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,

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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,

[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

[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

[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

[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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[58] 42 C.F.R. § 411.353(f).