
Total spend on Radiation Oncology (3)	11,395	12,171	\$190,453	\$16,714	100%
Total spend on Radiation Oncology for 6 Main Cancers	7,956	8,484	\$138,438	\$17,400	73%
Spend on Single Episode, Single Cancer Beneficiaries	6,900	6,900	\$123,791	\$17,941	65%
Non-Suppressed Spend on Single Episode, Single Cancer Beneficiaries	6,132	6,132	\$112,013	\$18,267	59%
Total spend on all services during a radiation oncology episode (4)	11,395	12,171	\$388,175	\$34,065	204%
Total spend on non-radiation oncology services during a radiation oncology episode	11,395	12,171	\$197,722	\$17,352	104%

- 1 Cases starting in CY16 and CY17, run out through March 2018
- 2 An episode is defined as the 90-days following a Radiation Oncology Treatment Planning Episode
- 3 Radiation Oncology was defined using a set of CPT codes derived from a list published by ACRO. Certain modifications were made to the list to incorporate spending that is part of Radiation Oncology but which ACRO does not include because ACRO focuses on spending by Radiation Oncologists.
- 4 Include all medical spend during the defined 90-day window of a Radiation Oncology Episode
- 5 Reflects spending by Medicare only, out-of-pocket costs to the beneficiary are addressed separately.

Total spending for Maryland Medicare fee-for-service beneficiaries in 2016 and 2017 for radiation oncology related services was approximately \$190 million (or \$95 million per year) at an average cost of \$16,714 per episode. Spending on the top 6 cancers in our analysis represented 73% of all spending on radiation oncology.

We also calculated the total medical spend for beneficiaries while they were in a 90-day radiation oncology treatment episode. An additional \$197 million of spending was provided on non-radiation oncology services. This would include both other cancer treatment costs as well as unrelated medical spending. The average total cost of care (both radiation therapy related and non-radiation therapy services) was \$34,065 per 90-day episode. Since the average Maryland Medicare beneficiary incurs approximately \$11,700 of cost per year, this subset of beneficiaries is clearly more acute than average of all beneficiaries, and they incur higher costs for their radiation oncology and other services.

Different cancers and treatment modalities have different costs. Therefore, any comparison of site of service costs must consider the mix of cancers treated and the modalities used. As shown in Table 12, the cost per episode (including member cost share) can range from less than

\$10,000 for bone and brain metastasis to over \$35,000 for prostate IMRT. It is important to note that the site of service categories in this study are based on how they were coded and reported to Medicare, so there could be some inconsistencies.

**Table 12. Studied Radiation Oncology Spending by Cancer and Modality, 2016 and 2017**

Cancer	Modality	Episodes by Site of Service (1)			Total Medicare Spending (in 000's)	Total Beneficiary Spending	Total Spending (in 000's)	Cost per Episode	% of Total Studied
		Hospital	Hospital-Owned Freestanding	Non-Hospital Owned Freestanding					
BONE METASTASIS	CRT	351	122	36	\$3,561	\$964	\$4,525	\$8,890	3%
BRAIN METASTASIS	CRT	198	70	12	\$2,054	\$560	\$2,614	\$9,337	2%
BREAST	IORT	75	-	-	\$356	\$95	\$450	\$6,004	0%
BREAST	IMRT	131	52	32	\$4,465	\$1,207	\$5,672	\$26,381	4%
BREAST	CRT	1,087	515	113	\$24,910	\$6,774	\$31,684	\$18,474	22%
<b>Total Breast</b>		1,293	567	145	\$29,730	\$8,076	\$37,806	\$18,856	27%
HEAD AND NECK	IMRT	264	68	31	\$9,556	\$2,593	\$12,150	\$33,470	9%
LUNG	PBT	-	-	24	\$727	\$186	\$913	\$38,033	1%
LUNG	CRT	259	84	37	\$4,520	\$1,226	\$5,746	\$15,120	4%
LUNG	SBRT	389	63	9	\$8,658	\$2,381	\$11,039	\$23,947	8%
LUNG	IMRT	351	51	43	\$11,635	\$3,171	\$14,806	\$33,271	10%
<b>Total Lung</b>		999	198	113	\$25,540	\$6,963	\$32,503	\$24,812	23%
PROSTATE	BRACHYTHERAPY	55	150	53	\$2,314	\$603	\$2,917	\$11,307	2%
PROSTATE	IMRT	812	443	152	\$39,258	\$10,625	\$49,883	\$35,454	35%
<b>Total Prostate</b>		867	593	205	\$41,572	\$11,229	\$52,800	\$31,712	37%
<b>Total</b>		3,972	1,618	542	\$112,013	\$30,385	\$142,399	\$23,222	
<b>% of Episodes</b>		65%	26%	9%					

Source: CCW data

The Table above represents a subset of the total \$190.5 million in total radiation oncology spending due to CMS data and cell size restrictions. The total of the analyzed data is the \$112 million in non-suppressed charges. Consistent with data from CMS presented earlier in the report, 65% of radiation oncology episodes were performed in a hospital outpatient center, while 35% were done in freestanding facilities. As expected given the number of non-hospital owned centers in the State, only 9% of studied radiation oncology episodes were performed at non-hospital owned freestanding centers

The most expensive per episode costs are found in prostate care, \$31,712 per episode, and lung cancer with \$24,812 per episode. In line with national studies, the most expensive modality by cancer type is IMRT for prostate care which averages \$35,454 per episode, but head and neck related IMRT is close behind with \$33,470 per episode.

To compare cost by site of service, the focus was placed on specific modality/cancer combinations. To examine modality costs, we reviewed combinations that met two criteria: (1) reflect a significant percent of total spend; and (2) have sufficient volumes in all 3 site of service buckets to allow for a valid conclusion.

Tables 13A and 13B examine this in more detail for breast and prostate cancer where volumes are significant and there is considerable variation in treatment.

**Table 13A. Breast CRT Cost by Site of Service**

Site of Service	% of Cases	Total Avg. Cost	Total Ratio of Breast CRT Avg.	Beneficiary % of Cost	% of Average FSF Cost (1)
Hospital	63%	\$22,302	121%	22%	188%
Hospital-Owned Freestanding	30%	\$11,593	63%	20%	98%
Non-Hospital Owned Freestanding	7%	\$13,018	70%	20%	110%
Total	100%	\$18,474	100%	21%	156%

(1) FSF is the combination of hospital-owned and non-hospital-owned freestanding facilities

**Table 13B. Prostate IMRT Cost by Site of Service**

Site of Service	% of Cases	Total Avg. Cost	Total Ratio of Prostate IMRT Avg.	Beneficiary % of Cost	% of Average FSF Cost (1)
Hospital	58%	\$43,900	124%	22%	183%
Hospital-Owned Freestanding	31%	\$23,284	66%	20%	97%
Non-Hospital Owned Freestanding	11%	\$25,797	73%	20%	108%
Total	100%	\$35,454	100%	21%	148%

(1) FSF is the combination of hospital-owned and non-hospital-owned freestanding facilities

Examining the cost differential by site of service for breast CRT and prostate IMRT produces very similar results. Total hospital outpatient costs are about 185% of freestanding facility costs (188% for breast CRT and 183% for prostate IMRT), or about 120% the average across all sites of service. In both cases, hospital outpatient facilities retain about 60% of the volume (63% and 58%).

This analysis also highlights that the beneficiary portion of the spending represents about 21% of total spending. We found that this cost-share is consistent across all sites of service for the radiation oncology cases analyzed. However, as indicated in this report, between 75% and 80% of beneficiary costs are covered by a third-party (secondary insurance, Medicaid, etc.).

While hospital-owned freestanding facilities are marginally cheaper in both scenarios than non-hospital-owned freestanding facilities, the difference is small and it is not conclusive that it is a function of site of service as opposed to other variations.

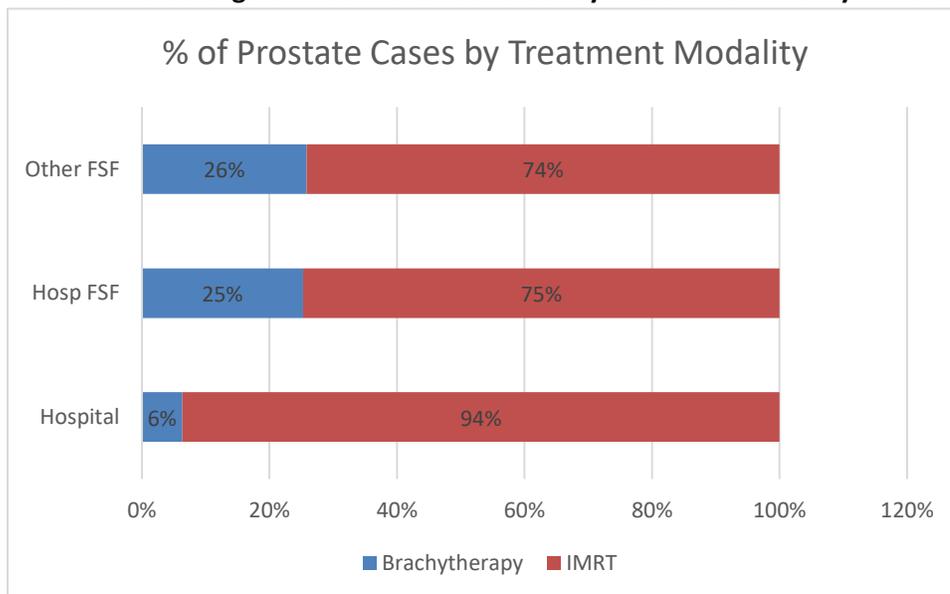
For the purpose of this report, the findings above highlights the point that further shifts from freestanding facilities to hospital outpatient centers can have a negative impact on the total

cost of care, especially since these patients tend to use more resources than the average of all Medicare patients for all of their services.

As several of the GAO studies have pointed out, even if freestanding facilities are less expensive for a specific modality, the savings could be eroded if facilities are disproportionately using more expensive treatment options, regardless of clinical necessity. For example, CRT is clinically indicated for most breast cancer cases, and the literature does not tend to support using IMRT as a standard of practice for many of these types cases. Therefore, if IMRT is used more heavily by a provider at a particular site of service compared to the overall state average by site of service, it may indicate providers in a particular site of service are overusing more expensive treatment options, potentially for reimbursement purposes. Since this was the subject of many national reports, we used our Maryland data to attempt to determine if there are practice variations in choosing a modality based on the site of service.

Tables 14, 15, and 16 show the modality usage by site of service for prostate, breast, and lung cancers. It is important to note that our data does not present all modality options but only the most prominent ones. For example, for prostate cancer, 7% of cases have used a modality of CRT, however, since the number of cases was extremely low in some sites of services, these data were suppressed in our analysis.

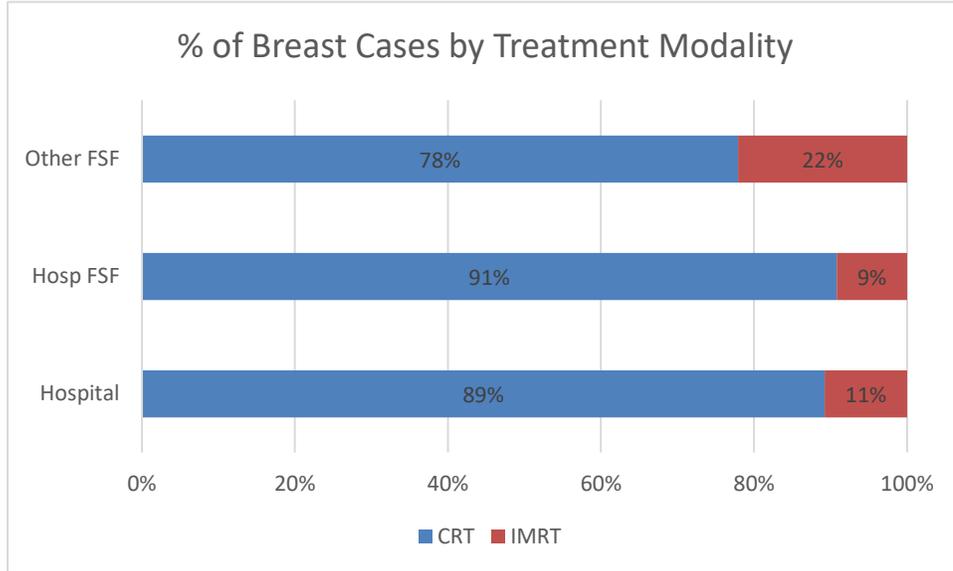
**Table 14. Percentage of Prostate Cancer Cases by Treatment Modality and Site of Services**



When comparing the use of Brachytherapy versus IMRT for prostate cancer, non-hospital owned freestanding facilities used IMRT 74% of time compared to 75% at hospital-owned freestanding facilities, and 94% for hospital outpatient departments. The per-episode cost of IMRT for prostate cancer is \$35,454 compared to \$11,307 for Brachytherapy. Hospital outpatient departments, therefore, have a greater tendency to use the more expensive IMRT

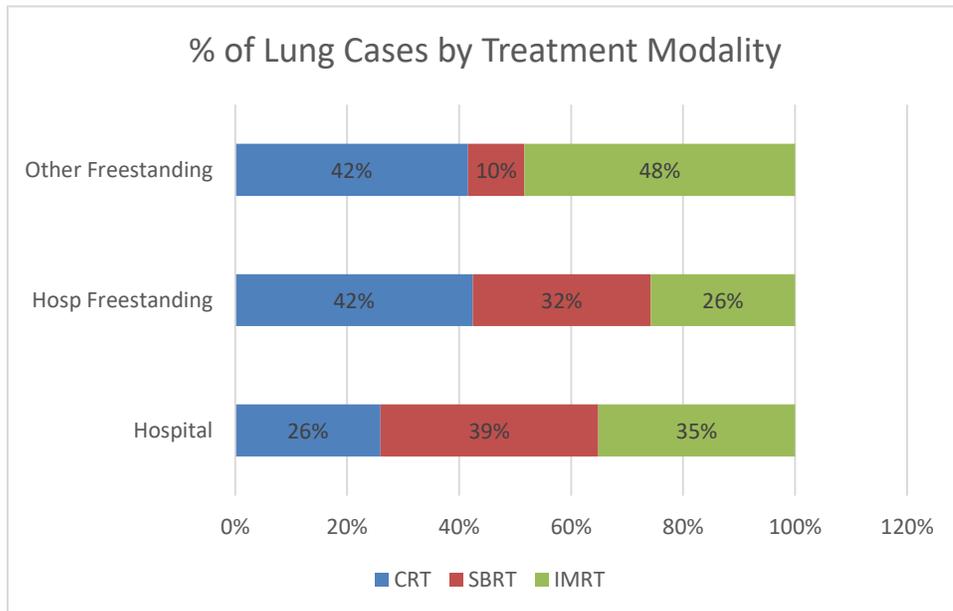
modality for prostate cancer than freestanding facilities, which is one of the drivers of the cost difference shown in Table 13B - \$43,900 average cost at a hospital facility versus approximately \$24,000 when performed in a freestanding facility.

**Table 15. Percentage of Breast Cancer Cases by Treatment Modality and Site of Services**



In breast cancer cases, non-hospital owned freestanding centers used IMRT twice as frequently as hospital owned facilities, however, they represent a small number of cases overall.

**Table 16. Percentage of Lung Cancer Cases by Treatment Modality and Site of Services**



For lung cancer, IMRT and SBRT combined account for between 58% and 74% of cases, with hospital outpatient facilities showing the highest combined use. Freestanding facilities utilize CRT more frequently and SBRT less frequently than hospital outpatient departments. Non-hospital-owned freestanding facilities use IMRT for lung cancer, the most expensive service, more frequently than their counterparts.

When looking at the data for breast and lung cancer, non-hospital owned freestanding centers used IMRT more frequently than hospital-owned facilities, however the cell size for these modalities at non-hospital facilities are small. Secondly, it is notable that hospital outpatient centers use IMRT for prostate cancer, the most costly radiation therapy modality, at a greater rate than freestanding facilities. Further examination would be required to determine the reason for these trends in services. Regardless, this study shows that usage of IMRT is a driver of the higher average cost for prostate cancer services at hospital outpatient centers.

In summary, Maryland Medicare data show that radiation therapy services are more expensive on a per-episode basis when performed at a hospital outpatient facility. As illustrated in Table 17, this holds true for each of the cancer types that we have analyzed. It is important to note that of the freestanding facilities, the radiation therapy episodes we examined are more expensive when performed at a non-hospital owned freestanding facility – \$21,499 versus \$14,565 at a hospital owned freestanding facility.

**Table 17. Total Single Episode Cancers by Site of Service**

<b>Cancer Type</b>	<b>Hospital Outpatient</b>	<b>Hospital Owned Freestanding</b>	<b>Non-Hospital Owned Freestanding</b>
BONE METASTASIS	\$8,814	\$6,396	\$6,756
BRAIN METASTASIS	\$12,898	\$6,688	\$6,637
BREAST	\$22,343	\$11,883	\$14,525
HEAD AND NECK	\$36,069	\$20,464	\$28,425
LUNG	\$27,753	\$12,639	\$20,946
PROSTATE	\$37,056	\$19,755	\$27,100
<b>TOTAL</b>	<b>\$26,188</b>	<b>\$14,565</b>	<b>\$21,499</b>

## Value-based Oncology Models

### Nationally

In an effort to achieve transformation of the health care system, CMS has been promoting value-based payment models across the health care system, moving away from fee-for-service payment that includes volume-based incentives. Value-based models are designed to

encourage all healthcare providers to deliver high quality care at lower total costs. The stated goals for value-based purchasing by CMS are:

- Financial Viability of the Payment System;
- Payment Incentives linked to quality and efficiency;
- Joint Clinical and Financial Accountability of Physicians and Providers;
- Effective and Evidence-based care;
- Ensuring Access;
- Safety and Transparency;
- Smooth Transition and Care Coordination; and
- Electronic Health Records.

Since the implementation of the Affordable Care Act (ACA), CMMI (Innovation Center) has been supporting the development and testing of innovative health care payment and delivery models. While value-based models have been operating for various medical disciplines such as primary care, oncology services have only recently entered into this environment. Until recently, CMS has not permitted Maryland to participate in such models, as CMS wanted assurances that there would be no overlaps with the State's current global budget payment structure. In recent months, CMS has permitted Maryland to begin to look at Maryland participating in certain value-based models to ensure that, under the Total Cost of Care All-Payer Model, there could be adequate incentives in place for non-hospital providers to provide value-based and transformative care.

Due to the prevalence and cost of cancer care, the Innovation Center has been studying the cost, utilization, and quality of cancer treatment, which includes the use of radiation therapy. Below is a summary of the existing and potential national models that could bring value-based oncology and/or radiation therapy services to Maryland.

#### [Oncology Care Model \(OCM\)](#)

The Oncology Care Model (OCM) is the first broadly implemented oncology value-based model initiated by CMS. It is a 5-year model that began on July 1 2016. It is intended to provide incentives for practices to address the complex needs of chemotherapy patients in a comprehensive and patient-centered manner.

The Model currently consists of 184 practices across the country, which include 6,500 practitioners, 150,000 unique beneficiaries, and 200,000 episodes per year. There are currently 13 commercial payers participating in the model as well, making this a multi-payer model. The Oncology Model incorporates a two-part payment system for participating practices, creating incentives to improve the quality of care and furnish enhanced services for beneficiaries who undergo chemotherapy treatment for a cancer diagnosis. The two forms of payment include a per-beneficiary Monthly Enhanced Oncology Services (MEOS) payment for the duration of the episode and the potential for a performance-based payment for episodes of chemotherapy care. The \$160 MEOS payment assists participating practices in effectively managing and

coordinating care for oncology patients during episodes of care, while the potential for performance-based payment incentivizes practices to lower the total cost of care and improve care for beneficiaries during treatment episodes.

The Oncology Care Model focuses on Medicare FFS beneficiaries receiving chemotherapy treatment and includes the spectrum of care provided to a patient during a six-month episode that begins with chemotherapy. OCM participants are Medicare-enrolled physician groups (including hospital-based practices) that furnish chemotherapy treatment. In addition, OCM participating practices must:

- Provide enhanced services, including:
  - The core functions of patient navigation;
  - A care plan that contains the 13 components in the Institute of Medicine Care Management Plan outlined in the Institute of Medicine report, *“Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis”*;<sup>50</sup>
  - Patient access 24 hours a day, 7 days a week to an appropriate clinician who has real-time access to practice’s medical records; and
  - Treatment with therapies consistent with nationally recognized clinical guidelines.
- Use data to drive continuous quality improvement; and
- Use certified electronic health record technology.

CMS utilizes clinical data and quality measures as a key mechanism to verify clinical improvements, assess patient health outcomes and appropriate coordination of care, and ensure continued quality of care for Medicare beneficiaries. CMS tracks participant performance on multiple quality domains using patient- and practice-reported measures as well as claims-based measures.

Applicants had the option to choose a one-sided or two-sided risk model. The one-sided risk model provides rewards but lower payment incentives while the two-sided risk model includes both reward and penalties, but the payment incentives are greater. All participants chose the one-sided risk model. However, regardless of the type of model chosen, all models are required to shift to a two-sided risk model in three years.

Until recently, CMS has not permitted Maryland to participate in such models, as they wanted to determine how we could ensure that there are no overlaps with Maryland’s current global budget payment structure. In recent months, CMS has permitted Maryland to begin to look at Maryland joining such value-based models to ensure that under the Total Cost of Care Model

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<sup>50</sup> Institute of Medicine, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, 2013

there could be adequate incentives in place for non-hospital providers to provide value-based and transformative care.

#### Bundled Payment for Care Improvement Advanced (BPCIA)

CMS issued a request for applications on January 9, 2018 for the Bundled Payment for Care Improvement Advanced. The goal of this model is to support providers in investing in practice innovation, care redesign, enhanced care coordination, and adoption of best practices. It piggybacks on the former Bundled Payment for Care Improvement program, but the new Model qualifies as an Advanced Alternative Payment Model (Advanced APM) which potentially qualifies providers for MACRA benefits. The program will start on October 1, 2018.

It entails a single payment and risk track for certain clinical episodes triggered by an inpatient stay or outpatient procedure with an episode period of 90 days. There are 29 inpatient clinical episodes and 3 outpatient clinical episodes. The outpatient episodes include Percutaneous Coronary Intervention (PCI), Cardiac Defibrillator, and Back and Neck (except spinal fusion). Under the current model none of the approved episodes are oncology based.

The episode is based on total cost of care for all items and services furnished to a participating patient, including outlier payments. Payment will also be linked to quality under a pay-for performance methodology. Participants will take on downside risk under this model. CMS aims to avoid duplicating payments with other CMS models such as the Oncology Care Model or under an Accountable Care Organization.

While this model currently does not include oncology services, Maryland could provide an opportunity in the future to expand the BPCIA model concept to include oncology or radiation therapy services if desired (see discussion of HSCRC model exploration below).

#### Radiation Therapy Model

The OCM model discussed above is a chemotherapy triggered model which, while it could have a positive impact on the cost and quality of cancer care in the State if implemented, does not directly address the primary issue considered in this study – radiation therapy. The Innovation Center is currently considering a model where the evaluated episode is triggered by a radiation therapy service. It is possible that the model could be operational in the next 2-3 years.

The Patient Access and Medicare Protection Act (PAMPA) (P.L. 114-115) directed the Secretary of Health and Human Services to submit a report to Congress on the development of an episodic alternative payment model (APM) for Medicare payment for radiation therapy services furnished in non-facility settings.<sup>51</sup> This report was submitted to Congress on November of 2017 entitled “Episodic Alternative Payment Model for Radiation Therapy Services.” The report recommended that CMS implement an Episodic Alternative Payment Model for Radiation Therapy Services.

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<sup>51</sup> Patient Access and Medicare Protection Act Pub. L. No. 114-115, 129 Stat 3131 (2015).

The report states that an episodic payment model for radiation therapy services could incentivize the use of clinical guidelines. An adherence to clinical guidelines may be measured and rewarded through the use of standardized, evidence-based, and well-tested clinical quality measures, or monitored through claims data and/or site visits.<sup>52</sup>

According to the report, “radiation therapy furnished in the freestanding and outpatient hospital settings has historically been paid on a per-service basis through the Physician Fee Schedule or the Hospital OPPS, respectively. Under the current fee-for-service system, some stakeholders have indicated there may be a financial incentive to provide more technically complex services. Both incentives may generate higher Medicare expenditures. An episode payment model offers the opportunity to shift incentives to focus on higher quality, more cost-effective care.”<sup>53</sup>

“For external beam radiation, the total radiation dose is typically split into daily fractions (i.e., the total radiation amount is divided into multiple treatments, which are known as fractions). Because Medicare pays on a per-fraction basis, there is an incentive to furnish more, rather than fewer, fractions... Modifying payment under an episode payment model could change the incentives and encourage physicians to pick higher-value modalities and furnish fewer fractions, where appropriate.”<sup>54</sup>

If, in fact, a radiation therapy model were adopted by CMS or Maryland, it would be essential to align the two models to ensure that they are not doubling incentives. A Medicare analysis showed that 31% of radiation therapy patients received chemotherapy 30 days before or 90 days after radiation. Since the OCM model episode is 6 months long, these treatments would be captured in the OCM episode. Anecdotal information shows that across all relevant cancers, approximately 15-20% of all chemotherapy patients receive radiation therapy concurrently. Nonetheless, the report indicated that an OCM and radiation therapy model could run concurrently with appropriate alignment.

#### Overview of Models

While these are the models in existence or being considered today, we should not be limited to considering only these models. CMS is and will continue to consider models that are intended to reduce cost, improve quality, and move the health care system to one that is patient-centered. Maryland should consider any new oncology models that are approved in the future as well.

However, it is important to note that since Maryland’s hospitals are considered an alternative payment model where there is two-sided risk (both upside and downside risk), it is important that adoption of these types of physician models in Maryland also have two-sided risk.

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<sup>52</sup> CMS, “Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services”, pg. 17.

<sup>53</sup> Ibid, pg. 17.

<sup>54</sup> Ibid, pg. 19.

All of the models discussed in this section could have value under the Total Cost of Care All-Payer Model in Maryland, but it is important for the HSCRC to vet these and any new models to ensure that there is continued value to the new TCOC Model. For such models to fit appropriately under the Maryland Model, it is important that costs and quality data continue to be tracked and evaluated, and that participation agreements are reviewed and approved (whether by CMS or Maryland) as required in the existing Care Redesign Programs (see below). In all of the models shown above, Medicare tracks and evaluates the participants to ensure that they comply and meet the goals of the program.

One observation regarding the aforementioned oncology models is that the quality metrics weigh heavily on process measures. Outcome data for most cancers requires long performance periods, which creates challenges to utilize outcome measures for rewards. However, it is important for CMS and HSCRC to consider whether certain outcome measures could be used in the evaluation process and consider how such measures can aid in improvement of Maryland's overall quality requirements under the All-Payer Model (i.e., Readmissions, Potentially Avoidable Utilization, etc.).

### Maryland

In an effort to expand the GBR incentives in Maryland's All-Payer Model, the State, with the approval of CMS, initiated a Care Redesign initiative. This initiative permits hospitals that are conveners in Medicare and HSCRC approved value-based payment models to share data, resources, and savings with both hospital and non-hospital providers. In 2017, the General Assembly adopted Chapter 226 (see Appendix III) to make it clear that the compensation arrangements and sharing of resources under these pre-approved and monitored models do not violate the Maryland self-referral law.

This legislative change cleared the way for the HSCRC, in conjunction with CMS, to implement its Care Redesign Program. In response to Maryland stakeholders' requests for greater provider alignment and transformation tools under the All-Payer Model, the State proposed a Care Redesign Amendment ("Amendment") to the All-Payer Model Agreement. The Amendment aims to modify the All-Payer Model by supporting:

- Effective care management and population health activities;
- Improvement in care for high and rising risk populations;
- Efforts to provide high quality, efficient, well-coordinated episodes of care;
- Hospitals and their Care Partners in monitoring and controlling Medicare beneficiaries' Total Cost of Care (TCOC) growth; and
- The next steps toward delivery system transformation

As of January 30, 2018, eighteen hospitals are participating in Care Redesign Programs and the number of participants is expected to continue to rise. The Amendment proposed two

voluntary, hospital-led programs, which align hospitals and their care partners through common goals and incentives. The two programs are known as (1) The Hospital Care Improvement Program (HCIP), and (2) Complex and Chronic Care Improvement Program (CCIP).

The HCIP is implemented by participant hospitals and hospital-based providers and aims to:

- Improve inpatient medical and surgical care delivery;
- Provide effective transitions of care;
- Ensure an effective delivery of care during acute care events, beyond hospital walls;
- Encourage the effective management of inpatient resources; and
- Reduced potentially avoidable utilization with a byproduct of reduced cost per acute care event.

Examples of categories of care redesign interventions in the HCIP include: care coordination, discharge planning, clinical care, patient safety, patient and caregiver experience, population health, and efficiency and cost reduction. Care Partners who choose to participate may receive incentive payments based on reducing internal costs through a reduction in unnecessary utilization and resources, efficient practice patterns, and improved quality.

The CCIP is implemented by participant hospitals, and community providers and practitioners; and aims to:

- Strengthen primary care supports for complex and chronic patients in order to reduce avoidable hospital utilization;
- Enhance care management through tools such as effective risk stratification, health risk assessments, and patient-driven care profiles and plans; and
- Facilitate overall practice transformation towards person-centered care that produces improved outcomes and meets or exceeds quality standards.

Examples of categories of Care Redesign Interventions in the CCIP include: care management, workforce capacity development, and health information technologies. In the CCIP, participant hospitals deploy care management resources and technology that align and support community-providers who work with the participant hospital. Care partners who choose to participate will have access to care management tools and resources targeted to high utilizer and rising risk patients that will support implementation of care plans, provide care coordination, and help manage care transitions. Participation in the CCIP is also tailored to leverage the Medicare Chronic Care Management (CCM) fee. Care partners who choose to participate may receive incentive payments from hospitals based on defined activities that improve quality of care and reduce potentially avoidable utilization of hospitals.

As discussed above, Maryland to date has not been permitted to participate in value-based models approved by CMS nationally (except for the HCIP and CCIP). However, with recent CMS clearance, the HSCRC has been exploring potential new models since it is essential to ensure

that non-hospital providers are operating with similar incentives to hospitals operating under the new TCOC Model. To that end, the HSCRC has formed a Stakeholder Innovation Group (SIG) to identify the most promising areas for development and implementation of alignment models and population health activities.

The Stakeholder Innovation Group has indicated an initial preference for the development of additional Advanced Alternative Payment Models (AAPM). The enhanced Total Cost of Care Model allows for development of care delivery and payment programs in two major categories:

1. **Care Redesign Programs** which must include a hospital and are funded out of global budgets; and New Model Programs, which are not directly associated with hospitals and are funded by CMS or some other funding source.
2. **New Model Programs**, similar to the Maryland Primary Care Program, require a longer approval time (likely 1-2 years), while Care Redesign Programs, similar to the Hospital Care Improvement Program, require less time.

The calendar established by CMS requires any new programs to be initiated for approval in June of 2018. Currently, the SIG is exploring options for development of a Maryland version of BPCI Advanced, which is one of several approved AAPM Models not currently available to Maryland providers. Opportunities to develop these programs with either a hospital or a physician group practice convener are under consideration.

## Conclusion

Based on the available information as summarized above, HSCRC staff concludes that it would be imprudent and potentially damaging to the Maryland Total Cost of Care All-Payer Model if self-referral of radiation therapy, CT, and MRI services were permitted under the self-referral law in the current fee-for-service environment. Various studies have shown that the incentives under fee-for-service arrangements can and have led to increasing volumes of services under the current reimbursement structure. Most of these findings revolved around diagnostic services and Intensity-Modulated Radiation Therapy (IMRT); however, the risks are too high in Maryland to assume that the same results would not extend beyond these services in a fee-for-service payment system. As shown in the Maryland data, radiation therapy is a high cost service; therefore, fluctuations in volume and cost from the base year for the total cost of care calculation can impact the total cost of care calculation and create strain on the requirements of the Total Cost of Care All-Payer Model. This is illustrated in Table 11, which shows that the average total cost of care (both radiation therapy related and non-radiation therapy related services) was \$34,065 during a 90-day episode across all cancers. The average Maryland Medicare beneficiary incurs approximately \$11,700 of cost in an entire year.

As stated in the legislative request, the ramifications to the State and the health care system of failing the total cost of care model are great. The legislative request states: “if Maryland loses the waiver, we simply cannot absorb the costs associated with the impact of a \$2.3 million loss in Medicare and Medicaid payments to the Maryland health care system every year.” Clearly the risks are high.

However, under the auspices of value-based alternative payment models, this discussion could also lead to positive opportunities for total cost of care savings in Maryland. In 2017, the General Assembly adopted legislation to provide an exemption in the self-referral law for an alternative payment model approved by the federal Centers for Medicare and Medicaid Services, whether it includes only Medicare Beneficiaries or both Medicare Beneficiaries and non-Medicare beneficiaries. This has permitted Maryland to consider implementing alternative payment models that go beyond just hospital services under its Care Redesign initiative. However, the in-office ancillary provision prohibiting self-referrals of radiation therapy, CT and MRI did not change.

This study shows that radiation therapy services are more expensive when conducted in a hospital outpatient department (\$26,188 per episode across all cancer types) than in a freestanding facility, whether owned by a hospital (\$14,565) or not owned by a hospital (\$21,499). This realization can lead to strategic thinking around how to best provide care at the most reasonable cost under an innovative value-based double sided risk model.

Heretofore, Maryland has not been permitted by CMS to participate in national models such as the Oncology Care Model (OCM) and the Bundled Care for Performance Improvement Advanced (BPCIA), limiting Maryland’s options in allowing physicians to participate in MACRA eligible programs that are not hospital-based. Currently only hospitals can be a convener under a care redesign alternative payment model in Maryland. With CMS’ clearance, HSCRC is now considering implementing models that would permit non-hospital providers to convene a value-based model. The existing self-referral law would prohibit radiation therapy providers from being conveners, or a medical oncology practice from being a convener, if it wishes to collaborate with a radiation therapy practice that it owns. Under a value-based Advanced Alternative Payment Model (Advanced APM), the volume incentives are removed, mitigating the aforementioned risks of altering the self-referral law under a fee-for-service model.

It is important to note that collaborations between non-hospital-based medical oncology practices and radiation therapy practices work well today and, if approved by the HSCRC and CMS, such arrangements can continue to work well under an Advanced Alternative Payment Model. However, the existing self-referral law would still restrict certain integrated community oncology service providers from referring within their group under an advanced alternative payment model even though the incentive to drive volume or increase the cost of the service is no longer present.

Various studies have shown the shifts of care from physician offices to hospital-owned care. This shift has occurred in Maryland too. As stated above, there are many reasons for this shift,

including the incentive for hospitals to establish networks to bring community physicians under the same incentives that are encumbered by hospitals. These shifts are causing growing hospital financial losses for physician services and the concentration of the physician market at hospitals. The HSCRC collects data on the amount of unregulated losses that are incurred by hospitals each year. A majority of these losses relate to subsidizing and paying for physician services even after reimbursements are incurred. The burden of physician losses has grown significantly over the past 10 years.

Table 18 shows that unregulated losses for physician services have grown between 2008 and 2017 by 165% - from \$219 million to \$581 million, respectively. These losses reflect the net losses after hospitals collect reimbursement related to the employed physicians' services. In 2007, physician losses represented 1.95% of net patient revenue. It now represents 3.84% of net patient revenue. Net physician related losses have grown 165% since 2008. While these losses are not entirely caused by hospitals acquiring physician services, it is, however, indicative of the financial burden that hospitals incur as the shift from physician offices to hospitals continues. Frequently when hospitals make requests to the Commission for rate increases, physician losses are frequently part of the reason for the subject hospital's financial pressure.

**Table 18. Gross in Maryland Hospital Physician Losses, FY 2008-2017**

	FY 2008	FY 2011	FY 2018	Growth FY 08-18
Net Patient Revenue (in 000's)	\$11,224,501	\$12,666,545	\$15,158,464	35.0%
Physician Losses (in 000's)	\$219,236	\$333,473	\$581,800	165.4%
Physician Losses as % of Net Patient Revenue	1.95%	2.63%	3.84%	

Source: FYs 2008, 2011, and 2018 HSCRC Disclosure Reports and Part B Data Set

As outlined in this report, CMS has developed and is continuing to develop models that can lessen the need for hospitals to acquire physician practices in order to align the financial interests of physicians with the All-Payer Model incentives. For years, HSCRC staff has maintained that a healthy provider market is one that has both hospital-based and non-hospital community-based physicians and providers working together for better patient care, and that it makes financial sense for hospitals to collaborate (not acquire) with community providers to the greatest extent practicable.

It is in the best interests of the Maryland Total Cost of Care All-Payer Model for as many physicians as possible, particularly those who provide high cost services, to participate in an alternative payment model based on value (not volume) that uses the same incentives under which hospitals operate, regardless of the ownership arrangement. Under MACRA, it is also in the best interest of many physician specialties to participate in an Advanced Alternative Payment Model.

Therefore, serious consideration should be given to altering the Maryland Patient Referral Law in a very limited way so that providers of oncological radiation therapy and therapeutic CT services may participate, and/or be conveners, in an Advanced Alternative Payment Model regardless of the ownership arrangement in Maryland. If so desired by the legislature, the following limitations and caveats should be applied to provide maximum protection for the Maryland Total Cost of Care All-Payer Model:

- Provide an exemption under an Advanced Alternative Payment Model (with two-sided risk) approved by CMS whether the model may be applied to only Medicare beneficiaries, or to both Medicare beneficiaries and individuals who are not Medicare beneficiaries.
- The exemption would only apply to patients and physicians participating under these approved models, and only for the period of time that the provider is participating in the approved model.
- Limited to oncological radiation therapy and therapeutic CT services only.
- As other Care Redesign Programs, the Model is vetted by the HSCRC and guided by participate agreements with the State (and the federal government as required), reporting, and evaluation.
- To the extent practicable, utilize as many outcome measures as reasonably possible in the evaluation process.
- Options to expand Models beyond Medicare so that the model is multiple payer or all-payer.

As the Health Services Cost Review Commission and the Maryland General Assembly consider any changes to the Maryland self-referral law, it is important to ensure that the Maryland Board of Physicians possesses the appropriate resources and authority to enforce the existing statute and any changes made to it. While this topic is beyond the purpose of this paper, it is advisable that the HSCRC work with the Board of Physicians to ensure that they are ready to enforce the law and any changes.

In the 2015 MHCC study on the self-referral law, the MHCC and their contractor Discern Health stated that Maryland's self-referral restrictions may prevent providers from testing innovative care delivery models under value-based purchasing arrangements. In addition, in the *Roadmap for Implementing Value Driven Health care in the Traditional Medicare Fee-for-Service Program*, CMS claims that "to support these [value-driven] payment systems, CMS would need to consider appropriate modifications to the physician self-referral rules so that hospitals and other institutional providers may reward physicians for improving quality and efficiency in their

local healthcare delivery settings.”<sup>55</sup> This statement refers to the national self-referral laws that apply to Medicare beneficiaries, which are less restrictive than Maryland’s self-referral law.

This report provides limited and measured options to permit oncological value-based Advanced Alternative Payment Models to take place in Maryland regardless of ownership structure in a manner that ensures that such a change to the Maryland self-referral law is consistent with the underlying goals and principles of the Maryland Total Cost of Care All-Payer Model.

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<sup>55</sup> [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/VBPRoadmap\\_OEA\\_1-16\\_508.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/VBPRoadmap_OEA_1-16_508.pdf)

THOMAS MAC MIDDLETON  
Legislative District 28  
Charles County

Chair

Finance Committee

Executive Nominations Committee

Rules Committee

Legislative Policy Committee

Spending Affordability Committee

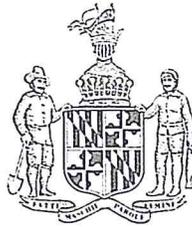
Senate Chair

Joint Committee on

Unemployment Insurance Oversight

Joint Subcommittee on Program Open

Space/Agricultural Land Preservation



THE SENATE OF MARYLAND  
ANNAPOLIS, MARYLAND 21401

October 17, 2017

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Mr. Nelson Sabatini  
Chair, Maryland Health Services Cost Review Commission  
4160 Patterson Avenue  
Baltimore, MD 21215

Dear Mr. Sabatini:

I am writing today to respectfully request that the Maryland Health Services Cost Review Commission (HSCRC) study an issue that has been the subject of a number of bills in Annapolis regarding changes to Maryland's self-referral law. As it relates to the jurisdiction of the Finance Committee, I am very concerned that the proposed changes could negatively impact Maryland's All-Payer Model agreement.

Recent legislation has ranged from broader bills impacting self-referral to a more recent proposal for the creation of an "integrated community oncology program". The stated purpose of the bill was to exempt a health care practitioner who has a beneficial ownership interest in radiation therapy equipment, and practices medicine at an integrated community oncology center in the program from general prohibitions against self-referrals by health care practitioners. The bill also would have provided for an evaluation of the new program once established as to how it impacted quality and cost of care and specifically how it would "achieve the goals and milestones of Maryland's all-payer model contract".

I am concerned about this retrospective type of approach because if a new program is already established that does in fact create problems under the State's All-Payer Model agreement, it might be too late to undo the impacts at that point in time. As you know, under Maryland's unique all-payer system, the state is required to reduce inappropriate utilization and place strict limits on health care spending, both in and outside of the hospital setting. As a part of this, there has always been broad agreement that we must pay particular attention prior to the introduction of new or additional health care services in the State.

We must consider not only whether there is sufficient need for new programs but also whether a new program will create negative pressure within what was the All-Payer Waiver and is now the All-Payer Model contract. We all know how high the stakes are as both consumers and

health care providers. If Maryland loses the waiver, we simply cannot absorb the costs associated with the impact of a \$2.3 billion loss in Medicare and Medicaid payments to Maryland health care system every year.

This summer, Chairman Pendergrass and I requested that the Maryland Health Care Commission (MHCC) study the State's Certificate of Need process with a report to be completed by May 2018. Although the issues are not directly related, for the reasons described above, I believe that the HSCRC's jurisdiction over the waiver, makes it the more appropriate agency to examine any impact this proposed policy change would have on the All-Payer Model Contract. It is my hope, however, that the HSCRC could complete the evaluation as to the impacts of these in the same time frame as the other MHCC study. Without this kind of analysis, I do not believe that we know enough about the impacts of these legislative self-referral proposals to be able to determine that they would not put our all-payer system in jeopardy.

Maryland's unique health care system does mean that we must often take a more cautious approach in order to preserve what I believe to be one of the best health care systems in the Country. Thank you for your work and for your consideration of this important matter. If you have any questions, please contact David Smulski.

Very truly yours,



Thomas McLain Middleton  
Chairman, Senate Finance Committee

## **Appendix II**

### 42 C.F.R. § 411.357 Exceptions to the referral prohibition related to compensation arrangements.

- (a) Rental of office space**
- (b) Rental of equipment**
- (c) Bona fide employment relationships**
- (d) Personal service arrangements**
- (e) Physician recruitment**
- (f) Isolated transactions**
- (g) Certain arrangements with hospitals**
- (h) Group practice arrangements with a hospital**
- (i) Payments by a physician**
- (j) Charitable donations by a physician**
- (k) Nonmonetary compensation**
- (l) Fair market value compensation**
- (m) Medical staff incidental benefits**
- (n) Risk-sharing arrangements**
- (o) Compliance training**
- (p) Indirect compensation arrangements**
- (q) Referral services**
- (r) Obstetrical malpractice insurance subsidies**
- (s) Professional courtesies**
- (t) Retention payments in underserved areas**
- (u) Community-wide health information systems**
- (v) Electronic prescribing items and services**
- (w) Electronic health records items and services**

### 42 C.F.R. § 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

- (a) Physician services**
- (b) In-office ancillary services**
- (c) Services furnished by an organization (or its contractors or subcontractors) to enrollees**
- (e) Academic medical centers**
- (f) Implants furnished by an ASC**
- (g) EPO and other dialysis-related drugs**
- (h) Preventive screening tests, immunizations, and vaccines**
- (i) Eyeglasses and contact lenses following cataract surgery**
- (j) Intra-family rural referrals**

42 U.S. Code § 1395nn - Limitation on certain physician referrals

**(a) Prohibition of certain referrals...**

**(b) General exceptions to both ownership and compensation arrangement prohibitions**

**(1) Physicians' services**

**(2) In-office ancillary services**

**(3) Prepaid plans**

**(4) Other permissible exceptions:** In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

**(5) Electronic prescribing**

**(e) Exceptions relating to other compensation arrangements**

**(1) Rental of office space; rental of equipment**

**(2) Bona fide employment relationships**

**(3) Personal service arrangements, including physician incentive plan**

**(4) Remuneration unrelated to the provision of designated health services**

**(5) Physician recruitment**

**(6) Isolated transactions**

**(7) Certain group practice arrangements with a hospital**

**(8) Payments by a physician for items and services**

## Chapter 226

**(Senate Bill 369)**

AN ACT concerning

**Maryland Patient Referral Law – Compensation Arrangements Under Federally Approved Programs and Models**

FOR the purpose of exempting, under certain circumstances, a health care practitioner who has a certain compensation arrangement with a health care entity from a certain provision of law that prohibits a health care practitioner from referring a patient or directing certain persons to refer a patient to a certain health care entity; providing that the exemption is null and void if the Maryland Insurance Commissioner issues a certain order; providing that a certain provision of this Act may not be construed to permit certain actions, impose certain obligations, require the disclosure of certain information, authorize a certain payment, permit an arrangement that violates certain provisions of law, modify certain definitions or exceptions, or require a compensation agreement to comply with a certain provision of this Act; establishing a certain filing fee; requiring a certain participation agreement and other documents to be filed for approval with the Commissioner within a certain period of time before a certain exemption is implemented; providing for a certain exception; requiring the Commissioner to make a certain determination within a certain period of time; requiring the Commissioner to issue a certain order to a filer under certain circumstances; requiring the Commissioner to hold a hearing before issuing an order and to give written notice of the hearing to the filer within a certain period of time; requiring the notice to specify certain matters; requiring a filer to submit a revised filing under certain circumstances; requiring the Commissioner to make a new determination under certain circumstances; making a certain filing subject to a certain fee; ~~altering a certain definition;~~ defining a certain ~~terms~~ term; and generally relating to patient referrals, compensation arrangements under federally approved programs and models, and the business of insurance.

~~BY repealing and reenacting, without amendments,  
Article – Health Occupations  
Section 1–301(a) and (g) through (i)  
Annotated Code of Maryland  
(2014 Replacement Volume and 2016 Supplement)~~

BY repealing and reenacting, with amendments,  
Article – Health Occupations  
Section ~~1–301(e), (k), and (l)~~ and 1–302  
Annotated Code of Maryland  
(2014 Replacement Volume and 2016 Supplement)

~~BY adding to  
Article – Health Occupations~~

~~Section 1-301(k)  
Annotated Code of Maryland  
(2014 Replacement Volume and 2016 Supplement)~~

BY adding to  
Article – Insurance  
Section 2-112(a)(12) and 15-143  
Annotated Code of Maryland  
(2011 Replacement Volume and 2016 Supplement)

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

### Article – Health Occupations

~~1-301.~~

~~(a) In this subtitle the following words have the meanings indicated.~~

~~(e) (1) “Compensation arrangement” means any agreement or system involving any remuneration, INCLUDING CASH OR IN-KIND COMPENSATION, 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:~~

~~(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;~~

~~(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;~~

~~(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. The arrangement is for identifiable services;~~

~~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~~

~~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;~~

~~(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;~~

~~(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;~~

~~2. The amount of the compensation under the arrangement 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~~

~~3. The health care entity needs the services of the practitioner to meet community health care needs and has had difficulty in recruiting a practitioner;~~

~~(vi) Payments made for the rental or lease of office space if the payments are:~~

~~1. At fair market value; and~~

~~2. In accordance with an arm's length transaction;~~

~~(vii) Payments made for the rental or lease of equipment if the payments are:~~

~~1. At fair market value; and~~

~~2. In accordance with an arm's length transaction; or~~

~~(viii) Payments made for the sale of property or a health care practice if the payments are:~~

~~1. At fair market value;~~

~~2. In accordance with an arm's length transaction; and~~

~~3. The remuneration is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made.~~

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

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

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

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

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

~~(k) "IN-KIND COMPENSATION" MEANS THE SHARING OF STAFF, RESOURCES, INFRASTRUCTURE, TECHNOLOGY, SOFTWARE, DATA, OR ANALYTICS.~~

~~[(k)](L) (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.~~

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

~~(i) Magnetic resonance imaging services;~~

~~(ii) Radiation therapy services; or~~

~~(iii) Computer tomography scan services.~~

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

~~(2) "Referral" includes:~~

~~(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~~

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

1-302.

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

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

(2) In which the practitioner's immediate family owns a beneficial 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.

(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.

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

(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;

(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;

(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;

(4) A health care practitioner who refers in-office ancillary services or tests that are:

(i) Personally furnished by:

1. The referring health care practitioner;
2. A health care practitioner in the same group practice as the referring health care practitioner; or
3. 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;

(ii) Provided 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

(iii) Billed by:

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

(5) A health care practitioner who has a beneficial interest in a health 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

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

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

(7) A health care practitioner or member of a single specialty group practice, including any person employed or affiliated with a hospital, who has a beneficial interest in a health care entity that is owned or controlled by a hospital or 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;

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

(i) The beneficial interest was held or the compensation arrangement was in existence on January 1, 1993; and

(ii) Thereafter the beneficial interest or compensation arrangement of the health care practitioner does not increase;

(9) A health care practitioner when treating an enrollee of a provider–sponsored organization as defined in § 19–7A–01 of the Health – General Article if the health care practitioner is referring enrollees to an affiliated health care provider of the provider–sponsored organization;

(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]

(11) A health care practitioner who refers a patient to a hospital in which the health care practitioner has a beneficial interest if:

(i) The health care practitioner is authorized to perform services at the hospital; and

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

**(12) SUBJECT TO SUBSECTION (F) OF THIS SECTION, A HEALTH CARE PRACTITIONER WHO HAS A COMPENSATION ARRANGEMENT WITH A HEALTH CARE ENTITY, IF THE COMPENSATION ARRANGEMENT IS FUNDED BY OR PAID UNDER:**

**(I) A MEDICARE SHARED SAVINGS PROGRAM ACCOUNTABLE CARE ORGANIZATION AUTHORIZED UNDER 42 U.S.C. § 1395JJJ;**

**(II) AS AUTHORIZED UNDER 42 U.S.C. § 1315A:**

1. AN ADVANCE PAYMENT ACCOUNTABLE CARE ORGANIZATION MODEL;

2. A PIONEER ACCOUNTABLE CARE ORGANIZATION MODEL; OR

3. A NEXT GENERATION ACCOUNTABLE CARE ORGANIZATION MODEL;

(III) AN ALTERNATIVE PAYMENT MODEL APPROVED BY THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES; OR

(IV) ANOTHER MODEL APPROVED BY THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES THAT MAY BE APPLIED TO HEALTH CARE SERVICES PROVIDED TO BOTH MEDICARE BENEFICIARIES AND INDIVIDUALS WHO ARE NOT MEDICARE BENEFICIARIES.

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

(F) IF THE MARYLAND INSURANCE COMMISSIONER ISSUES AN ORDER UNDER § 15–143 OF THE INSURANCE ARTICLE THAT A COMPENSATION ARRANGEMENT FUNDED BY OR PAID UNDER A PAYMENT MODEL LISTED IN SUBSECTION (D)(12) OF THIS SECTION VIOLATES THE INSURANCE ARTICLE OR A REGULATION ADOPTED UNDER THE INSURANCE ARTICLE, THE EXEMPTION PROVIDED UNDER SUBSECTION (D)(12) OF THIS SECTION FOR A HEALTH CARE PRACTITIONER WHO HAS THE COMPENSATION ARRANGEMENT WITH A HEALTH CARE ENTITY IS NULL AND VOID.

(G) SUBSECTION (D)(12) OF THIS SECTION MAY NOT BE CONSTRUED TO:

(1) PERMIT AN INDIVIDUAL OR ENTITY TO ENGAGE IN THE INSURANCE BUSINESS, AS DEFINED IN § 1–101 OF THE INSURANCE ARTICLE, WITHOUT OBTAINING A CERTIFICATE OF AUTHORITY FROM THE MARYLAND INSURANCE COMMISSIONER AND SATISFYING ALL OTHER APPLICABLE REQUIREMENTS OF THE INSURANCE ARTICLE;

(2) (I) IMPOSE ADDITIONAL OBLIGATIONS ON A CARRIER PROVIDING INCENTIVE–BASED COMPENSATION TO A HEALTH CARE PRACTITIONER UNDER § 15–113 OF THE INSURANCE ARTICLE; OR

(II) REQUIRE THE DISCLOSURE OF INFORMATION REGARDING THE INCENTIVE-BASED COMPENSATION, EXCEPT AS REQUIRED UNDER § 15-113 OF THE INSURANCE ARTICLE;

(3) AUTHORIZE A HEALTH CARE ENTITY TO KNOWINGLY MAKE A DIRECT OR INDIRECT PAYMENT TO A HEALTH CARE PRACTITIONER AS AN INDUCEMENT TO REDUCE OR LIMIT MEDICALLY NECESSARY SERVICES TO INDIVIDUALS WHO ARE UNDER THE DIRECT CARE OF THE HEALTH CARE PRACTITIONER;

(4) PERMIT AN ARRANGEMENT THAT VIOLATES:

(I) § 14-404(A)(15) OF THIS ARTICLE; OR

(II) § 8-508, § 8-511, § 8-512, § 8-516, OR § 8-517 OF THE CRIMINAL LAW ARTICLE;

(5) NARROW, EXPAND, OR OTHERWISE MODIFY:

(I) ANY DEFINITION IN § 1-301 OF THIS SUBTITLE, INCLUDING THE DEFINITION OF “IN-OFFICE ANCILLARY SERVICES”; OR

(II) ANY EXCEPTION IN SUBSECTION (D)(4) OF THIS SECTION INCLUDING THE EXCEPTION FOR REFERRALS FOR IN-OFFICE ANCILLARY SERVICES OR TESTS; OR

(6) REQUIRE A COMPENSATION ARRANGEMENT TO COMPLY WITH THE PROVISIONS OF SUBSECTION (D)(12) OF THIS SECTION IF THE COMPENSATION ARRANGEMENT IS ~~DESCRIBED IN~~ EXEMPT UNDER ANY OTHER PROVISION OF SUBSECTION (D) OF THIS SECTION.

Article - Insurance

2-112.

(a) Fees for the following certificates, licenses, permits, and services shall be collected in advance by the Commissioner, and shall be paid by the appropriate persons, including health maintenance organizations, to the Commissioner:

(12) FEES FOR REQUIRED FILINGS UNDER § 15-143 OF THIS ARTICLE.....\$125

15-143.

**(A) IN THIS SECTION, “PARTICIPATION AGREEMENT” MEANS A CONTRACT THAT:**

**(1) IS EXECUTED BY A PAYOR OR PROGRAM ADMINISTRATOR AND OTHER PARTICIPATING ENTITIES; AND**

**(2) DESCRIBES THE REQUIREMENTS FOR PARTICIPATION IN A PAYMENT MODEL SUBJECT TO THIS SECTION.**

**(B) THIS SECTION APPLIES ONLY TO A PAYMENT MODEL DESCRIBED IN § 1-302(D)(12) OF THE HEALTH OCCUPATIONS ARTICLE:**

**(1) THAT APPLIES TO INDIVIDUALS COVERED UNDER HEALTH INSURANCE; AND**

**(2) UNDER WHICH THERE IS CASH COMPENSATION.**

**(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, AT LEAST 60 DAYS BEFORE AN EXEMPTION PROVIDED UNDER § 1-302(D)(12) OF THE HEALTH OCCUPATIONS ARTICLE FOR A PAYMENT MODEL SUBJECT TO THIS SECTION IS IMPLEMENTED, THE PARTICIPATION AGREEMENT AND OTHER DOCUMENTS RELEVANT TO THE PAYMENT MODEL UNDER WHICH A COMPENSATION ARRANGEMENT BETWEEN A HEALTH CARE PRACTITIONER AND A HEALTH CARE ENTITY IS FUNDED OR PAID SHALL BE FILED WITH THE COMMISSIONER.**

**(2) THE FILING UNDER PARAGRAPH (1) OF THIS SUBSECTION IS NOT REQUIRED IF THE COMPENSATION ARRANGEMENT IS FUNDED FULLY BY OR PAID FULLY UNDER THE MEDICARE OR MEDICAID PROGRAM.**

**(D) WITHIN 60 DAYS AFTER THE DOCUMENTS REQUIRED UNDER SUBSECTION (C)(1) OF THIS SECTION ARE FILED, THE COMMISSIONER SHALL DETERMINE IF ANY COMPENSATION ARRANGEMENT BETWEEN A HEALTH CARE PRACTITIONER AND A HEALTH CARE ENTITY FUNDED BY OR PAID UNDER THE PAYMENT MODEL:**

**(1) IS INSURANCE BUSINESS; AND**

**(2) VIOLATES THIS ARTICLE OR A REGULATION ADOPTED UNDER THIS ARTICLE.**

**(E) (1) IF THE COMMISSIONER DETERMINES THAT A COMPENSATION ARRANGEMENT IS INSURANCE BUSINESS AND VIOLATES THIS ARTICLE OR A REGULATION ADOPTED UNDER THIS ARTICLE, THE COMMISSIONER SHALL ISSUE AN**

**ORDER TO THE FILER THAT SPECIFIES THE WAYS IN WHICH THE COMPENSATION ARRANGEMENT VIOLATES THIS ARTICLE OR A REGULATION ADOPTED UNDER THIS ARTICLE.**

**(2) (I) THE COMMISSIONER SHALL HOLD A HEARING BEFORE ISSUING AN ORDER UNDER PARAGRAPH (1) OF THIS SUBSECTION.**

**(II) THE COMMISSIONER SHALL GIVE WRITTEN NOTICE OF THE HEARING TO THE FILER AT LEAST 10 DAYS BEFORE THE HEARING.**

**(III) THE NOTICE SHALL SPECIFY THE MATTERS TO BE CONSIDERED AT THE HEARING.**

**(3) IF THE COMPENSATION ARRANGEMENT BETWEEN A HEALTH CARE PRACTITIONER AND A HEALTH CARE ENTITY CHANGES DURING ITS TERM:**

**(I) THE FILER SHALL SUBMIT A REVISED FILING TO THE COMMISSIONER FOR REVIEW OF THE CHANGES; AND**

**(II) THE COMMISSIONER SHALL MAKE A NEW DETERMINATION, AS PROVIDED UNDER SUBSECTION (D) OF THIS SECTION.**

**(F) A FILING UNDER SUBSECTION (C) OF THIS SECTION IS SUBJECT TO THE FEE REQUIRED UNDER § 2-112(A)(12) OF THIS ARTICLE.**

**SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ June 1, 2017.**

**Approved by the Governor, April 18, 2017.**

## Appendix IV

### Summary of Key Studies and Reports

Title and Author	Key Findings
Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA's Scrutiny: GAO, 1994	Florida physicians with a financial interest in joint-venture imaging centers had higher referral rates for almost all types of imaging services than other Florida physicians. Physicians with an interest in imaging centers that offered MRI services ordered twice as many MRI scans as other physicians.
Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions: GAO, 2012	From 2004 through 2010, the number of self-referred and non-self-referred advanced imaging services – MRI and CT – both increased, with the larger increase among self-referred services. For example, the number of self-referred MRO services increased over this period by more than 80 percent, compared with an increase of 12 percent for non-self-referred MRI and CT services. Medicare spent approximately \$190 million more in 2010 than it would have without these self-referral incentives.
Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny: GAO, 2013	The number of Medicare prostate cancer-related intensity-modulated radiation therapy (IMRT) services performed by self-referring groups increased rapidly, while declining for non-self-referring groups from 2006 to 2010. Over this period, the number of prostate cancer-related IMRT performed by self-referring groups increased from about 80,000 to 366,000. The growth in services performed by self-referring groups was due entirely to limited-specialty groups – groups comprised of urologists and a small number of other specialties – rather than multispecialty groups. Self-referring providers were 53% more likely to refer their prostate cancer patients for IMRT than non-self-referring providers.
Physician self-referral and physician-owned specialty facilities: Robert Wood Johnson, 2008	There is strong evidence that self-referral increases the utilization of health care services and indirect evidence that at least some of this increase is not medically appropriate. The factors that lead to self-referral include: (1) the opportunity to be paid both a professional fee and a facility fee, (2) fee-for-service payment and the opportunity to increase the volume of services provided, (3) the ability to profit from services that use little of the physician's time, (4) cost containment policies, (5) efficiency, (6) higher reimbursement for certain services.
A Detailed Diagnosis of Integrated Community Oncology: BRG Health Care, 2015	Integrated community oncology practices share a number of common characteristics, including care coordination, patient-physician communication, and personal attention, but are uniquely shaped by the communities in which they operate. Integrated community oncology practices provide access to cancer care at a lower cost than hospital outpatient departments. The most quantifiable benefit for patients, which has been demonstrated in multiple studies, is lower out-of-pocket costs for cancer treatment delivered in the community setting comparable to hospitals.

<p>Cost Differences in Cancer Care Across Setting: The Moran Company, 2013</p>	<p>By a variety of metrics, estimated chemotherapy spending is higher under the Hospital Outpatient Prospective Payment system (OPPS) than corresponding payments in the physician office under the Medicare Physician Fee Schedule (MPFS) for the same set of patients despite lower unit payment rates for drugs in the OPPS during the 2009-2011 period. Our comparison of service use rates across settings leads to the conclusion that patients receive more chemotherapy administration sessions on average when treated in the outpatient hospital—and that the dollar value of chemotherapy services used is meaningfully higher in the outpatient hospital.</p>
<p>Radiation Oncology Physician Practice in the Modern Era: A Statewide Analysis of Medicare Reimbursement: Cureus, 2017</p>	<p>We queried the 2013 Medicare Provider and Utilization and Payment Data for radiation oncologists in New York State, obtained from <a href="http://www.CMS.gov">www.CMS.gov</a>. We demonstrated that physicians working at urology practices generate increased revenues by combining high patient volumes with increased IMRT utilization. This report supplements and extends earlier work documenting practice patterns for combined urology and radiation oncology groups. Our study confirms prior research which demonstrated that freestanding centers utilized IMRT at a higher rate than hospital-based practices but provides richer detail by practice site. While improper variation in IMRT utilization can increase costs without improving outcome, appropriate use of IMRT can be highly beneficial.</p>
<p>Total Cost of Cancer Care by Site of Services: Physician Office vs Outpatient Hospital: Avalere, 2012</p>	<p>Avalere Health analyzed three years of commercial health plan data to examine the differences in the total cost of care for cancer patients based on the site of service of chemotherapy or radiation therapy. Our risk-adjusted results suggest that treatment for patients receiving chemotherapy in a HOPD costs on average 24 percent more than treatment received in a physician’s office. We also found care for patients treated in a physician’s office less expensive regardless of the length of the chemotherapy duration. Similar to unadjusted numbers, radiation therapy episodes of one or two months were more expensive when HOPD-managed, while episodes of three months were less expensive when HOPD-managed.</p>
<p>Site of Service Cost Difference for Medicare Patient Receiving Chemotherapy: Milliman, 2011</p>	<p>On an annualized basis, taking into consideration the average number of member months that chemotherapy patients are covered by Medicare a year, the total costs for physician office patients and hospital outpatient patients are approximately \$47,500 and \$54,000, respectively. This produces an annual cost difference of approximately \$6,500 per patient per year. Patient pay amounts were about 10% higher for the hospital outpatient patients, which total over \$650 per patient per year.</p>
<p>Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014, JAMA April 2018</p>	<p>Spending on chemotherapy drugs is lower when the medicine is administered in physician offices as opposed to hospital outpatient facilities, according to a 10-year study of more than 280,000 commercially insured patients.</p>

<p>Implications of Hospital Employment of Physicians on Medicare and Beneficiaries: Physicians Advocacy Institute, 2017</p>	<p>This study was not focused on Oncology but highlighted the growing rates of physician practice acquisition. Physician employment by hospitals grew by 49% between 2012 and 2015. Healthcare services provided in hospital outpatient (HOPD) settings are reimbursed at higher rates than when provided in physician offices. Physicians employed by hospitals perform a higher volume of services in HOPD settings than in physician offices.</p>
<p>The Value of Community Oncology: Site of Care Cost Analysis: Xcenda, 2017</p>	<p>The study included 6675 patients receiving chemotherapy, radiation, and/or surgery for the 3 types of cancer between July 10, 2010, and June 20, 2015. Results showed that the mean total price per month per patient for community practices was \$12,548, whereas the mean total for hospital-based practices was \$20,060, an almost \$8000 difference. Community practices also saw 28% fewer emergency department visits 3 days post-treatment and 18% fewer emergency department visits after 10 days.</p>
<p>Differences in Health Care Use and Costs Among Patients With Cancer Receiving Intravenous Chemotherapy in Physician Offices Versus in Hospital Outpatient Settings: J Oncology Pract, Jan. 2017</p>	<p>This retrospective study, which was based on medical and pharmacy claims data, included patients (age, 18 to 64 years) initiating IV chemotherapy/biologic treatment between January 1, 2006, and August 31, 2012, who were diagnosed with early or metastatic breast cancer, metastatic lung cancer, metastatic colorectal cancer, or non-Hodgkin lymphoma or chronic lymphocytic leukemia. Cancer-related inpatient hospitalizations were lower in the physician office (PO) group than in the Hospital outpatient (HOP) group. Although quality-of-care metrics were similar between the HOP and PO groups, follow-up all-cause costs (\$82,773 PO v \$122,473 HOP) and cancer-related health care costs (\$69,037 PO v \$108,177 HOP) were higher in the HOP group than in the PO group.</p>
<p>Cost Differential by Site of Service for Cancer Patients Receiving Chemotherapy: The American Journal of Managed Care, March 2015</p>	<p>To compare the costs of: 1) chemotherapy treatment across clinical, demographic, and geographic variables; and 2) various cancer care-related cost categories between patients receiving chemotherapy in a community oncology versus a hospital outpatient setting. Data from the calendar years 2008 to 2010 from the Truven Health Analytics MarketScan Commercial Claims and Encounters Database were analyzed. Patients receiving chemotherapy treatment in the community oncology clinic had a 20% to 39% lower mean per member per month cost of care, depending on diagnosis, compared with those receiving chemotherapy in the hospital outpatient setting. This cost differential was consistent across cancer type, geographic location, patient age, and number of chemotherapy sessions.</p>
<p>Urologist' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer: New England Journal of Medicine, October 2013</p>	<p>Using Medicare claims from 2005 through 2010, I constructed two samples: one comprising 35 self-referring urology groups in private practice and a matched control group comprising 35 non-self-referring urology groups in private practice, and the other comprising non-self-referring urologists employed at 11 National Comprehensive Cancer Network centers matched with 11 self-referring urology groups in private practice. The rate of IMRT use by self-referring urologists in private practice increased from 13.1 to 32.3%, an increase of 19.2</p>

	percentage points. Among non–self-referring urologists, the rate of IMRT use increased from 14.3 to 15.6%, an increase of 1.3 percentage points.
Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer: GAO June 2013	GAO estimates that in 2010, self-referring providers likely referred over 918,000 more anatomic pathology services than if they had performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers. These additional referrals for anatomic pathology services cost Medicare about \$69 million. To the extent that these additional referrals were unnecessary, avoiding them could result in savings to Medicare and beneficiaries, as they share in the cost of services.
Impact of Medicare Payments of Shift in Site of Care for Chemotherapy Administration: BRG Research Group, June 2014	By 2012 approximately 0.77 million claims had shifted into the hospital outpatient department setting on an annual basis. Chemotherapy claims attributable to 340B hospital acquisitions of physician-based oncology practices (0.12 million) account for at least 15.6 percent of the shift in the site of care from physicians’ offices to hospital outpatient departments. Medicare and Medicare beneficiaries incurred additional costs (allowed amount) of \$196.55 million for chemotherapy claims attributable to the 86 340B hospitals’ acquisitions of physician-based oncology practices. These additional costs represented 39.8 percent of the total allowed amount and were a function of increased utilization and higher reimbursement rates in hospital outpatient departments.
Hospital Acquisitions of Physician Practices and the 340B program: Avalere Health LLC, June 2015	This analysis found that 61 percent of hospitals identified as potentially acquiring physician practices between 2009 and 2013 participated in the 340B Program. This 61 percent 340B participation rate among the acquiring hospitals is higher than the overall 45 percent 340B participation rate among all hospitals in the study. It is beyond the scope of this study to determine whether 340B itself is contributing to physician practice acquisitions. However, the results suggest that policy makers may want to consider whether the 340B program creates financial incentives for hospitals to acquire a community-based physician practice.
Total expenditures per patient in hospital-owned and physician-owned physician organizations in California: JAMA, Oct. 2014	From the perspective of the insurers and patients, between 2009 and 2012, hospital-owned physician organizations in California incurred higher expenditures for commercial HMO enrollees for professional, hospital, laboratory, pharmaceutical, and ancillary services than physician-owned organizations. Although organizational consolidation may increase some forms of care coordination, it may be associated with higher total expenditures.
Presentation to the MHCC Provider Carrier Work Group: Discern Health	Maryland’s self-referral restrictions may prevent providers from testing innovative care delivery models under value-based purchasing arrangements

Appendix V

340B HOSPITALS

Hospital	Comments
Garrett County Memorial Hospital	
Holy Cross Hospital	
Holy Cross Hospital - Germantown	
Johns Hopkins Bayview Medical Center	
Johns Hopkins Hospital	
MedStar Franklin Square Hospital Center	
MedStar Good Samaritan Hospital	
MedStar Harbor Hospital	
MedStar St. Mary's Hospital	
MedStar Union Memorial Hospital	
Mercy Medical Center	
Northwest Hospital Center	
Peninsula Regional Medical Center	Began participating 10/17
Prince Georges Hospital Center	
Shady Grove Adventist Hospital	
Sinai Hospital	
St. Agnes	
University of Maryland Medical Center	
University of Maryland Medical Center Midtown Campus	
University of Maryland Rehabilitation &Orthopeadic Institute	
Washington Adventist Hospital	
Western Maryland Regional Medical Center	
Bon Secours	Approved not participating
Union of Cecil	Approved not participating
Med Star Southern Maryland Hospital Center	Approved not participating