Appendix A- Workgroup Members and Attendance

Participant		Meeting 1	Meeting 2	Meeting 3	Meeting 4	Meeting 5
Harbhajan	Ajrawat	**X**	**X**	**X**	**X**	**X**
Salliann	Alborn	**X**	**X**			
Alex	Blum					
Albert	Blumberg	**X**	**X**	**X**	**X**	**X**
J. Michael	Brooks		**X**			
Kimberly	Cammarata	**X**	**X**	**X**	**X**	**X**
Adrienne	Ellis			**X**		
John	Fleig	**X**			**X**	
Nick	Grosso	**X**	**X**	**X**	**X**	**X**
Wynee	Hawk	**X**	**X**	**X**	**X**	
Regina	Holiday					
Laurie	Kuiper	**X**			**X**	
Edward	Lee	**X**	**X**	**X**	**X**	
Arnold	Levy	**X**	**X**	**X**	**X**	**X**
Loralie	Ma	**X**	**X**	**X**	**X**	**X**
Erin	McMullen	**X**	**X**	**X**	**X**	**X**
Steve	Ports	**X**	**X**		**X**	**X**
Gary	Pushkin	**X**		**X**	**X**	**X**
P. Gregory	Rausch		**X**	**X**		
William	Regine	**X**	**X**	**X**	**X**	**X**
Deborah Daniel	Rifkin or Winn	**X**	**X**	**X**	**X**	
Kimberly	Robinson	**X**		**X**	**X**	
Timothy	Robinson	**X**	**X**	**X**	**X**	**X**
Matthew	Sahayda					
Nicole	Stallings	**X**	**X**	**X**	**X**	**X**
Joel	Suldan	**X**	**X**	**X**	**X**	**X**
Pegeen	Townsend	**X**	**X**		**X**	**X**
Benjamin	Turner	**X**	**X**	**X**		**X**
Francisco	Ward					
Moody	Wharam	**X**	**X**	**X**	**X**	**X**
Joe	Winn	**X**		**X**		

Appendix B

STATE OF MARYLAND

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

January 8, 2015

The Honorable Peter Hammen
241 House Office Building
6 Bladen Street
Annapolis, MD 21401

Dear Chairman Hammen:

The Maryland Health Care Commission (MHCC) is submitting the MRI (Magnetic Resonance Imaging) Self-Referral Study that you requested on behalf of the Health and Government Operations Committee at the conclusion of the 2013 legislative session. The study found that financial ownership was not related to MRI referral rates for practices that owned MRI equipment during the period of the study. However, practices that had a financial interest in MRI equipment had higher MRI referral rates than comparison practices in 2010 prior to divestiture and in 2012 after the Court of Appeals affirmed the divestiture order.

Braid-Forbes Health Research, LLC conducted the study under a small procurement contract awarded in May of 2014. The study examined 2010 and 2012 Medicare and privately insured claims for the eight most commonly ordered MRI procedures by orthopedists. The claims data used in the study are part of the MHCC's Medical Care Data Base for 2010 and 2012. The study tested the effects of ownership on utilization patterns before and after the forced divestiture of ownership in MRI devices by comparing the MRI use rate of orthopedic practices that owned MRIs in 2010 and after divestiture in ownership in 2012 with use rates for similar orthopedic practices that did not have a financial interest in MRI devices.

Despite a limited budget, the study was rigorous and included a systematic review of previous research, a descriptive analysis, and an inferential statistical component. A systematic assessment of previous research on self-referral for office-based services is complicated because much of the work has been sponsored by specialty societies with strong positions on the issue of self-referral. For studies without known biases, such as those conducted by the U.S. Government Accountability Office (GAO) and several academic researchers, findings consistently show that

physicians with financial gain in referring for a procedure tend to have higher utilization rates than physicians without a financial ownership interest.

In the descriptive analysis, the consultant found that practices with a financial interest in MRI equipment compared to other orthopedic practices had higher MRI use rates in 2010. The MRI use rate per capita declined for all orthopedic practices from 2010 to 2012, but rates were somewhat higher at the practices that formerly had a financial interest in MRI imaging equipment. This finding is consistent with national trends between 2010 and 2012.

The consultant developed a statistical model that accounted for the probability of receiving an MRI based on:

- financial ownership of the MRI equipment in 2010,
- patient's age and sex, insurance status (high deductible for the privately insured or Medicaid eligibility for Medicare), and
- practice attributes specific to a practice (practice attribute variable).

The practice attribute variable reflected characteristics of a practice that could not be separately defined, including age of the practitioners, prevailing practice patterns, and geographic location. When controlling for patient characteristics, insurance status, and practice attributes, financial ownership did not have a statistically significant impact on the rates of MRI use. The practice attribute variable was statistically significant for privately insured patients for all practices. For Medicare patients, the MRI use rate is higher and statistically significant for three of the five practices. Stated simply, ownership of an MRI did not increase the probability that a patient would receive an MRI, but other practice attributes associated with these same practices did increase the probability. The increased probability of receiving a MRI is statistically significant for both Medicare and the privately insured populations in most practices.

The Commission heard two presentations on this study. At the November meeting, Ms. Braid-Forbes presented the principal research findings. MHCC staff presented the statistical results and the draft final report at the December meeting. Prior to the November meeting, MHCC staff met with physicians from the orthopedic practices and their legal counsel. A draft of the report was provided to the practices in December and several comments provided by the group's legal counsel are reflected in the final report.

The Commission wishes to emphasize that the results of this study need to be carefully qualified due to its limited scope. The challenge for policy makers is that the results of this study show both that the practices with a financial interest in MRI equipment in 2010 had higher use rates and that those higher rates of use did not change compared to other practices after divestiture. It is unclear why these practices did not have a steeper decline in use rates. It could be that the use rates decline more slowly over time after divestiture than has been shown in the literature for the increase in use rates and that the timeframe for the study was too short. This study design presumes that a change in MRI ordering behavior will be abrupt following a change in the ownership of MRI equipment. Several research studies have documented abrupt increases in referrals when practices acquire a financial interest in MRI equipment, but the impact of divestiture has been studied only in Maryland. Differences in patient clinical conditions

relevant to MRI use could play a role. Some orthopedists have suggested that the age of the physician also plays a role in MRI use rates, with younger physicians who trained when MRIs were readily available being more likely to order MRIs than older physicians who trained before MRIs were widespread. Investigating how the specific patient risks or practice factors contribute to use are outside the scope of the current study.

The MHCC also notes that the orthopedic practices that were forced to divest their interest in MRI equipment in 2011 represent a small number of the total patients seen by orthopedists and the MRIs received by their patients represent a small proportion of the total number of MRIs performed in the State. In 2012, the five practices saw about 60,000 Medicare and privately insured patients. Control practices saw over 300,000 Medicare and privately insured patients in the same year. Any change to current Maryland law that would exempt MRIs from the self-referral prohibition would apply to all orthopedists and other specialties such as urology, cardiology, and neurology as well. These other specialties would significantly expand the numbers of practices and patients affected. If the experience described in the literature on gaining a financial interest is a guide, MRI use rates would be expected to rise in Maryland absent any other delivery or payment reforms. If the law were narrowly construed to only apply to practices which previously had an interest in MRI equipment, one would predict that MRI use rates would not increase more than are currently seen due to this change. However, such a narrow solution would likely prove unworkable.

A better solution may be to link the longstanding issue of self-referral to two broad positive health care trends. The first trend is the widely endorsed effort to realign care on dimensions of value. The second is the movement toward growing practice integration either through outright consolidation or through collaborative arrangements. In a more integrated system of care delivery where providers receive gainsharing or shared savings payments while being held accountable for patient health outcomes, incentives to provide unneeded care will diminish. Decisions on whether to own advanced office-based equipment, as opposed to referring the service to an efficient collaborator, will be based on cost calculations and quality considerations. Some orthopedists argued that when they owned MRI equipment and managed the imaging staff, image quality improved and the need for repeat images declined. Ownership of equipment could be viable and cost effective, if large group practices, likely to own these devices, committed to delivering care under the new payment models now taking root in the health care system.

Under a new model, ownership of office-based imaging could be permitted if three conditions are met:

1. the practice demonstrates that a very high proportion of care is reimbursed under risk-based financial arrangements;
2. the practice can demonstrate sufficient scale as to make ownership of imaging equipment viable and agrees to bundle imaging use under the risk-based arrangement; and
3. the practice commits to ongoing reporting of quality metrics linked to its patient outcomes.

These conditions would represent significant challenges to all large single specialty practices operating in Maryland today. Medicare is slowly moving toward risk-based financial

arrangements through the Medicare Shared Savings Program (MSSP), but Medicaid and private carriers have been slow to introduce these innovations in Maryland. Even under the MSSP program, specialists have been slow to engage in the program. MHCC believes more time is needed to introduce these changes before an exemption should be considered. MHCC would be happy to work with specialty groups and payers to develop program ideas that could meet the three conditions identified.

If you require further information regarding this study please contact me at 410-764-3566.

Sincerely,

Ben Steffen
Executive Director

Enclosure
cc:

Thomas M. Middleton, Chair, Senate Finance Committee
Joan Carter Conway, Chair, Senate Education, Health and Environmental Affairs
Kirill Reznik, State Delegate
Laura Herrera, M.D., Acting Secretary, DHMH
Craig Tanio, M.D., Chairman MHCC
Lisa Simpson
Patrick Carlson

Assessment of Changes in Advanced Imaging Referrals by Orthopedists 2010-2012

Prepared by Braid-Forbes Health Research, LLC

For the Maryland Health Care Commission

December 23, 2014

Appendix C

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Figures

Tables

Appendices

I. Executive Summary

This study examines trends in the prescribing of magnetic resonance imaging (MRI) services in Maryland. Specifically, it examines the ordering of MRI services by non-radiology group practices in Maryland that owned or leased MRI equipment and furnished MRI services in their medical offices prior to June 2011.

Section 1877 of the Social Security Act (the Stark law) and its amendments prohibit physicians from referring Medicare patients for a designated health service to an entity in which the physician or a family member has a financial interest unless an exception applies. Radiology and certain imaging services are subject to this prohibition. The Stark law allows for certain exceptions, including a broad exemption for certain in-office services that are ancillary to an office visit, leaving open the possibility that non-radiologist physicians could provide their Medicare patients' radiological imaging services. The General Maryland Assembly passed a self-referral law in 1993 that regulated self-referral for all local insurers. This law explicitly excluded MRI and CT imaging from in-office ancillary services. The prohibition against non-radiology practices self-referring patients for MRI and CT services was confirmed by the Maryland Court of Appeals in January 2011.

Beginning in the middle and late 1990s outside of Maryland, physicians began to purchase MRI equipment and perform these services in their own offices, rather than refer them to an outside facility. Concurrent with this trend was an increase in the total number of MRI services performed. The U.S. Government Accountability Office (GAO) and other researchers have studied the effect of financial ownership on physician referral and care patterns. Studies consistently find that physicians with financial gain in referring for a procedure tend to have higher utilization rates than physicians without a financial stake.

This study tests the effects of ownership on utilization patterns since the Maryland Board of Physicians enforced the divestiture of ownership in MRI devices by several orthopedic practices in 2011. This study compares the use rate of these orthopedic practices before (2010) and after (2012) the divestiture in ownership. These practices are compared to two control groups: selected similar orthopedic practices, and other orthopedists in the state. Medicare and private insurance claims data were examined for more than 120,000 patients for the orthopedists practices which divested in 2011 and for a similar number of patients for the similar orthopedic practice control group, and over 300,000 patients for the second control group. The study accounted for different patient characteristics, e.g., age, gender, coverage by a high deductible plan for privately insured patients and Medicaid dual eligibility with Medicare, using logistic regression to control for these differences.

This study found no evidence that financial interest influenced MRI rates in 2010 compared to 2012 for patients with either private insurance or Medicare. Differences in the rates of MRI use do not seem to be related to the period when the practices had a financial interest in MRI equipment. Practices with a financial interest in the equipment in 2010 had higher rates of MRI use in both 2010 and 2012. The higher rate is statistically significant for privately insured patients for all practices. For Medicare patients the MRI use rate is higher and statistically significant for three of the five practices.

It is possible that the timeframe required for this study one year before divestment and the year immediately following divestment was too short a timeframe to capture changes in physician behavior. The study design presumes that a change in MRI ordering behavior will be abrupt following a change in financial interest in the equipment. Other factors could influence MRI use, such as age of physician, income of patient, and other patient conditions that could not be measured in this study.

II. Introduction

The Health and Government Operations Committee requested this study of trends in the prescribing of magnetic resonance imaging (MRI) services in Maryland. This request arose from the Committee's consideration of House Bill 536 during the 2013 General Assembly Session. The HB 536 would have required that the Department of Health and Mental Hygiene conduct a study on the ordering of MRI services by non-radiology group practices in Maryland that owned or leased MRI equipment and furnished MRI services in their medical offices prior to June 2011.[1]

Section 1877 of the Social Security Act, known as the Stark law,[2] prohibits physicians from referring Medicare patients for a designated health service to an entity in which the physician or a family member has a financial interest unless an exception applies. This law was originally enacted in 1989 to apply to clinical laboratory services and was expanded in 1993 and 1994 to include additional services.[3] Radiology and certain imaging services are included as designated health services that are subject to this prohibition.

The Stark law allows for certain exceptions, including a broad exemption for certain in-office services that are ancillary to an office visit, leaving open the possibility that non-radiologist physicians could provide their Medicare patients' radiological imaging services. Advanced imaging such as MRI and computerized tomography (CT) scanners were not common in-office services at the time of passage of the Stark law. As MRI and CT equipment became less expensive, more non-radiology practices began to purchase and operate this equipment under the in-office ancillary exception.[4] In Maryland, the General Assembly passed a unique self-referral law in 1993 that regulated self-referral for all local insurers. This law explicitly excluded MRI and CT imaging from in-office ancillary services.[5] Some non-radiology practices interpreting specific language of the Maryland law began owning MRI equipment and self-referring for these services. There is complicated history of attempts to enforce the law by the Maryland Board of Physicians, legal challenges, and eventually confirmation by the Court of Appeals in January 2011 of the prohibition against non-radiology practices self-referring patients for MRI and CT services. [6]

The initial federal Medicare exemption for in-office ancillary services from anti-self-referral laws came about because it was thought to be more convenient for the patient to have the service performed the same day as the office visit. At the time of this exemption, X-ray equipment was the in-office imaging modality that was most common. MRIs were not yet in physician offices. By the middle and late 1990s this began to change. Physicians, including orthopedists, who previously referred patients for MRIs to independent radiology practices, began to purchase MRIs and perform these services in their own offices. Concurrent with this trend was a tremendous increase in the total number of MRI services

[1] Letter from Peter A. Hammen, Chair, Health and Government Operations Committe to Ben Steffen, Executive Director, Maryland Health Care Commission, dated July 10, 2013.
[2] 42 U.S.C.§1395nn, the regulations are at 42 CFR. §411.350 - §411.389.
[3] See https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/
[4] Quadri, Rehan et. al. "The Maryland Self-Referral Law: History and Implications." *Journal of the American College of Radiology* 11.8 (2014: 771-776).
[5] Ibid.
[6] Potomac Valley Orthopaedic Associates v. Maryland State Board of Physicians, No. 18, 2011 WL 198239, at 1 (Md. 2011)

performed. Many studies have attempted to examine the extent to which the financial interest of the self-referring physicians contributed to the explosive growth in the number of services, and whether the excess number of these services was of any benefit to the patient or was unnecessary care.

III. Study Design

This project tests the effects of ownership on utilization patterns since the Maryland Board of Physicians enforced the divestiture of ownership in MRI devices by several orthopedic practices in 2011. This project provides a unique natural experiment in physician self-referral to determine whether practice patterns changed after divesting a financial interest, compared with gaining a financial interest. Because exactly which practices had MRIs and divested their financial interest are known, there is greater certainty about the groups with the financial interest. The availability of the all-payer database in Maryland allows a nearly complete look at the practices' utilization patterns.[7] We can also control for insurance type, i.e., Medicare versus private insurance. This study compares the use rate of these orthopedic practices before (2010) and after (2012) the divestiture in ownership. These practices are compared to two control groups: selected similar orthopedic practices, and other orthopedists in the state. Regression analysis is used to control for other confounding factors.

There are dozens of CPT™[8] medical procedure codes describing MRI scans. This study focuses on eight specific procedure codes. MHCC selected the following codes for study:

- 72146 Magnetic resonance (e.g., proton) imaging, spinal canal and contents, thoracic; without contrast material
- 72148 Magnetic resonance (e.g., proton) imaging, spinal canal and contents, lumbar; without contrast material
- 72195 Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)
- 72141 Magnetic resonance (e.g., proton) imaging, spinal canal and contents, cervical; without contrast material
- 73221 Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; without contrast material(s)
- 73721 Magnetic resonance (e.g., proton) imaging, any joint of lower extremity; without contrast material
- 73718 Magnetic resonance (e.g., proton) imaging, lower extremity other than joint; without contrast material(s)
- 73218 Magnetic resonance (e.g., proton) imaging, upper extremity, other than joint; without contrast material(s)

These codes are billed with a modifier to indicate whether the service provided is the professional service (reading and interpreting the MRI results) or technical (conducting the scan). If no modifier is billed, the services is presumed to be global (including both the professional and technical proportion). Counting claims billed with a professional service modifier (26) and a technical component modifier (TC) would count one service twice. For this study to obtain a correct count of unique services, we counted claims with a professional service modifier (26) and global claims (no technical or professional service modifier).

[7] Medicaid claims data and information on care provided to the uninsured are not included.

[8] CPT Copyright 2012, American Medical Association.

IV. Literature Review

The effect that financial ownership has on physician referral and care patterns has been studied both by the U.S. Government Accountability Office (GAO) and many other researchers. Studies consistently find that physicians with financial gain in referring for a procedure tend to have higher utilization rates than physicians without a financial stake. Several studies also have examined whether this increased utilization has benefits, such as detecting more cancer or reducing episode of care costs. These studies failed to find a benefit. Detection of cancers was lower and the cost of the episode of care was higher for those with a financial interest, suggesting that the increase in utilization was unnecessary care. Some studies also looked at whether the same physicians change their ordering behavior after entering into a financial relationship, so-labeled "switchers." Again, researchers found an increase in utilization associated with gaining a financial interest.

While the evidence is significant, there are some limitations to these studies and gaps in our knowledge. First, all the studies compared utilization differences, not differences in the services ordered. In theory, patients could obtain an order and choose not to receive the scan or test. Without access to data that systematically captures the physician orders, utilization is the best proxy for orders. From a payer and policy perspective, actual utilization is of greater interest than orders. Some of these studies had to identify the physicians with a financial interest through algorithms involving the identifiers on their claims and matching to third-party sources of information. Some of the studies used Medicare claims or privately insured data, which would not have contained all of the physicians' practice. For those that studied specific practices where the financial interest was known and the entire practice was studied, the samples were small. There is a gap in the literature in studying the effect on change in utilization of divesting from a financial interest, compared to entering into a financial relationship.

Numerous articles in the literature have studied the relationship between physician financial interest and self-referral for services. The services studied have often been diagnostic imaging such as MRI and CT, but also have included pathology biopsy for prostate cancer detection. Authors of these studies had several different approaches to studying the relationship of self-referral and utilization. Those approaches included:

- Difference in utilization patterns between physicians with a financial interest and those without at the same point in time (Hillman, 1990; Baker, 2010; Shah et al., 2011; Mitchell, 2012; GAO, 2012)
- Difference in utilization patterns before and after a physician enters into a financial relationship, known as "switchers" (Bhargavan et al., 2011; GAO, 2012; Baker, 2010)
- For diagnostic tests, a difference in positive findings as a marker for inappropriate utilization. (Mitchell, 2012; Paxton et al. , 2012; Lungren et al., 2013)
- Benefits to patients who received diagnostic services from a physician with a financial interest, compared to patients who received referral to diagnostic services from a physician without a financial interest, to assess if the increased utilization associated with self-referred services led to lower total costs or shorter length of illness. (Hughes et al, 2010; Baker, 2010; Shreibati and Baker, 2011)

In each of the studies, physicians with a financial interest in a service had greater utilization. In those that looked at possible benefits to the increased utilization, no benefit was found either in higher cancer detection or in lower total episode of care costs.

However, a recent study by the GAO on self-referral for physical therapy (PT) services found mixed results. While self-referring family practice and internal medicine providers in urban areas generally referred more PT services than non-self-referring physicians in the same specialties, self-referring orthopedic surgeons referred on average fewer PT services than non-self referring orthopedic surgeons. For all three specialties, the physicians who self-referred referred more beneficiaries, but referred for fewer services per beneficiary. (GAO, 2014a)

In the *Journal of Law, Medicine and Ethics,* Christopher Robertson et al. (2012) reviewed the literature on the effect of financial relationships on the behaviors of health care professionals. Robertson reviewed three types of financial relationship: physician's role as referrers; physician payer interactions, including reimbursement schemes intended to reduce costs and pay-for-performance; and financial relationships between physicians and representatives from the drug and device industries. Their review found evidence that financial relationships bias physician decisions to divergent degrees in all three areas. However, they noted that the studies had limitations. The studies were observational, rather than randomized controlled trials. As such, the physicians choosing to enter the financial relationship may be different in some way from those physicians choosing not to enter into the financial relationship under study. The measures were means and other measures of central tendency. It is possible that all physicians are not equally susceptible to financial interests. More importantly, while some studies included practice guidelines and independent review to demonstrate that the financial interest was against the interests of the patient, many do not specify the optimal rate for the service studied.

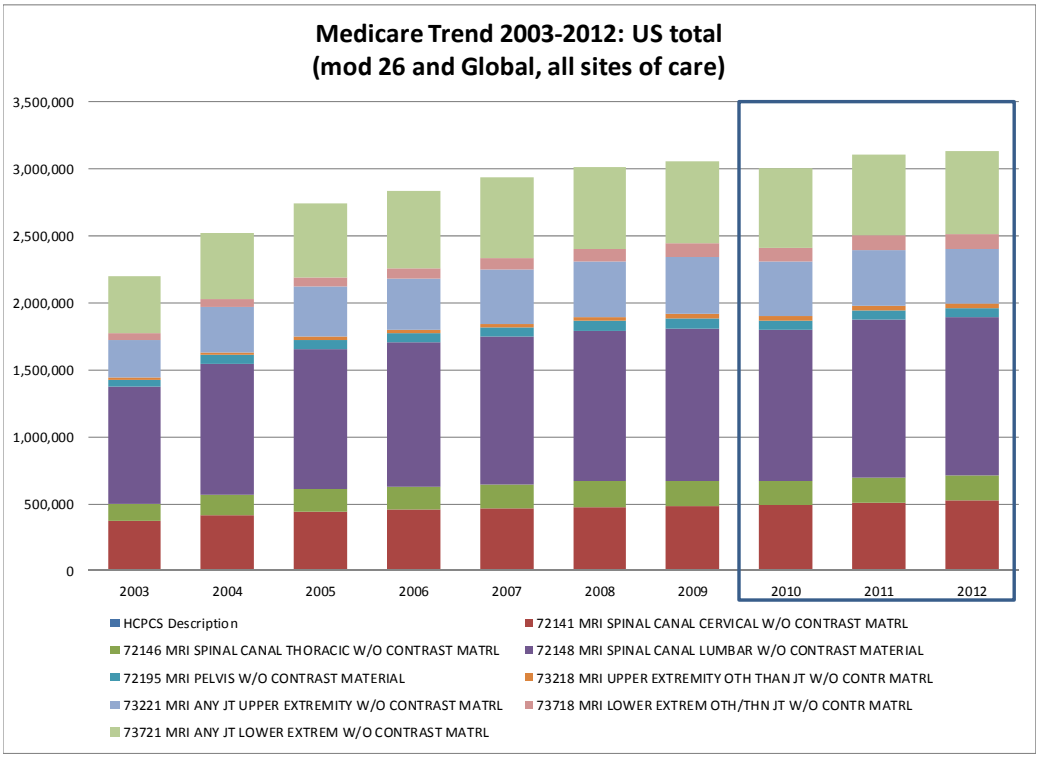
V. MRI utilization trends

Nationally, MRI use rates for the Medicare population rose quite rapidly in the early 2000s and then leveled off in recent years. It is important to take account of temporal trends in use rates unrelated to ownership. While Medicare is not the entire population receiving MRI services, this population uses a disproportionate number of medical services. High use rates for imaging has also caught the attention of the Centers for Medicare and Medicaid Services (CMS) and Congress, which has made adjustments to Medicare payment policy related to imaging services over the past 10 years. Changes in reimbursement for MRI services for the Medicare population could potentially affect providers' incentives to provide these services.

Figure 1 shows the national utilization for the selected MRI procedure codes. Utilization is presented for all sites of care (hospital, physician office, free-standing)[9] and without regard to the specialty ordering the service. In 2003, 2.1 million of these MRI services were provided to traditional Medicare beneficiaries (Medicare Advantage HMO claims are not included). By 2005, that had grown to 2.7 million services, an increase of 25 percent in just two years. However, growth moderated after 2005 and even declined slightly in 2010. The GAO (2014b) found similar trends for advanced diagnostic imaging services in general. Figure 1 shows total counts of services and do not take into account the number of Medicare beneficiaries. The time period for this study is 2010 through 2012, which corresponds to a national leveling off of utilization of these services.

[9] We count services that are billed either global or with a professional component modifier 26.

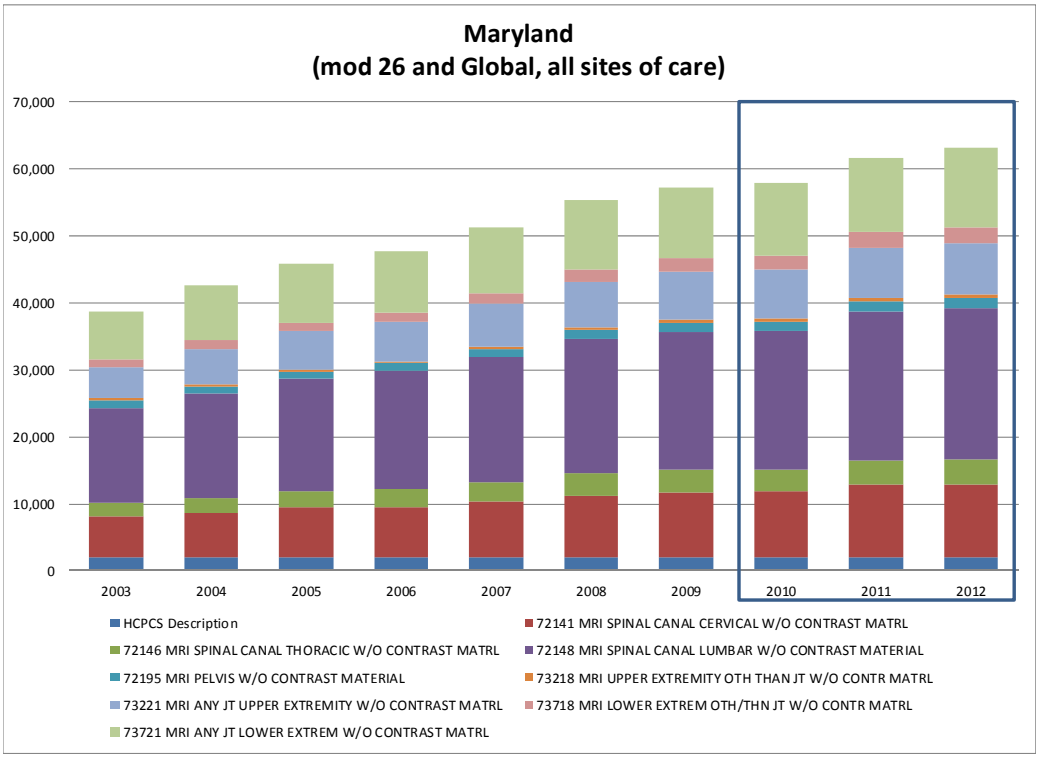
Figure 1 Medicare Trend Selected MRI Services 2003-2012: US Total



Source: Braid-Forbes Health Research analysis of Medicare Physician Supplier Procedure Summary Files (PSPS,) 2003-2012.

Interestingly, the pattern of total utilization in Maryland for these services has not mirrored the national pattern. Figure 2 shows the same MRI services for Maryland only. The growth in services in Maryland during this same period was less steep from 2003 to 2005, but since then has continued growing at greater than the national percentage rates for these same MRI services. Over the entire 10-year span, the number of services grew from just over 36.6 thousand in 2003 to 61 thousand in 2012, a 67 percent increase, compared to a national increase of 43 percent over the same period.

Figure 2 Medicare Trend Selected MRI Services 2003-2012: Maryland

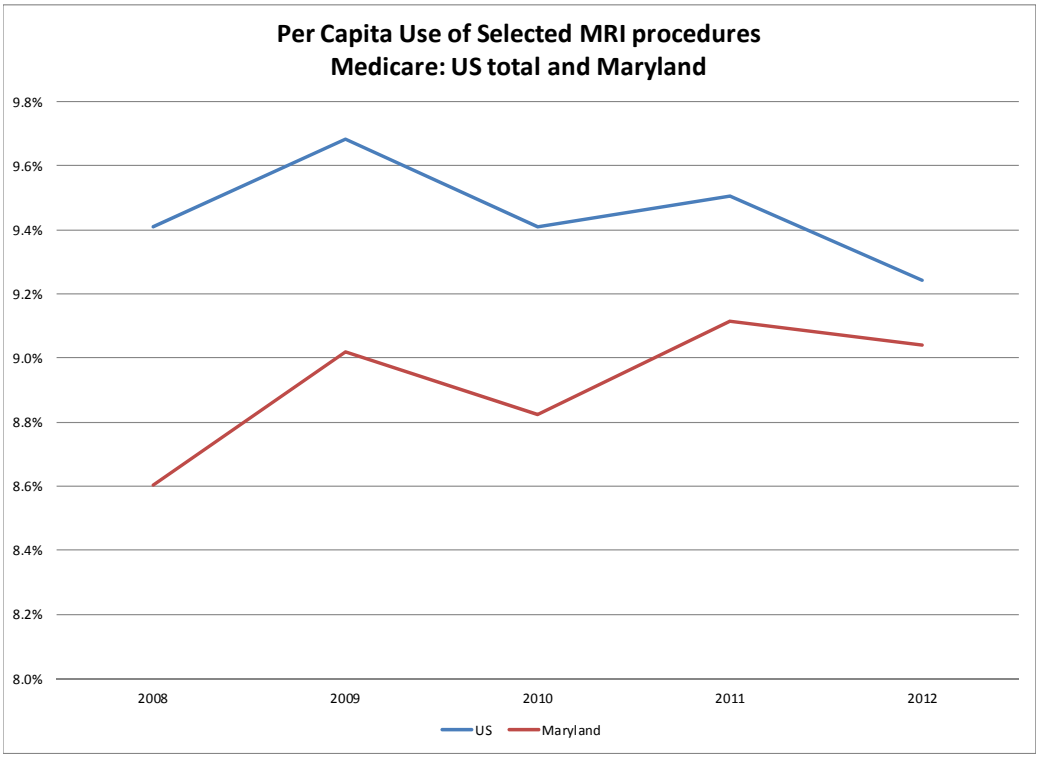


Source: Braid-Forbes Health Research analysis of Medicare PSPS files, 2003-2012.

Figure 3 shows a comparison between the national utilization and Maryland utilization on a per capita basis for years 2008 through 2012.[10] The Y axis shows the count of these MRI services as a percent of the total Medicare population with Part B coverage. Nationally, 9.4 of these MRI services were performed per 100 Medicare beneficiaries in 2008, increasing to 9.7 in 2010, and falling to 9.2 in 2012. In Maryland, 8.6 of these MRI services were performed per 100 Medicare beneficiaries in 2008, increasing to 9.0 in 2012. Again, the utilization is across all sites of care (hospital, physician office, free-standing) and without regard to the specialty ordering the image. Shifts between the site of care for the image, hospital and physician office or free-standing, are not shown. Changes in the specialty of the physician ordering the image also are not taken into account, as this would require a different dataset and a more complicated analysis.

[10] The Medicare Part B enrollment data by state was not available on the CMS website for years before 2008. The claims data used to compute the utilization trends are for traditional fee-for-service Medicare beneficiaries, and does not include Medicare Advantage (Part C). Medicare Advantage enrollment data is subtracted from the total Part B enrollment data. Medicare Advantage enrollment was not available on the CMS website for years before 2008.

Figure 3 Per Capita Use of Selected MRI procedures Medicare US and Maryland



Sources: Braid-Forbes Health Research analysis of Medicare PSPS files, 2008-2012; Medicare enrollment data, and Medicare Advantage enrollment data.

Medicare payment rates for diagnostic imaging service have declined sharply since 2009. CMS has changed the assumptions for utilization and interest rate in the formula that determines the practice expense portion of the payment rate. For high-cost equipment (such as MRI) the assumption of the amount of time the machine is in use has gone from 50 percent to 90 percent,[11] which decreased the allocation of the cost of the machine to each service. CMS also changed the assumption of the interest rate that would be associated with the purchase of any equipment. It has gone from 11 percent to a sliding scale based on useful life and total cost of the equipment; in this case for MRI it would be 5.5 percent. This has also reduced the total payment rate. The Deficit Reduction Act of 2005 required that, beginning January 1, 2007, Medicare payment for certain imaging services under the physician fee schedule not exceed the amount Medicare pays under the Outpatient Prospective Payment System (OPPS). The OPPS rates change from year to year and can trigger a reduction in the physician payment rate. Table 1 shows the Medicare payment rates for the code with the highest utilization (72148) for Maryland from 2009 through 2014. During the study period (2010 through 2012), Medicare payment for this service declined slightly.

[11] CMS's calculation of a 50 percent utilization rate was based on 25 hours per week out of a 50-hour work week, 50 weeks per year. The 90 percent utilization rate would translate to 45 hours per week. In a survey commissioned by MedPAC in 2006 of six markets, the median use rate among MRI providers was 46 hours per week.

Table 1: Medicare payment rate for 72148 for Maryland

	Maryland Technical Component (TC) Payment		National Practice Expense Assumptions	
Year	Locality 01 ($)	Locality 99 ($)	Utilization Assumption (%)	Interest Rate Assumption (%)
2009	479.87	442.70	50	11
2010A	405.39	380.03	90	11
2010B	414.31	388.39	90	11
2011	427.62	399.57	75	11
2012	393.97	371.65	75	11
2013	340.05	320.78	75	5.5
2014	186.31	175.89	90	5.5

Source: Medicare Physician Fee look-up tool, accessed at http://www.cms.gov/apps/physician-fee-schedule/overview.aspx.

Other policy changes affecting advanced diagnostic imaging such as MRI include the requirement in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that, beginning January 1, 2012, suppliers of the technical component of these imaging services, including MRI, be accredited by a designated accrediting organization in order to receive Medicare payment for these services. (GAO, 2014b)

VI. Study Questions

The study questions are:

1. Did orthopedic practices that divested interest in MRI machines in 2011 change how often they ordered MRIs for their patients?

2. Did practices that had a financial interest in MRI machines have different rates of ordering MRIs for their patients than similar practices for similar patients before and after their divesture of the financial interest?

VII. Methodology

Our analytic approach compared the difference in use rates by patients attributable to the orthopedic practices that divested MRI ownership over time compared that to those that did not have an ownership stake in MRI machines. The orthopedic practices that had a financial interest are referred to as “cases” and the comparison group “controls.” Use of an MRI includes MRI services received by patients, regardless of whether this was in the ordering physician’s office, a radiology practice, or at a hospital. Simplistically, this can be represented by a rate: the number of patients getting an MRI compared to total patient seen by each practice. We assume that the conditions of the patients seen at the practices

are similar over the time period of the study. There are two control groups: selected similar orthopedic practices, and all orthopedic practices in the state.

The practices identified as having a financial interest in 2010 are identified in Appendix A. The similar practices are identified in Appendix B. The methodology for selecting other orthopedists as a second control is described in Appendix C.

In our data investigation, we found that we could not use the National Provider Identifier (NPI) to identify claims for the selected practices in the Medicare data because organizational NPI was not routinely captured on that file. However, we could use the Federal Tax Identifier to identify Medicare claims for the specific practices. Further, we found that using the Federal Tax Identifier lead to a more robust capture of claims in the private insurance database. We used the Federal Tax Identifier for both datasets for consistency. For one of the practices identified as case, the federal tax identifier that we had did not capture all of their claims. We drop this practice from the analysis. The Federal Tax Identifier is not linked to physician specialty and so we could not have a second control group using the Medicare data. For the private claims we used the NPI, which does have a link to the specialty of the physician, to identify other orthopedists in the state.

We also looked for evidence of billing for MRI services among the practices with a financial interest in the case group. We did find claims for MRI services for all practices except one. It is possible that this one practice had shut down its MRI facilities before the final ruling required them to. It is also possible that this practice billed for MRI services under a different federal tax ID.

We assessed the extent to which a patient was seen by more than one orthopedic practice in the same year. We excluded these patients from the study, if they were seen by both the practices with the financial relationship (cases) and the similar orthopedic practices (control group 1). This was less than 2 percent of the private insurance patients in both years, and less than 2 percent of Medicare patients. If patients were seen by either the cases or the similar practices and were patients seen by the other orthopedists in the state (control group 2), the patient was included once with the case or control group 1. This was less than 10 percent of the patients seen by the second control group. For the practice specific effects, if a patient was seen by more than one case practice or by more than one control group 1 practice, the patient was assigned to the practice with the first visit.

Using regression to control for differences in patient populations: Difference in difference estimation using logit regression

The rate of MRI referral is an easily understandable way to measure the difference in practice patterns. However, the rates can vary based on patient characteristics. We used a logit regression model to account for these differences. The logit model is commonly used in assessing the contribution of various factors to the probability of a dichotomous event. Using a logit model, the predicted probabilities are bounded between zero and one, an attribute that is lacking when the more familiar ordinary least squares regression methodology is employed.

We specified two models, one using the private insurance claims and one using the Medicare claims. Both models take into account whether the patient was seen by a practice in the case or a control group, the patient's age and sex. For the private insurance claims model, we also include whether the

patient was covered by a high-deductible plan.[12] For the Medicare model, we include whether the patient was dually eligible for Medicaid. The second control group was included in the private insurance model, but could not be included in the Medicare model due to data issues. Including these patient variables allows us to account for possible differences in rates of ordering MRI by a practice due to these patient characteristics and isolates the practice differences. We also included the year 2012 to account for trends in use rates that occurred across all practices over time. Algebraically, the model is given by:

Private Insurance Patient Model

$$\ln\left(\frac{p_i}{1-p_i}\right) = const + \alpha_1 CG_1 + \alpha_2 CG_2 + \alpha_3 HIGH + \alpha_4 AGE + \alpha_5 SEX + \alpha_6 YEAR2012 + \sum_{k=1}^{K} \delta_k \text{PRACTICE}_k + \sum_{k=1}^{K} \beta_k FINANCIAL_k$$

Medicare Patient Model

$$\ln\left(\frac{p_i}{1-p_i}\right) = const + \alpha_1 CG_1 + \alpha_2 CG_2 + \alpha_3 DUAL + \alpha_4 AGE + \alpha_5 SEX + \alpha_6 YEAR2012 + \sum_{k=1}^{K} \delta_k \text{PRACTICE}_k + \sum_{k=1}^{K} \beta_k FINANCIAL_k$$

Where p_i is the probability that a patient receives an MRI. The transformation on the left-hand side of ensures that the estimated equation is nonlinear, with the marginal impact of any single explanatory variable contingent on the levels of the other regressors. The explanatory variables are defined as follows:

CG_1 is a binary variable that is equal to one if patient i's physician is a member of the first control group;

CG_2 is a binary variable that is equal to one if patient i's physician is a member of the second control group;

MEDICARE is a binary variable that is equal to one if patient i's has Medicare coverage;

HIGH is a binary variable that is equal to one if the patient was covered under a high deductible plan

DUAL is a binary variable that is equal to one if the Medicare beneficiary was dually eligible for Medicaid coverage;

AGE is patient i's age;

SEX is a binary variable representing patient i's sex;

[12] High-deductible plans are also known as consumer-directed health plans.

YEAR2012 is a binary variable that equals one if year equals 2012.

PRACTICE is a binary variable for each practice in the treatment group

FINANCIAL is a binary variable that is equal to one for each practice in the treatment group when it had a financial interest in administering MRIs.

Note that the model's specification permits the coefficient on the variable FINANCIAL to vary by practice, and thus it does not presume that practices in the treatment group respond identically to a financial interest. The model also does not presume that the practices behave identically in terms of MRI procedures in the absence of a financial interest.

VIII. Results

More than 60,000 patients in each year were identified for the practices with a financial interest in 2010 (cases) and the similar practices (control group 1). More than 150,000 patients were identified as having seen an orthopedist in the second control group. The counts of patients in each group, case, control 1 and control 2, for each year and insurance type are shown in Table 2. The average age of the patients seen by each group was similar, as was the percent of patients that were female. The number of patients with a high-deductible plan was slightly higher among the cases compared to either control group, and rose between 2010 and 2012 for all groups. The number of Medicare patients seen by cases were slightly more likely to be dually eligible for Medicaid, compared to similar practices in control group 1.

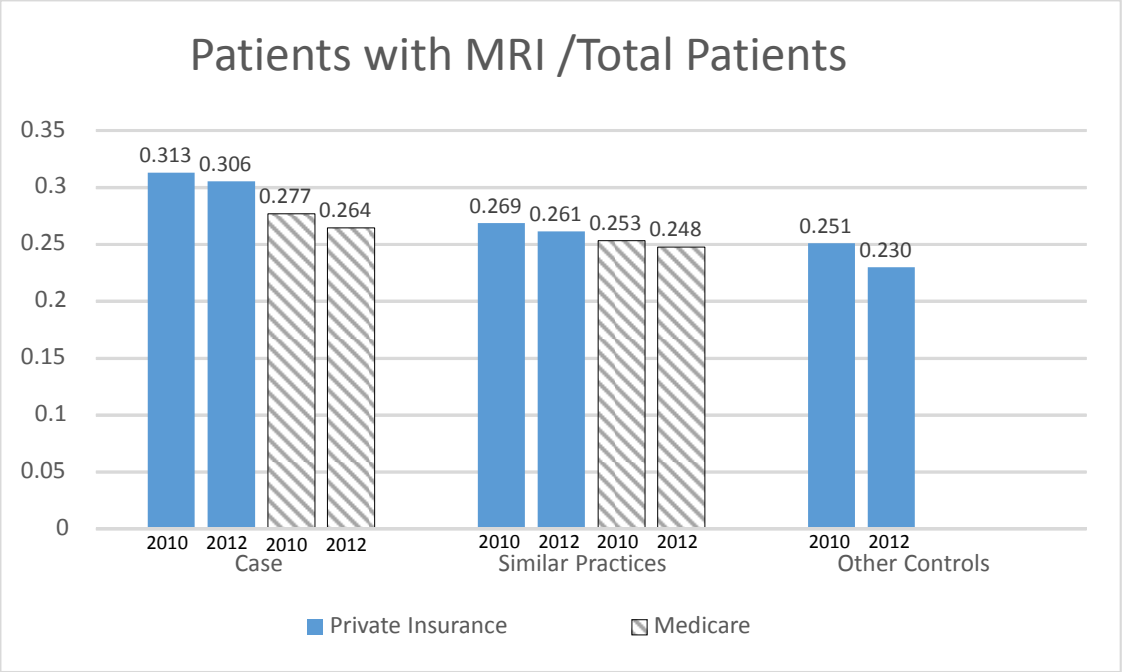
Table 2: Patient counts and demographics

	Case				**Control 1: Similar Practices**				**Control 2: Other**	
	Private		**Medicare**		**Private**		**Medicare**		**Private**	
	2010	**2012**	**2010**	**2012**	**2010**	**2012**	**2010**	**2012**	**2010**	**2012**
Patients	41,250	43,376	19,403	20,264	46,583	50,635	14,465	15,621	171,368	208,261
Number of Images	12,927	13,252	5,371	5,358	12,529	13,233	3,665	3,870	43,139	47,914
Average Age	43.6	43.6	73.7	73.3	42.2	42.6	73.8	73.3	44.2	44.6
% Female	55%	56%	67%	66%	55%	55%	66%	66%	56%	56%
% Dual			13%	14%			12%	13%		
% High Deductible	15%	17%			13%	14%			14%	16%

Table 3 shows the rate of referral of patients for MRIs for the cases and two control groups. The rate decreased very slightly for the practices with a financial interest (case) for privately insured patients between 2010 and 2012. The rate also decreased very slightly for the similar practices in control group 1 and decreased by a greater degree in the second control group. The rate of referral was higher for the cases than either control group to start in 2010. The rate of referral for these practices before they had a financial interest in MRI equipment was outside the scope of this study; therefore, we cannot say whether the rate of referral for the case group was always higher or is higher due to their financial interest in 2010. For Medicare patients, the rate of referral for MRIs came down between 2010 and

2012 by a greater degree than seen in the privately insured patients for both the case and control group 1.

Figure 4: Rate of referral of patients for MRIs for cases and two control groups



The results of the logit regression analysis are shown in Tables 4 and 5. The logit regression analysis controls for measurable differences in the patient populations between the groups, as well as practice-specific effects among the different practices that make up the case group (those with a financial interest in 2010). Differences we are able to measure are patient sex, patient age, high- deductible plan (privately insured), and dual eligibility for Medicaid (Medicare beneficiaries). Standard risk adjustment methodologies were not developed to assess risk of needing an advanced diagnostic image, but are more typically used to predict mortality or inpatient resource use. For example the Elixhauser comorbidities[13] were developed to predict differences in length of stay and hospital charges for inpatient admissions. As such, these measures were too general for the specific needs of this study.

The variable column in Table 4 relates to the variables described above in the logit regression model. The parameter estimate column shows a positive number when the characteristic represented by the variable is more likely to contribute to the patient receiving an MRI referral and negative when the patient is less likely to be referred for an MRI with when the characteristic is present. The column labeled "Pr>|t|" shows a number less than 0.05 when the characteristic is statistically significant. If the number is greater than 0.05, the characteristic does not contribute to the outcome of being referred for an MRI.

Table 4 also shows that persons with a high-deductible plan (high) are less likely to receive an MRI, though only slightly so. The likelihood of having an MRI increases with age up to age 65. The 65 and

[13] Elixhauser A et al. "Comorbidity Measures for Use with Administrative Data" Medical Care 36 (1): 8-27.

older category was only as likely as the age 18 to 25 age group to receive an MRI. Even controlling for these patient characteristics, each of the case practices had higher rates of MRI use among their patients than the controls. These rates were higher in 2010 and 2012 and did not appear to be related to the period when the practice had a financial interest in MRI equipment (2010).

Table 3: Private Payers Regression Results

Parameter Estimates					
Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	1	0.14121	0.00183	77.19	<.0001
year2012	1	-0.01847	0.00126	-14.70	<.0001
sex_cd	1	-0.01371	0.00116	-11.77	<.0001
high	1	-0.00661	0.00161	-4.10	<.0001
age_18_25	1	0.09956	0.00280	35.57	<.0001
age_25_40	1	0.12832	0.00216	59.29	<.0001
age_40_65	1	0.15594	0.00175	89.32	<.0001
age_GE_65	1	0.09239	0.00257	36.01	<.0001
Practice A	1	0.11188	0.00441	25.37	<.0001
Practice B	1	0.07149	0.00414	17.25	<.0001
Practice C	1	0.04183	0.00385	10.88	<.0001
Practice D	1	0.09549	0.00568	16.80	<.0001
Practice E	1	0.03448	0.00799	4.32	<.0001
F_ Practice A	1	-0.00928	0.00635	-1.46	0.1438
F_ Practice B	1	0.00395	0.00591	0.67	0.5045
F_ Practice C	1	-0.02290	0.00552	-4.15	<.0001
F_ Practice D	1	-0.02154	0.00820	-2.63	0.0086
F_ Practice E	1	-0.01653	0.01130	-1.46	0.1432

High deductible plan significant, less likely to get MRI

Age is significant 40-65 more likely to get MRI

All practices have significantly higher use than controls

Higher use does not seem to be related to MRI ownership

The results are similar for Medicare patients. In the Medicare data, only the patients of the first control group (similar practices) were able to be included. Again, age is a predictor of receiving an MRI: the older the patient, the less likely this is. Three of the five practices had higher MRI use rates than the control groups. The one group with a lower rate was the practice that that did not bill for any MRI services in 2010. For one practice, the rate was not significantly different. Consistent with the results for the private insurance practices, the differences in the rates of MRI use do not seem to be related to the period when the practices had a financial interest in MRI equipment, except for one practice.

Appendix C

Table 4: Medicare Regression Results

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-0.7594	0.0349	474.2658	<.0001
year2012	1	-0.0431	0.0268	2.5867	0.1078
dual	1	0.0147	0.0278	0.2807	0.5962
sex_cd	1	0.0195	0.0184	1.1269	0.2884
age_65_70	1	-0.1452	0.0322	20.3729	<.0001
age_70_75	1	-0.1940	0.0328	34.9410	<.0001
age_75_80	1	-0.3679	0.0343	114.9998	<.0001
age_80_85	1	-0.5798	0.0363	254.6780	<.0001
age_GE_85	1	-0.9191	0.0383	575.5514	<.0001
Practice A	1	0.0479	0.0408	1.3758	0.2408
Practice B	1	0.1870	0.0360	26.9392	<.0001
Practice C	1	0.0835	0.0425	3.8640	0.0493
Practice D	1	0.1538	0.0362	18.0203	<.0001
Practice E	1	-0.2575	0.0577	19.9061	<.0001
F_ Practice A	1	0.0907	0.0595	2.3219	0.1276
F_ Practice B	1	0.1174	0.0510	5.3009	0.0213
F_ Practice C	1	-0.0485	0.0593	0.6684	0.4136
F_ Practice D	1	-0.0529	0.0520	1.0317	0.3098
F_ Practice E	1	0.0706	0.0804	0.7716	0.3797

Age is significant Older less likely to get MRI

Several practices have significantly higher use than First Control Group

But does not seem to be related to MRI ownership, except for 1 practice

IX. Conclusions

For patients with private insurance and Medicare, this study found no evidence that financial interest influenced MRI rates in 2010 compared to 2012. For practices with a financial interest in the equipment in 2010, their rates of MRI use are higher in both 2010 and 2012. The higher rate is statistically significant for privately insured patients for all practices. For Medicare patients the MRI use rate is higher and statistically significant for three of the five practices. The higher rates persist even after controlling for factors such as age and coverage by a high-deductible plan (privately insured patients), and dual Medicaid eligibility (Medicare beneficiaries).

X. Limitations

It is possible that the timeframe required for this study one year before divestment and the year immediately following divestment was too short a timeframe to capture changes in physician behavior. The study design presumes that a change in MRI ordering behavior will be abrupt following a change in financial interest in the equipment.

The study could not make use of the broader population of patients receiving care from other orthopedists in the Medicare analysis, because the NPI field was not useable in the Medicare data.

Other factors could influence MRI use, such as age of physician, income of patient, and other patient conditions that could not be measured in this study.

Physicians can order tests without patients following through and getting the test. There is no record in the claims data of an order, only of the service when a patient actually receives the test. It is possible that patients with different insurance coverage may have different rates of fulfilling the test orders. We were able to control for insurance type, private and Medicare and for high-deductible plan design to control for different rates of fulfillment due to greater or lesser insurance coverage. It is also possible that patients with more social support are more able to comply with orders to obtain medical services.. It is well known that patients with low socio-economic status are less likely to receive many preventive measures. We were not able to control for patient income.

We did not explore whether the type of diagnostic scan that orthopedists made a referral for differs among the groups or changes over time, e.g., greater use of CT or other imaging modality. It is possible that groups with a financial interest in MRI equipment would be more inclined to use that equipment over another imaging modality, whereas groups without a financial interest in an MRI machine might use other modalities as well.

Other interesting questions that this study did not address due to funding and time constraints are:

- Was there a shift in site of service between office-based use of MRI services and hospital-based used of services?
- Was there a shift in modality of imaging service, e.g., from X-ray or CT to MRI?
- Is there a benefit to increased use of MRI, e.g., lower health care costs due to greater efficiency, increased patient convenience or compliance? When the MRI services are diagnostic, are there higher rates of detection of the anomaly?
- Are reimbursement rates for MRI services reasonable relative to the actual cost of providing the services?

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Appendix A
Practices with Financial Interest in 2010 – Cases

Orthomaryland

Orthopedic Associates of Central Maryland

Peninsula Orthopedic Associates, P.A.

Potomac Valley Orthopedics Associates

Robinwood

Appendix B
Similar Orthopedic Practices without a Financial Interest in 2010 – Control Group 1

Center for Advanced Orthopedics (Hollywood and Waldorf)

Greater Washington Orthopedic Group

Maryland Orthopedic Specialists

Metro Orthopedics and Sports Therapy

Mid-Maryland Musculoskeletal Institute

Montgomery Orthopedics

Orthopedic Surgeons of Montgomery Count

Orthopedic Associates

Orthopedic Solutions

Orthopedic Center

Southern Maryland Orthopedic and Sports

Summit Orthopedic

Appendix C
Methodology for Identifying Other Orthopedists

The steps used to identify other orthopedists in Maryland were as follows:

1) Identify most common CPT in the claims for the case and control group 1 that are also in musculoskeletal range 20000-29999 and those not likely to be used by other specialties

The top 5 CPT codes were:

20610	Arthrocentisis, aspiration and or injection; major joint (shoulder, hip, knee subacromial bursa	41.2%
20605	Arthrocentisis----intermediate joint	3.9%
20550	Injection, single tendon sheath or ligament aponeurosis	3.8%
29881	Arthroscopy, with meniscectomy	2.6%
29826	Arthroscopy, shoulder; decompression of subacromial space	2.1%

With the exception of 20550, we included these and arthroscopy procedures (excluding spine) as more likely to be done by orthopedists than other physicians. Those codes were:

- 20600 through 20610
- 23395 through 23491
- 24300 through 24498
- 25260 through 25492
- 26340 through 26596
- 27097 through 27187
- 27380 through 27499
- 27650 through 27745
- 28200 through 28360
- 29805 through 29848
- 29855 through 29907

These codes represented 67 percent of the CPT in the musculoskeletal range for patients of the case and control group 1 practices (58,010 out of 86,859)

2) Identify the NPI of all providers with these CPT (those already identified under the case and control group 1).

- Count = 289,655
- Unique NPI =10,466 (82% had 9 or fewer of these CPT)

3) Limit to NPI that had a threshold number of these CPT

We counted the number of times that the case and control group 1 billed one of the selected orthopedic CPT in 2010. Range was 16 to 8117. We applied a threshold of 10 or more of these CPT to the other orthopedic NPI.

- Count = 1843

4) Look up in NPI file to identify specialty

We matched the NPI to the subset of the national NPI file where Maryland was indicated in the state or practice state field. The NPI file was downloaded in July 2014. It is a cumulative file that includes expired NPI with an expiration date. All NPI with a Maryland address or Maryland practice location were extracted.

- Match = 1,125
- Did not match = 1843-1125= 718

5) Exclude if specialty is not orthopedic or generic specialty code

For the matches, we identified which had a taxonomy code[14] (any of the 15 positions) that was orthopedic:

Orthopaedic Surgery - 207X00000X
Adult Reconstructive Orthopaedic Surgery - 207XS0114X
Foot and Ankle Surgery - 207XX0004X
Hand Surgery - 207XS0106X
Orthopaedic Surgery of the Spine - 207XS0117X
Orthopaedic Trauma - 207XX0801X
Pediatric Orthopaedic Surgery - 207XP3100X
Sports Medicine - 207XX0005X

Any NPI with an orthopedics taxonomy code in any of the 15 taxonomy code fields was identified as an orthopedist. There was a total of 872 orthopedic NPIs in Maryland. NPIs can be for either the individual physician or the practice or billing entity. This number does not correspond to the number of individual orthopedic physicians in the state.

I also identified those that had a generic "specialist" taxonomy code= 174400000X

- Orthopedic count: 303
- Specialist count: 87
- Overlap: 8
- Total unduplicated: 382
- Drop from #5 count: 1125-382=743

There were 303 confirmed orthopedists that billed 10 or more of the CPT codes identified above.

For the 79 NPIs where only "specialist" was indicated but who billed the orthopedic CPT identified above, we selected seven where the name of the practice clearly indicated orthopedics.

[14] Taxonomy codes from http://www.wpc-edi.com/reference/):

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AGENDA

Provider/Carrier Workgroup- Study on Self-Referral

June 24th 2015

A. Introduction
   a. Review of the Charge- Ben Steffen
   b. Overview of workplan- Ben Steffen

B. Background on Maryland Self-referral Law and Stark Law --Statute and Court of Appeals Decision – Wynee Hawk- Board of Physicians

C. Alignment of Current State Self-referral law with Maryland's All-Payer Model Agreement with the Centers for Medicare and Medicaid Innovation – Donna Kinzer- HSCRC

D. MHCC approach to considering exceptions under Maryland Law Ben Steffen

E. Workgroup Comment (voluntary):
   a. Is it feasible and desirable to consider an exemption from Maryland Self-referral law if providers:
      i. participate in incentive-based reimbursement programs,
      ii. report on patient satisfaction and clinical quality,
      iii. demonstrate sufficient practice volume?

F. Public Comment

G. Next meeting- Wednesday July 22, 2015 3:00-5:00 PM At MHCC

Date Change for Upcoming Meetings:

Original Meeting Date	New Meeting Date
Wednesday August 26, 2015	**Wednesday September 2, 2015**
Wednesday September 23, 2015	**Wednesday October 7, 2015**

Note: Speaking on the Item D will be voluntary. Each participant will be limited to 5 minutes for comment.

Provider/Carrier Workgroup- Study on Self-Referral

Introduction and MHCC Approach

Ben Steffen

June 24, 2015

Criteria for an Exemption - Health Occupations §§1-301 – 305 and COMAR 10.01.15.05 and .06

Section 1-301 (b)(1) defines "Beneficial interest" means ownership, through equity, debt, or other means, of any financial interest.

Section 1-302(d)(5) of the statute provides that an applicant may be granted an exemption if the Secretary determines:

- …that the health care practitioner's beneficial interest is essential to finance and to provide the health care entity; and
- …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;

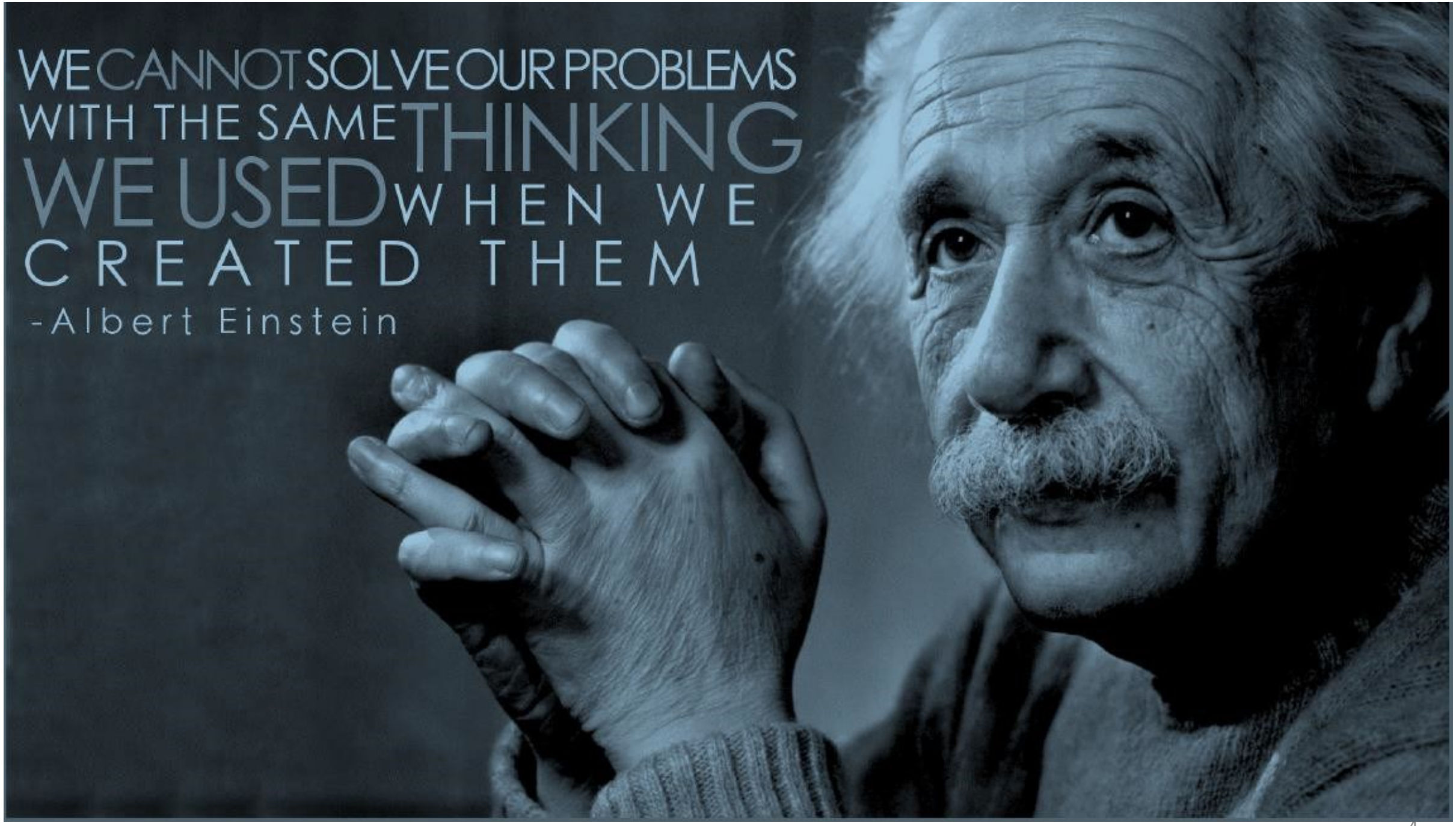
COMAR 10.01.15 - Exemption from Self-Referral Laws

- Defines format for exemption request
- Requires the Secretary to respond in 90 days
- Requires applicant to agree to relinquish the “beneficial interest”, if the Secretary denies the application
- Provides opportunity to renew the exemption

History of Exemption Process

The Secretary received two applications for exemptions since 2011

- Both applicants provided self-referral services prior to the Court of Appeals decision upholding BOP declaratory ruling
  - Orthopedic practice requested an exemption to provide advanced MRI services
  - Urgent care facility requested exemption to provide CT services in urgent care setting
- MHCC assessed whether the imaging services were needed to ensure appropriate access
  - Asked applicants to report volume of services provided, capabilities of imaging equipment
  - Inventoried other organizations providing advanced imaging services in the respective communities
  - Assessed capacity of other organizations to absorb additional volume
  - Concluded that advanced imaging services provided by the applicants were not essential to ensure appropriate access in their respective communities.
- Secretary agreed with MHCC's conclusion in one case and approved the exemption in the second.
- Applicant received a second exemption in 2013.


WE CANNOT SOLVE OUR PROBLEMS
WITH THE SAME THINKING
WE USED WHEN WE
CREATED THEM
-Albert Einstein

What MHCC said

… ownership of office-based imaging could be permitted if three conditions are met:

- the practice demonstrates that a very high proportion of care is reimbursed under risk-based financial arrangements;
- the practice can demonstrate sufficient scale as to make ownership of imaging equipment viable and agrees to bundle imaging use under the risk-based arrangement; and
- the practice commits to ongoing reporting of quality metrics linked to its patient outcomes.

What MHCC was thinking

Practice demonstrates that a very high proportion of care is reimbursed under risk-based financial arrangements

- Practices participate with multiple payers in a meaningful way in value and risk based payments.
- Participation is broad and deep. Practices must be engaged for a significant share of patient care

CMS …. “30 percent of all fee-for-service payments to providers to quality initiatives through alternative payment models--particularly accountable care organizations (ACOs) and bundled payments--by 2016 and 50 percent by 2018, …. goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018.”

Caveats:

- Blended payment methods (e.g. capitation + pay for Performance +FFS)
- Payers have been slow to develop risk-based initiatives for specialists

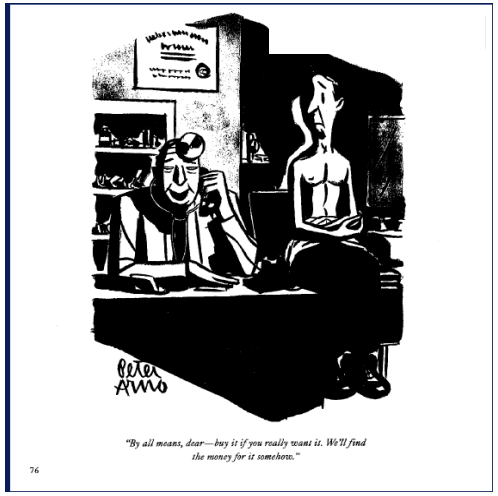
What MHCC was thinking

Sufficient scale

- Organization has sufficient size, ability to self-refer will not produce inefficiencies or lower quality of care

Caveat:

- Rapid proliferation of new capabilities will be very difficult to manage and compromise previous investments.
- Human scale, especially in clinical setting is important



Neither these works

What MHCC was thinking

Quality reporting focused on patient outcomes

- Start with meaningful performance measures at the level of the organization.
- Support culture changes focused on improving care, not on hitting narrow targets
- Incentivize intrinsic motivation = putting the patient first + continual striving to become a better physician

Caveats: Incentives based on measures that physicians don't view as highly important for patient care

- Align measures -- multiple overlapping but not quite identical quality measures are a significant drag on the performance improvement
- Meaningful quality and performance measures for specialties are limited, but can be developed, eg cardiology and anesthesiology

Wynee E. Hawk, RN, JD
Policy and Legislation

Timeline

- 1989 — "Stark I" part of Omnibus Budget Reconciliation Act; only applied to clinical laboratory services and Medicare
- 1993 — Maryland Patient Referral Law (MPRL) enacted
- 1994 — "Stark II" (42 USC 1395nn) extended to cover additional "designated services" and to apply to Medicaid. The federal statute is narrower than Maryland, because it (1) only applies to physicians; and (2) covers only self-referrals of certain designated services
- 2006 — Board issued DR 2006-1, interpreting the MPRL for the first time; in the DR, the Board interpreted the exceptions very narrowly
- 2011 — Maryland Court of Appeals upholds DR 2006-1 (*Potomac Valley*)

Maryland's Patient Referral Law (MPRL)

Md. Health Occupations Article, §1-302

- Enacted in 1993
- Prohibits a health care practitioner from referring a patient to a health care entity in which the practitioner (or an immediate family member) owns a "beneficial interest" or has a "compensation arrangement." Md. Health Occ. Code Ann. §1-302
- MPRL was patterned after federal Stark Law, and was designed to curb potentially inappropriate utilization of medical tests and services
- "Because the general rule is so broad and sweeping, numerous exceptions had to be made accommodate situations in which there is no significant threat of overutilization." Potomac Valley Orthopaedic Assocs. V. Md. Bd. Of Physicians, 12 A.3d 84, 88 (Md. 2011) (quoting DR 2006-1 at 13-14).

MPRL Does Not Apply

- Where there is no **"beneficial interest"** or **"compensation arrangement"** between the referring physician and the health care entity
  - "Beneficial interest" is defined as "ownership through equity, debt, or other means, of any financial interest." HO §1-301(b)
  - "Compensation arrangement" means "any agreement or system involving any remuneration between a health care practitioner … and a health care entity" but not including "[a]mounts paid under a bona fide employment agreement [.]" HO §1-301(c).

- Where the **referral comes within a specific exception**, such as:
  - "Group practice" exception (HO §1-302 (d) (2))
  - "Direct supervision" exception (HO §1-302 (d)(3))
  - "In-office ancillary services" exception (HO §1-302 (d) (4))

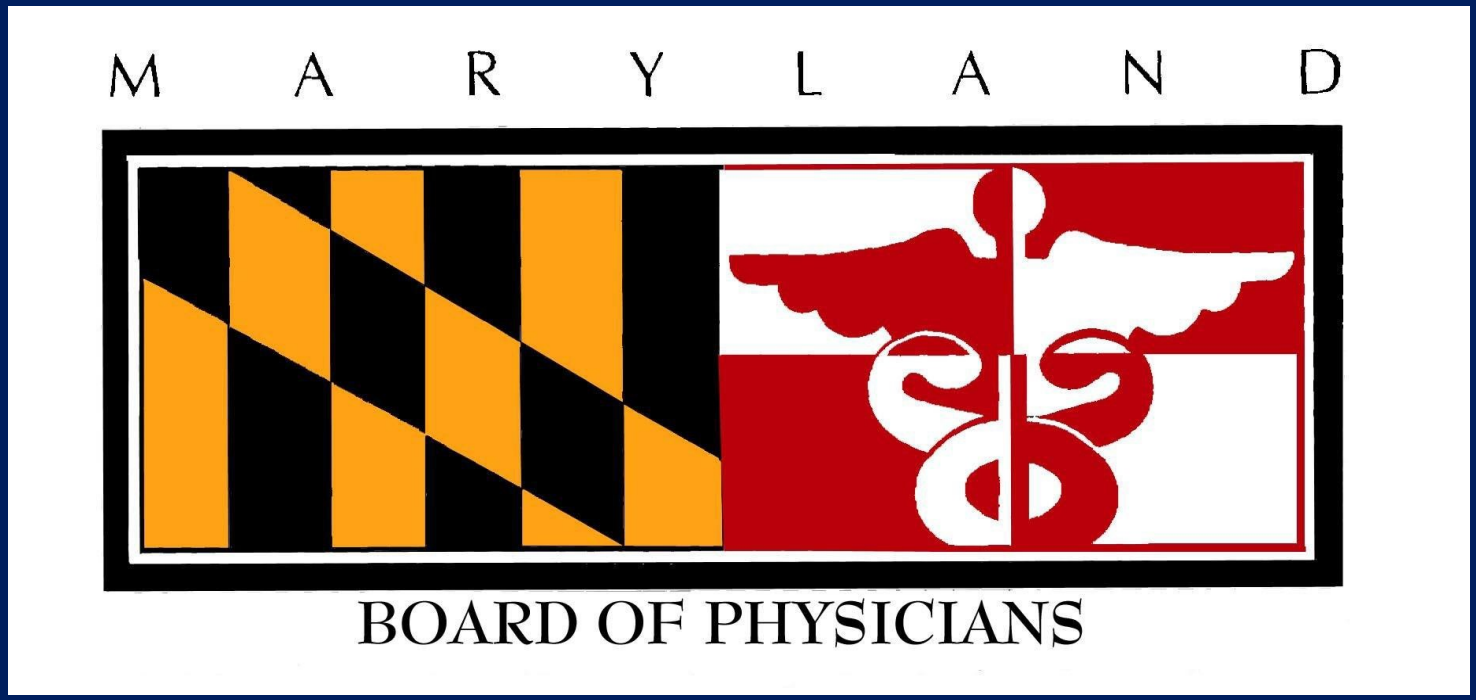
Declaratory Ruling 2006-1

- The Board was petitioned to decide whether the "group practice" and "direct supervision" exceptions permitted physicians ***who had an ownership interest*** in their group practice to refer patients for in-office MRI and CT scans.
- Seven example cases were reviewed by the Board, all in which the referring physician had an ownership interest in the entity furnishing the MRI or CT scan. Also examined was a fact pattern ("Variation 3") in which the referring physician was *not* an owner but rather an employee of the practice that furnished the scan.
- The Board's conclusions were based on its interpretation of the definitions in HO §1-301 and the exceptions in §1-302, The Board construed the exceptions very narrowly.

PHYSICIAN-EMPLOYEE	PHYSICIAN-EMPLOYEE
Board concluded that a physician-owner could not use either the "group practice" or "direct supervision" exceptions to make an in-office referral for MRI/CT scans.	Board concluded that a physician-employee could permissibly refer for an in-office MRI/CT scan in certain circumstances without needing to rely on any exception listed in HO § 1-302 (d)

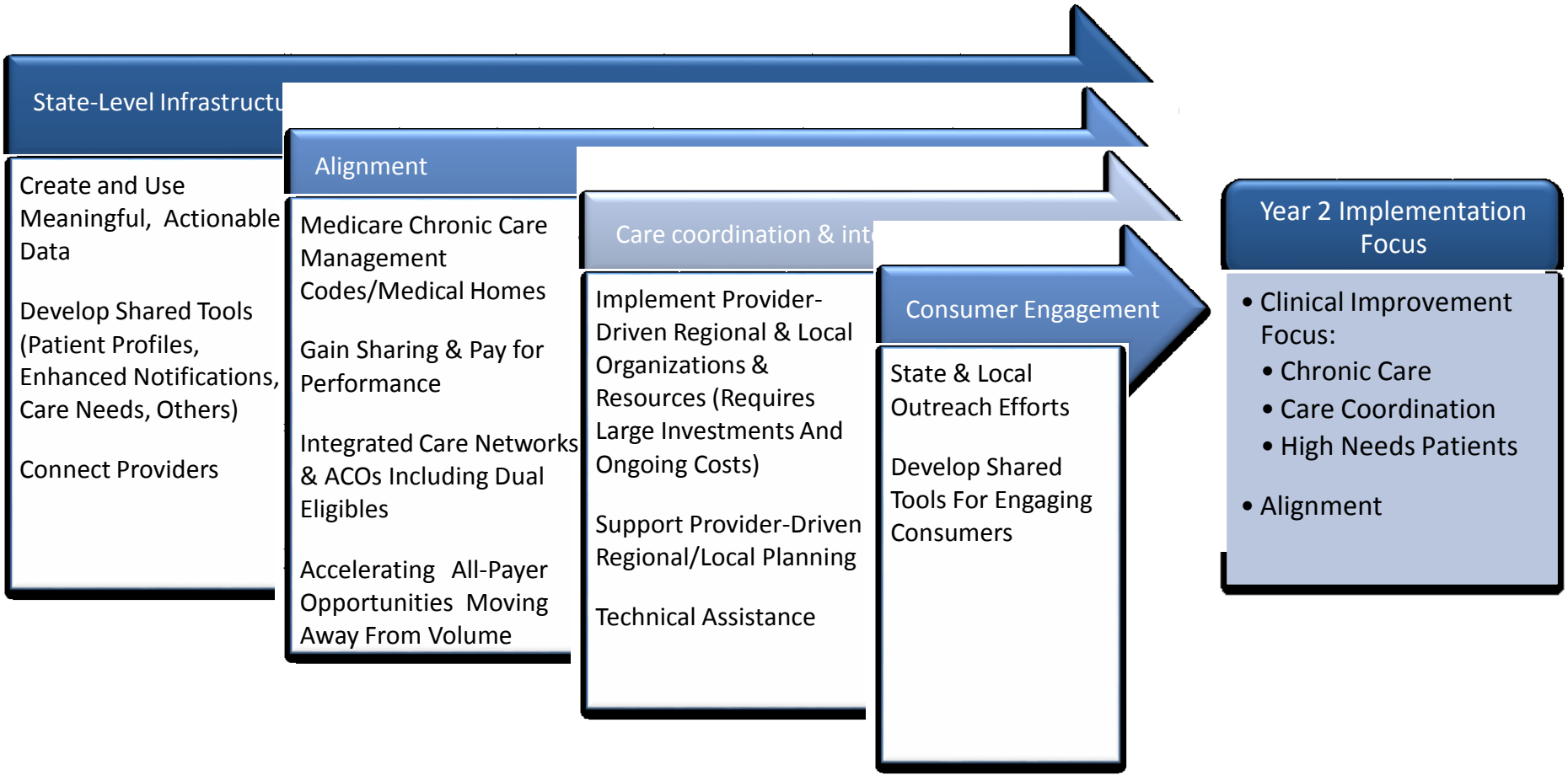
- DR 2006-1 was adopted and affirmed by the Maryland Court of Appeals in Potomac Valley.

Questions?



MD's Strategic Roadmap to Achieve the Triple Aim

The current focus on "Alignment" includes both clinical and financial components



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

AGENDA

Provider/Carrier Workgroup- Study on Self-Referral

July 22, 2015

3:00 pm- 5:00 pm

Existing shared savings programs and opportunities

A. Introductions and Recap of June meeting - Ben Steffen and Erin Dorrien- MHCC (3:00-3:05)

B. Goals for the meeting: Ben Steffen (3:05- 3:15)
   a. Develop consensus on what constitutes accountability
   b. Determine how we link accountability with flexibility

C. A discussion the continuum of accountability Srinivas Sridhara- MHCC (3:15-3:30)

D. Accountable Programs

   a. Programs that exist or are near deployment -
      i. Medicare- Guy D'Andrea and Pranali Trivedi, Discern (3:30-3:50)
   b. Private Payer programs - John Fleig- United Health Care, Dr. Daniel Winn CareFirst (3:50-4:00)
   c. MHA Gain Sharing Approach – Nicole Stallings- Maryland Hospital Association (4:00-4:15)
   d. Other models that could be considered- (4:15- 4:30)
      i. Clinically integrated organizations - Srinivas Sridhara
      ii. Mandatory Preauthorization - Erin Dorrien
      iii. Certificate of Need- Ben Steffen
   e. Other Suggestions

E. Discussion --- Ben Steffen (4:30-5:00)
   a. Feasibility for implementing Maryland?
   b. Must all patients be covered by accountable programs?

F. Wrap-up – what we heard -- Guy D'Andrea and Pranali Trivedi

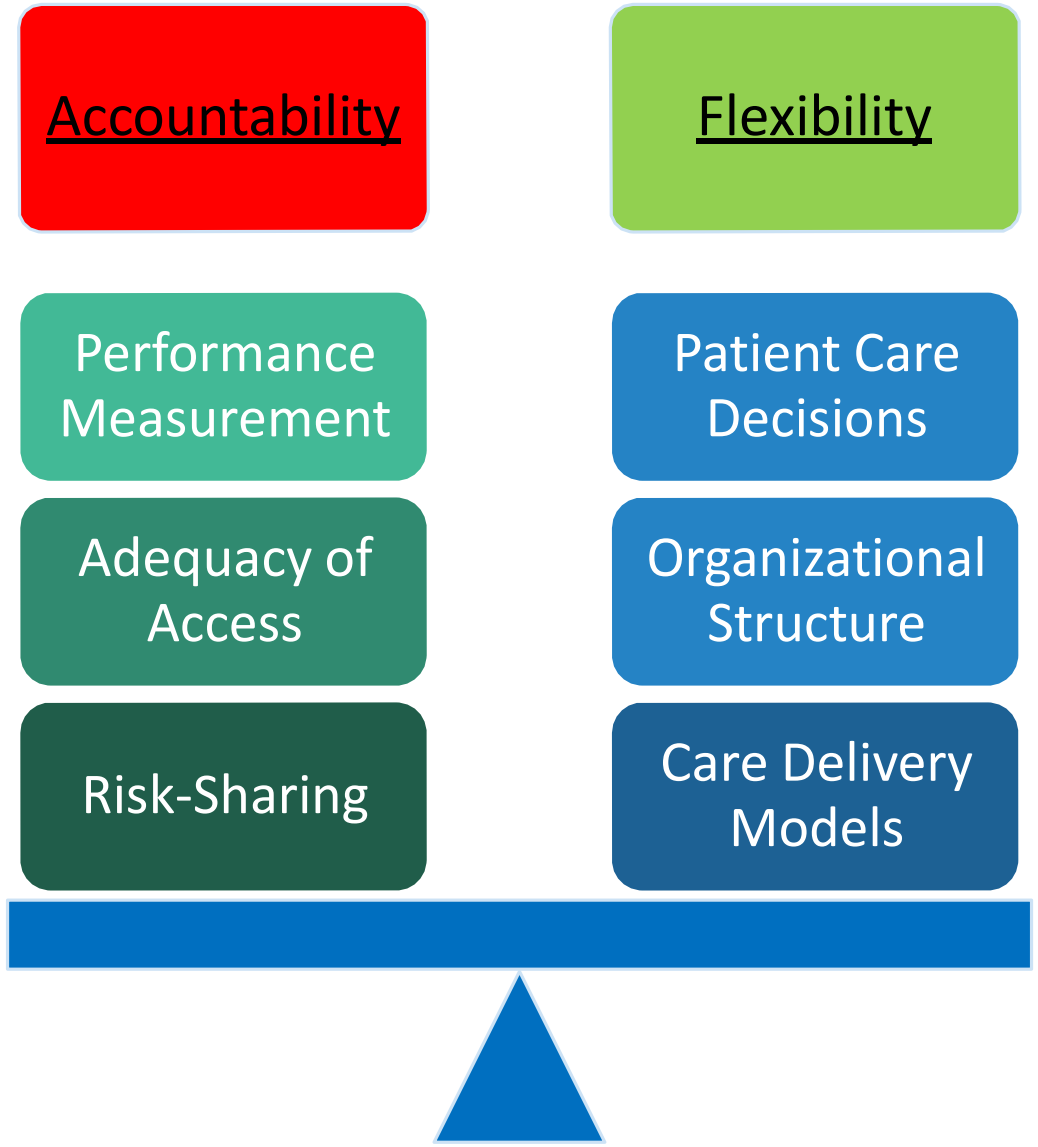
Provider-Carrier Workgroup – Study on Self-Referral

JULY 22, 2015

MHCC | MARYLAND HEALTH CARE COMMISSION

Core Principle

Providers who take on greater accountability should have greater flexibility in managing their practices and patients.



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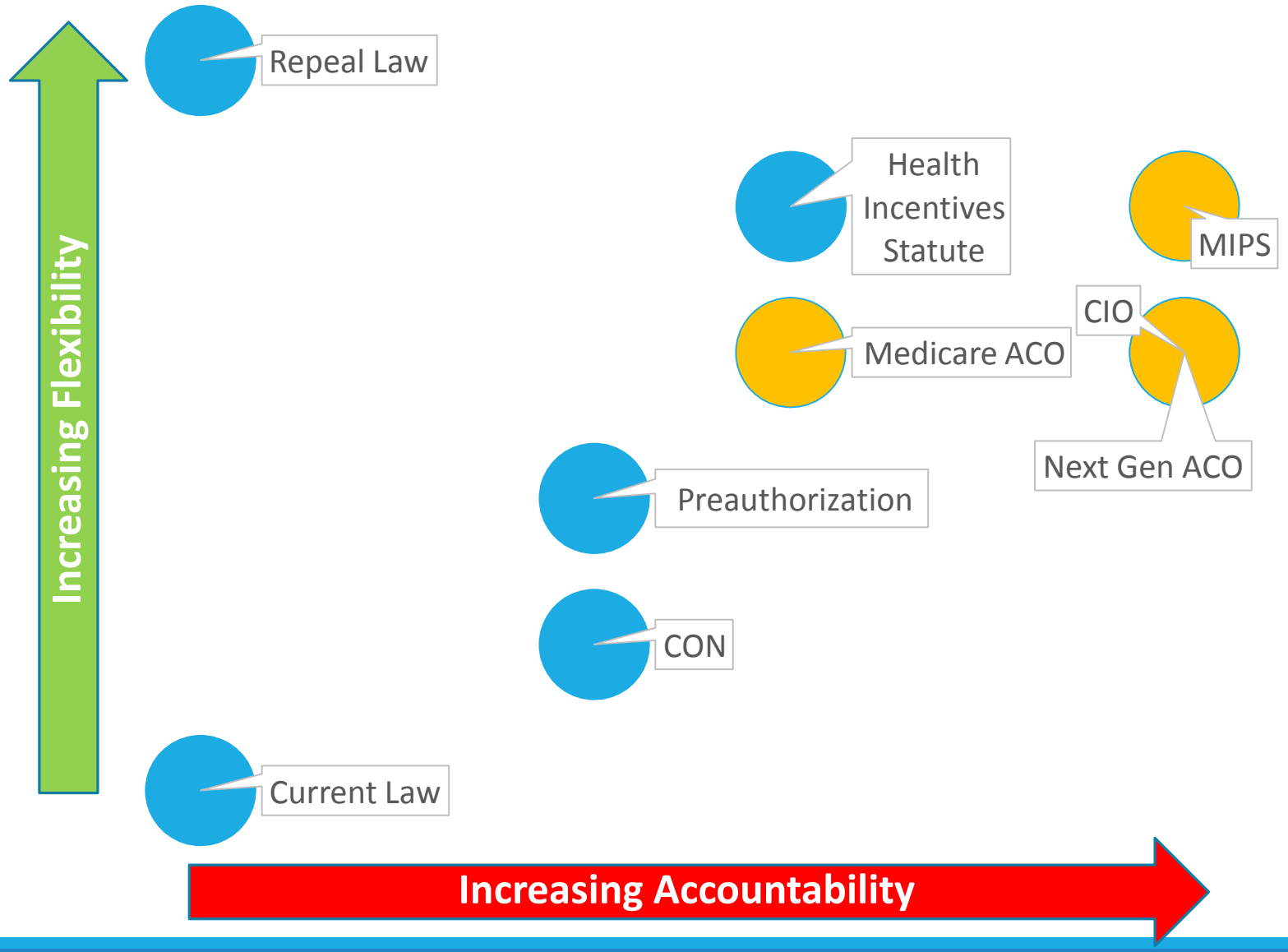
Accountable Programs

Continuum of Options: Making Trade-Offs



Medicare

Medicare Incentive Programs that promote Accountability: Current and Future

Presentation to MHCC
Provider/Carrier Workgroup -
Study on Physician Self-Referral

July 22, 2015

Discern Health
1120 North Charles Street
Suite 200
Baltimore, MD 21201
(410) 542-4470

Presentation Overview

- Current Medicare Incentive Programs to Promote Accountability in Payment
  - Physician Quality Reporting System
  - Value-Based Payment Modifier
  - Meaningful Use
- Forthcoming Changes
  - Medicare Sustainable Growth Rate (SGR)
  - Medicare Access and CHIP Reauthorization Act (MACRA)
  - Merit-based incentive payment system (MIPS)
- Medicare Accountable Care Organizations (ACOs)

Current Medicare Incentive Programs

Physician Quality Reporting System (PQRS)

- **Overview**: PQRS uses incentive payments to encourage eligible health care professionals (EPs) to report on specific quality measures applied to Medicare Part B claims.
- Each year, providers receive feedback reports on whether they satisfactorily reported required measures, making them eligible for an **incentive payment** equal to a percentage of the provider's estimated total allowed charges for covered services
- Beginning in 2015, CMS introduced a **negative payment** for providers failing to meet satisfactory quality measure standards
- Providers receiving a negative payment will be paid 1.5% less than the Medicare Physician Fee Schedule (MPFS) amount for those services rendered January 1 to December 31, 2015.

Value-Based Payment Modifier (VBPM)

- Provides for **differential payment** to a provider based on a comparison of quality measures and cost of care measures.
- Currently VBPM applies to groups of 100 or more eligible physicians. Beginning in 2017, the VBPM will also be implemented for individual providers.
- If a group fails to achieve satisfactory quality/cost benchmarks, the Value Modifier is set at -1%
- Payments made under the Value Modifier must be budget neutral - upward payment adjustments for high performance must balance the downward payment adjustments applied for poor performance.

Meaningful Use

- The Medicare and Medicaid Electronic Health Care Record (EHR) Incentive Programs provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology.

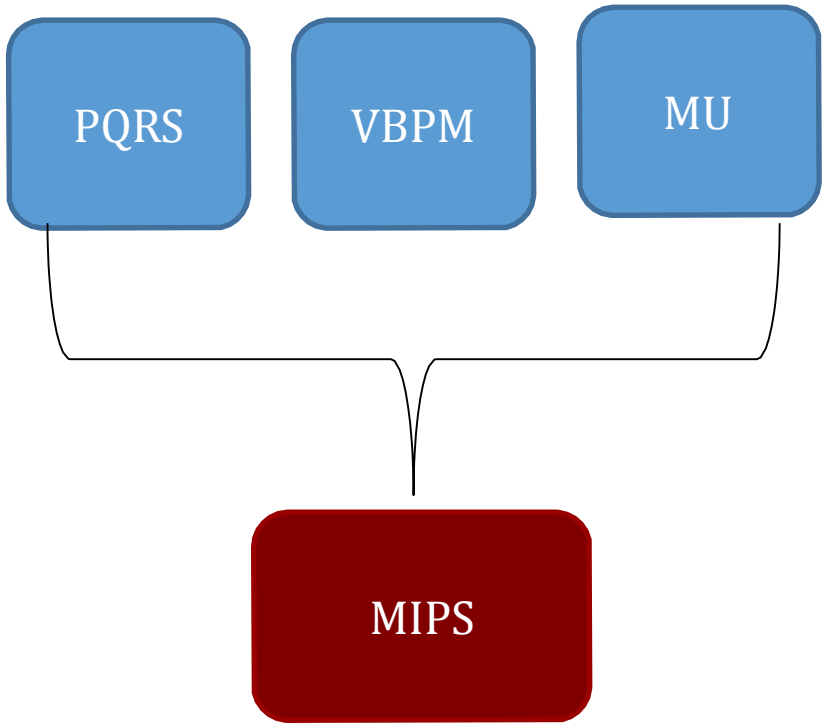
Forthcoming Changes to Medicare Incentive Programs

SGR and MACRA

- Medicare Sustainable Growth Rate (SGR) permanently repealed and replaced with Medicare Access and CHIP Reauthorization Act (MACRA) April 2015
- Medicare rates were frozen at pre-April levels through June, then raised 0.5% in the second half of 2015
- Will continue to increase 0.5% each year from 2016 through 2019.
- **MACRA will shift Medicare compensation from fee-for-service to pay-for-performance.**

Merit-Based Incentive Payment System (MIPS)

- Under MACRA, consolidation of MU, PQRS and VBM incentives and penalties while continuing to measure performance as specified by those programs
- MIPS will annually measure Medicare Part B providers in categories below to determine Medicare reimbursement:
  - VBM-measured quality
  - VBM-measured resource use
  - MU
  - clinical practice improvement
- Providers participating in an alternative payment model (APM) are rewarded with an additional financial incentive of 5% of their Medicare reimbursements received in the prior year



Medicare ACOs

Medicare Shared Savings Program (MSSP)

- CMS program that helps a Medicare fee-for-service program providers become an ACO to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs.
- Preceded by Pioneer ACO program
- MSSP has various payment models across the country:
  - One sided risk (vast majority)
  - Two sided risk
  - Advanced payment

Advance Payment ACO Model

- Supplementary incentive program for selected participants (physician-based and rural providers) in the MSSP ACOs.
- Participants receive upfront and monthly payments, which they can use to make important investments in their care coordination infrastructure.
  - An upfront, fixed payment: Each ACO receives a fixed payment.
  - An upfront, variable payment: Each ACO receives a payment based on the number of its historically-assigned beneficiaries.
  - A monthly payment of varying amount depending on the size of the ACO: Each ACO receives a monthly payment based on the number of its historically-assigned beneficiaries.

Summary

Medicare – Parameters of Accountability

- Quality
  - Clinical performance
    - Process
    - Outcomes
    - Utilization
  - Patient experience
- Financial
  - Adjustments to fee-for-service
  - Bundled payment
  - Risk for overall costs (one-tailed or two-tailed)

Medicare – Parameters of Flexibility

- MedPAC 2011 Report addresses challenges in Stark Law and states that value-based payment arrangements could mitigate them.
  - "….under an alternative payment structure in which providers are rewarded for constraining volume growth while improving the quality of care, the volume-increasing effects of self-referral would be mitigated. Therefore, the preferred long-term approach to address self-referral is to develop new payment systems."
- In the 2016 Physician Fee Schedule Proposed Rule, CMS suggests two exceptions to Federal Stark Law:
  - Assistance to physicians to employ non-physician practitioners, and
  - Clarification for FQHCs and rural health clinics to determine the geographic areas that they serve.
- The 2016 Proposed rule also solicits comments on impacts of Stark on financial relationships in light of alternative payment/delivery models, indicating that CMS will address this issue in the near future.

MARYLAND HEALTH CARE COMMISSION

Private Payer Programs

MHA Gain Sharing Approach

Gainsharing: Foundation for Physician Alignment & Engagement

Nicole Stallings

Vice President, Policy & Data Analytics

Maryland Hospital Association

Background

- New All-Payer Model Agreement effective January 2014
- Aggressive financial and quality requirements
- Extensive monitoring from CMS, HSCRC
- Success under new spending caps requires volume control and cost reduction
- Several new HSCRC payment policies in place
- All hospitals operating under global budget

Opening Perspectives

- Effective hospital/physician collaboration is essential to meet the aggressive quality and financial requirements under the five-year waiver demonstration and to succeed under global budgets.
- Gainsharing is the direct payment by hospitals to physicians, based on quality and efficiency. Unlike "Shared Savings," it is based on hospital costs, not Medicare payments.
- HSCRC's Physician Alignment & Engagement Workgroup agreed gainsharing should be explored as a *first step* for interested providers, while working to pursue initiatives that will move the state toward the longer term goal of population-based models.

MHA's Gainsharing Program

- Comprehensive (all costs, all DRGs) inpatient only program modeled after demonstrations in New York and New Jersey
- Based on methodology approved by CMS three times
- Voluntary physician participation
- No change in physician reimbursement; incentive only
- Hospital/Physician Steering Committee conditions incentive payments based on specific quality and care redesign initiatives
- Utilizes severity adjusted, physician specific data to identify clinical and non-clinical savings opportunities, determine incentive payments

Design Principles

- Purpose: Recognize the important role of physicians in contributing to efficient hospital operations
  - Rewards achieved levels of performance, incent improved performance
  - Safeguards to ensure patient protections, maintain quality of care
- Measurement: Performance is rewarded based on regionally derived Best Practice Norms
  - 25th percentile of lowest patient costs in MD hospitals
  - Responsible Physician/Physician of Record eligible for incentive
  - Ability to add specialists, consultants and ancillary physicians

Patient Protection

Regulatory Concerns	Characteristics of Approach
Cherry picking, quicker-sicker, stinting and steering	Severity of illness adjustment
Phantom savings	Uniform methodology
New and untried practices	Limit on incentive payments
Compensation to induce referrals	Volume requirements
Patient participation	Requires patient notice

Quality Components

- Integral part of determining incentive payment
- Standard measures: mortality, readmissions (within 7 and 30 days)
- Other measures determined by Hospital/Physician Steering Committee

Sample Quality Measures			
Efficiency	**Outcomes**	**Patient Experience**	**Other**
• Delinquent medical records • Timely operative report dictation • Calling consultants in a timely manner • First case start times in OR	• Hospital-acquired complications • Medication errors • Returns to the OR • Readmission	• HCAHPS – Physician Domain • Validated patient complaints	• Compliance with hospital policies • Attendance at Grand Rounds

Demonstration Experience

- Increased physician engagement
- Initial savings offset initial physician payment
- Additional physician participation after initial payments
- Hospital/Physician Steering Committee critical to focus opportunities for improvement/identification of processes that need to be put in place
- Quality scores improve on targeted initiatives
- Communication with physicians is key – one-on-one, departmental meetings, routine reports

Physician Dashboard

Current - July 2013 through June 2014; All Payor Claims

Provider : 01 - General Medical Center

ams Analytics

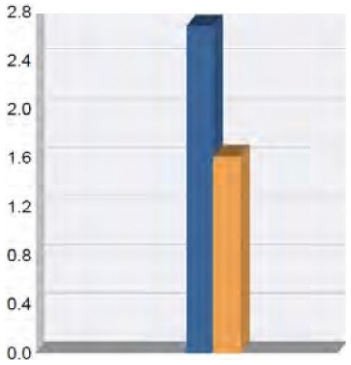
Responsible Physician	10000	Specialty		
Physician's First Name		**Physician's Last Name**		

QUICK STATISTICS	cost		Average LOS		INCENTIVE	Performance		Improvement		Total	
	Prior	**Current**	**Prior**	**Current**		**Prior**	**Current**	**Prior**	**Current**	**Prior**	**Current**
Your Information		$2,120,483		2.7	**Maximum Incentive**		$21,906		$0		$21,906
Best Practice Norm (BPN)		$1,677,763		1.6	**Your Incentive**		$8,245		$0		$8,245
Variance		$442,719		1.1	**Unearned Incentive**		$13,661		$0		$13,661

Discharges by Complexity Level (SOI)

Current	SOI1:	105	SOI2:	111	SOI3:	13	SOI4 :	0	**Total :**	229
Prior	S01 1:		S012:		S013:		S01 4 :		**Total :**	

LOS Summary



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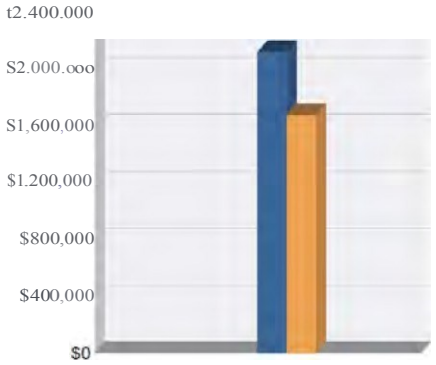
Cost Summary



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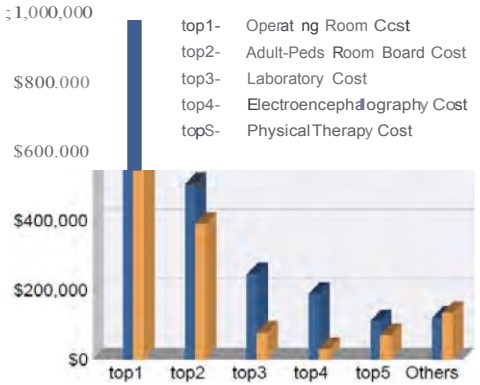
Top Cost Centers



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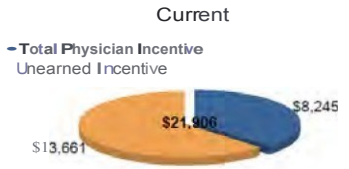
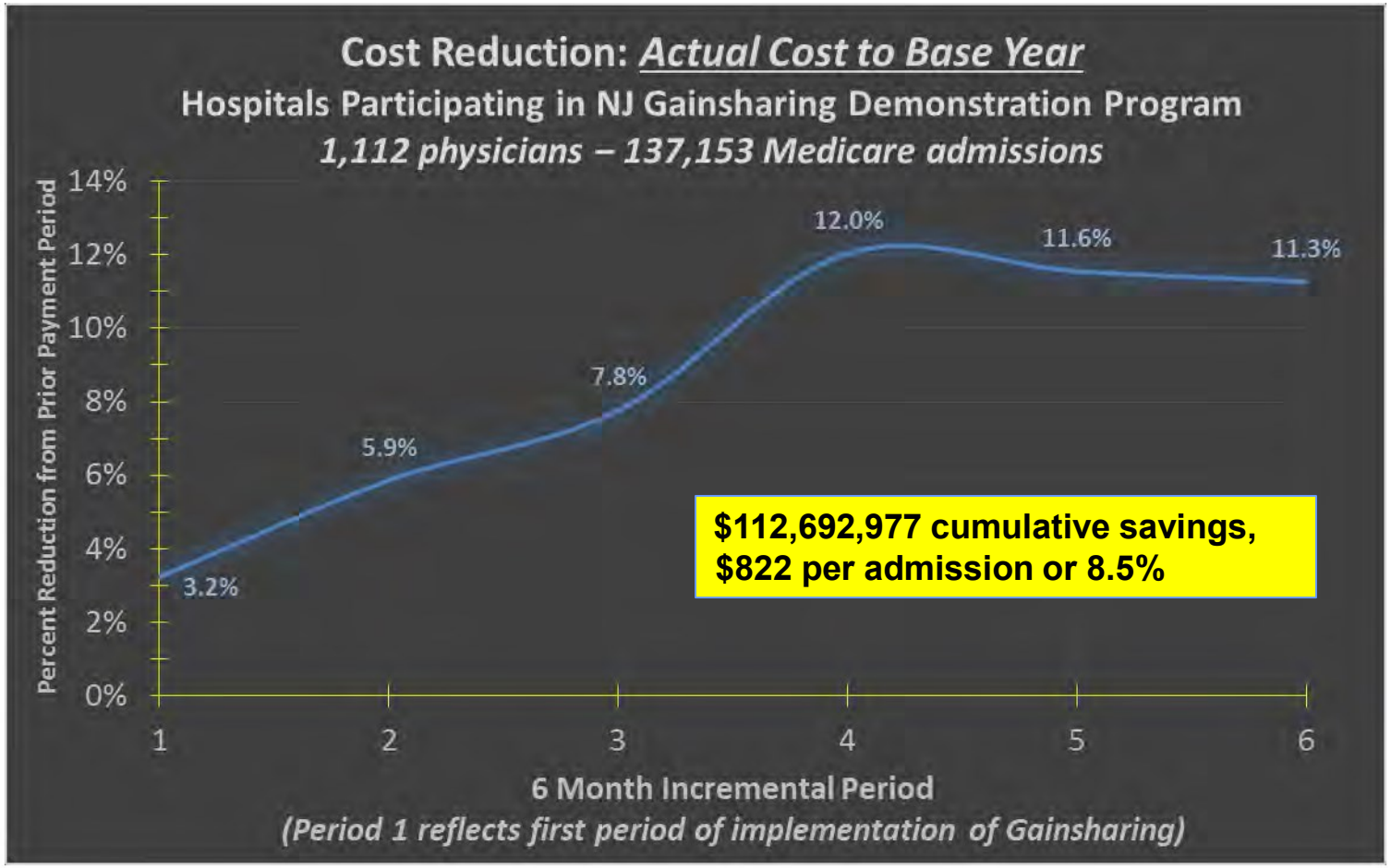
No Prior Period Utilization.



Co$t Center Summary

		Your Cot		BPN		Variance	
		Prior	**Current**	**Prior**	**Current**	**Prior**	**Current**
Top1	Operating Room Cost		$941,846		$891,696		550,150
Top2	Adult-Peds Room Board Cost		$505,028		5390,949		$114,079
Top3	Laboratory Cost		$245,652		576,869		$168,783
Top4	Electroencephalography Cost		$188,838		$29,160		$159,678
TopS	Physical Therapy Cost		$110,455		$70,200		$40,255
Top6	Occupational Therapy Cost		566,766		$41,173		525,593
Top7	Radiology Cost		536,139		$69,826		$-33,669
TopS	Respiratory Therapy Cost		$6,854		$17,104		$-10,249
TopS	Magnetic Resonance Technology Cost		$5,448		51,192		$4,256
Top10	Emergency Room Cost		$4,598		54,345		$253

NJ Medicare Demo - 12 hospitals
6 Payment Period Results (36 months)



NOTE: *Savings analysis is a comparison of actual cost to base year cost adjusted for inflation, case-mix and SOI (i.e. expected cost). The statements contained in this document are solely those of NJHA/AMS and do not necessarily reflect the views or policies of CMS.*

Program Status

- Program Steering Committee convened to provide oversight, approve adjustments to methodology
- Over half of Maryland's hospitals have signed Letters of Intent to participate
- HSCRC, MedChi and MHA have initiated conversations with CMMI regarding waiver authority
- Exploring additional implementation mechanisms (existing ACOs, commercial program)

Gainsharing: Foundation for Physician Alignment & Engagement

Nicole Stallings

Vice President, Policy & Data Analytics

Maryland Hospital Association

Implementing Accountability to Permit Self-Referral

Clinically Integrated Organizations

Established under HB 598 / SB 723 (2009)

Clinically Integrated Organizations are:

- A joint venture between a hospital and physicians that has:
  - Received an advisory opinion from the FTC; and
  - Has been established to evaluate and improve practice patterns and promote collaboration and efficiency; OR
- A joint venture between a hospital and physicians that:
  - Is accountable for total spending and quality; and
  - Is an Accountable Care Organization, as defined by CMS.

CIO's may enter into a contract with an insurance carrier

- Clinical integration, such as the ability to freely share medical records between CIO and carrier must a be a central feature
- May include performance incentives and payment for coordination of services
- Must include an evaluation of the program

Regulated by the Maryland Insurance Administration and monitored/evaluated by the Maryland Health Care Commission

Statute may be amended to permit self-referral within CIO's

Mandatory Preauthorization

Maryland law requires that all payers and pharmacy benefit managers implement an electronic preauthorization process.

- Requests for pharmaceuticals are approved in real-time or within one business day after receiving all pertinent information.
- Requests for non-urgent medical services are approved within two business days after receiving all pertinent information.

Amend Maryland statute to require preauthorization for services for which a self-referral exemption was issued.

Certificate of Need

Amend the Certificate of Need statue to include certain equipment regulated under the current self-referral statute.

Regulated Service	Number of States
Computed Tomography Services (CT)	12 + DC
Mobile Hi Technology (CT/MRI/PET, etc.)	15 + DC
Magnetic Resonance Imaging (MRI) Scanners	18 + DC
Positron Emission Tomography Scanners	19 + DC
Radiation Therapy	22 + DC

Retrieved from http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

Steps in Bringing a Service under Health Planning and CON

1. Change Statute

2. Develop new state health plan chapter - define eligibility for offering service, need methodology, establish application schedule

3. CON process review standards
   a. The most cost-effective approach to meeting identified needs;
   b. Geographically and financially accessible;
   c. Financially viable; and
   d. Will not have a "MAJOR" significant negative impact on the cost, quality, or viability of other health care facilities and services.

Likely that MHCC would be reluctant to expand health planning/CON to technologies such as advanced imaging

MARYLAND HEALTH CARE COMMISSION

Other Suggestions

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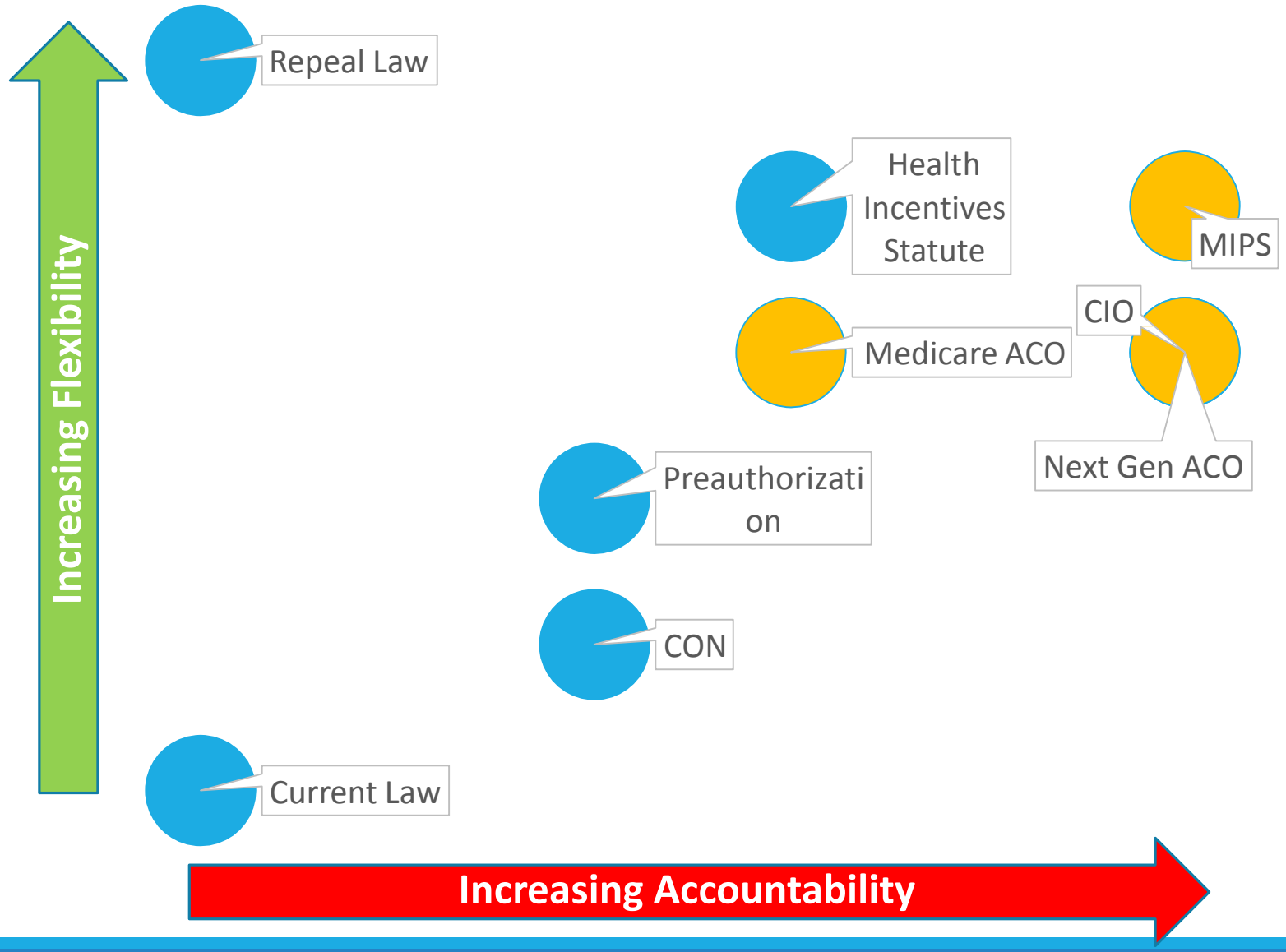
Discussion

Continuum of Options: Making Trade-Offs



MARYLAND HEALTH CARE COMMISSION

Wrap-up & Next Steps

IN THE MATTER OF	*	**BEFORE THE**
SANFORD J. SIEGEL , M.D	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number: D32029	*	**Case Number: SR 0-9911-0141**

* * * * * * * * * * * * *

CONSENT AGREEMENT

Based upon information received by the Maryland State Board of Physicians (the "Board"), pursuant to its authority under the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("Health Occ.") §§ 14-101 *et seq.* (2009 Repl. Vol.) and the Maryland Patient Referral Law ("MPRL"), Health Occ. §§ 1-301 *et seq.,* the Board conducted an investigation of Sanford J. Siegel, M.D. (the "Respondent"), License Number 032029, in his capacity as a licensee and as President and Chief Executive Officer of Chesapeake Urology Associates, PA ("CUA").

The pertinent provisions of the MPRL provide the following:

§ **1-302. Prohibited referrals; exceptions; disclosures.**

(a) *Prohibited referrals.* -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;

* * *

(c) *Applicability of subsection (a).* -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.

The State and the Respondent jointly submitted this Consent Agreement for consideration by the Board. The Consent Agreement memorializes an agreement between the Board and the Respondent that resolves the Board's investigation. By its terms, CUA agrees to the monitoring and reporting requirements set forth herein. In consideration for CUA's agreement to comply with these obligations, the Board hereby closes its investigation effective as of the date of this Consent Agreement. The Board voted to adopt this Consent Agreement.

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent was licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on March 5, 1985, and his license is presently active.

2. The Respondent is President and CEO of Chesapeake Urology Associates ("CUA"), a urology practice with offices located throughout the State of Maryland. The Board's investigation of the Respondent was undertaken in his capacity as a licensee and as President and CEO of CUA.

3. The Board's investigation in this matter did not relate to Respondent's or any other CUA physician's clinical judgments or treatment of patients, but related instead to a particular aspect of CUA's compliance with the MPRL.

4. The Board's investigation commenced in June 2011 and focused on whether the structure of referrals made by CUA physicians for the furnishing of radiation therapy services at CUA's Prostate Center is legally permissible in light of the Board's decision in Declaratory Ruling 2006-1 ("DR 2006-1") and the MPRL. CUA has maintained throughout the investigation that its referral practices associated with the

delivery of radiation therapy services at its Prostate Center are legal and comply fully with OR 2006-1 as well as the MPRL.

5. ·As of the date of this Consent Agreement, CUA has 53 physicians -- 46 urologists, four radiation oncologists, and three pathologists. Of the 46 urologists, 34 are owners, each holding an equal 100 shares of stock in CUA, and 12 are salaried employees. CUA's four radiation oncologists and two of the three pathologists are salaried employees. The third pathologist is an independent contractor.

6. As President and CEO of CUA, the Respondent spends approximately ten percent of his time as a practicing urologist and 90 percent of his time presiding over the administration of CUA. He is responsible for overseeing the running of CUA, including its approximately 400 employees. In 2006, the executive committee of CUA voted to build a new medical office as part of its group practice that would be dedicated to the treatment of men with prostate cancer. CUA's medical office, also known as the Prostate Center, would offer radiation oncology consultation services and radiation therapy treatment to prostate cancer patients, including intensity-modulated radiation therapy ("IMRT").

7. Prostate cancer starts in the prostate gland, which is a small, walnut-sized structure within the male urogenital system. Prostate cancer is the second leading cause of cancer death in American men. IMRT is a type of external beam radiation therapy that uses multiple small radiation beams of varying intensities to precisely radiate a tumor. For the treatment of prostate cancer with external beam radiation therapy, IMRT delivers high doses of radiation precisely to the prostate while minimizing risk of collateral dam ge to adjacent structures.

8. In building the Prostate Center, CUA sought to integrate radiation therapy using IMRT into its medical practice. CUA's leadership viewed the building of the Prostate Center as an opportunity to create a cancer treatment center that specialized in the treatment of prostate cancer and that offered men with prostate cancer an alternative setting to hospitals and radiation oncology centers that treat patients with various forms of cancer.

9. At the time that CUA decided to build and operate the Prostate Center, it performed a financial analysis to determine the economic feasibility of the project. This analysis included a projection of revenue using estimated rates of reimbursement along with estimated patient volume based upon historical utilization of IMRT. Based upon its financial analysis, CUA projected that, with an initial investment in the construction of the Center and the purchase of equipment, it would ultimately be able to realize a profit from the delivery of IMRT at the Prostate Center.

10. CUA's financial analysis assumed that a certain number of CUA patients diagnosed with prostate cancer by a CUA urologist would ultimately choose to receive IMRT at the Prostate Center, after a consultation with a CUA radiation oncologist, who would make an independent, professional judgment about the full range of treatment options for the patient, including whether the patient was an appropriate candidate to receive IMRT. CUA's leadership believed that patients choosing IMRT would prefer the continuity of care and specialization that the Prostate Center offered.

11. In early 2007, CUA's executive committee of which the Respondent was a participant held a series of meetings to discuss, among other things, the status of the

construction of the Prostate Center and CUA's plan, after the Prostate Center became operational, to retain a group of radiation oncologists as employees of CUA.

12. As CUA conceptualized the development of the Prostate Center's operational protocols, it was determined that CUA's urologists would discuss various treatment options with their patients diagnosed with prostate cancer and, when appropriate, refer patients for a radiation oncology consultation with one of the radiation oncologists employed by CUA. The radiation oncologist employee would review the patient's records, conduct an independent medical examination of the patient, and then discuss with the patient the radiation oncologist's recommendations of appropriate treatment options. The radiation oncologist employee would then document the consultation and discussion in CUA's electronic medical record system.

13. Since June 2007, CUA has continuously owned and operated the Prostate Center as one of CUA's medical offices located in Owings Mills, Maryland. The Prostate Center is not a distinct legal entity, but rather is part of CUA.

14. CUA employs four radiation oncologists. The radiation oncologists are salaried employees of CUA and do not have, nor have they ever had, any ownership interests in CUA. The salaries of the radiation oncologists are fixed by the terms of the radiation oncologists' employment contracts and are not dependent upon the number of patients who receive radiation therapy at the Prostate Center. The radiation oncologists do not receive any kind of bonus, distribution, or other incentive-based compensation from CUA for referring or treating patients with radiation therapy at the Prostate Center.

15. The radiation oncologists provide consultations for patients with prostate cancer and prescribe, manage, and supervise the care of those patients who choose to be treated with IMRT at the Prostate Center.

16. In certain circumstances, when a CUA patient is diagnosed with prostate cancer by a CUA urologist, the patient is referred to one of CUA's radiation oncologists for a consultation to evaluate the full range of appropriate treatment options for the patient, including IMRT. When the radiation oncologist meets the patient for the consultation, no other CUA physician has already ordered radiation therapy or any other type of treatment.

17. As part of the consultation, the radiation oncologists conduct an extensive medical examination that includes a review of the patient's medical chart and pathology reports related to the patient's cancer diagnosis, a complete physical examination, and an interview with the patient to learn of the patient's family and medical history. The radiation oncologists make an independent, professional judgment about the full range of appropriate treatment options for the patient and discuss those options with the patient.

18. When the radiation oncologists recommend IMRT as a treatment option for patients, the radiation oncologists routinely offer alternative locations where the patients can choose to obtain treatment. If a patient chooses to receive IMRT at the Prostate Center, the radiation oncologists take on the professional responsibility for that patient's continued care throughout the course of the patient's IMRT treatment.

19. Consistent with the plan for the operation of the Prostate Center, the Respondent as well as other CUA urologists – both owners and employees of the group

practice – have referred many prostate cancer patients to CUA's radiation oncologist employees for radiation oncology consultations and certain of those patients received a recommendation of IMRT from the radiation oncologist employees of CUA. Some of those patients have chosen to receive IMRT at the Prostate Center. Other of those patients who are seen by a CUA radiation oncologist for a consultation either choose a different therapy (such as brachytherapy or surgery), active surveillance, or choose to have IMRT at a location other than CUA's Prostate Center.

DISCUSSION

The Board's investigation focused on concerns that the manner in which CUA patients are referred for IMRT at the Prostate Center violates the MPRL by "directing an employee" – the radiation oncologist employees of CUA – "to refer a patient to a health care entity . . . in which [the urologist owners of CUA] . . . own[] a beneficial interest." *See* Health Occ. § 1-302(a). The investigation also focused on whether CUA had an "arrangement" with its radiation oncologist employees that CUA's urologist owners "know or should know has a principal purpose of assuring indirect referrals that would be in violation of [the MPRL] if made directly." Health Occ. § 1-302(c).

The Respondent and CUA's other urologists deny ever having "direct[ed]" a radiation oncologist employee to make any referral to the Prostate Center. The Respondent, on behalf of CUA, as well as CUA's radiation oncologist employees, attested that no CUA urologist has ever directed or pressured any one of the radiation oncologist employees to recommend external beam radiation therapy or any other form of treatment to any patient, to increase the number of radiation therapy treatments the radiation oncologists administer, or to convince patients to choose to receive radiation

therapy at the Prostate Center instead of at another location. The Respondent, on behalf of CUA, further denies that CUA's arrangement with its radiation oncologist employees has a "principal purpose of assuring indirect referrals" that would violate the MPRL if made directly.

This Board has previously construed the relevant provisions of the MPRL. In Declaratory Ruling 2006-1, which principally concerned referrals by orthopaedic surgeon owners of medical group practices for performance of magnetic resonance imaging ("MRI") scans within the physicians' medical offices, the Board ruled that, under several fact patterns, "[a] referral by an orthopedic physician for an MRI to be performed on or by an MRI machine owned or leased by the orthopedic practice . . . is an illegal self-referral within the meaning of the Maryland [Patient] Referral Law."

The Board further addressed a fact pattern labeled in the Declaratory Ruling as "Variation 3," in which "a physician who is an *employee* of the medical practice that provides the MRI scan evaluates the patient and orders the MRI to be done by that practice," and in which "[t]he physician-employee does not have any beneficial interest in the medical practice." (Emphasis added.) The Board stated, with respect to Variation 3, that it was "unable to make an all-encompassing ruling on all cases in which the referring physician is an employee of the practice" and that referrals for MRI scans by employee physicians "may or may not violate the [Patient] Referral Law, depending on the circumstances."

The Board identified two circumstances in which a referral under Variation 3 would violate the MPRL. The Board ruled that the referral by the employee physician would be "an illegal self-referral" within the meaning of the statute if the employee is

'"directed' by an employer who is a beneficial owner to make the referral to the health care entity owned by the employer...." The Board also ruled that "if the referral is made according to an 'arrangement' or 'scheme' by which prohibited referrals are made indirectly," then the referral would violate the MPRL.

The Board made clear in DR 2006-1, however, that not all referrals by employee physicians violate the MPRL. Specifically, the Board ruled that if "an employee physician (1) is not directed to make the referral; (2) there is no arrangement or scheme by which self-referrals are accomplished; and (3) the employee physician is employed under a 'bona fine employment agreement,' then a referral to the employer's MRI facility under Variation 3 does not violate the Maryland [Patient] Referral Law." The Board further explained in its ruling that a "bona fide employment agreement" is "an otherwise valid employment agreement which by its terms does not require referrals to the employer's health care entity, which in practice does not require referrals to the employer's health care entity and under which no form of remuneration or compensation or favorable treatment is directly or indirectly tied to referrals to the employer's health care entity."

On judicial review, the Court of Appeals upheld Declaratory Ruling 2006-1 in its entirety. *See Potomac Valley Orthopaedic Associates, eta/. v. Maryland State Board of Physicians, eta/.,* 417 Md. 622 (2011). CUA was a party to the *Potomac Valley* case.

Shortly after the Court of Appeals issued its decision in *Potomac Valley,* the Board posted a document on its website entitled "Self Referral Law - Educational Update" with historical background about the MPRL and details about the Court of Appeals' ruling. The Board explained that a referral for an MRI made by an orthopaedic

physician who has a "beneficial financial interest" in the orthopaedic practice violates the law. Under a separate heading, entitled "Physician-Employees," the Board explained, consistent with its analysis in Variation 3 set forth in DR 2006-1, that "where a physician who is an employee of the medical practice (but who does not have any beneficial interest in the medical practice that provides the MRI scan) evaluates the patient and orders the MRI to be done by that practice, the referral does not violate the law," as long as certain requirements are satisfied, namely that (i) the physician works under a valid employment contract; (ii) the employment contract by its terms does not require referrals to the employer's health care entity, (iii) the employment relation does not in practice require referrals to be made to the employer's health care entity, (iv) no form of remuneration or compensation or favorable treatment is directly or indirectly tied to referrals to the employer's health care entity, (v) the employee is not directed to make a referral to the employer's health care entity, and (vi) there is no arrangement or scheme by which the prohibited referrals are made indirectly, which the referring physician knows or should know has as a principal purpose the making of otherwise prohibited referrals.

This case presents the same basic facts as "Variation 3" in Declaratory Ruling 2006-1. Physicians who are employees of CUA, the radiation oncologists, evaluate patients, recommend appropriate treatment options and, when chosen by the patient, prescribe, manage and supervise the furnishing of IMRT at CUA's Prostate Center. The radiation oncologist-employees of CUA do not have a beneficial interest in CUA.

With regard to subsection (a) of § 1-302, the Board finds that a health care practitioner with a beneficial interest in a health care entity could give prohibited

"direct[ion]" to an employee to make a referral either expressly or by implication. Thus, the Board would have been required to find a violation of § 1-302(a) in this case if the State had demonstrated that the Respondent or other CUA urologist owners expressly or impliedly directed CUA-employed radiation oncologists to refer patients for performance of IMRT at CUA's Prostate Center.

In subsection (c) of§ 1-302, the MPRL requires the Board to resolve questions of intent. That provision prohibits any "arrangement or scheme" that has "a *principal purpose* of assuring indirect referrals that would be in violation of subsection (a) of this section if made directly." (Emphasis added.) Thus, the Board would have been required to find a violation§ 1-302(c) in this case if the State had demonstrated that the Respondent or other CUA urologist owners had an arrangement or scheme in place the principal purpose of which was to assure indirect referrals that would have violated § 1-302(a) if such referrals had been made directly.

In evaluating possible violations of§ 1-302(a) or§ 1-302(c), the State could rely on statements or other evidence directly tending to show that a physician-owner "directed" an employee to make a referral, or that an arrangement has a "principal purpose" to assure indirect referrals that would be prohibited if made directly. Evidence of a pattern of overutilization of a particular procedure associated with referrals by a physician-employee could imply an intent that an employment relationship, in practice, required referrals to be made to the employer's health care entity.

ORDER

Based on the foregoing Findings of Fact and without any finding that the Respondent or any other CUA physician violated the Maryland Patient Referral Law, it is this 11th day of March, 2013, by a majority of a quorum of the Board considering this case:

ORDERED that beginning April 1, 2013, and through October 1, 2014, the Respondent, in his capacity as a licensee and as President and CEO of CUA, shall fully and satisfactorily comply with the following terms and conditions:

1. The Respondent shall ensure that during the above-referenced time period CUA employs no more than four (4) radiation oncologists at any one time;

2. The Respondent shall ensure that CUA through its Prostate Center performs IMRT procedures on no more than 45% of those patients who are newly diagnosed with prostate cancer by CUA urologists during the time period April 1, 2013 through October 1, 2014;

3. The Respondent shall be responsible for ensuring that CUA submits written reports to the Board on a quarterly basis detailing the information listed in subparagraphs (i) through (v) below. The written reports shall be submitted to the Board no later than 30 days following the end of the preceding quarter, so that the first written report shall be submitted on or before August 1, 2013 reporting on the period April 1, 2013 through June 30, 2013, the second written report shall be submitted on or before November 1, 2013 reporting on the period July 1, 2013 through September 30, 2013, and so forth. The last of the six written reports shall be submitted on or before November 1, 2014. Each written report shall detail the following:

    (i) the number of patients newly diagnosed with prostate cancer by CUA urologists during the preceding quarter;
    (ii) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who were referred to or seen by any radiation oncologist employed by CUA for a radiation oncology consultation;

[1] The Board takes no position as to the appropriateness of any particular utilization rate for IMRT outside the facts and circumstances of this Consent Agreement.

(iii) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who were advised by any radiation oncologist employed by CUA who furnished a radiation oncology consultation that IMRT was a viable treatment option for that patient's cancer;

(iv) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who, following a consultation with any CUA radiation oncologist, chose to receive IMRT at a facility owned by CUA; and

(v) the total number of patients newly diagnosed with prostate cancer by CUA physicians from April 1, 2013 through the end of the quarter for which the report is being submitted who, to the best of CUA's knowledge, following a consultation with any CUA radiation oncologist, chose to receive IMRT at a facility other than one owned by CUA.

4. The Respondent shall provide to the Board any CUA medical or billing records that the Board staff requests in order to verify the data reported by CUA in response to Paragraph 3(i)-(v).

5. The Respondent shall ensure that all patients newly diagnosed with prostate cancer by CUA urologists are provided with materials describing the full range of treatment options for prostate cancer and that all such patients who choose to receive a radiation oncology consultation from a radiation oncologist employed by CUA and who are deemed appropriate candidates for IMRT are informed that there are alternative locations available at which they can receive IMRT.

ORDERED that in the event that the Respondent, at any time during the period April 1, 2013 through October 1, 2014, is unable to ensure adherence by CUA to the requirements set forth in paragraphs 1 through 5 above, the Respondent shall immediately notify the Board as to the reasons why compliance with the requirements is not possible; and be it further

ORDERED that the Board's investigation of Case Number SR 0-9911-1041 is hereby closed; and be it further

ORDERED that, subject to (a) Respondent fulfilling the requirements set forth in paragraphs 1 through 5 above for the period April1, 2013 through October 1, 2014, and (b) Respondent ensuring that any radiation oncologists employed by CUA continue to work under valid employment contracts that by their terms or in practice do not require referrals to CUA, that no form of remuneration or compensation to the radiation oncologists is directly or indirectly tied to referrals to CUA, and that the radiation oncologists are not directed to make referrals to CUA, the Board will not reconsider the legal question of whether CUA physicians' referrals of patients for radiation oncology consultations and the provision of IMRT at a facility owned by CUA complies with the MPRL; and be it further

ORDERED that subject to the terms of this Consent Agreement the Board reserves all rights it is granted under Maryland law to conduct future investigations ; and be it further

ORDERED that this Consent Agreement is a public document pursuant to Md. St. Govt. Code Ann. §§ 10-611 *et seq.*

3/27/13
Date

Andrea Mathias, M.D.
Chair
Maryland Board of Physicians

CONSENT

I, Sanford Siegel, M.D., acknowledge that I am represented by counsel and have consulted with counsel before entering into this Consent Agreement. By this Consent Agreement and for the sole purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Agreement and its conditions.

I acknowledge the validity of this Consent Agreement. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Agreement.

I sign this Consent Agreement after having an opportunity to consult with counsel, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of the Consent Agreement.

3/27/2013
Date

Sanford Siegel, M.D.

Reviewed and Approved by:

Howard R. Rubin, Esquire

STATE OF :

CITY/COUNTY OF Baltimore

I HEREBY CERTIFY that on this 27th day of July, 2013

before me, a Notary Public of the foregoing State and City/County personally appeared Sanford Siegel, M.D, License Number 032029, and made oath in due form of law that signing the foregoing Consent Agreement was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Notary Public

Commissiqn,expires:

ANN M.LESINI
NOTARYPUBUCSTAIEOFMARYLANO
My *Commission* Expires *811312015*

Meeting 1

June 24, 2015

Provider/Carrier Workgroup – Study on Self-Referral

Observations: Edward J. Lee, M.D.

Maryland Oncology Hematology, P.A.

The focus of the meeting is clearly defined: 2 issues involving "self referral" are under discussion. One involves diagnostic radiology and the second therapeutic radiation. I will confine my comments to the issue of therapeutic radiation, since oncologists are largely only concerned with therapeutic treatments, not diagnostic imaging. The two remain very different issues.

In all situations and circumstances, the administration of therapeutic radiation is guided by a radiation oncologist – an individual whose scope of practice primarily involves patients with cancer. The only other medical specialty that also deals primarily with cancer patients is medical oncology. Radiation oncology practices exist in academic centers, hospitals and independently within the state of Maryland. Academic centers and hospitals have medical oncologists within their employ, and integrated, undoubtedly high quality care of cancer is practiced. Radiation oncology is also permitted as a free-standing independent practice—although there are relatively few of these. The establishment of a radiation practice represents a significant financial investment, and if no affiliation with medical oncology exists, a flow of patients is less certain.

All three of the "incumbent" entities (academic centers, hospitals and independent radiation operators) have aligned to state that allowing medical oncology to partner with radiation, resulting in shared ownership of the technology, is a bad idea. They have stated in legislative hearings and in this workgroup that the joint ownership is motivated by greed, will result in overutilization, potentially cause harm to patients and is a threat to the Maryland Waiver and payer system by causing increased health care costs overall.

It is worth noting that cancer care is clearly a major component of health care costs today. While much of this is due to chemotherapy drugs administered by medical oncologists in all of the settings defined above (academic center, hospital and community based private practices), radiation is also very expensive. Currently, several Proton Beam facilities are under construction at very significant costs to their institutions (Hopkins, Maryland, Medstar) for treatments that may be of benefit to very specific patients, however, the vast majority of patients treated with radiation receive relatively standard, yet nonetheless costly treatments.

It seems paradoxical that it is acceptable for a radiation oncologist to own her equipment yet to deny the partnership of medical and radiation oncologist to own their own equipment. One argument is that the medical oncologist will refer more patients for radiation, inappropriately, regardless of harm to the patient. Yet, it is not the medical oncologist who decides to deliver radiation--rather the radiation oncologist. The free standing radiation group has precisely the same motivation as does a group that contains both medical oncologists and radiation oncologists: to treat patients.

An argument has been made that in having employed radiation oncologists, that the profit motive would no longer exist, yet hospital and academic physicians are paid by scales involving RVU (relative value units) which measure work done, and whether it is the hospital or a separate physician association (for example, University of Maryland Physicians P.A.) that issue the paycheck, the same exact motivation to treat exists. Physicians treat patients. I do want to be clear here – I sincerely believe that radiation doctors clearly think through risk and benefit, and decide not to give radiation when appropriate to not give it, but we (as physicians who treat patients with cancer) are always looking for ways to help our patients. When your tool is radiation (or chemotherapy), and you spend your life using it and often achieving gratifying results, you do not want to deprive a patient of the opportunity for benefit.

It was suggested that radiation can do harm to patients, which is true, but its use must be weighed versus the benefit it provides in killing cancer cells. The

implication of this comment in the last meeting was clear: in the rush to maximize revenue, patients would be treated inappropriately and in a sloppy fashion that would increase the toxic effects of radiation. It is difficult to know what to say to this argument and its cynicism. All of what is done to treat patients for cancer is dangerous if applied inappropriately, indiscriminately or without proper safeguards and monitoring. Surgery is a very dangerous thing, as is anesthesia, yet we allow practitioners to perform these in various settings and with almost no restrictions. A surgeon makes the decision to operate, usually based on the judgment that the risk of not doing surgery exceeds the risk of doing it. We allow those physicians--trained specifically to do that--to make the determination of when to apply their skills. Trust is established between physician and patient, and treatment proceeds. The same applies in radiation – that same radiation oncologist who is considered safe and appropriate to practice in a freestanding radiation-only group, is that same physician who could co-exist with a medical oncology practice, with benefit to each, and especially to the patient.

The benefit is “integrated” care. Many hospitals and centers have stated in the course of this process that they believe in integrated care and that they practice it already—that there is plenty of access to integrated care. Yet, the substantial proportion of care for cancer that is delivered in community based private practice settings in Maryland does not have the ability to deliver integrated care. The medical records are separate, and communication and coordination, while often very good, are not “integrated” – patients have separate charts, separate appointments, separate co-pays, and sometimes very separate treatment venues. In community based practices, HIPPA prevents one practice from looking into the medical record of the companion practice so as to be certain of when things are going to happen for optimal coordination. This “fragmentation” of care in the community (the opposite of the gold-standard today in oncology) changes how care is provided. This can result in delays of treatment and suboptimal patient care, which can result in increased costs through more ER visits and overnight stays in the hospital for cancer patients.

In the other 49 states, radiation oncology is indeed able to be practiced side by side with medical oncology. It was suggested that “a majority” of those other 49

states restrict supply of radiation through “certificate of need” programs. According to the National Conference of State Legislatures, only 23 of those states have a Certificate of Need requirement for radiation, and in some of those (New York, for example), that requirement for a CON applies only to hospitals, not physician “private practice” facilities. In fact, the idea of applying CON to physician practices in NY was extensively reviewed within the last few years, yet the state Department of Health rejected the concept.

In the other 49 states, the practice of radiation is conducted by physicians trained at academic medical centers. In all of those states, payers ascertain that the patient receiving radiation fits the profile of patients who need such treatment. Indeed, this means that there is a database in the records of the payers for costs in different settings. As was suggested near the end of the first workgroup meeting, perhaps payers can bring more to future discussions by bringing information regarding what they know of the site-of-care cost differentials for radiation therapy. Certainly no one seems to deny that such care in different settings has different costs. Data is what is needed if this workgroup is to produce a consensus result/recommendation.

In a study conducted by the Millman group, the cost of care for Medicare cancer patients was greatest in academic centers, higher in hospital based settings and lowest in community based settings. The increase over community based care was 2 to 3 fold for hospitals and more for academic settings. Not only was the cost to payers higher, but also the cost to patients was higher. Facility fees, still charged by those who administer care in “regulated” space, is part—but not all—of these additional increments.

The specific substantive requests you made were to address:

1. Participation in incentive based reimbursement programs
2. Report on patient satisfaction and clinical quality
3. Demonstrate sufficient practice volume

With regard to the first, my first thought is that medical oncology practices in Maryland are not permitted to pursue the CMS model designed to share savings

with practices (called the “Oncology Care Model,” or OCM), so this makes it harder (impossible) for us to participate in one potential model that is very likely to be widely adopted elsewhere in the USA. The OCM would pay oncologists to manage care so as to reduce costs and resource utilization. Aetna has spoken with our practice (30 oncologists, 9 offices, 100,000 visits per year), yet their model as proposed asks for the same supervisory management but does not pay for it, and does not define the manner in which shared savings would be calculated or defined, or when savings would be shared. CIGNA also has a model which is closer to the CMS model but it is very difficult to know how to define shared savings.. Our practice is ready and willing to participate in opportunities like this that are out there, but the models must be appropriate and fair, and—as you pointed out—value-based models aren’t as plentiful as we’d like. There is not yet a deep selection for specialists to choose from, and ACOs can be problematic because they are largely hospital-centric models that don’t always make it easy (or enticing) for specialists to join. In oncology it can be especially challenging to participate in current alternative payment models: Our practice is often the de-facto primary care provider for our patients during the course of their treatment (and sometimes for years after), and while many of these models like and want credit for the savings our Pathways and patient management can provide, they don’t appropriately value that savings—nor want to give us credit for it.

It seems a potential ethical conflict to use a financial incentive to encourage physicians to diagnose and treat less. Our practice already defines staging rigorously, uses treatment guidelines (pathways by NCCN) and works proactively 24/7 to minimize the use of emergency rooms and hospitals. We do that because it is good patient care. We work hard to recognize those situations when ER/hospital visits are necessary, as our patients really do not want to go to hospitals or emergency rooms.

With regard to the second request you made, satisfaction and clinical quality are hard things to measure. Our patients like that we are on time (mostly), answer questions directly, and get back to them with results. There are websites that collect comments from patients – is this how to define patient satisfaction? Customer surveys? Quality delivery is a critical issue – but what measures are

useful? Is it useful that staging information is recorded? Is it patient outcomes – hospitalization? Death? Relapse of cancer?

I think in this day and age, quality cancer care is making sure that all the appropriate information is collected, communicated to the patient and interested parties, and that treatment decisions are made based on that information and the unique perspective that each individual brings to their own specific circumstances. The question is how to measure this, and I do not know that the Institute of Medicine or ASCO tool sets adequately answer this. The requirements of ICD10 (coming soon) deal with one specific part of this but the rest is very unique to each individual.

As to the third issue of practice volume (or scale), I am not entirely sure I understand this. If the question is whether a given practice would support a radiation oncology center, basic models exist to define what volume of patients are needed for this to be viable. Practically speaking, oncology practice in the community is threatened nationally; we get paid far less to perform the same outpatient services (at the same or better outcome level), which means we've learned to be far more efficient. The same service paid for in the community will generate less revenue from Medicare or another payer than the same service delivered in a hospital or hospital-owned outpatient center. When hospitals increase volumes, the cost of delivering care in the state of Maryland increases significantly. Allowing medical and radiation oncology to coexist in community based centers provides a more stable base for these important services.

At the root of the arguments against integrated community based cancer care are the statements that the doctors in the community are driven by greed, and that these treatment tools are too dangerous if they fall into the wrong hands. This has largely already happened across the rest of the nation, and no large scale complaints by patients or payers have surfaced. There is no widespread call to act against the integration of oncology practices across the states. In fact, a bill introduced in California last year to implement Maryland's form of patient referral law was voted down in its committee, only receiving one vote in support. These arguments against any change to the patient referral law for radiation are

defensive arguments for which there is no data to support. Indeed, they are offensive. One could equally argue that hospitals have radiation and do not want competition. It is all in one's perspective.

The economics however, can be defined. The payers in the room know what medical oncology services cost in different settings, and may well be able to query their colleagues in other states ("what does radiation cost for breast/lung/rectal cancer in community settings/hospital settings/academic settings") to determine relative costs. This is subject to data, and if the data suggests the costs are lower, then this will not have an adverse impact on the Maryland Waiver. It is not good enough for some to assume that volumes for the utilization of these services would increase so greatly that it would offset the per-treatment cost savings overall. It may distribute dollars differently and this is, of course, the central issue. Your question to the hospitals was a good one: In relation to the global budget model, if we can deliver a service more cheaply, why wouldn't we want to take advantage of that? I feel that the answers offered to you were actually non-answers, which side-stepped your point.

But in truth, the central issue ought to be quality, but not quality as measured by staging recorded in an electronic medical record or by some complex analysis of web sites and questionnaires. What is important is the quality of life for patients – time spent in and out of hospitals, time spent at home and with loved ones. It is also the valued relationship between patients and doctors that brings them to our doors and us to the office every day.

Ben Steffen of the Maryland Health Care Commission led introductions and discussed trying to move beyond initial positions. He discussed the guiding principles of accountability and flexibility. Acknowledging that physicians are trained and oriented to be accountable to their patients the workgroup should look at accountability more broadly. He discussed how newer payment models are asking physicians to be more accountable to costs to the healthcare system as a whole. This should be the starting point, with increased accountability there should be increased flexibility.

Srinivas Sridhara of the Maryland Health Care Commission laid out the goals of the meeting to set the parameters for what accountability and flexibility can mean. He presented a continuum of options for increasing accountability and flexibility but stressed that the options presented were not the only options available. Both federal programs available through Medicare and state specific options are outlined.

- Several participants pointed out that the Federal government are in the process of reviewing existing Stark Law for potential revisions that indicate relaxing its parameters
- Dr. Blumberg added that one option of the charge to MHCC may include whether there is need to take any action, and/or whether the existing law allows exceptions as is.
- Dr. Ma commented on the need to order an appropriate scan and integrate with the EMR, which is in the radiologist purview. The patient needs to have the best exam.
- Dr. Grosso commented that in order for alternate payment models to work- for doctors to assume more risk- they need to have control of all of the care.
- Dr. Levy and Dr. Ajrawat commented that the current self-referral law limits the amount of control physicians in private practice can have over patient care.

Guy D'Andrea of Discern Health discussed Medicare physician incentive programs to promote accountability. These included physician quality reporting system (PQRS), value-based payment modifier (VBPM) and meaningful use. He also discussed forthcoming changes including Medicare sustainable growth rate (SGR), Medicare Access and CHIP reauthorization (MACRA) and merit-based incentive payment systems (MIPS). Lastly he discussed Medicare accountable care organizations. Mr. D'Andrea pointed out that Medicare is moving toward a two tailed risk-based model for its ACOs.

- Dr. Ma commented with ACO/CIO, with various physician specialties and aligned incentives, ownership of equipment is not as important.
- Dr. Grosso noted personal experience in having to request repeated imaging exclusively performed by radiologists.
- Ms. Townsend noted that under all the Medicare ACO programs it isn't possible to mandate that the beneficiaries stay in the defined service region.
- Dr. Levy commented that a flaw in Meaningful Use is that frustrated physicians drop Medicare coverage, leaving a portion of patients behind.

Dr. Daniel Winn of CareFirst discussed incentive programs from the private payer perspective. Currently, CareFirst is running programs for primary care, rheumatology and oncology. The

programs vary by specialty but the physicians are not required to take on additional risk, but eligible for rewards when certain benchmarks are met.

- Dr. Grosso noted that Report of the HSCRC Physician Alignment and Engagement workgroup stated that Maryland's self-referral law inhibits progress to implementing alternative payment models.
- Steve Ports, HSCRC, replied that the report looks at three approaches: 1) gainsharing, 2) pay for performance between hospitals and non-hospital physicians, 3) larger ACO/integrated care network for unmanaged Medicare population.

Nicole Stallings of the Maryland Hospital Association (MHA) presented on MHA's gainsharing initiatives. MHA's gainsharing program is modeled after demonstrations in New York and New Jersey. The program is based on incentives with no other changes to physician reimbursement. The program is aimed at increasing physician engagement by providing opportunities for participation in physician steering committees and providing personalized reports on performance. Currently the program steering committee has been convened and over half of Maryland's hospitals have signed letters of intent to participate.

- Dr. Levy and Dr. Lee commented on the need to engage physicians in the community rather than physicians associated with the hospital.
- Dr. Blumberg asked about how this program connects to outpatient medicine. Ms. Stallings commented that hospitals and local physicians working together is critical.
- Dr. Lee noted the rise of hospitalists over time.
- Dr. Winn noted the narrowing of hospital role over time with an increased focus to keep patients out of hospitals. As a result, community physicians must be engaged in the process.

MHCC staff presented potential options to implement accountability to permit self-referral. Clinically Integrated Organizations, prior-authorization, and changes to the Certificate of Need statute were all presented as mechanisms to allow for self-referral.

- Mr. Steffen clarified that regulations for the CIO program were never promulgated.
- Dr. Blumberg and Dr. Ajarwat noted their experience indicates that the existing preauthorization process is not in compliance with parameters.
- Dr. Grosso noted preauthorization model obviates the reason to have your own imaging equipment because of the long time necessary to achieve preauthorization.
- Several participants commented that Certificate of Need option is not appealing.

STATE OF MARYLAND

Craig P. Tanio, M.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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AGENDA

Provider/Carrier Workgroup- Study on Self-Referral

September 2, 2015

3:00 pm- 5:00 pm

Physician Led Models and Aligning Quality and Cost Incentives

A. Redefining the problem

B. Physician Directed Accountability and Quality Models
   a. Dr. Lee
   b. Dr. Blumberg & Dr. Ma

C. Discussion of possible solutions
   a. Dr. Levy, Dr. Grasso, & Dr. Ajrawat
   b. Nicole Stallings- Maryland Hospital Association

D. Next Steps- Draft Report Findings

Defining The Problem

Origin of Self-Referral Restrictions

- Fee For Service was predominant payment model
- Perceived conflict of interest: providers can generate volume to drive their own revenue
- Federal Government enacted Stark Law to restrict reimbursement in cases of potential conflict
- Maryland passed additional restrictions on self-referral

The Environment Is Changing

- New payment and care delivery models are emerging, including managed care, capitation, pay-for-performance, among others
- Federal, State, and commercial systems are increasingly moving away from FFS to value-based payment
  - HHS goal to tie 30% of Medicare FFS to alternative payment models by 2016; 50% by 2018
- When physicians take on risk for utilization in these models, the original problem is mitigated
- Greater emphasis on integrated delivery models, which are an important platform for delivering high quality of care at a lower cost
- Existing Maryland Self-Referral Law (and possibly Stark in some cases) may prohibit optimized organization and care delivery
- CMS has identified alternative payment models as a possible solution to Stark issues
  - 2016 Physician Fee Schedule Proposed Rule solicits comments regarding impacts of Stark on financial relationships in light of alternative payment/delivery models.
  - MedPAC 2011 report identifies challenges in existing Stark Law and recommends emerging VBP arrangements as a mitigation strategy

Statement of the Problem

- Maryland's self-referral restrictions may prevent providers from testing innovative care delivery models under value-based purchasing arrangements.

Medical Oncology

2015 Perspective

QUALITY IN ONCOLOGY

CONFIRMING THE DIAGNOSIS (everything fits)

STAGING (exam, imaging)

EXPLANATION AND DISCUSSION

GOAL OF TREATMENT

TREATMENT PLANNING

END OF LIFE

WITH THE PATIENT? ON THE COMPUTER?

ACCOUNTABILITY IN ONCOLOGY

Almost all medications and treatments require pre-authorization. Many are very costly.

Such pre-authorization has become progressively more work intensive for administrative staff as payers are requiring steadily increasing amounts of supporting documentation leading to multiple interactions.

Treatments are required to conform with a recognized standard, most commonly "Pathways" – NCCN (National Comprehensive Cancer Network) most commonly used by payers.

RESOURCES CURRENTLY UTILIZED IN ONCOLOGY PRACTICE

SHINE program: identifies those without medical insurance and facilitates obtaining Medical Assistance for those who need it; deals with the financial crises that develop in the lives of people (power, food, child care, transportation, medications)

Social Workers
Navigators
Support Groups
Triage Nurses
Mid-level providers (PA or NP)
On Call Physicians

MARYLAND ONCOLOGY HEMATOLOGY, P.A.

A medical oncology practice consisting of 30 physicians in 9 offices with 100,000 patient visits yearly.

The business side of the practice is managed in collaboration with U.S. Oncology, a national organization, supplying expertise in all aspects of administration, including HR, regulatory affairs, drug acquisition and utilization, and interactions with payers.

USON has pioneered the use of pathways which remains a major project within the group.

USON currently:
19 states
998 physicians
28 practices

US Oncology relationships with Managed Care

CONTRACTS: 300 (of significance)

FIRST “VALUE BASED CONTRACT”: 2007

CURRENT VALUE BASED CONTRACTS: MORE THAN 100

VALUE BASED CONTRACTS – US ONCOLOGY

Rationalized drug rates/tier drug pricing: fee for service, benefits are mutual, risk is minimal (60+ contracts).

Pay for Performance: base agreement (fee for service) with defined measures (COPI, pathways, cost effectiveness), management fees = carrot, some risk for the practice – 25 + contracts.

Comprehensive Care Management: fee for oversight of care and shared savings comparing cost of care to the "local market" – 5 states, 6 contracts.

VALUE BASE CONTRACTS – US ONCOLOGY

Episode of Care/Bundled Payments: 2 contracts with national payers for “oncology care” not including radiation, 4 contracts including radiation– typically drugs and stem cell transplants are excluded (moderate risk).

Exclusive Capitated Care: relationships with commercial payers, managed medicare and IPA (independent physician associations) for cancer care – 6 contracts, risk.

New Payment Models and the Role of Radiology

Loralie D. Ma, M.D., Ph.D., FACR

Albert L. Blumberg, M.D., FACR

The Reasons Behind the Change

- Fee for service, without appropriate checks and balances, rewards volume
- More procedures equals more money for those performing procedures
- However, as the U.S. spends an alarming 17 percent of its GDP on healthcare, and this percentage has been continuing to grow, at some point healthcare will become unaffordable

The Reasons behind the need for change

- When healthcare costs go up, healthcare becomes less affordable for everyone, leaving many uninsured or underinsured
- If there is no system of checks and balances, other options have to be considered

MPFS Comparison 2015 to 1010

		2015			2010			Delta 2015 compared to 2010		
Exam		**Global**	**Tech**	**Prof**	**Global**	**Tech**	**Prof**	**Global**	**Tech**	**Prof**
MRI Brain w/o	70551	$250.16	$171.11	$79.06	$538.20	$459.91	$78.29	**($288.04)**	**($288.80)**	$0.77
MRI Brain w/	70552	$349.22	$253.13	$96.09	$601.25	$506.68	$94.57	**($252.03)**	**($253.55)**	$1.52
MRI Lspine w/o	72148	$241.49	$162.04	$79.45	$493.00	$414.31	$78.69	**($251.51)**	**($252.27)**	$0.76
MRI Lspine w/	72149	$348.79	$252.71	$96.09	$599.69	$505.12	$94.57	**($250.90)**	**($252.41)**	$1.52
MRI Pelvis w/o	72195	$411.47	$333.15	$78.32	$536.29	$458.74	$77.55	**($124.82)**	**($125.59)**	$0.77
MRI Pelvis w/	72196	$450.26	$356.80	$93.46	$593.92	$502.39	$91.52	**($143.66)**	**($145.59)**	$1.94
MRI Lower Extr Jt	73721	$256.42	$183.72	$72.70	$517.38	$445.49	$71.89	**($260.96)**	**($261.77)**	$0.81

MPFS Comparison 2015 to 1010

		2015			2010			Delta 2015 compared to 2010		
Exam		**Global**	**Tech**	**Prof**	**Global**	**Tech**	**Prof**	**Global**	**Tech**	**Prof**
CT Head w/o	70450	$126.00	$80.45	$45.56	$206.37	$161.37	$45.00	**($80.37)**	**($80.92)**	$0.56
CT Head w/	70460	$176.17	$115.53	$60.64	$268.27	$208.53	$59.75	**($92.10)**	**($93.00)**	$0.89
CT Abd/Pelvis w/o	74176	$217.24	$123.41	$93.83	$515.09	$394.05	$121.04	**($297.85)**	**($270.64)**	**($27.21)**
CT Abd/Pelvis w/	74177	$340.05	$241.67	$98.38	$654.38	$525.40	$128.98	**($314.33)**	**($283.73)**	**($30.60)**

Integrated Care Payment Models and Bundled payments

- As previous attempts to have Medicare use HMOs have not been successful, and as the government has difficulty controlling healthcare providers at a micro level, consideration began in the Centers for Innovation for a macro solution

- Instead of paying per procedure, which drove up the number of procedures, payment will now be grouped in various manners

Accountable Care Organizations

- The control is in the hands of the primary care physicians of the ACO (in Maryland)
- For an agreed upon number of lives, the cost of care is negotiated
- If the ACO is able to keep costs under the negotiated level, they may receive additional reimbursement (Incentive)
- If the ACO is not able to keep costs below a certain level, they may have to return money (Risk)

Bundled Payments

- Episodes of Defined Care types will be paid at a fixed rate
- The actual disbursement of payments to different providers is yet to be determined
- Currently most reimbursement for procedures is still fee for service, although this will likely change

The Role of Imaging

- While imaging has come under scrutiny for its cost and its increased usage over the last decade, imaging is highly useful and can help to diagnose disease, triage patients, and direct care

- Overutilization of imaging is harmful due to increased radiation exposure to the public, increased cost, as well as the detection of additional findings which cause worry to the patient and cost to the health care system

- Underutilization of imaging is harmful as patients may not be diagnosed and evaluated in a timely manner

Quality in Imaging

- Quality of imaging, and the appropriateness of imaging are of the utmost importance
- The right test, at the right time, performed optimally with results given promptly to the caregiver, for the benefit of the patient, is the goal of imaging
- Imaging must be performed with the least amount of radiation needed for the exam
- Radiation therapy should only be performed if necessary
- Anything less is unacceptable, and harmful to the patient

The Role of the Radiologist

- To help determine if the correct test is ordered
- To direct the best protocol for the examination with the highest quality equipment and to render an interpretation for the optimum patient care
- To be accessible to patients in many geographic locations
- To help guide other members of the ACO or other Integrated Care entity in the appropriateness of imaging
- To help avoid overutilization, while making sure imaging is not underutilized as patients should have appropriate care, and not withholding of care

Access does not equal Ownership

- Imaging and Radiation therapy may be accessible in many scenarios, without ownership by the ordering physicians
- Examples include hospitals, but can also include members participating in ACOs and Integrated Care Networks
- The necessary piece in this puzzle is integration of the Radiology information system into the Electronic Medical Record of the Healthcare Entity
- This allows ease in ordering, knowledge of other examinations the patient has had, and allows transmission of that information to other members of the ACO or other Integrated Care Entity

Examples

- Advanced Radiology and ARS have connectivity to over 2000 practices, with connectivity of web portal for images and reports, as well as connectivity to EMRs
- RadNet participates in New Jersey with a Healthcare system, with full integration and also has Radiologists who guide the performance of imaging, to assure the right test at the right time
- This has resulted in a significant savings in the last year for that healthcare system

Examples: American College of Radiology survey of members of the Radiology Integrated Care Network 2015

- Thirty-two percent of these practices have been capitated by a health plan prior, and only 27 percent (or six respondents) have been approached to work in an alternative payment model by either a community hospital, independent practice association (IPA), or Accountable Care Organization (ACO).
- The primary model proposed was an ACO, with disease-specific bundle and capitated model tied for second.
- Two of the groups are getting capitated payments, three groups report they continue to be paid fee-for-service in their models, and only one reports a shared-savings agreement.

Examples: American College of Radiology survey of members of the Radiology Integrated Care Network 2015

- It appears that all arrangements are tied to reporting of quality measures and cost savings. Five respondents in this sample reported having contracts with one ACO. A majority of them were involved in IT decision-making and were using some form of clinical decision support.

- Although there had been some discussions in sharing in the savings, it had not actually taken place, and the message was that it is too soon to tell how their efforts would translate to bonuses.

Examples: Radiology benefits managers (RBMA) data 2015

- Alternatively, 80 RBMA members participated in the RIMTF's Alternative Payment Models mini-Survey. Forty-seven percent represented hospital-based private practices and the other 53 percent were a combination of hospital-based and imaging-center based private practices. Thirty-seven percent (or 21) are either currently in an alternative payment model or planning to enter into such an agreement; about half (12) have entered into a final agreement.

Examples: Radiology benefits managers (RBMA) data 2015

- A majority of the 12 were able to provide some input into the process, whether it was hospital board participation, planning for the use of clinical decision support, or discussions of sharing in the savings.

- Only a few were in capitated agreements, some in shared savings/risk models, a majority (58 percent) reported being in fee-for-service with a potential bonus, with some indications of gain-sharing and episodic fee-for-service agreements as well. Almost all of the agreements are tied to reporting of some type of quality measure which varied significantly in the type of measure.

Conclusions by Radiology and RBMAs

- Both the ACR and RBMA encourage radiology practices to prepare for when the opportunity to become involved in new payment models arises. The recent announcement by Secretary Burwell (to tie 30 percent of fee-for-service Medicare payments to quality or value through APMs, ACOs, or bundled payments by the end of 2016, and 50 percent of payments to these models by the end of 2018) shows that the transition is inevitable. Medicare, private payors, and ACOs' focus has been centered on establishing primary care services for patients and has not yet given specialists the same kind of attention. However, radiologists and their practices can help their local institutions and communities realize their value-added services.

Conclusions from ACR and RBMA

- The ACA and MACRA mandate that fee-for-service payments be maintained. Therefore, moving forward, it is likely that radiology will continue to see a mixture of payment mechanisms in addition to fee-for-service

- It is important to reiterate that radiology practice's value-added contributions must be recognized in order to optimize radiology contributions and to participate in shared savings.

Question: If there is integrated care with risk, is the self referral law needed?

Answer: Yes

- While the SGR repeal bill does incentivize physicians to move towards coordinated care models, it also retains a modified fee-for-service policy now referred to as the Merit-based Incentive Payment System (MIPS)

- Self-referral restrictions will still need to be retained for the MIPS program to work well. Even in private markets within various states, some sort of modified fee-for-service component needs to be retained for the considerable future

- As a result, self-referral restrictions will help eliminate unnecessary imaging which will help preserve health care dollars plus improve patient care

Question: With Clinical decision support mandated by CMS starting 2017, will there still be a problem with self referral? Answer: Yes

- With respect to CDS policy and self-referral, the provisions passed within PAMA last year are NOT a panacea for abuse based on financial self-interest
- This is due to the fact that the policy only requires ordering physicians to consult, not adhere to, the appropriateness criteria
- While there is the outlier policy that mandates providers whose ordering behavior consistently deviates from the AC be subjected to prior authorization, that is restricted to 5% of the ordering physician population
- Without a hard stop, ordering physicians who are financially self-interested can still generate unnecessary referrals and continue overutilization

Maryland is Special and Unique

- Maryland is the only State to receive the Medicare Waiver, with additional Federal funding of approximately 1.6 billion annually
- In order for Maryland to maintain the Waiver, and receive its funding, it must maintain a cost of health care to Marylanders below a certain level
- Initially, this was only for hospitals, but will be expanded within the next year or two to the outpatient setting as well

Why is Self Referral Important in this Context?

- Self referral of Imaging and Radiation therapy has been shown over and over again to increase utilization
- While some studies with faulty designs have had some confounding data, the US government's own GAO has found that self referral drives procedures and increases costs
- Exceptions to the self referral law or its dismantling can only lead to more scanners, more Radiation therapy equipment and more utilization
- Increased utilization leads to increased cost and greatly threatens our unique Maryland Waiver

A Final Question

- Q. Does the Maryland self referral law keep ACOs and other Integrated Care models from incentivizing providers within their networks?

- A. No. While the Federal Stark laws invoking anti-kickback statutes may do so, Maryland's self referral law does not. CMS is considering these statutes in regards to the bonusing of physicians for meeting certain metrics, within an integrated care practice, which is covered under the Federal Stark Law.

Conclusions

- Radiologists are beginning to participate in the new Integrate Care Networks, with an import role in Clinical Decision Report and in Quality Metrics

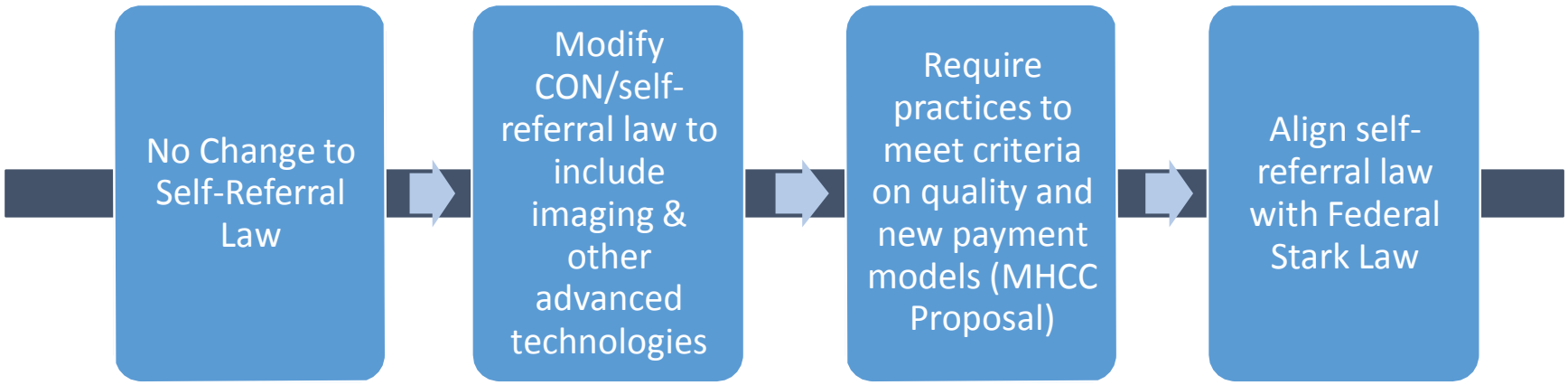
- Radiology practices, in providing all types of imaging, to all patients, regardless of insurer, with ease of access due to multiple geographic locations, web access to images and reports, integration with referrers' EMRs, is best equipped to participate in the new Integrated paradigm

Conclusions, continued

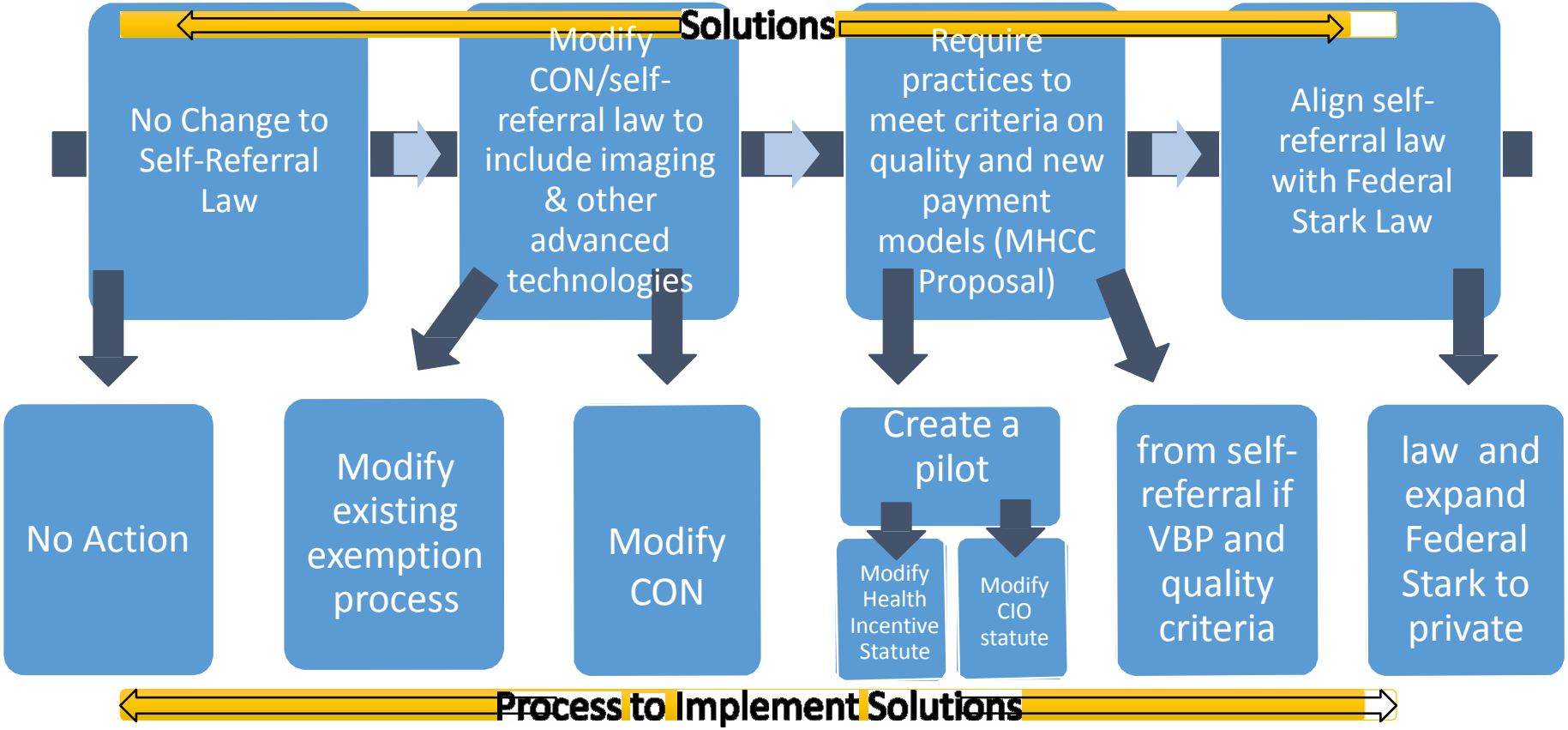
- Access does not need Ownership!
- Multiple physician groups can work together in an integrated manner, without the need for the ordering physician to own the equipment or employ physicians of other specialties in order to obtain the technical component of high-cost procedures
- Our current Statute provides the opportunity for exemptions, if deemed appropriate, by the Secretary of DHMH
- Maryland's Self Referral Law is important to the maintenance of Maryland's unique waiver

Discussion of Possible Solutions

Spectrum of Solutions



Regulatory and Operational Process for Achieving Each Solution



Provider/Carrier Workgroup – Study on Self-Referral: A Proposal

We are grateful to MHCC for having recommended to Chairman Hammen in April 2015 the convening of a group of broad stakeholders "to determine a path forward for modernization of current law to better align Maryland statute with emerging payment models and health care reform." We believed then—and continue to believe today—that this is a critically important question to ask and answer as Maryland seeks to be a leader in the delivery of high quality, affordable health care. And, we commend MHCC (and all of our fellow Workgroup members) for the time and effort that has been put into our work over the course of our first two meetings.

The two meetings of our Workgroup to date have yielded important insight on the ways that our current patient referral law can obstruct innovative care models. In light of this important feedback, we write now to ask all of you to consider, in advance of our third meeting set for early September, a specific proposal that we believe speaks directly to the purpose for which this body was convened. In making this proposal, we are mindful of MHCC staff's belief that "the workgroup's charge should be kept narrow," and we do not believe the proposal we present in this document expands on the charge as articulated in Mr. Steffen's April 6, 2015 letter to Chairman Hammen. In fact, we believe our proposal responds directly to the charge that was put to us.

Our proposal, for discussion at our September 2 meeting, is that Maryland modernize its Patient Referral Law by joining several other states in incorporating the federal Stark law (and the Stark law's implementing regulations) to serve as our State patient referral law. The chief advantage of incorporating the federal law is that it allows the Maryland Patient Referral standards to consistently track the arrangements, prohibitions, and administrative processes available under federal law.

Achieving state-level consistency with the large, complex, and rapidly growing body of regulation under the Stark Law is a daunting task. Maryland's Patient Referral Law has not been substantially updated since its passage in 1993. As a result, many physician practices and other healthcare entities are required to comply with two increasingly inconsistent sets of law. **As other states have done, we propose to amend our Patient Referral Law ensure that it automatically remains consistent with the federal Stark Law and any implementing regulations.**

The federal Stark Law is a rapidly evolving legislative and regulatory structure. Since the passage of the modern form of the law in 1993, it has undergone major changes through three separate phases of rulemaking extending through 2007.[i] The Centers for Medicare and Medicaid Services ("CMS") also made important changes to rules governing common practices like percentage-based compensation and payment for leases in the 2009 Inpatient Prospective Payment System rule.[ii] The Affordable Care Act made a large number of changes to the Stark law as well, including new disclosure requirements for in-office diagnostic imaging services and a process to self-disclose violations.[iii]

Of particular interest to this Workgroup, CMS has recently devoted significant attention to easing the transition to integrated, value-based care. For example, in 2011, CMS and the HHS Office of Inspector General established special waivers of the Stark Law, Anti-Kickback Statute,

and Civil Monetary Penalty law for Medicare Shared Savings Program Accountable Care Organizations and similar programs.[iv] CMS also proposed, but did not finalize, a detailed Stark exception for gainsharing in the 2009 Medicare Physician Fee Schedule.[v] The most recent proposed Physician Fee Schedule rule for 2016 includes a detailed set of new gainsharing proposals. CMS is actively soliciting comment on these proposals, suggesting that it may propose a new exception covering gainsharing and other integrated care arrangements soon. ***Unfortunately, Maryland's law does not reflect these modern changes***.

We have identified at least eight states – Colorado, Kentucky, Michigan, Montana, Utah, Virginia, Washington, and Wisconsin – that have adopted the federal Stark Law as part of their state healthcare regulatory structure. These states typically provide that conduct of health professionals is unlawful or prohibited if it "violates 42 U.S.C. § 1395nn [e.g., the Stark law] or a regulation promulgated under that section."[vi] Other states simply adopt the Stark law's exceptions, using language to the effect that the law "shall not apply to a financial relationship or referral for designated health services if the financial relationship or referral for designated health services would not violate 42 U.S.C. § 1395nn, as amended, and any regulations promulgated thereunder, as amended, if the designated health services were eligible for payment under Medicare."[vii] In addition to these eight states, California, Pennsylvania, and Texas have incorporated the federal Stark law into specific parts of their healthcare industries.[viii]

The structure adopted by these states presents a simple and easy-to-execute solution for Maryland to remove a significant barrier for integration in the State. This would allow Maryland to transition from a State with an unusual compliance framework that is inconsistent with federal law and the law of every other state, to a streamlined policy that automatically evolves with CMS's extensive and frequent rulemakings. In particular, it would allow Maryland to capture the benefits of CMS's new, energetic focus on facilitating integration while balancing the federal fraud and abuse framework.

Maryland has a long tradition of leadership in healthcare policy. We are committed to working with the other members of the Workgroup to develop policy alternatives that complement our State's unique leadership role in healthcare reform. We acknowledge that the law of our State may require elements that are not present in federal law. However, we cannot ignore CMS' efforts to clear the way for the rapid growth of integrated care models, even as our law has stood still. We humbly submit that Maryland should *at least* match the baseline of flexibility available to hospitals, physicians, and other providers in every other state. **We look forward to working with you to develop this easy, low-cost, and extremely practical alternative to foster innovation here in Maryland.**

Sincerely,

Dr. Harry Ajrawat
Dr. Nicholas Grosso
Dr. Arnold Levy
Members, MHCC Provider/Carrier Workgroup – Study on Self-Referral

[i] Stark "Phase I" regulations, 66 Fed. Reg. 856 (2001); Stark "Phase II" regulations, 69 Fed. Reg. 16054 (2004); and Stark "Phase III" regulations, 72 Fed. Reg. 51012 (2007).
[ii] 73 Fed. Reg. 48434 (2008).
[iii] Affordable Care Act § 6003.
[iv] 76 Fed. Reg. 67802 (2011). See also 79 Fed. Reg. 62356 (2014), further extending these through November 2, 2015.
[v] 73 Fed. Reg. 38502 (2008).
[vi] *See* Mich. Comp. Laws § 333.16221(e)(iv)(B). *See also* Wis. Stat. Ann. § 49.45(3)(L) (prohibiting Medicaid payments if a relationship is illegal under the federal Stark law); Utah Code Ann. § 58-67-801 (stating that a financial relationship must be disclosed to patients if it falls under the federal Stark law).
[vii] *See* Colo. Rev. Stat. § 25.5-4-414(2)(b) & (c). *See also* Ky. Rev. Stat. § 205.8461(2)(b); Mont. Code Ann. § 45-6-313(2); Va. Code Ann. § 54.1-2413(E); Rev. Code Wash. § 74.09.240(3).
[viii] Tex. Health & Saf. Code § 142.019 (home health and hospice); Ann. Cal. Welf. & Inst. Code 14528.1(e)(2) (assisted living facilities); and 34 Pa. Code § 127.301(c) (payment of workers compensation claims).

Ben Steffen of the Maryland Health Care Commission led introductions and outlined the purpose of the meeting, which was to try to move the group toward consensus on some issues. Mr. Steffen broke the meeting into three parts;

- redefining the problem, as it existed when the self-referral statute was originally conceived, and what challenges existed in Maryland and nationally;
- several physicians in private practice to talk about how reimbursement is changing; and,
- open-ended discussion on potential solutions.

Guy D'Andrea of Discern Health began his presentation by providing context for the Maryland self-referral law. He discussed the Maryland law, which was passed in 1993 when fee-for-service was the predominant payment model, which at that time led to a perceived conflict of interest for providers to refer for services which they owned. At that time, the Federal Government enacted the Stark Law to restrict reimbursement and limit potential conflict. Maryland passed additional restrictions. The problem at that time was the perceived economic incentive built into the fee-for-service model where revenue could be generated by referring for more services.

Mr. D'Andrea then outlined the changing environment. New payment models are emerging which are focusing on total cost of care and pay-for-performance, etc. In an environment where providers take on risk, some concerns that precipitated the passage of the Maryland self-referral law, and Stark, may be mitigated. He posited that the self-referral statute, as currently constructed, might not align with shifting goals in the health care system where providers are being asked to become more integrated. CMS has identified alternative payment models as the long term solution to issues raised under Stark.

Mr. D'Andrea then created a new statement of the problem: "Maryland's self-referral restrictions may prevent providers from testing innovative care delivery models under value-based purchasing arrangements."

- Dr. Blumberg pressed Mr. D'Andrea, and other workgroup members to share specific cases where current law stops innovative care delivery and the movement towards new payment models. He believes that, perhaps, we need to add some guiderails for applying for an exemption which is already in current law
- Dr. Ajrawat questioned whether this law was still needed at all.

Dr. Lee presented the medical oncology perspective. He first outlined what medical oncology does, and the accountability standards that already exist in the oncology field, including the most commonly used "Pathways"- the national comprehensive cancer networks. He also outlined resources that a medical oncologist uses, including the SHINE program. Dr. Lee then discussed his practice, Maryland Oncology Hematology, P.A, that is managed in collaboration with U.S. Oncology, which is in 19 states and employs almost 1000 physicians. U.S Oncology has more than 100 value-based contracts. Fifteen practices outside of Maryland completed a letter of intent with CMS to participate in a new payment model. Physicians in Maryland are not able to participate in the CMS program. Dr. Lee went through various value-based contracts, including

models centered on pharmaceuticals, pay for performance, comprehensive care management, bundled payments, and exclusive capitated care.

- Mr. Steffen asked how revenue/compensation is shared. Dr. Lee said there were various ways to share revenue if practices are given the ability to offer radiation therapy. Within Maryland that is open to discussion, some practices share revenue equally, some in an RVU process.
- Dr. Regine then asked what in the law prevents Dr. Lee from integrating care, since the practice shares a building with two prominent hospital systems. Dr. Lee responded that while his practice model may not change with a change in the law, a change would allow physicians without the same arrangement to offer more services to patients.

Dr. Albert Blumberg and Dr. Loralie Ma presented on new payment models and the role of radiology. Dr. Ma first outlined the original problem that due to fee-for-service, which is still the predominant payment model, volume is still rewarded. With increased volume come increased costs and healthcare becomes less affordable for all. They presented on the role of the radiologist in accountable care organizations (ACOs), which are largely driven by primary care physicians. The radiologist's role in an ACO or other integrated care entity is to guide other members of the ACO in the appropriateness of imaging. Dr. Ma discussed how access does not equal ownership and a referring physician does not need to own the equipment to ensure access. In a survey conducted by the American College of Radiology, 27% have been approached to work in an alternative payment model by physicians of other specialties or by hospitals. Moving forward, it is likely that the fee-for-service model will continue to be the dominate payment model, especially in imaging. They concluded that there is no need for the change in the law.

- Dr. Ajrawat commented that as radiology centers are concentrated around the Baltimore and D.C. Metro areas, they are not serving the entire state of Maryland.
- Joel Suldan commented that if the payer does not care if the physician self-refers, then we should not care. However, most payments are still in the fee-for-service payment model where the payer would care.
- Dr. Levy argued that the law needs to be fluid and change with new payment models.

Mr. Steffen moved to a discussion of the various perspectives, and asked participants to move away from the positions they are dug into and think about new and different ideas. Mr. D'Andrea walked through possible solutions, including no change to the law; modifying CON or self-referral law to include imaging and other advanced technology; requiring practices to meet criteria on quality and payment; and fully aligning the Maryland self-referral law with the Federal Stark law. Mr. Steffen then walked through the regulatory and operational process for achieving each solution.

- Dr Levy, Dr. Grasso, and Dr. Ajrawat proposed fully aligning the statute with the Federal Stark law. They stated this would be less administratively burdensome than the current exemption process and the state law would then change with the federal law. The state law has not been amended since 1993 and the federal state law has been amended several times.

- Nicole Stallings from the Maryland Hospital Association asked for specific examples for when the law is a problem. She suggested we dig deeper into the specific issues that this law may be causing as a way to look into changing the law. She also suggested that the current exemption process would resolve access issues that may occur.

STATE OF MARYLAND

Craig P. Tanio, M.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

AGENDA

Provider/Carrier Workgroup- Study on Self-Referral

October 7, 2015

3:00 pm- 5:00 pm

Findings and Policy Options

A. Workgroup Findings

B. Options from Workgroup Members
   a. Nicole Stallings
   b. Dr. Lee
   c. Dr. Levy

C. Discussion of Options Presented by MHCC and Discern

D. Public Comment

E. Next Steps

PETER A. HAMMEN
46th Legislative District
Baltimore City

Chair
Health and Government Operations Committee

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The Maryland House of Delegates
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THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

May 28,2015

Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Steffen:

Thank you for your April 6, 2015 letter and workplan regarding the use ofthe new Provider-Carrier Workgroup to review and recommend changes to the State's prohibition on self-referral. The workgroup, with representation from affected stakeholder groups, is the appropriate vehicle for undertaking this charge. The workplan affords ample opportunity for consideration of all facets of the issue and preparation of legislation to be introduced at the 2016 SeSSIOn.

Please proceed with the workplan and keep me apprised periodically of the workgroup's progress. As Lisa Simpson is on maternity leave, Linda Stahr is the committee analyst assigned to monitor the workgroup. Please keep Linda informed of the workgroup meetings.

Sincerely,

'P a.tJ--

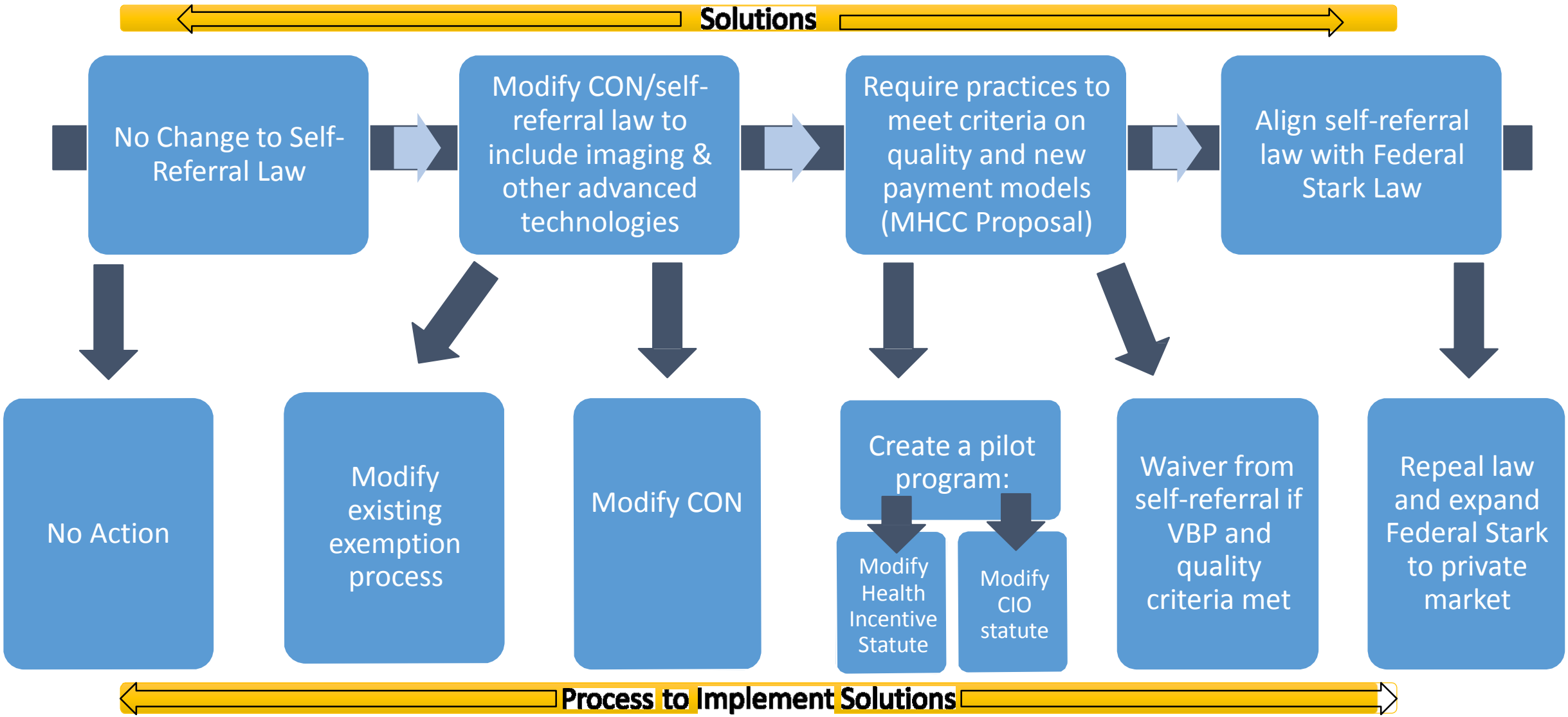
Peter A. Hammen

Cc: Delegate Kirill Reznik

Maryland's Self Referral Law: Policy Options

October 7, 2015

Spectrum of Solutions



Options Available through Existing Regulatory Framework

- Option 1: Clarify Application of Maryland Patient Referral Law to Distributions from Value-Based Models, including Shared Savings Programs, Gainsharing, and Clinically Integrated Networks.
  - Seek individual guidance from respective licensing board to clarify application of law in cases where payment reform methods are going to be tested.

Options Available through Existing Regulatory Framework

- Option 2 – Adjust Exemption Process
- Lengthen Exemptions Available through Current Process
  - Current exemption linked to license renewal, in most cases 2-years.
  - 2 year timeframe is too short to justify investment in equipment, particularly large capital investments.
  - Option can be accomplished through regulatory change
- Expand MPRL exemption process to further define and test MHCC "value-based" criteria.

Options Which May Require Legislative Change

- Option 3: Permit Pilot Tests of Self-Referral Arrangements
- Selection of pilot practices could be based on;
  - Practices that address known access and need concerns;
  - Practices that appropriately integrate services delivered by hospitals and physicians, and/or;
  - Practices that can demonstrate significant scale.
- Pilot practices should be required to report on quality/performance.
- During this period, monitor federal government policy and implementation of phase 2 of the waiver.

Option 4: Allow Referrals Authorized by Financially Responsible Party

- Amend statute so that self-referral prohibitions will not apply where payor has authorized the provider to self-refer.
- Authorization from payor could be across-the-board, or case by case.

Option 5: Allow Referrals Authorized Under Value-Based Models

- Amend the statue so self-referral prohibitions will not apply in cases where;
  - The patient is covered by a recognized value-based model;
  - The organization holding the contract is financially responsible to absorb at least 50% of costs in excess of a specified target; or,
  - The organization holding the contract has authorized the physician to self-refer.
- Value-based arrangements could include Shared Savings Program, Gainsharing, Accountable Care Organizations, and Clinically Integrated Networks

Option 6: Amend the Maryland Physician Referral Law by adding an Exemption that any arrangement permitted under Stark is permitted, unless prohibited in the MPRL.

- Amend MPRL to outline specific exemptions in Stark that would be prohibited in Maryland.

Options with less consensus among stakeholders

- Option 7: Leave current Maryland Patient Referral Law unchanged
- Option 8: Add an exemption to the Maryland Patient Referral Law making any arrangement permitted in Stark are also permitted in Maryland
- Option 9: Repeal the current Maryland Patient Referral Law

Craig P. Tanio, M.D.
CHAIR

STATE OF MARYLAND

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October 5, 2015

To: Self-Referral Workgroup

From: Maryland Health Care Commission

Re: Self-Referral Policy Options

This memo provides background on the formation of the Maryland Patient Referral Law (MPRL) Workgroup ; a summary of the key themes of the workgroup discussions to date; and a description of the policy options that have been proposed by workgroup members. The workgroup will review these options at its October 7th meeting, with the intent of achieving consensus on findings at its final October 26th meeting.

Background

The Maryland Health Care Commission (MHCC) is a public, regulatory commission with broad authority over health care delivery in Maryland. The Governor, with the advice and consent of the Maryland Senate, appoints fifteen Commissioners that broadly reflect the perspectives of consumers, employers, health care providers, and insurance carriers. Recognizing MHCC's ability to convene stakeholders with disparate interests, the General Assembly passed HB 779 during the 2014 Legislative Session creating the Health Care Provider-Carrier workgroup. The workgroup serves as a forum for identifying and resolving policy disputes among providers, carriers, and consumers. After the 2015 Legislative Session, Del. Peter Hammen, Chairman of the Health and Government Operations Committee, requested MHCC to convene the workgroup to discuss Maryland's law on self-referral.

Maryland law on self-referral is broad. One of the better known and most contentious provisions is a prohibition on self-referral for office-based services that would otherwise enjoy exemptions from Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also commonly referred to as the "Stark Law." Under the Annotated Code of Maryland, Health Occupations Article, §1-301 *et seq*., referrals are prohibited when the referring health care practitioner stands to benefit financially from the referral. Specifically, a health care practitioner may not refer a patient to a health care entity in which the health care practitioner has a beneficial interest, in which the practitioner's immediate family owns a beneficial interest of at least 3 percent, or with which the practitioner or the practitioner's immediate family has a compensation arrangement. §1-302(a).

In 2006, Maryland enforced the self-referral law by halting an orthopedic practice from referring patients for advanced imaging services to an imaging center owned by that practice. Practices affected

claimed they should be exempt from the law. In 2011, the Maryland Court of Appeals, in Potomac Valley Orthopaedic Associates (PVOA), et al. v. Maryland State Board of Physicians, 417 Md. 622 (2011) ruled that exemptions do not apply to services such as those offered by PVOA. Once the Court had ruled, the Board took action to force approximately ten orthopedic practices to divest of the MRI devices. The ten orthopedic practices lost their ability to self-refer for imaging services in 2011.

In 2013, the House Health and Government Operations Committee asked MHCC to study the impact of the prohibition on self-referral on MRI use rates for orthopedic practices that had previously owned advanced imaging equipment. MHCC released a report in 2014 that found use rates of MRI for the 'ownership' practices did not decline after the imposition of the prohibition. The study also found that MRI use rates were higher prior to the prohibition and remained higher after prohibition for these practices than use rates at comparable orthopedic practices that did not own this equipment.

The results from the MHCC study supported certain arguments of both proponents and opponents of the current MPRL. Utilization rates of MRI did not change for the 'ownership' practices after divestiture of the equipment, but utilization rates among ownership practices were higher than for a comparison group. In the January 7, 2015 transmission letter that accompanied the report, the MHCC suggested that prohibition on ownership of office-based imaging could be relaxed if a practice met three conditions that could diminish incentives to overuse the service:

- The practice demonstrates that a very high proportion of care is reimbursed under risk-based financial arrangements;
- The practice can demonstrate sufficient scale as to make ownership of imaging equipment viable and agrees to bundle imaging use under the risk-based arrangement; and
- The practice commits to ongoing reporting of quality metrics linked to its patient outcomes.

MHCC's rationale for offering the suggestions was based on evidence that when practices adopted value-based reimbursement and were operationally of appropriate scale, incentives for overuse declined. The MHCC further noted in the letter that at that time very few Maryland practices could meet the three criteria.

Several specialty groups sought to remove the prohibition on self-referral in the 2015 legislative sessions. One bill (HB 683) broadly addressed self-referral. Another bill (HB 944) focused on therapeutic imaging for cancer treatment. Neither of the bills passed either the House of Delegates or the Senate. At the conclusion of the Legislative Session, the MHCC agreed to convene the provider-carrier workgroup to further examine the question consistent with MHCC's recommendations.

In June 2015, the MHCC convened a workgroup to discuss the MPRL, and to discuss options for Maryland's self-referral policy going forward. The workgroup met in June, July, and September of 2015, with two additional meetings planned for October.)

Workgroup Findings and Conclusions

1. Maryland's statute prohibiting certain physician self-referrals may prevent physicians from creating innovative models of health care delivery, even when fee-for-service incentives are absent or minimized.
2. Maryland has an interest in promoting innovative models of health care delivery that improve quality, enhance patient experience, and control costs.
    a. Both public and private payors are experimenting with different payment models to incentivize cost-effective care.

   b. These innovative care models can replace fee-for-service reimbursement with alternative payment provisions intended to diminish incentives for over-utilization.
   c. An overarching framework to consider any evolution of the existing law would tie additional flexibility in delivery models, including self-referral, to additional accountability. For example, accountable care organizations (ACO's) or clinically integrated organizations (CIO's) with a two-sided risk-sharing arrangement would reduce incentives for over-use.
3. Maryland law provides a process by which physicians can be granted an exemption from the self-referral statute. The two-year time period for such exemptions is insufficient to justify new capital investments in most cases.
4. Workgroup members do not agree on:
   a. The extent to which overutilization is still a problem.
   b. The extent to which Maryland's self-referral statute actually prevents physicians from creating innovative models of health care delivery (and whether other federal and state laws are also barriers)
   c. Whether Maryland physician groups could meet the "value-based" criteria defined by the MHCC Commissioners. (For example, most physician reimbursement in Maryland is still fee-for-service.)
5. The federal government has provided some opportunities for innovation under Stark:
   a. Medicare ACO rules provide for exceptions from kickback and physician self-referral restrictions.
   b. Both the Centers for Medicare & Medicaid Services and MedPAC have identified alternative payment models as a substitute for self-referral prohibitions, but have not yet proposed specific policies.
6. By December 2016, Maryland must submit a plan to transition Maryland's new hospital payment model ("waiver") to an "all cost" global budgeting model with implementation scheduled for January 2018. Specific features of the waiver (Version 2) are not yet known:
   a. Version 2 will have a significant impact on the entire Maryland health care system.
   b. Any changes to the self-referral statute should ideally complement and, minimally, not conflict with Version 2.

Policy Options

The workgroup is charged with identifying options to evolve the current law to permit some flexibility to providers, particularly in the framework of innovative payment and delivery models, while retaining the controls on over-use of care. Based on feedback from the workgroup members, MHCC has summarized the following policy options as a middle ground between repealing the self-referral statute and leaving it as it is. The workgroup will consider these options during its October 2015 meetings.

These options are not listed in any specific order within three groupings based on the degree of agreement among workgroup members. Note also that the options may not be mutually exclusive; the State may pursue more than one of these simultaneously.

Options where there appears to be some agreement across stakeholders

Option 1. Lengthen Exemptions Available Through the Current Process.

Within the framework of the existing law, there has been general consensus that the length of the current exemption (two years) is not adequate, given the investment needed for equipment. Seek

regulatory, and statutory changes if necessary, to allow DHMH to grant longer self-referral exemptions. (Specifically, change COMAR 10.01.15.07 to provide that exemptions from the prohibition granted by the Secretary will remain effective for a term specified by the Secretary. Unless the Secretary establishes a shorter period for good cause, the term will equal: (i) for equipment leased by the physician, the length of the lease term; or (ii) the anticipated useful life of the relevant equipment (not buildings), whichever is less.)

Legislation not required

Option 2. Clarify Application of MPRL to Distributions from value-based models, including Shared Savings Programs, Gainsharing, and Clinically Integrated Networks.

Request the respective licensing board to issue guidance to clarify that payments from health care entities or their affiliates to referrers that are attributable to distributions from Medicare shared savings plans, comparable arrangements with commercial payors, organized gainsharing programs, other hospital-driven programs for reducing potentially avoidable utilization, etc., do not constitute a prohibited compensation arrangement. Note that other Maryland laws may also apply to gain-sharing arrangements, and would be outside the scope of the interpretation of the self-referral law.

Legislation not required

Options that have some support among stakeholders

Option 3. Permit Pilot Tests of Self-Referral Arrangements.

Expand the MPRL exemption process to further define and test the MHCC's "value-based" criteria under which Maryland should consider granting exemptions. This approach would provide a pathway for a limited number of physicians to gain relief from the self-referral statute in order to implement value-based care models that meet the MHCC criteria. Selection of pilot practices may prioritize those that address known access and need concerns; appropriately integrate services delivered by hospitals and physicians; and can demonstrate significant scale. Pilot practices should be required to report on quality/performance and on the specific issues and challenges the self-referral statute creates for implementing value-based care models. During this period the workgroup may monitor federal government policy and developments in Version 2 of the waiver. Based on the findings of the pilot, the workgroup would submit any recommended changes to the General Assembly for the 2018 Legislative Session.

Legislation probably required, possibly complete through regulatory changes

Option 4. Allow Referrals Authorized by Financially Responsible Party.

Amend the statute so that self-referral prohibitions will not apply in cases where the payor (self-insured employer or insurance carrier) has authorized the physician to self-refer. Authorization from a payor could be given either across-the-board (e.g., in the agreement between the payor and the provider) or in a particular case (e.g., through a prior authorization process administered by the payor). For example, implementation could be limited initially to certain services, such as oncology, or when a payor contracts with a Clinically Integrated Organization (CIO).

Legislation required

Option 5. Allow Referrals Authorized Under value-based models, including Shared Savings Programs, Gainsharing, and Clinically Integrated Networks.

Amend the statute so that self-referral prohibitions will not apply in cases where (a) the patient is covered by a recognized value-based model, (b) the organization holding the contract is financially responsible to absorb at least 50% of costs in excess of a specified target (which shall not be more than the costs the payor would be expected to incur in the absence of the shared savings arrangement), and (c) the organization holding the contract has authorized the physician to self-refer, either across-the-board or with respect to the particular patient. Recognized value-based models will be defined in regulations and may evolve over time, as best practices and state/federal policy changes.

Legislation required

Option 6. Amend the Maryland Physician Referral Law by adding an exemption that stating that any arrangement permitted under Stark is permitted, unless prohibited in the MPRL.

This approach would enable Maryland providers to proceed with assurance that waivers and exemptions defined in Stark and the supporting federal regulations apply to innovative arrangements in Maryland. At the same time, this approach would enable stakeholders and policymakers to address the specific prohibitions in the MPRL in a sequential and systematic manner. The State could use an array of tools, including limited pilots, exemptions for specific reform initiatives and, in some cases, leaving the prohibition in the MPRL in place on the specific protections in the MPRL. Should the workgroup proceed with such an approach, the Stark preemption provision would need to be drafted carefully to ensure that specific prohibitions under MPRL are retained, while clarifying that arrangements not specifically prohibited are allowed subject to Stark.

Legislation required

Options with less consensus among stakeholders

Option 7. Leave the current Maryland Patient Referral Law unchanged.

Maryland law provides for appropriate protections against over utilization. Current law provides for additional benefits by limiting fee-splitting that sometimes penalize certain providers. Leaving the law unchanged may limit innovation.

Option 8. Add an exemption to the Maryland Patient Referral Law making any arrangement permitted in Stark also permitted in Maryland.

Many aspects of the MPRL contain ambiguity that creates the potential for significant liability or, at the very least, leaves the provider community in Maryland with virtually no guidance on how our State's self-referral law applies to new payment arrangements contemplated by the ACA. And, many arrangements that are integral to value-based care are not clearly protected under the MPRL. Serious investment in value-based care cannot occur in Maryland while this kind of uncertainty and risk exists under the MPRL.

Legislation required

Option 9. Repeal the current Maryland Patient Referral law.

Medicare and Medicaid programs would be governed directly by Stark. MPRL prohibitions on self-referral for certain office-based services would be eliminated for all patients. Certain other MPSL

prohibitions that also are included in Stark would now be exempted for patients insured by private health insurance.

Legislation required

Maryland
Hospital Association

Comments to MHCC's Provider-Payer Work Group

BACKGROUND

The Maryland Hospital Association (MHA), representing the state's 64 hospital and health system members and the patients and communities they serve, appreciates the opportunity to participate in the Maryland Health Care Commission's (MHCC) Provider-Payer Work Group, which was charged with exploring changes to Maryland's self-referral law to align with emerging payment models and health care reform. **While MHA is willing to evaluate perceived legal barriers to integrated care delivery, we cannot support any change that diminishes patient protections or jeopardizes Maryland's all-payer hospital rate setting agreement with the federal government.**

Under that agreement, which was implemented in January 2014, Maryland's hospitals are transforming care delivery through innovations aimed at getting Marylanders the right care, at the right time, in the right setting – often outside the hospital. The agreement holds Maryland's hospitals accountable for the total cost of care provided in the state and hospitals operate under fixed budgets.

WHAT WE ARE FOR:

1. **Protect patients:** Numerous federal government and peer-reviewed studies have concluded that self-referral leads to over-utilization of services. This not only raises costs artificially, it means that medical decisions are made based not solely on what is best for the patient, but also what is profitable for the provider. Maryland legislators enacted the strongest statute in the country precisely to protect patients from such financial self-interest, and this goal remains valid, due in part to the volume-based payment model physicians continue to operate under.
    - ***MHA supports maintaining these important patient protections.*** *State regulators should bolster the current oversight process and actively evaluate and enforce adherence to these provisions.*
2. **Ensure access to care**: As not-for-profit organizations with a shared mission of care, hospitals have a long history of supporting efforts to improve patients' access to care. **Maryland's statute already provides a needs-based exemption from the self-referral law to enhance this access to services**.[1] This exemption has only been requested twice since 2011.
    - ***MHA supports ensuring access to services where there is a demonstrated geographic need.*** *The exemption process should be revisited to provide for a longer term of duration while still ensuring appropriate access for the community. Requests for exemption should be transparent and provide an opportunity for engagement of impacted stakeholders.*
3. **Promote Collaboration and Innovation:** High quality, well-coordinated, integrated care is provided daily by clinicians across the state who do not hold ownership of or financial interest in a service. Aligning their payment incentives with the incentives of the rest of the state's providers is critical to success under Maryland's agreement with the federal government in order to encourage redesigned and improved care processes. Such arrangements can be achieved without altering existing protections against physician ownership or financial interest in a service or facility.
    - ***MHA supports clarifying Maryland's self-referral law to ensure compensation arrangements under bona-fide financial and risk-sharing alignment models are permissible.***

CONCLUSION

With appropriate oversight from state regulators, Maryland's existing self-referral statute remains the proper framework for protecting patients while also encouraging the innovation and collaboration that can lead to better care delivery. The well-being of our patients and the success of our state's unique agreement with the federal government, which promises lower costs and better care, are our priorities. MHA stands ready to work with all stakeholders who share those goals.

[1] Health Occupations §§1-301 – 305 and COMAR 10.01.15.05 and 0.6

To fulfill the charge of the Provider-Carrier Workgroup (PCW) (determining a path forward for modernization of current Maryland patient referral law to better align Maryland statute with emerging payment models and health care reform), we recommend that a well-defined pilot program for integrated community oncology (radiation therapy and medical oncology together in a group practice) be exempted from the patient referral law. The pilot program, including its application and selection process, should be administered by the MHCC under regulations established through DHMH rulemaking. Such a pilot program should allow for the following:

- Not more than five radiation therapy facilities to be established and operated within the following counties:
    - Baltimore County;
    - Calvert County;
    - Charles County;
    - Saint Mary's County;
    - Talbot County;
    - Caroline County;
    - Wicomico County;
    - Worcester County;
    - Somerset County;
    - Harford County;
    - Cecil County;
    - Frederick County
    - Garrett County;
    - Dorchester County;
    - Kent County
    - Prince George's County;
    - Washington County;
    - Montgomery County; and
    - Carroll County.
- Each facility should be at least 50% owned by a physician group practice;
- Each facility should be allowed to operate for a minimum of 10 years, provided it remains at least 50% owned by a physician group practice;
- Each group practice owning such facility(ies), and each commercial carrier contracting with such group practices, should report quarterly to MHCC information necessary to determine the following;
    - Referral rates for radiation oncology consultations and utilization rates for radiation therapy services by the practice's physicians,
    - Referrals for radiation therapy by practice's physicians in compliance with nationally accepted guidelines (pathways compliance),
    - Effects of integrated community oncology centers on average patient out-of-pocket costs, unplanned hospital utilization (ER visits, hospital admissions, and days in the hospital) by patients, overall radiation utilization rates, healthcare costs in the state, and the Maryland All-payer Waiver relative to the equivalent outpatient services provided across other care settings, and
    - Health outcomes of patients treated by integrated community oncology centers relative to statewide averages across other care settings.
- MHCC should report annually to the legislature the analysis performed and the data collected from the participating pilot program facilities over the prior year.

- Following a pilot program facility's completion of 10 years of treating patients (and subsequent reporting as outlined above), MHCC will submit to the legislature a comprehensive report summarizing their findings for that facility compared to state averages for other care settings. The final report should include a recommendation on whether or not to grant the practice an exemption from the Maryland Patient Referral Law (MPRL) prohibition on radiation therapy ownership based on their performance within the pilot program. Recommendations should be based on the following:
    - Radiation utilization,
    - Pathways/guidelines compliance for radiation therapy,
    - Average cost per patient, per episode cost of care for integrated treatment,
    - Average patient out-of-pocket costs, and
    - Average unplanned hospital utilization rates per patient.
- Following the final report from MHCC, only an act of the legislature could authorize either granting practices owning pilot program facilities a broader exemption from the MPRL, or removing participating facilities from the pilot program.
- Each group practice with ownership in such facilities should meet the following criteria as of January 1, 2016, and at the time they apply, are accepted, and begin operating a facility under the pilot program:
    - Be composed entirely of physician owners who are oncologists or specialists who primarily treat oncology and hematology patients, and who are licensed and practice in Maryland;
    - Average more than 50,000 patient visits in Maryland per year throughout the practice for the past three years;
    - Demonstrate that the group practice has accepted Medicare and Maryland Medical Assistance Program patients for the preceding three consecutive years;
    - Demonstrate that the group practice has been treating patients in Maryland for at least ten years; and
    - Be affiliated with a national organization having expertise and technical capabilities sufficient to support:
        - Collection, analysis, and reporting required information to the state,
        - Practices' use of evidence-based clinical pathways through electronic medical records,
        - Conduct innovative oncology payment model studies with carriers in Maryland, and
        - Enroll cancer patients in clinical trials in at least one of the practice's locations in Maryland.

We believe such a pilot program will allow the state to conduct overall cost of care comparisons between community- and hospital-based integrated oncology services, as well as fragmented cancer care between stand-alone medical oncology and radiation oncology practices, by collecting information on cost, cost savings, and utilization, while concurrently allowing providers and carriers to work together on improving emerging oncology payment models—to include more integrative, value-based oncology efforts in a way that mitigates risk and allows benefits to patients, providers, and carriers. We recommend this for the following reasons:

- Free-standing, community-based radiation oncology is lower both in terms of cost per treatment and for total cost of care (per episode) than hospital-based oncology, when measured by either costs to carriers or patient out-of-pocket costs. Currently most radiation patients in Maryland are treated in hospital-owned facilities.
- Risk is low due to the distinct differences between radiation oncology and diagnostic imaging. In oncology, a therapeutic service like radiation requires prior authorization, following evidence-based clinical pathways, and can only be administered after patient consultation with a radiation oncologist. A diagnostic service like imaging does not require the same. With these checks and balances, at most there would be a shift of patients to the low-cost setting for care, not an increase in the number of radiation patients treated. Moving outpatient services for expensive oncology services off hospital campuses will support the Maryland Waiver, and improve hospital profitability under their Global Budget Revenue caps.
- Clinical pathways are designed to reduce costly variation in care through recommended care processes for specific clinical situations. The ability to expand such work to radiation oncology—working between forward-thinking payers and oncology practices with national affiliations like The US Oncology Network—can provide both sides with the opportunity to test ways in which the integration of community cancer services can theoretically magnify cost savings in such models. This can increase the quality of care, patient experience, and efficiencies in care coordination while reducing duplication, medical errors, and hospital utilization.
- There are many innovative projects between payers and providers across the country underway, but none have yet determined how best to fit oncology services into major shifts away from fee for service. We need to be able to explore this, and allowing radiation gives us more “flexibility” in making it work.
- Oncology services in general are very expensive, with new drugs and new therapies adding to the increasing cost of providing “standard of care,” which itself is increasingly integrated in nature (dual- and multi-modality treatments). Much more testing of innovative payment models addressing cost and quality in oncology are needed.
- Already, due to unique features in Maryland, oncologists here are excluded from participating in CMS's Oncology Care Model pilot.
- A majority of cancer care (particularly chemo-therapy) nationally is provided in the independent, community based provider setting. Not being able to include these providers in new oncology models built around integrated care will hamper efforts to develop such models in Maryland.
- Regardless of what the PCW study ultimately recommends, the shift to performance based models will happen, and has been happening nationally. Maryland should modify the referral statute so that carriers and all oncology providers here can be a part driving positive change.

The Maryland Patient Referral Law Limits Innovation
Executive Summary

Over the past several months, this Workgroup has met to discuss reform of the Maryland Patient Referral Law ("MPRL") to protect value-based payment methods in this State. Recently, we proposed a simple solution: **protect any arrangement that is legal under the federal Stark law**.

As we transition to value-based compensation, hospitals, physicians, and other healthcare providers are considering new commercial arrangements to achieve cost savings and quality improvements. However, **this kind of significant investment requires legal clarity**. No provider will devote significant resources and make capital expenditures in the face of substantial legal uncertainty.

Unfortunately, while the Stark law has undergone **decades of regulation and judicial interpretation** to clarify its rules, the MPRL has no such record. Many aspects of the MPRL contain ambiguity that creates the potential for significant liability or, at the very least, leaves the provider community in Maryland with virtually no guidance on how our State's self-referral law applies to new payment arrangements contemplated by the ACA. **And, as we show below, many arrangements that are integral to value-based care are not clearly protected under the MPRL. Serious investment in value-based care cannot occur in Maryland while this kind of uncertainty and risk exists under the MPRL.**

For example, the following relationships are either **clearly** or **potentially** prohibited or limited under the Maryland Patient Referral Law:

- Certain care coordination functions performed by critical **non-physician practitioners like nurses and licensed clinical social workers,** who are not regulated under the Stark law.
- Innovative incentive payment models designed by **private payors,** which are often more aggressive than federal models.
- Gainsharing and ACO shared savings payments to providers, because **Maryland law does not contain the waivers that exist under the federal Stark law.**
- The common practice of distributing value-based incentive payments to physicians through an **"intervening entity,"** and other innovative compensation models allowed by the Stark law's "indirect compensation" rules.
- Provider contracts that are **conditioned on in-network referrals**, which allow management of cost and care quality.
- Provider contracts that include **productivity bonuses** based on the "volume or value of referrals."
- Important existing **"risk-sharing"** arrangements between physicians and managed care organizations or independent physician associations, which are often the precursors to ACOs.

The MPRL is also missing many commonly-used Stark law exceptions, which casts doubt on certain common arrangements. For example:

- The MPRL lacks a "catchall" **fair market value exception** that allows a variety of different providers to structure relationships so long as formal requirements are met.
- The MPRL provides no clear avenue to provide **electronic health records or other information technology** to community providers, inhibiting integration.
- Unlike the Stark law, the MPRL does not include any protection for temporary, **technical noncompliance** with the standards of an existing exception – it is purely strict liability.

Stark provides a set of clear "ground rules" that any provider can use to invest in innovative models of care. **This is a significant advantage over proposed MPRL approaches that include bureaucratic approval of individual waivers**.

The accelerated shift to value-based payment makes this issue particularly urgent, as even the federal government is now suggesting new Stark exceptions are necessary. **But any new federal Stark protections for integrated care will only increase the uncertainty in Maryland.**

Maryland has committed to massive, system-wide reform in the form of its all-payer hospital waiver. However, it has not created the kind of legal and regulatory certainty necessary for large-scale investment in innovative care models. Simply put, no investor will commit substantial funds when **there is a real risk that extremely common value-based payment strategies are illegal**. Moreover, investors will be reluctant to commit to Maryland providers when **it is unclear that such new and evolving federal protections will even be available to healthcare providers in Maryland**.

Maryland can easily avoid this outcome without changing the unique features of its law. **This can be accomplished very simply by adding a new exemption covering any relationship that is legal under federal law.**

Sincerely,

Dr. Harry Ajrawat
Dr. Nicholas Grosso
Dr. Arnold Levy
Members, MHCC Provider/Carrier Workgroup – Study on Self-Referral

The Maryland Patient Referral Law Limits Innovation

ISSUE & BACKGROUND:

Both the Maryland Patient Referral Law ("MPRL") and the federal self-referral statute (or "Stark law") restrict financial relationships between physicians and certain referral sources.[1] The MPRL was passed in 1993, and the Stark law was significantly amended to its "modern" form in the same year.[2] The laws are similarly structured: both contain extremely broad prohibitions on relationships between healthcare practitioners and healthcare entities like hospitals. However, over time the Stark law has been fleshed out with regulations and other interpretations, while the MPRL has not. **In other words, while the Stark law has been modified in many important ways to keep pace with the rapidly changing healthcare industry, the MPRL has essentially stood still. There have been no fundamental revisions to the MPRL since its passage in 1993.**

This issue is particularly pressing as both the federal government and the State of Maryland are working to transition away from fee-for-service and toward value-based care. Traditional fraud and abuse laws are designed to address risks of a volume-based payment system that is increasingly outdated. The new value-based payment system will require providers to invest in new contractual arrangements, information technology, personnel, and other infrastructure to improve quality while reducing costs. **However, the ambiguity and potential breadth of the MPRL creates large and unacceptable legal risk that prevents many providers from aggressively working to meet these goals.**

Under the fee-for-service system, the more services provided by a healthcare provider, the more total reimbursement he, she, or it may receive. Therefore, in this context, a physician who has a financial relationship with a healthcare entity may have an incentive to inappropriately refer patients for care that is unnecessary, inefficient, or wasteful. As a result, traditional fraud and abuse laws (including the Stark law and the MPRL) appropriately focus on limiting financial incentives that may affect a physician's referral decisions.

However, the incentives under a value-based payment system are fundamentally different. New "value-based" reimbursement systems, including Accountable Care Organizations ("ACOs") and bundled payment programs, pay based on *savings* rather than volume. These programs are explicitly based on collaboration between physicians, hospitals, and other healthcare entities. Success under these payment systems is based on meaningful collaboration between multiple providers and entities to ease care transitions, manage patient status in multiple care settings, and reduce unnecessary care. Unfortunately, the financial incentives at the heart of these programs are often difficult to structure under a traditional fraud and abuse system designed to limit exactly this kind of coordinated care.

The federal government and the State of Maryland have committed to transitioning to a value-based payment system. This year, CMS created aggressive goals to move 85% of care to value-

[1] The Stark law is at 42 U.S.C. § 1395nn, with implementing regulations at 42 C.F.R. Part 411, Subpart J. The MPRL is at Md. Health Occ. Code 1-301 *et seq*.

[2] Omnibus Budget Reconciliation Act of 1993, P.L. 103-66.

based models by 2016, and 90% by 2018.[3] CMS further committed that 30% of Medicare payments would move entirely outside fee-for-service models to Alternative Payment Models ("APMs") by 2016, and 50% by 2018.[4] The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") reflects Congress's support of this view. Under MACRA, all payment increases after 2019 will *require* participation in an APM or related incentive-based payment models.[5]

On one hand, Maryland has been a leader in implementing APMs. Under its revised all-payer hospital waiver, Maryland hospitals will commit to significant quality goals (including reduced readmission and hospital-acquired condition rates), as well as $330 million of Medicare cost savings, and aggressive caps on all-payer hospital cost growth.[6] The plan also calls for Maryland to shift "virtually all of its hospital revenue" to APMs.[7] As a reflection of Maryland's commitment to this approach, if the State fails to achieve these goals, it has agreed to end its unique all-payer Medicare alternative payment system – a policy that has been in place for 36 years.[8] **However, the MPRL may severely limit Maryland hospitals from working with other providers to achieve these goals.**

Although both the Stark law and MPRL are designed for a fee-for-service system, the Stark law has been the subject of decades of regulation and interpretation by courts and administrative agencies. CMS has taken pains to ensure that the Stark law evolves to provide a predictable legal framework for investment in healthcare entities through new exceptions, waivers, and guidance. By contrast, significantly less interpretive guidance exists for the MPRL – even as the reach of the law is potentially broader. As such, the precise impact of the MPRL is far more unclear. This naturally prevents providers from investing significant resources in integrated care models and other value-based strategies, as the MPRL raises the possibility of significant legal risk for coordinated care.

PROPOSAL:

Maryland could easily change the MPRL by adding a new exemption, which would clarify that the MPRL does not prohibit any relationship allowed under the Stark law.[9] **Note that this is not a proposal to repeal the MPRL.** The underlying prohibition of the MPRL would remain in place as would any unique flexibilities authorized under State law. **Instead, our proposal simply ensures that providers in Maryland can collaborate on the same terms as providers in other states under federal law.**

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[3] Centers for Medicare and Medicaid Services, Fact Sheet: Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume (January 26, 2015), available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html.

[4] Id.

[5] 42 U.S.C. § 1395L(z).

[6] Center for Medicare and Medicaid Innovation, "Maryland All-Payer Model," http://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/.

[7] Id.

[8] Id.

[9] The MPRL contains a list of exemptions at Md. Health Occ. Code § 1-302(d).

1) The MPRL has a significantly broader reach than the federal Stark law.

Although the Stark law is a broad prohibition, it is limited in certain important ways. First, the law only applies to referrals made by a "physician," defined as "a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor."[10] Second, the law only applies to referrals of "designated health services," defined as clinical laboratory services; therapy services; radiology and imaging services; radiation therapy services and supplies; durable medical equipment and supplies; certain nutritional equipment and supplies; prosthetics, orthotics, and other prosthetics; home health services; outpatient prescription drug services; and inpatient and outpatient hospital services.[11] Third, the Stark law provides that a "referral" does not include services that are personally performed by the "referring" physician.[12]

The MPRL's version of the prohibition is significantly broader. Rather than being limited to "physicians," the MPRL extends to all "health care practitioners," defined as a "person who is licensed, certified, or otherwise authorized . . . to provide health care services in the ordinary course of business or practice of a profession."[13] And, the MPRL is not limited to "designated health services," but instead extends to *all* health care services.[14] Moreover, it does not exclude a physician's personally performed services from the definition of "referral."[15] Further, the MPRL is an "all payor" statute, which means it applies to commercial payors as well as Medicare and Medicaid.

As a result, the MPRL appears to apply in a far broader set of contexts than the Stark law. For example:

- Unlike the Stark law, the MPRL regulates referrals made by a Registered Nurse acting as a care coordinator in an ACO, or a Licensed Clinical Social Worker assisting patients in a Patient-Centered Medical Home.[16]
- Unlike the Stark law, the MPRL regulates physician ownership of ambulatory surgical centers, which provide certain surgical services at significantly lower cost than competitors.[17]
- A group of specialists who do not participate in Medicare wish to join a local hospital to assist in achieving shared savings under a private payor arrangement. Assuming that there are no referrals made for federal health care program business to the local hospital,

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[10] 42 C.F.R. § 411.351, definition of "physician".

[11] Id., definition of "designated health services."

[12] Id., definition of "referral."

[13] Md. Health Occ. Code § 1-301(h).

[14] Md. Health Occ. Code § 1-301(l).

[15] Id.

[16] RNs and LCSWs are licensed under Md. Health Occ. Code § 1-801(d).

[17] Services paid under an ASC composite rate are excluded from the definition of DHS. See 42 C.F.R. § 411.351, definition of "designated health services."

the Stark law would not apply. However, the MPRL would still regulate this relationship.

As a result, **financial relationships involving these individuals or entities are subject to additional regulation in Maryland**. As discussed in more detail below, this is problematic because many of the financial relationships at the heart of integrated care arrangements **may be impeded under Maryland law**.

2) Value-Based Payment arrangements are problematic under patient referral laws – and federal waivers do not cover the MPRL.

Reform of the MPRL has become an urgent need as CMS and the State have aggressively moved to implement integrated care and value-based payment models. This is true because the payment models driving these programs **often create financial relationships between practitioners and healthcare entities**. If CMS and the State are not aligned as they attempt to solve this fundamental aspect of integrated care, the result will be **significant regulatory uncertainty for providers**.

For example, payment models based on "gainsharing" or "shared savings" frequently involve payments based on the *joint* experience of one or more physicians and healthcare entities. As such, the achievement of shared savings and quality goals reflects the combined efforts of multiple distinct healthcare entities. Unfortunately, payments to one healthcare entity that are partially based on the actions of another may be considered a prohibited "payment for referrals." A related concern arises when a single entity (often the hospital or a hospital-owned entity) receives the payment, and is then responsible for further "downstream" payments. In this event, each payment creates a financial relationship that must be protected.

These issues are even more problematic because many relevant provisions of Stark and the MPRL prohibit payment based on the "volume or value of referrals." For example, the MPRL's protection of independent contractor arrangements and several Stark law compensation exceptions contain such a restriction.[18] This standard often cannot be met for shared savings or gainsharing, because the ultimate payment could be characterized as *reducing* the "volume or value of referrals." Although this seems to be an absurd result, it is consistent with the law.

The federal government recognized this potential problem as early as 2008, when CMS proposed a gainsharing exception to the Stark law.[19] CMS has authority to create new Stark law exceptions if they pose "no risk of patient or program abuse," and has used this authority to create important exceptions in the past.[20] But the agency's attempt to create a gainsharing exception proved enormously complicated, such that it was forced to conclude that, **"the**

[18] See e.g., Md. Health Occ. Code § 1-301(c)(2)(iii); 42 C.F.R § 411.357(a), (b), (d), (e), (f), (h), (k), (l), (m), (p), (u), (v), and (w).

[19] 73 Fed. Reg. 38502, 38548.

[20] 42 U.S.C. § 1395nn(b)(4).

majority of commenters urged [the agency] to finalize such an exception or exceptions only if substantial modifications were made to the conditions proposed."[21]

The federal government was not able to successfully support integrated care until the passage of the Affordable Care Act ("ACA"). The ACA created new, large-scale shared savings programs in the form of Accountable Care Organizations ("ACOs") under the Medicare Shared Savings Program ("MSSP") and similar demonstrations under the Center for Medicare and Medicaid Innovation ("CMMI").[22] The ACA also gave CMS the authority to waive Medicare payment rules – including fraud and abuse laws – "as may be necessary to carry out the provisions" of these programs.[23]

Using this authority, CMS determined that waivers of the Stark law, Anti-Kickback Statute, and certain elements of the Civil Monetary Penalty law were necessary to implement these programs.[24] As a result, the agency created waivers allowing unprecedented flexibility to pay for start-up costs, distribute shared savings, and enter into other arrangements for physicians and entities participating, or working to participate, in the MSSP and CMMI initiatives.

These ACO waivers are the legal basis for much of the experimentation and innovation occurring in value-based care programs today. However, they contain important limitations. Most importantly, they apply *only* to Medicare payment rules. **As a result, they do not apply to state laws like the MPRL, other Medicare payment models, or innovative private payor arrangements.** Given the broader scope of the MPRL, this means many of the arrangements currently covered under the MSSP or CMMI initiatives may technically violate state law.

Perhaps recognizing these limitations, CMS has signaled its willingness to explore additional ways to broaden the Stark law. In a proposed federal rule in March 2015, CMS produced one of its most substantial solicitations of comments regarding the Stark law, with an extensive list of proposals with a clear intent to protect gainsharing and shared savings arrangements – whether public or private.[25] However, the content of this exception is entirely unknown. **In other words, even as Medicare is moving aggressively towards integrated care, CMS is still in the process of developing a fraud and abuse framework**.

The following concrete examples illustrate potential problems with this important mismatch:

- A Maryland MSSP ACO, composed of a hospital and multiple physician practices that refer to the hospital, has earned a shared savings incentive payment, in part by more efficient management of referrals. It now wishes to distribute these savings to the hospital and physician practices. Stark law liability is *explicitly waived* for these payments under the MSSP. However, it is unclear whether these payments are protected under the MPRL. The most obvious protection – the provision covering independent

[21] 73 Fed. Reg. 67992, 69793.

[22] 42 U.S.C. §§ 1395jjj and 1315a.

[23] 42 U.SC. § 1395jjj(f).

[24] 76 Fed. Reg. 67992 and 79 Fed. Reg. 62356.

[25] 80 Fed. Reg. 41686, 41929.

contractor arrangements – does not apply to compensation that "varies with the volume and value of referrals."[26]

- A set of independent physician groups that refer patients to each other for services enter into a private, performance-based payment agreement that provides for shared savings payments if they collectively reduce costs below a benchmark. The MPRL would reach these payments because it applies to purely private arrangements, these payments are under private contracts and the MSSP ACO waiver does not apply to state law.[27]

3) Indirect compensation arrangements:

One common method of distributing shared savings is to create a neutral "intervening entity" that is responsible for making payments to each provider and healthcare entity. This separate entity receives shared savings earned collectively by the ACO and makes flat-rate payments to each healthcare provider. As a result, the distribution of shared savings arguably no longer takes into account the volume or value of referrals from any given provider. This approach depends on the unique nature of the Stark law's indirect compensation rules. **Unfortunately, these rules have no equivalent under the MPRL.**

The Stark law restricts both "direct" and "indirect" compensation relationships between physicians and healthcare entities.[28] The MPRL's language is more general, and simply restricts any referrals from a health care practitioner to a health care entity with which the practitioner "has a compensation arrangement."[29] The MPRL goes on to provide that a "compensation arrangement means any agreement or system involving any remuneration between a health care practitioner [or immediate family member] and a health care entity."[30] The scope of these definitions is unclear, and may reach both "direct" and "indirect" compensation arrangements.

However, the Stark law includes a detailed definition of "indirect compensation," and an exception for indirect compensation relationships, which are frequently used to structure innovative payment arrangements. Because the scope of the MPRL's prohibition is unclear, it is not evident that these common arrangements to protect distribution of shared savings are available in Maryland.

Under the Stark law, an "indirect compensation" arrangement only exists when an unbroken chain of financial relationships (which may be ownership or compensation relationships) exist between a physician and a healthcare entity *and* the physician's aggregate compensation varies with the volume or value of referrals to the healthcare entity.[31] In other words, a prohibited

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[26] Md. Health Occ. Code § 1-301(c)(2)(iii).

[27] Note that this arrangement might also be required to meet a Stark law exception if referrals for services paid under Medicare are made. However, as detailed elsewhere in this document, the Stark law contains several important exceptions that are not available in Maryland.

[28] 42 C.F.R. § 411.353(a) and 411.354(c).

[29] Md. Health Occ. Code § 1-302(a)(3).

[30] Md. Health Occ. Code § 1-301(c)(1).

[31] 42 C.F.R. § 411.354(c)(2).

financial relationship only exists if the physician's most direct source of compensation reflects his or her referrals to the healthcare entity.

Furthermore, the indirect compensation *exception* provides additional protection for these arrangements.[32] Under this exception, even if an indirect compensation relationship exists, it will not trigger liability under the Stark law when certain formal requirements are met, so long the physician's compensation is fair market value for services and items actually provided and is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician for the healthcare entity.[33]

The Stark law's detailed indirect compensation rules are extremely important for value-based care arrangements. The "intervening entity" model discussed above is designed around these rules. Specifically, this model is able to avoid the issue of payments based on "volume or value" because the distributions from the last entity in the "chain" are paid on flat-fee basis. **Therefore, the Stark law makes it abundantly clear that no indirect compensation relationship exists in this model.**

By contrast, the MPRL lacks essential detail about the specific types of "compensation arrangements" allowable or protected under the law. **As a result, it is unclear whether this structure would protect parties from liability under the MPRL.**

4) The MPRL does not contain important "special rules" on compensation.

The federal government has acknowledged that a number of extremely common financial relationships were blocked by rules generally limiting payment based on the "volume or value of referrals." In order to accommodate these essential relationships, CMS created a set of "special rules on compensation."[34] Although the MPRL contains certain limited analogues of these rules, it is missing a number of important applications.

First, the Stark regulations establish that **a healthcare entity may condition employment or independent contractor relationships on referrals within a given network**, so long as certain formal requirements apply and the parties agree to respect alternative patient preferences.[35] This is an extremely important tool used to manage referrals to ensure that the highest-quality and/or most efficient providers are used. The MPRL contains no such provision.[36]

Second, the Stark law allows **"productivity bonuses"** to be paid to "physicians in the group practice" (including owners, employees, and certain contractors), so long as the bonus is not

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[32] 42 C.F.R. § 411.357(p).

[33] Id.

[34] 42 C.F.R. § 411.354(d).

[35] Id. at (d)(4).

[36] The MPRL does exempt certain in-network referrals from liability, so long as the practitioner is employed or affiliated with a hospital. However, this exemption does not allow *conditioning* the employment or contractor agreement on in-network referrals, and does not apply to other healthcare entities. See Md. Health Occ. Code 1-302(d)(6).

"directly related to the volume or value of the physician's referrals of DHS."[37] Certain measures of productivity are deemed not to relate directly to the volume and value of referrals, including total patient encounters, certain common measures of physician productivity (including Relative Value Units), or productivity based on non-DHS services.[38] This provides an important regulatory avenue to incentivize employed and contracted physicians to manage referrals and work to achieve certain quality goals. Although certain protections in the MPRL, may authorize payment based on productivity for certain kinds of physicians (for example, for employees), t**he MPRL contains no clear exception or other rule covering this kind of productivity incentive.**[39]

5) Major exceptions used in value-based payment arrangements are not present in the MPRL:

Another serious gap between the implementation of the Stark law and the MPRL lies in the set of exceptions for compensation arrangements. Over time, CMS has defined a number of substantive exceptions that cover important, common financial relationships. **Unfortunately, the MPRL has not been updated to reflect these exceptions.** As such, parties in Maryland must attempt to fit the same relationships into provisions on the state level that are inexact matches, and that were simply not designed to protect the same broad range of relationships. Again, this creates significant regulatory uncertainty that discourages providers from investing in innovative models of care.

Perhaps most importantly, CMS created an extremely flexible exception for **fair market value compensation arrangements**.[40] This exception applies to compensation between a healthcare entity and a physician or any group of physicians (whether or not they are a formal "group practice") for the provision of items and services, so long as compensation is fair market value, certain formal requirements are met and no more specific exception applies.[41] In addition, compensation must not take into account the volume or value of referrals or other business generated by the referring physician, and may not be based on a percentage of revenue generated or a per-unit-of-service fee.[42] Still, this exception is important because it allows parties to enter into a broad range of potential arrangements. Most importantly, unlike other common exceptions like the exception for personal service arrangements, this exception is not restricted to a defined set of providers. Any group of providers may take advantage of this "all purpose" exception, so long as they meet the exception's formal requirements.[43] This flexibility is

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[37] 42 C.F.R. § 411.352(i)(3). See also 41 C.F.R. § 411.351, definitions of "Physician in the Group Practice" and "Member of the Group or Member of a Group Practice."

[38] Id.

[39] Note that productivity bonuses paid to employees may be protected because the MPRL protects any compensation paid under an employment arrangement. Md. Health Occ. Code § 1-301(c)(2)(ii).

[40] 42 C.F.R. § 411.357(l).

[41] Id.

[42] Id.

[43] Id.

essential for exploring additional payment models and commercial partnerships as CMS and other payors expect providers to establish innovative arrangements.

Unfortunately, **no such "all purpose" exception exists for the MPRL**. The closest analogy is the exclusion of "independent contractors" from the definition of a "compensation arrangement."[44] However, this exclusion is limited to arrangements "between a health care entity and a health care practitioner." As a result, it may not protect arrangements purely between multiple health care entities, or between health care professionals.

Similarly, CMS has created an exception specifically to facilitate relationships between physicians and **"risk-sharing"** entities, including managed care organizations and independent physician associations. This allows coordination between physicians that might otherwise be prohibited under the Stark law, so long as any payments are for services provided to enrollees of a health plan and the arrangement is otherwise consistent with applicable healthcare laws and regulations.[45]

CMS has also created exceptions that allow healthcare entities to provide important information technology infrastructure (the **"EHR exception"**) and other **non-monetary compensation** to providers. The EHR exception allows hospitals or other healthcare entities to provide software, information technology, and training services to providers, so long as it is necessary and used predominantly to create, maintain, transmit, or receive electronic health records.[46] CMS has also created a set of exceptions for the provision of **community-wide health information systems** and **electronic prescribing items and services**.[47] Taken together, this set of exceptions allows a healthcare entity to ensure that its providers' information systems are consistent and interoperable, which facilitates integration and assists in smoother care coordination.

CMS also allows healthcare entities to provide limited amounts of other non-monetary compensation to providers.[48] In the value-based payment context, this may include limited training, care coordination services, and other services a hospital may wish to provide to assist community physicians in achieving their cost and quality goals.

Non-monetary compensation is an interesting example of how ambiguity in the MPRL can discourage investment. The MPRL contains two potential protections that *might* cover non-monetary compensation, but also may not. Under the MPRL, "amounts paid under a bona fide employment agreement" are not considered prohibited compensation.[49] Similarly, the provision protecting independent contractor arrangements covers an "amount of remuneration."[50] It is not clear that non-monetary compensation like an EHR system may be considered an "amount" paid

[44] Md. Health Occ. Code 1-301(c)(2)(iii).

[45] 42 U.S.C. § 411.357(n).

[46] 42 C.F.R. § 411.357(w).

[47] 42 C.F.R. § 411.357(u) & (v).

[48] 42 C.F.R. § 411.357(k).

[49] Md. Health Occ. Code § 1-301(c)(2)(ii).

[50] Md. Health Occ. Code § 1-301(c)(2)(iii).

to an employee under these provisions. In addition, it is unclear whether the provision of non-monetary compensation to a physician *group* could be considered an "independent contractor" arrangement for purposes of the provision protecting such arrangements.[51] Notably, the MPRL contains a set of broad exemptions limited to hospitals, which may limit the scope of possible innovative arrangements – these would continue to be protected under our proposal.[52]

The MPRL is also missing a number of important exceptions structuring relationships between physicians and other healthcare entities (particularly hospitals). In particular, the federal Stark law includes a specific exception for **payments by a physician** (so long as they are fair market value, and a more specific exception does not apply).[53] This allows physicians to purchase certain items or services from healthcare entities (including hospitals). This is important in the value-based payment context because important infrastructure and management services are often provided at the hospital level. This exception allows physicians to pay hospitals for these services on an extremely flexible basis. Moreover, this is a pragmatic acknowledgement that patient referral laws, which are intended to address potential influences on referral sources, should be less implicated by payments *from* a referral source.

Similarly, the Stark law contains a specific exception protecting **medical staff benefits** provided by a hospital. For example, the Stark law excepts incidental benefits provided by a hospital to its medical staff, so long as this compensation meets certain formal standards.[54] In part, this means the compensation must be offered to all staff members in the same specialty without regard to the volume or value of referrals, and the compensation must be available on the hospital's campus at times when the physician is making rounds or otherwise providing services to the hospital or patients (with certain exceptions for advertising and remote access).[55] Again, this allows a hospital to provide information technology, management services, accessibility services, and other common infrastructure to its medical staff in a way that allows it to manage costs and improve coordination.

In another example of the federal government's acknowledgment of evolving healthcare business norms, CMS has acknowledged that certain purely technical violations that are timely corrected should not give rise to liability. For example, CMS has created an exception for temporary non-compliance with signature requirements, for arrangements that otherwise satisfy the other elements of an applicable exception (for example, a written lease with fair market value terms).[56] In this event, Stark liability does not apply if the parties obtain a signature within ninety (90) days of the noncompliance (if inadvertent) or thirty (30) days (if not inadvertent).[57] Temporary noncompliance with other requirements may also be forgiven once every three years, if certain terms apply, including that the financial relationship satisfied the terms of an exception for at

[51] Id.

[52] Md. Health Occ. Code § 1-301

[53] 42 C.F.R. § 411.357(i).

[54] 42 C.F.R. § 411.357(m).

[55] Id.

[56] 42 C.F.R. § 411.353(g).

[57] Id.

least one hundred-eighty (180) days, the non-compliance was "beyond the control of the entity," and the entity promptly takes steps to rectify the non-compliance.[58]

CONCLUSION:

This is a historic moment for healthcare payment policy, as the fee-for-service system that has traditionally dominated reimbursement evolves into a new, more collaborative set of policies. At the same time, the fraud and abuse framework is currently in a state of flux as policymakers at the state and federal level attempt to respond to the risks and incentives of these arrangements. Given the commitment of CMS and Congress to value-based payment, it is clear that the federal government are well on their way to creating a fraud and abuse solution to allow all providers to participate in these post-fee-for-service models. This evolution of federal law could cause significant disruption for Maryland providers, as any permanent solution will likely represent a substantial discrepancy between state and federal law. As healthcare practitioners and entities invest time, money, and energy to create innovative new solutions under these payment policies, it is vitally important that all parties trust that Maryland will keep pace with federal law.

Finally, we acknowledge that certain arrangements discussed above may be available here in Maryland despite the important differences between state and federal law. In many cases this represents ambiguity within the MPRL. **Because of the limited amount of case law interpreting the MPRL, its exact scope and reach is still largely undefined. This ambiguity represents a risk to providers and healthcare entities, which will continue to limit experimentation and innovation**. In other cases, although Maryland law allows the same outcome as federal law, the method for doing so is extremely complex and technical. In an era that incentivizes efficiency and the reduction of waste, it is unwise to require healthcare providers and entities to comply with multiple sets of redundant, but differently framed, regulatory schemes. This is particularly true as both the payment models and the fraud and abuse framework governing them rapidly evolve.

As such, we recommend that a new exemption should be added to Maryland Health Occupations Code § 1-302(d), stating that notwithstanding any other provisions of the MPRL, the MPRL will not prohibit any arrangement that is allowable under the federal Stark law statute, its current and future implementing regulations, or any applicable federal waivers.

Sincerely,

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Dr. Nicholas Grosso
Dr. Arnold Levy
Members, MHCC Provider/Carrier Workgroup – Study on Self-Referral

[58] 42 C.F.R. § 411.353(f).

STATE OF MARYLAND

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AGENDA

Provider/Carrier Workgroup- Study on Self-Referral

November 3, 2015

3:00 pm- 5:00 pm

Building General Consensus

A. General Findings and Status

B. Presentation on Consensus Principals from MHA and MPCAC
   a. Nicole Stallings/ Dr. Levy

C. Plans for Report
   a. Submission to MHCC
   b. Submission to Committees

MHCC Payor-Provider Workgroup Discussions— Consensus Points

The Maryland Hospital Association and Maryland Patient Care and Access Coalition believe that the efforts of the Work Group have revealed the following **points of general consensus** that could form the basis for an initial, written work product from the Work Group to Chairman Hammen and the rest of the HGO Committee regarding potential modernization of the Maryland Patient Referral Law (MPRL):

- The Affordable Care Act, innovative private payor arrangements, and Maryland's all-payer hospital agreement have created in Maryland a more rapid move toward **value-based payment and provider integration**.

- The opportunities presented by a value-based payment system are **fundamentally different** from those in the traditional fee-for-service system.

- **The Maryland Patient Referral Law (MPRL) should be modernized to allow for the development of new bona-fide value-based payment models, risk-sharing arrangements, and alignment models**. The work group effort has resulted in general consensus that **greater clarity is needed** to ensure that emerging compensation arrangements under these models are permissible.

- This aim can be achieved by **working within the current MPRL framework**, which covers referrals involving all payors (government, commercial, private), applies to all health care practitioners (not just physicians as under the federal Stark law), and applies to all health care services (not just designated health services or entities providing designated health services as under the federal Stark Law).

- Maryland should consider **incorporating the elements from the federal Stark law** that can enhance the MPRL to provide payment clarity, predictability and stability to health care practitioners as they consider partnerships and new models designed to achieve value-based payment goals.

- Changes **should neither repeal the MPRL nor replace it with the federal Stark Law.**

- The well-being of patients must be paramount in the evaluation of any changes to the MPRL. Accordingly, any changes considered **must not diminish important protections for patients against inappropriate utilization or costs of healthcare services.**

- Any revisions to the MPRL **cannot jeopardize Maryland's all-payer rate setting agreement** with the federal government, which requires reduction in inappropriate utilization and strict limits on health care spending, both in and outside of the hospital.

Ben Steffen of the Maryland Health Care Commission opened the meeting with introductions and reviewed the work of the group so far. Mr. Steffen stated that a number of attorney's were consulted and all agreed that they would be unable to definitively answer the question, "do value-based arrangements violate the MPRL?" without specific facts about the particular arrangement. Mr. Steffen did note that, since the Maryland law was conceived from Stark, and purposely created as more restrictive then Stark, if an exemption is required from Stark, it would follow that an exemption would be required from the MPRL.

Nicole Stallings of the Maryland Hospital Association and Dr. Arnold Levy, of the Maryland Patient Care and Access Coalition, then presented a consensus document. The document outlined basic principles to serve as the foundation for changes to the MPRL and/or corresponding regulations to allow for new value based arrangements and recognize the changes to the healthcare landscape.

Dr. Loralie Ma and Pegeen Townsend of MedStar Health stated that, prior to making changes to statute, it would be important to exhaust all avenues for changes to regulation to allow new value based payment models.

Dr. Gary Pushkin advised the group to unify as physicians and health care providers and come together around the idea that the MPRL is outdated and needs to be changed.

Dr. Ajrawat reminded the group that the well-being of patients is the most important consideration.

Mr. Steffen reviewed next steps. Staff will write and circulate a report which will be presented to the Maryland Health Care Commission on November 19th. The report will be delivered to Chairman Hammen by December 1, 2015. He closed encouraging the stakeholders to continue to work together going into session.