



MARYLAND HEALTH CARE COMMISSION

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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