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,

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[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).