Maryland Provider-Carrier Workgroup-Study on Maryland's Self-Referral Statute

Health and Government Operations Committee

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The Maryland Health Care Commission (MHCC) is an independent regulatory agency whose mission is to plan for health system needs, promote informed decision-making, increase accountability, and improve access in a rapidly changing health care environment by providing timely and accurate information on availability, cost, and quality of services to policy makers, purchasers, providers and the public. The Governor, with the advice and consent of the Maryland Senate, appoints fifteen Commissioners who broadly reflect the perspectives of consumers, employers, health care providers, and insurance carriers. This report presents the work of the Health Care Provider-Carrier Workgroup that assessed possible changes in the Maryland Patient Referral Law. MHCC acknowledges the work of Discern Health LLC., in staffing the Workgroup and in developing the final report.

Executive Summary

The Health Care Provider-Carrier Workgroup was charged with developing recommendations to the Health and Government Operations Committee to review and recommend possible modifications to the Maryland Patient Referral Law (MPRL). The MPRL prohibits a health care practitioner from referring a patient or directing an employee or a person under contract with the health care practitioner from referring a patient to a health care entity in which the health care practitioner has a beneficial interest or a compensation arrangement unless the health care practitioner meets one of eleven specific exemptions set forth in the statute, including one that is known as the "in-office ancillary services" exemption. As the Workgroup learned over the course of its work, the MPRL is broader than—and differs from—the federal self-referral law (known as the Stark Law) in several significant respects. MPRL covers all health care practitioners licensed or certified under the Health Occupations Article. The law governs all health care services provided by health care practitioners to patients insured by commercial payors, Medicare, and Medicaid. The MPRL includes a narrower definition of "in-office ancillary services" than its federal counterpart by excluding from the exemption referrals of Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and radiation therapy services by non-radiology practices.

To broaden discussion and focus on value-based care, Maryland Health Care Commission (MHCC) staff asked the Workgroup to consider reforms that would allow greater flexibility and clarity in forming financial arrangements if providers committed to taking greater accountability for delivering high value, high quality care. Workgroup members offered proposals to: launch new programs while maintaining the status quo; define new exemptions under the existing law; launch new pilot programs; and align Maryland with the federal "Stark" law.

The Workgroup agreed that MPRL needed modernization. The Workgroup reached consensus on eight general principles that could provide the framework for specific changes to the MPRL. The eight principles are presented on page 8 of the report. These principles affirm the importance of modernizing the MPRL within the statute's current framework, while aligning the statute with new value-based payment models and risk-sharing arrangements that are fostered by the Affordable Care Act and the new hospital payment model. When appropriate, Maryland may wish to incorporate exemptions in the MPRL that have been already implemented as "Stark" waivers. The eight principles reflect the Workgroup's agreement that greater clarity is needed to promote greater innovation and experimentation around the new payment models.

Introduction

Maryland payors and providers are committed to implementing innovative models of health care delivery that improve quality, enhance patient experience, and control costs. As the importance of integrated care continues to grow, there is a need to modernize the State's self-referral law, known as the Maryland Patient Referral Law (MPRL). This approach is consistent with the approach the federal government has taken. For example, the Affordable Care Act permits the Secretary of the Department of Health and Human Services to waive application of the federal Stark Law to Accountable Care Organizations (ACOs) under programs like the Medicare Shared Savings Program. As ACOs and other risk sharing arrangements develop, health care organizations will seek to better align to coordinate patient care. Health care practitioners seeking to collaborate in delivering coordinated care to patients, and those looking to embrace value-based payment models as our health care system moves away from strictly fee-for-service payment structures, will benefit if there is greater clarity in the MPRL.

Background on the Law

The MPRL (Health Occupations Article § 1-301, *et seq*.) was passed by the General Assembly in 1993. The original law addressed the rising costs of health insurance and medical care. The MPRL is a broad statute. It goes beyond its federal counterpart in Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also commonly referred to as the "Stark law," to all health care practitioners licensed under the Maryland Health Occupations Article who deliver services to patients covered by Medicare, Medicaid, and the commercial insurance market. Moreover, the MPRL is not limited to "designated health services" as defined in Stark, but instead extends to all health care services.

Under the MPRL, any physician or health care practitioner is prohibited from referring a patient, or directing an employee or contractor of the practitioner to refer a patient, to a health care entity in which the practitioner, or the practitioner in combination with his or her immediate family, owns a beneficial interest in the entity or the practitioner, the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family, has a compensation arrangement with the entity.[1] The MPRL prohibits a health care entity or a referring health care practitioner from presenting to any individual, third party payor, or other person a claim, bill, or other demand for payment for health care services provided as a result of a prohibited referral. A health care practitioner who fails to comply with provisions of the statute is subject to disciplinary action by the health occupation board that licenses the health care practitioner. Payors are afforded remedies to recover payments that result from a

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

prohibited referral under Maryland Health Insurance Article § 15-110(c)-(f) for insurance products and under Maryland Health-General Article § 19-712.4 (a)-(e) for HMO plans.

The MPRL contains 11 exemptions from the prohibitions on self-referral in the MPRL. Of particular note, exemptions in Health Occupations §1-302(d)(2)-(4) permit referrals that would otherwise be prohibited if the referral of the patient is from one health care practitioner to another health care practitioner in the same group practice [(d)(2)], if the referring physician refers the patient to a health care entity for services or tests and either personally performs or directly supervises the services or tests [(d)(3)], or if the health care practitioner refers for in-office ancillary services or tests under certain conditions [(d)(4)]. Also of note, the exemption in §1-302(d)(5) allows the Secretary of the Department of Health and Mental Hygiene (DHMH) to grant an exception if a health care practitioner's beneficial interest is essential to finance the health care entity and the service is needed to ensure appropriate access for the community to the services provided at the health care entity. The next three exemptions protect certain arrangements between practitioners and hospitals.

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

The provision of the MPRL that has been the subject of the most attention, particularly over the last decade, is the definition of "in-office ancillary services." The MPRL defines permitted in-office ancillary services in Health Occupations §1-301(k) by expressly excluding MRI, radiation therapy, and CT services from the definition of "in-office ancillary services" for all physician groups or offices except for those consisting solely of one or more radiologists. This specific provision has been the subject of significant attention and, after a 2004 Attorney General's Opinion stated that the law barred self-referral for advanced imaging, the target of repeated efforts at reform.[2,3,4,5,6,7,8]The question of whether non-radiology practices were permitted to self-refer for advanced imaging was resolved in 2011 when the Maryland Court of Appeals, in *Potomac Valley Orthopaedic Associates (PVOA), et al. v. Maryland Board of Physicians (MBP),* affirmed the declaratory ruling by the MBP that the prohibition against physician self-referrals applies to an orthopedic surgeon's referral of a patient to another health care provider in the same group practice for a MRI or a CT scan.[9] In affirming the MBP's declaratory ruling, the Court of Appeals also rejected the appellants' claims that the self-referrals at issue were permitted under the exemptions in Health Occupations §1-302(d)(2)-(3) referenced above.

[2] 89 Op. Att'y Gen. 10, 17 n.8 (Jan. 2004).
[3] H.B. 849, 424th Gen. Assem., Reg. Sess. (Md. 2007).
[4] S.B. 708, 425th Gen. Assem., Reg. Sess. (Md. 2008).
[5] H.B. 673, 426th Gen. Assem., Reg. Sess. (Md. 2009)
[6] H.B. 324, 427th Gen. Assem., Reg. Sess. (Md. 2010)
[7] H.B. 782 , 428th Gen. Assem., Reg. Sess (Md. 2011)
[8] H.B. 408, 429th Gen. Assem., Reg. Sess. (Md 2012)
[9] 417 Md. 622 (2011)

The application of the MPRL to in-office MRI and CT services is the only aspect of the MPRL that has been tested in the courts. This particular section shapes many practitioners' position on the entire law. In a volume driven health delivery system, there is reason to be concerned about self-referral for these services, especially when fee levels for these services are very favorable. Since 1993, many studies have concluded that ordering of advanced imaging and other services grows after practitioners obtain a financial stake in the service or capability that accounts for the self-referred service.[10,11,12] More recently, several studies have yielded more nuanced results and reimbursement levels for advanced imaging has declined for all providers.[13,14] Health reform's focus on greater integration of care and the shift away from fee-for-service reimbursement to value-based payment models and risk-sharing arrangements may not align well with current self-referral laws at either the federal or State levels.

Interest in modifying the MPRL continued after 2011. In 2013, legislation was introduced to require the Department of Health and Mental Hygiene to study the question of whether use rates for MRIs declined after practices lost the ability to self-refer.[15] The legislation did not pass, but the Chairman of the HGO committee, at the conclusion of the 2013 session, requested that MHCC 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.[16] 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 had not owned this equipment.

The results from the MHCC study supported certain arguments of both proponents and opponents of the prohibition on self-referral for advanced imaging in the current MPRL. Proponents pointed to the findings that utilization rates of MRI did not change for the 'ownership' practices after divestiture of the equipment. The MHCC study also found that utilization rates among ownership practices were higher than for a comparison group, which opponents pointed to as evidence for continuing the prohibition. In its 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:

[10] Baker, Lawrence. "Acquisition of MRI Equipment by Doctors Drives Up Imaging Use and Spending." Health Affairs 29.12 (2010): 2252-2259.
[11] General Accountability Office, "Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions," GAO-12-966 (Washington, D.C. September, 2012).
[12] Shreibait, Jacqueline B. and Baker, Lawrence C. (2011) "The Relationship between Low Back Magnetic Resonance Imaging, Surgery and Spending: Impact of Physician Self-Referral Status." Health Services Research 46.5(2011) 136
[13] Lawrence Casalino, "Physician self-referral and physician-owned specialty facilities", Research Synthesis Report The Robert Wood Johnson Foundation, 2008
[14] General Accountability Office, "Medicare Physical Therapy: Self-Referring Providers Generally Referred More Beneficiaries but Fewer Services per Beneficiary," GAO-14-270 (Washington, D.C. April, 2014).
[15] H.B. 536, 430th Gen. Assem., Reg. Sess. (Md 2013)
[16] Assessment of Changes in Advanced Imaging Referrals by Orthopedists 2010-2012, MHCC, (2014)

- 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 these 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 its transmission letter that the transition to value based care was just getting underway and very few Maryland practices could meet the three criteria in January 2015.

Two groups sought to amend the MPRL in the 2015 legislative session.[17,18] The first bill broadly addressed self-referral, while the second bill focused on radiation oncology and non-diagnostic CT scan services for oncologists. Neither of the bills received a vote in the House of Delegates or the Senate.

The Health Care Provider Carrier Workgroup

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.[19] The Workgroup serves as a forum for identifying and resolving policy disputes among providers, carriers, and consumers. After discussions with MHCC staff at the conclusion of the 2015 Legislative Session, Del. Peter Hammen, Chairman of the Health and Government Operations Committee, requested that MHCC convene a Provider-Carrier Workgroup to examine the MPRL. The Chairman's charge to the MHCC was 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.

Although MHCC agreed to convene the Workgroup, the MHCC staff recognized that any agreement would be difficult as both supporters and opponents held strong positions. MHCC began its work cautiously, hopeful that the evolution toward value-based payment arrangements in the underlying health care environment would lead to greater collaboration among the stakeholders.

MHCC selected members for the Workgroup from payors, hospitals, and members of the medical specialty societies that have been involved in this debate. In addition, several

[17] H.B. 683, 432nd Gen. Assem., Reg. Sess (Md. 2015)
[18] H.B. 944, 432nd Gen. Assem., Reg. Sess (Md. 2015)
[19] Health General §19-108.3 Health Care Provider-Carrier Workgroup

consumer representatives, the Maryland Board of Physicians, the Health Services Cost Review Commission, and the Health Education and Advocacy Unit of the Office of the Attorney General were invited to participate in the Workgroup. Members of the Workgroup are listed in Appendix A.

As convener, MHCC developed the work plan, identified approaches for clarifying potential areas for agreement, facilitated discussion during five Workgroup meetings, and worked between meetings to maintain the momentum toward consensus. MHCC used the framework presented in the Commission's transmittal letter as a starting point for discussion among the Workgroup members.

At the first meeting in June and the second meeting in July of 2015, MHCC presented the historical background and context for how and when the Maryland law was enacted, comparisons with federal Stark law, and recent studies and cases that tested it. Representatives from hospitals, several specialty societies, and the Board of Physicians shared their perspectives on self-referral policies, the current law, and their interest in modernization of the law, or maintenance of the status quo. Much of the discussion focused on the longstanding and hotly debated issue of patient referrals for MRI, radiation oncology, and CT services. There were few areas of consensus.

At the third Workgroup meeting, MHCC staff broadened the discussion by examining the impact of value-based payment models on physician accountability. Workgroup members described various alternative payment models, such as shared savings and gainsharing within their practices and health plans, and MHCC presented similar examples from the federal government through Medicare. By the end of the third meeting, MHCC staff concluded that the best known feature of the MPRL, the provision that carves out MRI, CT and radiation therapy services from the exception that protects referrals for in-office ancillary services, was not necessarily representative of the types of arrangements that stakeholders wished to develop. MHCC staff determined that focusing on imaging alone was too narrow, and identified the need to refocus the Workgroup in an effort to achieve broad consensus.

In the fourth meeting, Workgroup members were encouraged to think more broadly, particularly with regard to changes in the MPRL that would provide greater certainty about the permissibility under Maryland law for value-based initiatives. The time allocated to allowing members to present and react to various options was particularly useful in the fourth meeting. At the conclusion of the meeting, Workgroup members had built greater trust and agreed to continue to discuss areas of potential areas of agreement.

At the conclusion of the fourth meeting, MHCC staff recognized that the proposals had generated no consensus among the Workgroup. Rather than focus on a specific course of action, all the parties agreed that it would be possible to develop consensus on a set of general principles for modernizing the MPRL. In the interim between the fourth and fifth meeting, the

Maryland Hospital Association and the Maryland Patient Care and Access Coalition continued to discuss the general principles that would be the basis for consensus.

The fifth and final meeting was used to confirm the consensus the Workgroup achieved through the process. All materials, including agendas, presentations, and meeting summaries of the five Workgroup meetings are presented in Appendices D – H.

Agreement and Conclusions

MHCC identified a range of positions among Workgroup members. Some members felt no action was necessary as adequate clarity and structure already existed in the statute for physicians to pursue value-based models. These Workgroup members also argued that a process under the authority of the Secretary of DHMH already existed for practitioners to seek an exemption from the MPRL. Another practitioner group sought to align the MPRL with emerging payment models and value-based care by developing pilot programs for integrating community oncology (radiation therapy and medical oncology together in a group practice). Oher Workgroup members argued that the only way to allow physicians to pursue innovative payment and care delivery models was to replace the MPRL with the Stark law or to make already established Stark exemptions controlling under Maryland law. Advocates for MPRL repeal argued that the MPRL is broad and that prohibitions and exemptions are vaguely defined. They noted that, except for self-referral for advanced imaging and radiation oncology, little in the law has been clarified by the courts. This group warned that the MPRL law creates uncertainty that stifles innovation, investments, and efforts to develop value-based care.

Many Workgroup members had formed strong opinions largely based on the well-publicized and controversial restriction on self-referral for Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and radiation therapy services by non-radiology practices. Many Workgroup members were not aware of the broad sweep of the MPRL and its possible impact on reform initiatives. During the last several meetings, the Workgroup was able to put the controversial issue of self-referral for radiology services to the side and consider how the broad restrictions in the law might inhibit innovation, collaboration, and accountability. The Workgroup found that putting aside the most sensitive issue enabled the members to reach a consensus on a framework for modernization.

General Principles Agreed to by the MHCC Provider-Carrier Workgroup

At its last meeting, the Workgroup agreed that the following points of general consensus could form the basis for a report from the Workgroup to Chairman Hammen and the HGO Committee regarding potential modernization of the Maryland Patient Referral Law:

- The Affordable Care Act, innovative private payor arrangements, and Maryland's all-Payor 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 additional bona-fide value-based payment models, risk-sharing arrangements, and alignment models. The Workgroup 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-payor 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.

These general principles serve as a starting point for considering if any new compensation arrangement under public or private value-based payment models should be permitted under an exemption in the MPRL or accompanying regulations.

MHCC recognizes that some Workgroup members envisioned that specific recommendations for modernizing the statute would emerge; however, MHCC has determined that specific recommendations are premature. Due to the complex nature of the statute, achieving a consensus-based policy action to revise the MPRL requires multiple levels of stakeholder collaboration and agreement.

The MHCC commends the Workgroup members for their commitment to the process and success in developing the general principles and believes that these principles can serve as a foundation for further collaboration among stakeholders as they work with the General Assembly to develop meaningful modifications to the MPRL.

Appendices

A. Workgroup Members
B. MHCC Letter to Committee regarding Three Recommended Criteria for Possible Exception
C. MHCC MRI Report
D. Meeting 1
    1. Agenda
    2. Materials
    3. Notes
E. Meeting 2
    1. Agenda
    2. Materials
    3. Notes
F. Meeting 3
    1. Agenda
    2. Materials
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G. Meeting 4
    1. Agenda
    2. Materials
    3. Notes
H. Meeting 5
    1. Agenda
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