

Affordable Care Organizations in Michigan

A Whitepaper on ACOs and Michigan Law

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FOREWORD

A cornerstone of health care reform is the development of a new patient care model, known as an accountable care organization (“ACO”), that is designed to reduce fragmented or unnecessary care and excessive costs for Medicare fee-for-service beneficiaries. The Patient Protection and Affordable Care Act of 2010¹ (the “ACA”) authorized the creation of the Medicare Shared Savings Program, which allows providers to share in the cost reductions associated with more effective health care.

While much has been written about ACOs on a federal level, ACOs must exist as a legal entity formed under state law – and accordingly, operate in compliance with those state laws.

The purpose of this Whitepaper is to provide an overview of the key issues associated with organizing, creating, and operating an ACO, and the relationship between the ACO objectives on a federal level and the unique constraints of Michigan law. As ACOs are yet in their infancy, it is impossible to provide a detailed blueprint on how ACOs should or will function. Rather, this Whitepaper will highlight the key issues that health care providers and their counsel must consider when forming or participating in an ACO.

PART ONE - FORMATION AND GOVERNANCE

I. BACKGROUND ON ACO FORMATION AND GOVERNANCE

A. What is an ACO?

ACOs are legal entities that either manage and coordinate care, or provide care (as in the case of hospitals and physician groups) for Medicare fee-for-service beneficiaries under the Medicare Shared Savings Program ("MSSP"). These legal entities are intended to promote integrated healthcare by incentivizing participating providers and suppliers to work together to provide high quality and efficient care.²

ACOs are designed around three fundamental principles: 1) to improve care for its beneficiaries; 2) to enhance health in its population; and 3) to reduce the growth of its beneficiary expenditures. In practice, these principles require ACO participants to utilize evidence-based medicine and promote patient engagement to achieve measured quality improvements. Ultimately, ACOs are held accountable for improving the quality and reducing the cost of care for their patient populations. Importantly, if an ACO is able to reduce the cost of care and satisfy the performance requirements established by the Centers for Medicare and Medicaid Services ("CMS"), the ACO is eligible to receive a portion of the shared savings it generates.³

B. Who can Form and Participate in an ACO?

Under the ACA and federal regulations, there is a distinction between individuals and entities that are permitted to *form* an ACO, and those that are merely allowed to *participate* in an ACO that has already been created. To demonstrate the difference, it is helpful to have an understanding of key ACO terms.

Generally, an ACO "**participant**" is an individual or group of ACO providers/suppliers that alone or together with one or more other ACO participants comprises an ACO.⁴ Each participating provider or supplier must be identified by a Medicare-enrolled Taxpayer Identification Number ("TIN"). However, an ACO participant will not be eligible to be part of an ACO unless all of the providers/suppliers that bill through its TIN agree to participate in the ACO, and are in compliance with the requirements of the MSSP.⁵

A "**provider**" is a hospital; Critical Access Hospital ("CAH"); skilled nursing facility; comprehensive outpatient rehabilitation facility ("CORF"); home health agency; hospice participating in Medicare; clinic, rehabilitation agency, or public health agency that participates in Medicare (but only to furnish outpatient physical therapy or speech pathology services); or community mental health center that participates in Medicare (but only to furnish partial hospitalization services).⁶

A "**supplier**" is a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.⁷

An ACO "**professional**" is an ACO provider/supplier who is either: 1) a physician legally authorized to practice medicine and surgery by the State in which he or she performs such

function or action; or 2) a practitioner (a physician assistant,⁸ a nurse practitioner,⁹ or a clinical nurse specialist¹⁰).¹¹

Currently, there are seven groups of ACO participants eligible to *form* an ACO. These ACO participants are:

- 1) ACO professionals in group practice arrangements;
- 2) Networks of individual practices of ACO professionals;
- 3) Partnerships or joint venture arrangements between hospitals and ACO professionals;
- 4) Hospitals employing ACO professionals;
- 5) CAHs that bill under Method II;¹²
- 6) Rural Health Clinics ("RHC");¹³ and
- 7) Federally Qualified Health Centers ("FQHC").¹⁴

Each of the seven ACO participants that are eligible to form an ACO are centered around ACO professionals. ACO professionals are considered to be the foundation of an ACO because ACOs are designed to be provider-led organizations. For example, the clinical management and oversight of an ACO must be managed by a senior-level medical director who is a physician; one of its ACO providers/suppliers; and who is physically present on a regular basis at any clinic, office, or other location participating in the ACO.¹⁵ The leading role of ACO professionals allows ACOs to develop best practices, cost-effective strategies, and patient-centric policies based on the professionals' tacit knowledge of providing care that will ultimately contribute to the proper level of patient utilization on the health system. Therefore, it is not surprising that an ACO can only be formed with the participation of an ACO professional.

ACO professionals and ACO professional entities are not the only Medicare-enrolled providers and suppliers that are eligible to *participate* in an ACO. Skilled nursing facilities; pharmacies; CORFs; home health agencies; nursing homes; Medicare-enrolled hospices; certain Medicare-enrolled outpatient clinics, rehabilitation agencies or public health agencies; long-term care hospitals; and certain Medicare-enrolled community mental health centers are also permitted to participate in an existing ACO by way of a contractual relationship.¹⁶ The coordination and cooperation between these two categories of ACO participants is critical to improving care for patients, enhancing the health of communities and reducing the growth of Medicare expenditures. Together, these ACO participants create an integrated healthcare system that is accountable for a patient population.

In order to promote integration and achieve synergies throughout the healthcare system, the federal regulations require that each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO.¹⁷ A meaningful commitment may include a sufficient financial or human capital investment (time and effort) in the on-going operations of the ACO.¹⁸ The potential loss or recoupment of these types of investments is

likely to motivate the ACO participant and ACO provider/supplier to maximize their efforts to achieve the ACO's mission under the MSSP.¹⁹ A meaningful commitment may also be demonstrated by an ACO participant or ACO provider/supplier agreeing to comply with and implement the ACO's processes, and to be held accountable for meeting the ACO's performance standards for each required process.²⁰ Ultimately, the meaningful commitment of each ACO participant and each ACO provider/supplier will align the objectives of each individual or entity with that of the ACO.

C. ACO Legal Structure

The ACA and federal regulations require that an ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates.²¹ In addition to this requirement, the federal regulations establish four additional principles related to the legal structure of ACOs. First, the legal structure must allow the entity to receive and distribute payments for shared savings to participating providers and suppliers.²² Second, the structure must also allow for the repayment of shared losses or other monies determined to be owed to CMS.²³ Third, the legal structure must permit mechanisms for establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.²⁴ Finally, the legal structure must allow the ACO to fulfill the governance, leadership and management and patient-centeredness criteria of the MSSP.²⁵

ACO participants are not always required to create a new legal entity to operate an ACO under the MSSP. If an existing legal entity wishes to form an ACO, CMS will allow it to do so, as long as the existing entity has a structure that supports the four principles outlined above and is composed of eligible ACO participants.²⁶ However, if a proposed ACO is comprised of multiple, otherwise independent ACO participants, the federal regulations require that the ACO participants form an independent legal entity to operate the ACO.²⁷ This would also be true if a potential ACO participant consists of providers/suppliers that decide not to join the ACO. Even if an existing legal entity wishes to form an ACO under its current corporate form, it may need to consider whether that structure will allow it to evolve as an integrated healthcare system to meet the changing needs of its patient population.

As will be discussed below, an ACO may be formed as a partnership, corporation, limited liability company ("LLC"), foundation or other legal entity permitted under applicable State, Federal, or Tribal law. As with any other business venture, the decision concerning which corporate structure to utilize involves a detailed analysis of the entity's corporate strategy, organizational mission, goals and objectives and business needs. In addition, eligible ACO participants must consider the set-up process, taxation, liability and management/control characteristics of each of the available corporate forms in deciding which corporate structure to implement. This process can be complex, especially if a proposed ACO will involve numerous, independent entities. Ultimately, the decision regarding the corporate structure for the ACO should involve all ACO participants.

D. ACO Governance and Governing Body

According to the ACA, an ACO must establish a mechanism for shared governance.²⁸ Under the regulations, an ACO must maintain an identifiable governing body with authority to execute the functions of an ACO.²⁹ In doing so, the ACO must ensure that ACO participants and their designated representatives have meaningful participation in both the composition and control of the ACO's governing body.³⁰

As noted above, ACOs are designed to be provider-led organizations. As such, at least 75 percent of the control of the ACO's governing body must be held by ACO participants.³¹ In addition, the ACO governing body must include at least one Medicare beneficiary representative served by the ACO who does not have a conflict of interest with the ACO, and who does not have an immediate family member with a conflict of interest with the ACO.³² The Medicare beneficiary representative's role is to ensure that patients' interests are properly represented as the ACO seeks to improve care for beneficiaries and enhance health in the population.³³ The governing body members may serve in a similar or complementary manner for an ACO participant.³⁴

It should be noted that an ACO may be able to form a governing body that deviates from the ACO participant and Medicare beneficiary requirements. However, in order to do so, the ACO must describe to CMS why it seeks to differ from these requirements, and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.³⁵ This permitted deviation will play an important role for certain ACO participant entities that wish to form an ACO in light of applicable Michigan law.

The type of governing body used by an ACO will depend on the corporate structure, which will be discussed in more detail below. If an ACO is formed as a corporation, the governing body will likely be a Board of Directors as established by the by-laws of the corporation. If a Michigan corporation does not have a Board of Directors, then there must be a Section 488 Agreement among the shareholders or provisions in the Article of Incorporation providing an alternative governing structure.³⁶ If an ACO is formed as an LLC, the governing body will likely be a Board of Managers under the terms of the operating agreement of the LLC. If an ACO is formed as a foundation, the governing body will likely be a Board of Trustees. Ultimately, the ACO may be governed by any governing body that establishes a mechanism for shared governance amongst the ACO participants. The flexibility in available governing bodies will be dictated by Michigan laws related to the management of the legal entity that is selected for the ACO's formation.

E. ACO Operations – Leadership and Management

Under the ACA, an ACO must have a leadership and management structure that includes clinical and administrative systems.³⁷ It is important to note that an ACO's leadership and management structure is designed to be a dual system.

First, the ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose leadership team has demonstrated the ability to influence or direct

clinical practice to improve efficiency processes and outcomes.³⁸ The appointment and removal of the ACO's operational leader must be under the control of the ACO's governing body.³⁹

Second, as noted above, the clinical management and oversight of the ACO must be managed by a senior-level medical director who is a physician and one of the ACO's providers/suppliers.⁴⁰ The medical director must be a board-certified physician, licensed in a State in which the ACO operates, and be physically present on a regular basis at a location participating in the ACO.⁴¹ Together, this dual system encourages ACOs to hire and develop leaders and managers with the knowledge, skills and experiences that are uniquely tailored to different aspects of the ACO. Ultimately, the leadership and management requirements outlined in the federal regulations will help ACOs be more effective in achieving the triple aims of the MSSP.

CMS believes that the foregoing leadership and management structure will help ACOs become successful participants in the MSSP. However, an innovative ACO is permitted to request that CMS consider a management structure that does not satisfy the dual system components outlined above.⁴² This request will have to be made during the ACO application process and be substantiated by documentation demonstrating how the proposed management structure would support the goals of the MSSP.

F. ACO Operations – Required ACO Professionals and Beneficiaries

In addition to the numerous requirements outlined up to this point, the ACA requires that an ACO must have at least 5,000 assigned Medicare beneficiaries to participate in the MSSP as an ACO.⁴³ The ACO must also include enough ACO professionals, namely primary care physicians ("PCPs"), to sufficiently provide care for the number of Medicare fee-for-service beneficiaries assigned to the ACO.⁴⁴ During the application process, CMS determines whether a proposed ACO has satisfied the requisite beneficiary threshold. In doing so, CMS evaluates the number of beneficiaries historically assigned to the applicable ACO participants during each of the three years preceding the proposed effective date of the ACO contract. If CMS has collectively assigned 5,000 or more beneficiaries to the ACO participants during each of these years, the proposed ACO will have satisfied the requisite beneficiary threshold.⁴⁵

If an ACO's assigned beneficiary population falls below 5,000 at any time during the performance year, the ACO will be issued a warning and placed on a corrective action plan ("CAP").⁴⁶ A CAP is designed to help a struggling ACO regain the required number of fee-for-service beneficiaries so that it may continue in the MSSP. There are a number of strategies that could be part of a CAP, including a strategic expansion of the ACO to add more PCPs to the organization. However, while under the CAP, the ACO remains eligible for shared savings and losses during that performance year and its minimal savings rate ("MSR") will be set at a level consistent with the number of assigned beneficiaries.⁴⁷ If the ACO's assigned number of beneficiaries does not return to at least 5,000 or more by the end of next performance year, the ACO's agreement with CMS will be terminated and the ACO will not be eligible to share in savings for that performance year.⁴⁸

In general, a Medicare fee-for-service beneficiary is assigned to an ACO based on a methodology related to the beneficiary's utilization of primary care services by a physician who

is an ACO provider/supplier during the performance year for which shared savings are to be determined.⁴⁹ Beneficiaries are assigned to ACOs at various intervals throughout a performance year. First, CMS assigns beneficiaries to an ACO, in a preliminary manner, at the beginning of a performance year based on most recent data available.⁵⁰ As noted above, the historical data for a newly formed ACO will include the data from ACO participants in each of the three years before the start of the agreement with CMS. Second, the beneficiary assignments will be updated quarterly based on the most recent twelve months of data.⁵¹ Finally, CMS will make a final determination as to the appropriate assignment of a fee-for-service Medicare beneficiary after the end of each performance year, based on data from the performance year.⁵²

The methodology used by CMS to assign fee-for-service Medicare beneficiaries to an ACO is referred to as a "step-wise methodology".⁵³ The methodology is designed to assign beneficiaries after identifying all patients that received at least one primary care service from a physician who is a provider/supplier of that ACO.⁵⁴

The first step in the methodology focuses on Medicare beneficiaries that received primary care services from PCPs both inside and outside of the ACO. Under this process, CMS identifies all primary care services provided to a beneficiary by PCPs (ACO PCPs and non-ACO PCPs) during either the most recent twelve months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment) or the performance year (for purposes of final assignment).⁵⁵ Then, the beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by the ACO's PCPs are greater than the allowed charges for primary care services furnished by PCPs in other ACOs, and PCPs not affiliated with an ACO but otherwise identified by a Medicare-enrolled TIN.⁵⁶ In essence, a Medicare beneficiary is assigned to an ACO if that beneficiary utilizes the primary care services rendered by PCPs of the ACO more than primary care services available from the remaining PCPs in the community.

The second step in the assignment methodology considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any PCP, either inside or outside the ACO.⁵⁷ The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers in *another* ACO, and other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO but otherwise identified by a Medicare-enrolled TIN.⁵⁸ Here too, a Medicare beneficiary is assigned to an ACO if that beneficiary utilizes the primary care services rendered by non-PCPs of the ACO more than primary care services available from the remaining non-PCPs in the community.

It should be noted that step-wise assignment methodology in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.⁵⁹ In fact, an ACO's beneficiary assignments are reevaluated at various intervals throughout a performance year to account for this free choice and the reality that some beneficiaries may choose to receive health care outside of the ACO.

G. ACO Operations – Required Processes and Patient-Centered Criteria

According to the ACA, an ACO must promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.⁶⁰ An ACO must also have a patient-centric focus that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams.⁶¹

The ACO must develop and define the processes it will use to achieve these criteria.⁶² For each process, the ACO must explain how it will require ACO participants and ACO providers/suppliers to comply with and implement the process.⁶³ The ACO must also include procedures and penalties to remedy an ACO participant's and/or ACO provider's/supplier's failure to implement and/or comply with the required process.⁶⁴ Finally, the ACO must address how it will employ its internal assessments of cost and quality of care to continuously improve the ACO's care practices.⁶⁵

There are four main categories of required processes outlined in the federal regulations. The processes in each of these categories should be continually evaluated and periodically updated once they are implemented in the ACO. First, an ACO must develop processes designed to promote evidence-based medicine.⁶⁶ Evidence-based medicine will help ACO participants and ACO providers/suppliers determine the best practices for patient treatment and improve clinical decision-making. Processes related to evidence-based medicine should cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.⁶⁷

Second, an ACO must create processes designed to promote patient engagement.⁶⁸ There are a number of areas that CMS believes will help ACOs achieve a patient centeredness in the organization. An ACO must create and implement a patient experience of care survey to generate data based on beneficiary feedback.⁶⁹ The ACO should utilize this information to develop ways to improve the quality of care. As discussed above, an ACO must also allow for a beneficiary representative to meaningfully participate in the governing body of the ACO.⁷⁰ An ACO will also promote patient engagement by crafting a process to evaluate the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.⁷¹ This plan should describe how the ACO intends to partner with community stakeholders to improve the health of its population.⁷² Finally, the ACO should develop processes that clearly explain clinical knowledge and evidence-based medicine to beneficiaries, encourage beneficiary participation, allow for shared decision-making and permit beneficiaries to have access to their medical records.⁷³

Third, an ACO must adopt an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics.⁷⁴ These metrics will enable the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.⁷⁵ The resulting data will also help ACOs set performance standards and expectations for additional ACO participants and ACO provider(s)/supplier(s) that seek to join the ACO at a later date.

Fourth, an ACO must implement processes to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers.⁷⁶ Federal

regulations require that an ACO define its methods and processes to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO).⁷⁷

II. MICHIGAN-SPECIFIC ISSUES PERTAINING TO ACO OPERATION AND GOVERNANCE

A. ACO Governance – Governing Activities

In order to comply with applicable ACO regulations, the ACO governing body will consist of representatives from ACO participants, Medicare beneficiaries, and patient advocates; each with a unique perspective on the goals and mission of the ACO. However, these representatives must work together with a single vision towards executing the functions of the ACO, including the processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.⁷⁸ This fiduciary duty includes operating the Accountable Care Organization ("ACO") in such a manner that allows the ACO to accomplish its mission as imposed by the regulations and the shared savings agreement entered into with CMS.

As set forth in the regulations, an ACO's mission is to operate in a patient-centric manner that promotes better health and strives for enhanced coordination of care and quality improvement across health care settings, resulting in the delivery of cost efficient health care. It is important to note that the reduction of cost is not an express goal of an ACO. In fact, the U.S. Department of Health and Human Services ("HHS") has stated that the ACO is not just a mechanism to control or reduce costs, but rather the ACO's mission and focus is to improve the delivery of care with the expectation that such improvement will also reduce the cost of providing that care.⁷⁹ It would be inconsistent to place cost reduction ahead of the stated mission of an ACO to develop a patient-centered health care delivery model. The governing body members of an ACO must act consistently with these regulatory fiduciary duties to further the mission of the ACO.

Thus, the ACO's governing body has many balls to balance in its governance role. It is tasked with providing guidance and support in the organization's achievement of its mission to maintain quality of care and patient satisfaction, while constantly assessing the impact of these two issues on the organization's performance, including appropriate levels of care, cost reductions, reimbursement, and collaboration among providers and practitioners. The board will be required to perform these duties in good faith and without turning a blind eye to any one of the foregoing issues. At times, the governing body will need to conduct self-assessments to recognize and monitor the issues before the board that require management of the conflicting pressures its board members face. In these situations, the governing body will want to assure adequate transparency of decision-making, use of advisory committees or having certain members excuse themselves from certain deliberations.

In addition to this regulatory fiduciary duty imposed on the governing body of the ACO, it will also have State law based fiduciary obligations as a governing body of a legal entity formed under Michigan law. Whether the ACO is formed as a non-profit entity, a for-profit entity, limited liability company or a professional service corporation, each of the laws

governing these entities impose fiduciary duties upon their governing bodies as to the legal entity and its owners (or, for nonprofits, its mission). In most cases, the regulatory-based fiduciary duty and the governing body's state-based fiduciary duty will be in alignment. However, the governing body's ability to make decisions and perform acts that further the ACO's regulatory mission may be in conflict with its state-based fiduciary obligations to the entity and its owners (e.g., a proposed action which would increase shared savings, but result in a delivery model that was not patient-centered or enhanced coordination of care for the patient).

In these situations, it will be critical for the governing body to understand both its state law obligations to act in a manner that will further the financial interests of legal entity and its owners, and the additional regulatory duty to act in a manner that furthers the patient-centric mission of the ACO. It is also important to note that the ACO Final Federal Regulations and the CMS Comments related to those Regulations stated that the "[m]embers of the governing body shall have a fiduciary duty to put the ACO's interests before the interests of any one ACO participant or ACO provider/supplier." Depending upon the underlying ownership structure, the ACO governing body may have state law fiduciary obligations to ACO Participants who are also the ACO owners, and must be aware of this regulatory obligation to place the ACO's mission above that of the owners/ACO Participants. These regulatory fiduciary duties in an ACO may be foreign to some members of ACO governing bodies. Thus, it will be critical that the ACO's governing body understands this added dimension when making decisions regarding the operation of the ACO.

Finally, the federal regulations require that an ACO governing body must have a conflict of interest policy that applies to members of the governing body.⁸⁰ The conflict of interest policy must require each member of the governing body to disclose relevant financial interests.⁸¹ A "relevant financial interest" would be one that has the potential to bias, or have the appearance of biasing an individual's decisions related to the ACO.⁸² The conflict of interest policy must also provide a procedure to determine whether a conflict of interest exists, and set forth a process to address any conflicts that arise.⁸³ Additionally, the conflict of interest policy must address remedial actions for members of the governing body that fail to comply with the conflict policy.⁸⁴ As noted above, the conflict of interest policy should apply to non-ACO participant members of the governing body, such as Medicare beneficiary representatives and consumer advocate representatives (for Pioneer ACOs).

B. ACOs and Michigan Business Entities

As discussed above, the ACA and federal regulations offer eligible ACO participants a great deal of discretion and flexibility in the formation of an ACO. An ACO may be formed as any legal entity permitted under applicable State, Federal, or Tribal law. Therefore, the fundamental issues are: 1) Can an ACO be formed as any of the business entities that exist under Michigan law?; and 2) If so, do the applicable corporate entities allow the ACO to satisfy the governance and operational requirements outlined under federal law?

C. Corporate Practice of Medicine

Generally, the corporate practice of medicine doctrine ("CPOM") prohibits a for-profit entity, either a corporation or limited liability company, from providing medical services unless

the entity is organized as a professional corporation or professional limited liability company. An entity that is not a nonprofit, PC or PLLC is prohibited from employing a physician to provide medical services and receiving fees for services rendered. The rationale behind the CPOM is that a physician's medical treatment decisions should be based upon the patient's best interests, and not the profit-making interests of the corporation. Proponents of the CPOM claim that it is necessary to maintain physicians' independent medical judgment, while critics argue that the CPOM limits the available options for innovating health care delivery. The CPOM continues to apply in Michigan. However, with the passage of the ACA and the Final Federal Regulations, the question remains whether an ACO can be formed and operated as a for-profit corporate entity without violating Michigan's CPOM.

The Michigan Business Corporation Act states that "[a] corporation may be formed under this act for any lawful purpose, *except to engage in a business for which a corporation may be formed under any other statute of this state.*"⁸⁵ Thus, in Michigan, a general business corporation (i.e. one formed under the Michigan Business Corporation Act⁸⁶) may not practice a learned profession because the Professional Service Corporation Act⁸⁷ and Limited Liability Company Act⁸⁸ specifically govern the formation of an entity to practice a learned profession.⁸⁹ The "learned professions" have historically consisted of physicians, attorneys and dentists, among others, in which a unique patient/client relationship exists and specialized training is required to obtain a license to practice such professions.

In an effort to allow these physicians, and other learned professionals, to employ the protections of a corporation, Michigan passed the Professional Service Corporation Act ("PSCA"). However, a corporation incorporated under the PSCA must be one in which each shareholder of such professional service corporation is fully qualified to perform all of the professional services rendered by the corporation. In addition to a professional services corporation, another exception to Michigan's CPOM allows non-profit corporations (including hospitals) to employ physicians to provide medical services.⁹⁰

Even though the PSCA and the Michigan Nonprofit Corporation Act allow the formation of corporate entities to provide physician services, the types of entities allowed to practice medicine are still very limited. CPOM influences how physicians can be hired, the terms under which contracts are entered into, and the means by which professional services can be legally provided. Therefore, at first glance, Michigan's CPOM appears to limit the types of permissible entities that can form an innovative entity structure aimed at the concepts prevalent in an ACO.

Today, the entities under which ACO participants can form an ACO essentially fall into two categories: (1) provider organizations; and (2) contractual organizations. Provider organizations are organizations that render professional services that may only be performed by a licensed health care professional. A group practice ACO is an example of a provider organization. As such, provider organizations must be careful to comply with Michigan's CPOM and structure their ACOs under a professional corporation, a professional limited liability company or a nonprofit organization. On the other hand, contractual organizations historically do not render professional services and do not employ licensed persons from a learned profession. A Physician-Hospital Organization ("PHO") is an example of a contractual organization. Instead, contractual organizations organize a network of health care providers through participation agreements with licensed professionals or their corporate entities and make

this health care network available to third parties. Nonetheless, the health care services are provided by the individual health care network participants and not the contractual organization. Since these contractual organizations do not provide professional services and only manage or oversee the health care network, they may be formed as for-profit companies. Therefore, for-profit contractual organizations can contract with CMS as an ACO and operate without violating Michigan's CPOM.

In the commentary to the ACO regulations, CMS was quick to note that the Shared Savings Program is not a managed care program. Rather, the design of the Shared Savings Program is to achieve savings through improvements in the coordination and quality of care, and not through avoiding certain beneficiaries or placing limits on beneficiary access to needed care.⁹¹ In order for the ACO to effectively achieve these goals of improvements in the coordination and quality of care, the ACO will have to take a more active role in the process of how care is rendered than historically provided by traditional managed care programs including, for example, the development of treatment protocols and processes. This enhanced role in the design, implementation and management of the delivery model should not raise CPOM issues for provider organizations.

However, in order to develop the innovative care models necessary to be successful as an ACO, the roles of contractual organizations will evolve into something very different from the traditional role played by a PHO or other managed care delivery entity. As the roles of contractual organizations change, it will be important for innovators to keep in mind the implications of Michigan's CPOM. For an ACO structured as a Michigan business corporation or limited liability company, the ACO will need to carefully assess how it implements its operation and the underlying coordination of care to assure that it has not engaged in the practice of medicine (without a license) or in violation of the CPOM.

D. State Insurance Considerations and Risk Sharing

In 1995, the National Association of Insurance Commissioners ("NAIC") published a Memorandum to State Insurance Commissioners ("Memorandum"), which was meant to bring to the attention of the States the issue of regulating, from an insurance licensure perspective, health care provider arrangements with an individual, employer, or other group that resulted in the provider assuming all or part of the risk for health care expenses or service delivery.⁹² The Memorandum informed the States that providers that assume capitation and similar risks are engaged in the business of insurance, and thus, implicate state health insurance laws. These providers that engage in the business of insurance must obtain the appropriate license from the State's Department of Insurance. Subjecting providers to state insurance licensure laws meant that these providers would be required to maintain significant capital reserves, which most providers would not be able to meet.

The NAIC, did, however, recognize an exception to this general position. An arrangement where a provider agrees to assume all or part of the risk for health care expenses or service delivery under a contract with a duly licensed health insurer, for that insurer's policyholders, certificate-holders or enrollees, is an arrangement that does not require the provider to obtain a license from the State's Department of Insurance.

As set out in the Final Federal Regulations, ACOs are based on a risk-sharing model. The amount of risk-sharing is based on which "Track" an ACO chooses. A Track 1 ACO does not take on risk during its first three years;⁹³ however, it is only allowed to take advantage of a strictly-shared savings model one time. Any subsequent agreements in the Shared Savings Program must be as a Track 2 ACO.⁹⁴ A Track 2 ACO shares in the losses for the entire three-year ACO agreement period.⁹⁵ This risk raises the need of an ACO to consider state insurance and managed care laws. These state laws regarding the bearing of risk may require an ACO to obtain a health plan or other managed care organization license or certificate in order to operate as a Track 2 ACO.

Several comments in response to the ACO Proposed Rule (as published in the ACO Final Federal Regulations) opined that ACOs that assume risk for losses and/or perform other health plan functions regulated at the state level (for example, subject to state financial and consumer protection standards) should have to meet the same standards required of health plans. These standards include financial requirements (for example, capital, reserve and solvency requirements); network requirements (such as ensuring access to adequate numbers and types of providers); filing, reporting and disclosure requirements; and quality improvement requirements, including accreditation standards and other consumer protection standards.⁹⁶

Other commenters feared that the application of these onerous state regulations would serve as a barrier to ACO formation due to the added expense of compliance with state insurance regulations. Fortunately, CMS agreed with these commenters. CMS responded that it did not believe that it would be appropriate to subject ACOs to the same standards as health plans, because ACOs "are very different from health plans."⁹⁷ CMS emphasized "that under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share potential losses against the benchmark would be solely between the Medicare program and the ACO."⁹⁸ Although CMS's stance on this matter is favorable for ACOs, it is not binding on the states, and ACOs that will form in Michigan will need to review Michigan's insurance laws.

The Office of Financial and Insurance Regulation ("OFIR") is the State of Michigan agency responsible for regulating Michigan's financial industries, including insurance companies. A "health plan" in Michigan means all of the following:

- (i) An insurer providing benefits under an expense-incurred hospital, medical, surgical, vision, or dental policy or certificate, including any policy or certificate that provides coverage for specific diseases or accidents only, or any hospital indemnity, Medicare supplement, long-term care, or one-time limited duration policy or certificate, but not to payments made to an administrative services only or cost-plus arrangement.
- (ii) A multiple employer welfare arrangement ("MEWA") regulated under Chapter 70 that provides hospital, medical, surgical, vision, dental, and sick care benefits.⁹⁹
- (iii) A health maintenance organization licensed or issued a certificate of authority in Michigan.¹⁰⁰

- (iv) A health care corporation for benefits provided under a certificate issued under the Nonprofit Health Care Corporation Reform Act, 1980 PA 350, MCL 550.1101 to 550.1704, but not to payments made pursuant to an administrative services only or cost-plus arrangement.¹⁰¹

Michigan has yet to pass any legislation aimed directly at governing ACOs, and OFIR has not issued any formal statements regarding its position on whether – or when – an ACO would be required to obtain appropriate licensure under Michigan law. Therefore, it is an open question as to whether an ACO will fall within one of the above definitions and thus be subject to the myriad of regulations that govern health plans. Or, on the other hand, will Michigan ACOs fall within the NAIC exception and be exempt from the applicable insurance legislation and the onerous requirements that follow? It is recommended that organizations contemplating forming an ACO first contact OFIR to determine Michigan's current position on this issue.

E. Professional Licensure Implications

The success of an ACO requires the collaboration and cooperation of a variety of participants in the ACO. All parties involved in an ACO – directors, officers, participants, providers, suppliers, and even the patients – are in some way or another responsible for ensuring that the ACO accomplishes its mission.

In working towards the ACO's goal, it must not be forgotten, however, that an individual shall not engage in the practice of medicine unless licensed as a physician under Michigan's Public Health Code.¹⁰² Also, it is the physician who must act in the best interests of his or her patient.¹⁰³ Thus, it should be the physician who ultimately makes the decision regarding the type and amount of health care his or her patient receives. Licensure statutes and rules applicable to individual providers and provider organizations must be considered to determine how new management and accountability structures in an ACO environment affect the core roles and responsibilities of these professionals.

PART TWO - FRAUD AND ABUSE CONSIDERATIONS

I. BACKGROUND

Another important consideration for providers and their counsel is how ACOs will interplay with the myriad of laws enacted to prevent fraud and abuse in the health care setting. For example, the Physician Self-Referral Law (also known as the “Stark Law”), the Federal anti-kickback statute (“AKS”) and the civil monetary penalties law (“CMP”) are important tools used to protect patients and federal health care programs from harms including fraud, improper referrals, unnecessary overutilization, and underutilization.

It has been recognized that these important tools may unduly restrict the development of highly beneficial ACOs. In light of this and in order to facilitate the development of ACOs, Section 3022 of the ACA authorized the Secretary of Health and Human Services to waive these laws as necessary to carry out the Shared Savings Program. Based on public comments to certain proposed waivers and waiver design consideration¹⁰⁴ and the Secretary's own analysis,

the Secretary has determined that certain waivers of the foregoing laws are necessary in order to carry out the purposes of the Shared Savings Program.

On November 2, 2011, CMS and the HHS Office of Inspector General (“OIG”) jointly published an Interim Rule with Final Comment (“IFC”) establishing waivers of the Stark Law, the AKS, and certain provisions of the CMP law known as the Gainsharing CMP and the Beneficiary Inducement CMP.¹⁰⁵ The IFC establishes five waivers in connection with the Medicare Shared Savings Program. These waivers took effect upon publication of the IFC. CMS believes that the waivers provide sufficient flexibility to encourage investment in and participation in ACOs. The waivers incorporate safeguards that, in combination with the Shared Savings Program final rule,¹⁰⁶ are viewed as adequately protecting the Medicare program and its beneficiaries.

Four of the five waivers are available to protect arrangements involving an ACO, its participants and providers/suppliers if the ACO has a participation agreement and remains in good standing under that agreement. The fifth waiver, the pre-participation waiver, is available for start-up arrangements provided that the ACO is making good faith efforts to form an ACO and to submit an application to participate in the Shared Savings Program and the arrangement meets all other conditions of the waiver.

It is important to keep in mind that these waivers protect an arrangement with respect to only the four federal laws listed above. The arrangement will also need to comply with applicable state fraud and abuse laws and professional licensing regulations. Moreover, an arrangement must also comply with other applicable federal laws such as anti-trust laws and tax laws.

With respect to Michigan, several Michigan laws which protect patients and regulate the conduct of physicians may also affect the development and operation of ACOs. These laws include Michigan’s Health Care False Claim Act, Michigan fee-splitting laws, and a “mini-Stark” provision that is part of Michigan’s Public Health Code. The Michigan mini-Stark provision adopts certain exceptions set forth in the federal Stark Law. The Michigan laws will apply both to Medicare ACOs and to other ACO-like organizations being formed by private insurers. Compliance with these state laws is also required. The impact of these state laws on ACOs will be discussed after the federal waivers are discussed.

A. Safeguards in the Waiver Design and Application of the Waivers

1. Safeguards in the Waiver Design

The design of the waivers is based on the premise that the risks of fraud and abuse will be mitigated by the design of the Shared Savings Program, including the eligibility requirements, the quality of care requirements and accountability requirements. Moreover, the waivers themselves set forth additional safeguards against fraud and abuse. These include the requirements that the ACO’s governing body makes a bona fide determination that an arrangement is reasonably related to the purpose of the Shared Savings Program,¹⁰⁷ transparency through public disclosure of arrangements protected by the waivers, and a documented audit trail.

Within the context of the waivers, the broad purposes of the Shared Savings Program are as follows:

- (i) to promote accountability for the quality, cost, and overall care for a Medicare population as described in the Shared Savings Program;
- (ii) to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO, and;
- (iii) to encourage investment in infrastructure and redesigned care processes for high quality.

These purposes can involve promoting evidence-based medicine and patient engagement; meeting the requirements for reporting on quality and cost measures; coordinating care through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing clinical and administrative systems for the ACO; meeting clinical integration requirements of the Shared Savings Program; or meeting quality performance standards of the ACO. Arrangements with similar purposes that are unrelated to the Shared Savings Program are not covered by the term “purposes of the Shared Savings Program.”

Where a waiver requires that the terms of the arrangement be “reasonably related to the purposes of the Shared Savings Program,” the waiver need only be reasonably related to *one* of the listed purposes. It is the position of CMS that, if a reasonable relationship exists, the parties to an arrangement should be able to clearly articulate the nexus between the arrangement and the applicable purpose. An arrangement that includes both Medicare and non-Medicare patients is not precluded from qualifying for a waiver merely because the arrangement includes non-Medicare patients.

The Pre-Participation Waiver and the Participation Waiver require that the governing body of the ACO make a bona fide determination that the arrangement for which waiver protection is sought is reasonably related to at least one of the purposes of the Shared Savings Program. The governing body must duly authorize the arrangement and contemporaneously document their decision and the basis for such decision. Another safeguard in the design of these two waivers is the requirement to publicly disclose the arrangement being protected by these two waivers. There are significant requirements for documentation supporting these waivers and a requirement to retain such documentation for 10 years. All of these safeguards are intended to prevent the waivers from being used for fraudulent purposes.

2. Automatic Application

The waivers apply automatically if an arrangement satisfies the conditions set forth in the waiver. However, failure to comply with a waiver is not in and of itself a violation of one of these fraud and abuse laws. If an arrangement does not fit within a waiver, it must comply with Stark, AKS and CMP laws.¹⁰⁸

3. Uniform Application

The waivers apply uniformly to each ACO, ACO participant and each ACO provider/supplier participating in the Shared Savings Program.

4. Possible Future Narrowing of the Waivers

CMS intends to monitor ACOs entering into the Shared Savings Program in 2012 through June of 2013. If the Secretary determines that the waivers have the unintended effect of shielding abusive arrangements, the scope of the waivers will be narrowed.¹⁰⁹ If the waivers are narrowed, the modified waivers will apply to future ACO applicants and, for ACOs operating under a participation agreement at the time of the change, only after such ACOs renew their participation agreements.

B. Fraud and Abuse Laws Subject to the Waivers

The waivers set forth in the IFC relate to three different Federal statutes: the Physician Self-Referral Law, the Federal anti-kickback statute and two provisions of the Civil Monetary Penalties (“CMP”) Law. The waivers apply only to the specific provisions of the laws enumerated in the waivers and not to any other provisions of Federal or State law. The waivers are intended to provide flexibility to ACOs in varying circumstances.

Stark Law.¹¹⁰ The Stark Law is a civil statute which prohibits a physician from referring federal program beneficiaries for designated health services¹¹¹ to an entity with which the physician or an immediate family member has a financial relationship, unless an exception applies.¹¹² The entity receiving a prohibited referral may not bill a federal health care program for any items or services provided as a result of a prohibited referral.

Anti-Kickback Statute.¹¹³ The Anti-Kickback Statute (“AKS”) provides that persons may not knowingly offer, pay, solicit or receive, directly or indirectly, overtly or covertly, in cash or in kind, any remuneration for referring an individual to a person for the furnishing or arranging of any item or service for which payment may be made, in whole or in part, under a Federal health care program, or in return for purchasing, leasing, ordering or arranging for or recommending, purchasing, leasing, ordering or arranging for any good, facility, item or service for which payment may be made in whole or in part under a Federal health care program. There are numerous safe harbors and exceptions to the AKS which can be used to protect arrangements. An arrangement must strictly comply with the requirements of the safe harbor in order to be protected.

Beneficiary Inducement CMP.¹¹⁴ The Civil Monetary Penalties Law prohibits individuals and entities from offering or transferring remuneration to federal health care program beneficiaries where the individual or entity knows or should know the remuneration is likely to influence the beneficiary to order or receive items or services payable by a federal health care program from a particular provider, practitioner, or supplier.

Gainsharing CMP.¹¹⁵ The Civil Monetary Penalties Law prohibits hospitals and critical access hospitals from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries who are under the physician’s

direct care. Hospitals that make and physicians who receive such payments are liable for CMPs of up to \$2,000 per patient.

C. Details of the Five Waivers

The IFC sets forth five separate waivers which pertain to different aspects of the formation and operation of an ACO. An arrangement need fit within only one of the five waivers to be protected. However, an ACO may consist of many different arrangements and thus different waivers may apply to the different arrangements.

1. Pre-Participation Waiver¹¹⁶

The Pre-Participation Waiver set forth in the IFC provides that the Stark Law, AKS, and Gainsharing CMP are waived with respect to start-up arrangements that predate an ACO's participation agreement. Start-up arrangements include any items, services, facilities or goods (including non-medical items, services, facilities or goods)¹¹⁷ used to create or develop an ACO that are provided by the ACO, the ACO participant or ACO providers or suppliers. Examples of these items provided by the IFC (which are intended to be non-exhaustive) include infrastructure creation, care coordination mechanisms, clinical management systems, creation of a governance and management structure, hiring of and training of staff, EHR systems and other information technology, incentives to attract primary care physicians, and capital investments. Subsidies for these items are considered part of the start-up arrangement.

The requirements of the Pre-Participation Waiver are as follows:

- (i) The arrangement is undertaken by one or more parties acting with the good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a specified year ("Target Year"),¹¹⁸ and to submit a completed application to participate in the Program for the Target Year. The parties to the arrangement must include the ACO or at least one ACO participant of the type eligible to form an ACO. Drug and device manufacturers, distributors, durable medical equipment (DME) suppliers or home health suppliers may not be parties to the arrangement.
- (ii) The parties developing the ACO must be taking diligent steps to develop an ACO that will be eligible for a participation agreement that would take effect during the Target Year, including establishing the ACO's governance, leadership and management.
- (iii) The ACO's governing body must make and duly authorize a bona fide determination that the arrangement is reasonably related to at least one purpose of the Shared Savings Program.
- (iv) The ACO must create contemporaneous written documentation¹¹⁹ of the arrangement, its authorization by the governing body, and the diligent steps to develop the ACO. Such documentation must be retained for at least 10 years following completion of the

arrangement or, in the case of diligent steps, for 10 years following the date on which the ACO submits its application for the Shared Savings Program or the reasons why it failed to submit an application.

- (v) The description of the arrangement must be publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. However, the financial or economic terms of the arrangement are not required to be so disclosed.
- (vi) If an ACO does not submit an application for a participation agreement by the latest due date for the Target Year, the ACO must submit a statement on or before such date, in a form and manner to be determined by the Secretary, describing the reasons it was not able to submit an application.

For arrangements that comply with the foregoing requirements, the waiver period would start on the date of publication of the IFC for target year 2012 or one year preceding an application due date for a target year of 2013 or later. The end date for the waiver period depends on whether the application was approved, denied or not submitted. Since this waiver protects arrangements only prior to the starting date of a participation agreement, the waiver end date is the starting date of the participation agreement for ACOs that enter into a participation agreement for the Target Year. If a timely filed application is denied, the waiver end date is the date of the denial notice; however, if an arrangement qualified for the waiver before the date in the denial notice, the waiver period ends six months after the date of the denial notice. For ACOs that fail to submit an application by the due date for the Target Year, the waiver ends on the earlier of the application due date or the date the ACO submitted its reasons for not submitting application. Under procedures established by the Secretary, an ACO may apply for an extension of the due date. In order to receive such an extension, the ACO must be able to demonstrate it can successfully develop an ACO that would be eligible to participate in the Shared Savings Program by the next available application date. It is within the sole discretion of the Secretary to grant such a waiver. The decision of the Secretary in this regard is not reviewable.

The Pre-Participation Agreement Waiver covers ACO participants and ACO providers or suppliers that would meet the definitions of these terms set forth in the ACO Final Rule. The Pre-Participation Waiver does not cover arrangements involving drug and device manufacturers, distributors, DME suppliers, or home health suppliers.

The Pre-Participation Waiver may be used only one time.

2. ACO Participation Waiver.¹²⁰

The ACO Participation Waiver provides that the Stark Law, Gainsharing CMP, and the AKS are waived with respect to any arrangement of an ACO, one or more of its ACO participants, or its ACO providers or suppliers (or a combination thereof) provided all of the following conditions are met:

- (i) The ACO has entered into and remains in good standing under its participation agreement.
- (ii) The ACO complies with the requirements of the ACO Final Rule concerning its governance, leadership and management.¹²¹
- (iii) The ACO's governing body had made and duly authorized a bona fide determination that the arrangement is reasonably related to at least one purpose of the Shared Savings Program.
- (iv) The ACO must create written documentation¹²² of the arrangement, its authorization by the governing body, and the diligent steps to develop the ACO. Such documentation must be created contemporaneously with the authorization and must be retained for at least 10 years following completion of the arrangement and made available to the Secretary upon request.
- (v) The description of the arrangement must be publicly disclosed at a time or place and manner established in guidance issued by the Secretary. However, the financial terms or economic terms of the arrangement are not required to be so disclosed.

For an arrangement that complies with the foregoing requirements, the waiver period will begin on the start date of the participation agreement and will end 6 months following the earlier of the expiration of the participation agreement, (including any renewals), or the date on which the ACO has voluntarily terminated the participation agreement. For arrangements terminated by CMS, the waiver period will end on the date of the termination notice.

The Participation Waiver will protect any arrangement that meets its conditions including start-up arrangements. It is anticipated that some start-up activities may occur after the ACO enrolls in the Shared Savings Program and thus the Participation Waiver could be applicable to those post-participation agreement start-up activities.

3. Shared Savings Distribution Waiver¹²³

The Shared Savings Distribution Waiver provides that the Stark Law, Gainsharing CMP and AKS are waived with respect to distributions or use of shared savings earned by an ACO, provided all of the following conditions are met:

- (i) The ACO has entered into and has remained in good standing under its participation agreement.
- (ii) The shared savings are earned by the ACO pursuant to the Shared Savings Program.
- (iii) The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the

shared savings occurs after the expiration of the participation agreement.

- (iv) The shared saving are either (a) distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (b) used for activities that are reasonably related to the purposes of the Shared Savings Program.
- (v) With respect to the waiver of the Gainsharing CMP, payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the physician's direct care.

The Shared Savings Waiver is intended to protect the distribution of shared savings payments from the Medicare program. It permits shared savings to be distributed or used within the ACO in any manner, and also permits the shared savings payments to be distributed to outside parties, provided the arrangements are reasonably related to the purposes of the Shared Savings Program. However, this waiver will not apply to any similar payments received from a commercial or other payor.

4. Compliance with the Physician Self-Referral (Stark) Law Waiver¹²⁴

The Gainsharing CMP and AKS are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law if its requirements are met. It is important to note that this waiver does not waive application of the Stark Law to ACOs. Rather, the waiver applies *only if* a financial arrangement complies with an exception to Stark set forth at 42 CFR § 411.355 through §411.357.

The requirements that must be met for this waiver to protect an arrangement are as follows:

- (i) The ACO has entered into and has remained in good standing under its participation agreement.
- (ii) The financial relationship is reasonably related to at least one purpose of the Shared Savings Program.
- (iii) The financial relationship fully complies with a Stark exception set forth at 42 CFR § 411.355 through §411.357.

For an arrangement that complies with the above requirements, the waiver period will begin on the state date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals, or the date on which the participation agreement has been terminated.

The IFC notes that the agencies are willing to waive the Gainsharing CMP and AKS because of the specific safeguards imposed by the Shared Savings Program. This means that if an arrangement fully complies with Stark and meets the other requirements of the Stark Law Waiver, it will not be required to also comply with AKS and the Gainsharing CMP.

5. Waiver for Patient Incentives¹²⁵

The Waiver for Patient Incentives provides that the Beneficiary Inducement CMP and AKS are waived with respect to items and services provided by an ACO, its ACO participants and its ACO providers/suppliers to beneficiaries for free or below fair-market value if all of the following conditions are met:

- (i) The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
- (ii) The items and services are reasonably connected to the medical care of the beneficiary.
- (iii) The items and services are in-kind.
- (iv) The items or services (a) are preventive care items or services; or (b) advance one or more of the following clinical goals (i) adherence to a treatment regime; (ii) adherence to a drug regime; (iii) adherence to a follow-up care plan; or (iv) management of a chronic disease or condition.

For arrangements that comply with the foregoing requirements, the waiver period will begin on the date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals, or the date of termination of the participation agreement. Beneficiaries may keep items received before the participation agreement expired or was terminated and may receive the remainder of any service initiated and in progress before such expiration or terminations.

This waiver protects arrangements that incentivize beneficiaries to comply with recommended preventative services, treatment recommendations or a plan of care. Presumably, use of such items or services will lead to lower costs and/or improved outcomes for Medicare beneficiaries. CMS views beneficiary compliance with care management programs as being critical to the success of an ACO. The waiver can protect ACOs that give beneficiaries (including beneficiaries not assigned to the ACO) items or services obtained from manufacturers at discounted rates, but will not protect the discount arrangement between the ACO and the manufacturer.

Significantly, because this waiver is limited to “in-kind items or services,” this waiver will not protect the waiving or reducing of beneficiary copayments or deductibles. As noted in the IFC, the ACO Final Rule prohibits ACOs, ACO participants and ACO providers/suppliers, and others performing functions or services related to the ACO from providing gifts or other remuneration to beneficiaries to induce the beneficiaries to receive services from providers affiliated with the ACO or to remain in the ACO.¹²⁶ Moreover, the waiver will not protect the

provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO participants, or ACO providers or suppliers.

II. MICHIGAN-SPECIFIC ISSUES PERTAINING TO FRAUD AND ABUSE WAIVERS

The waivers set forth in the IFC do not apply to any state laws, nor do they preempt state law. Notably, Michigan has several laws that could potentially be triggered by shared savings payments being paid to an ACO by Medicare or by commercial health insurers. There are numerous ACOs being formed within Michigan which may participate in programs being developed by private insurers that seek to use care coordination to lead to better health outcomes for patients, higher quality services, and cost savings. The private insurers will provide payments to a commercial ACO for producing cost savings and/or meeting quality goals. As such, the commercial ACOs serve the same general purposes of the Medicare Shared Savings Program. Many commercial ACOs may have a component that participates in the Medicare Shared Savings Program. Commercial ACO initiatives may be necessary to help with the substantial start-up costs needed to establish ACO care coordination processes, clinical guidelines, and quality of care assessment processes.

State law compliance issues arise with respect to payments of shared savings under the Medicare Shared Savings Program, as well as payments from the private insurers. Both the payments and the manner in which they are distributed to the health care providers and suppliers who participate in an ACO must comply with state law as well as federal law. How an ACO chooses to distribute any shared savings payments will likely affect whether the payments are viewed as kickbacks, or as compensation for achieving goals set by Medicare or a private insurer that are not related to referrals or the monetary value or volume of referrals.

It is important that an ACO determine the distribution of such payments in a manner that does not reflect the value or volume of referrals made by a physician or other practitioner participating in the ACO. The agreements with the insurers who are making these payments should also clearly reflect the method by which a commercial ACO computes the payments. A commercial ACO could benefit by clearly documenting, prospectively, its method for distributing any payments for shared savings or meeting quality goals. Protections like these make it likely that the payments will be viewed as compensation for achieving goals, rather than as kickbacks for referrals.

A. Michigan's "Mini-Stark" Licensing Law

It is expected that an ACO's participants, providers and suppliers will tend to refer patients within the ACO rather than to providers and suppliers outside the ACO. This gives the providers and suppliers more control in managing the care of beneficiaries assigned to the ACO and a greater ability to control costs. Accordingly, it is likely that Stark issues will arise with respect to these referrals and any shared savings payments from Medicare or a commercial payer.

For a Michigan licensed physician, a failure to comply with Stark can result in a disciplinary action against the physician. The Michigan Public Health Code provides that a

referral by a physician for a designated health service that violates the federal Stark law, or a regulation promulgated under such law, constitutes unprofessional conduct which may result in disciplinary proceedings.¹²⁷ Stark and its implementing regulations as they existed on June 3, 2002 are incorporated by reference into this provision. Changes to Stark or its implementing regulations that occur after this date will not be taken into account unless the Michigan Department of Community Health issues a rule to incorporate the revisions. This “Mini-Stark” provision applies regardless of payment source, and will thus apply to payments from commercial health care insurers and quite probably to payments made to physicians by an ACO for achieving cost savings or quality goals. Accordingly, compliance with the federal Stark Law will need to be addressed.

Fortunately, the Stark Law provides several exceptions that could be applicable in the context of a Medicare ACO and in the context of a commercial ACO. The applicable exceptions include a personal services exception,¹²⁸ the fair market value exception,¹²⁹ the indirect compensation exception,¹³⁰ and the risk-sharing exception.¹³¹ This latter exception was designed to apply to arrangements between a managed care organization (“MCO”) or an independent practice association (“IPA”) and a physician for services provided to an enrollee of a health plan.¹³² Generally, an IPA consists of a network of physicians in a region or community—solo practitioners and groups of physicians—who agree to participate in an association to contract with health maintenance organizations, other managed care plans, and also vendors for the benefit of each of the physicians in the IPA. For commercial ACOs that are IPAs or MCOs, the risk sharing exception will be of considerable importance. It should be possible for an ACO operating in Michigan to use a Stark exception to protect referrals within the ACO as well as to protect any payments for meeting shared savings or quality goals distributed by the ACO to its participants.

B. Michigan Fee-Splitting Laws

Fee-splitting laws may also be implicated by the payments made to the providers and suppliers who participate in an ACO. The Public Health Code, which applies to physicians and other licensed health professionals, prohibits the dividing of fees for the referral of patients or accepting kickbacks on medical or surgical services, appliances, or medications purchased by or in behalf of patients.¹³³ A criminal statute also prohibits a physician or surgeon from dividing or promising to divide fees with any other physician or surgeon or person who consults with or sends patients for treatment or operation.¹³⁴ It is not likely that payments from Medicare or a private insurer that are clearly and accurately described as payments based on cost savings and/or the achievement of quality goals will be viewed as a kickback, provided that the payments are not based on the volume or value of referrals made by the physician or other provider or supplier or business generated by them for the ACO or for other participants in the ACO.

C. Michigan Health Care False Claim Act

It is not likely that Michigan’s Health Care False Claim Act (“HCFCA”)¹³⁵ will act as an impediment to the development of ACOs in Michigan. The HCFCA (not to be confused with the Michigan Medicaid False Claims Act¹³⁶, which only applies to Medicaid payments) makes it a felony to solicit, offer, pay or receive a kickback or bribe in connection with the furnishing of goods and services for which payment is or may be made in whole or in part by a health care

corporation or health care insurer, or who receives a rebate of a fee or charge for referring an individual to another person for the furnishing of health care benefits. The case law interpreting the HCFA has consistently held that the defendant must have intended to receive a fee for referrals in order to be held liable under this statute.¹³⁷ Accordingly, it is not likely that payments from Medicare or a private insurer that are clearly and accurately described as payments based on cost savings and/or the achievement of quality goals will be viewed as a kickback, provided that the payments received by a physician or other provider or supplier are not based on the volume or value of referrals made by the physician or other provider or supplier or business generated by them for the ACO or other participants in the ACO.

In summary, with respect to state law, it is imperative that ACOs have a well-defined method for distributing any payments based on savings produced by the ACO, or payments based on meeting quality goals. This method must not in any way take into account the volume or value of referrals made or other business generated by a participant in the ACO for any of the ACO's other participants (or for the ACO itself). Medicare already has a published methodology for determining shared savings payments which makes it clear that the payments are being made for achieving quality goals and producing cost savings.

Private insurers also need to have documented procedures for determining payments they make to an ACO that clearly establish such payments are based only on meeting quality goals and producing savings and not on business (referrals or otherwise) generated by or for the ACO or its participants. In turn, ACOs need established and documented methods for distributing payments among its participants in a manner that does not in any way take into account the volume or value of referrals or other business generated by a participant.

The state laws discussed above were written well before anyone contemplated that ACOs would become a part of our health care delivery system. As this model continues to evolve, it may be necessary to modify existing laws or adopt new laws that would specifically address the issues unique to ACOs.

PART THREE - PIONEER ACOs in MICHIGAN

On December 19, 2011, CMS announced that 32 organizations had been selected to participate in the Pioneer ACO Model.¹³⁸ The Pioneer ACO Model is an accelerated program for health care organizations and providers already experienced in providing integrated and coordinated health care at a lower cost to Medicare.¹³⁹ Although many of the legal structure, governance and operational requirements for ACOs under the Pioneer Model are similar to the normal ACO models discussed in this paper, Pioneer ACOs must comply with additional requirements designed to amplify the aims of better care for individuals, better health for populations, and lower growth in expenditures. For instance, Pioneer ACOs are required to have at least 15,000 assigned Medicare beneficiaries, unless the Pioneer ACO is located in a rural area.¹⁴⁰ In addition, the governing body of a Pioneer ACO must include both a patient representative and a consumer advocate, instead of just the patient representative.¹⁴¹ Because the Pioneer ACOs are already operational, they can serve as an invaluable guide for starting a new ACO under the ACA and federal regulations.

Three organizations in Michigan were selected to participate in the Pioneer ACO Model. These organizations are Genesys PHO, Michigan Pioneer ACO and The University of Michigan Health System.

Genesys PHO is a collaboration between Genesys Health System and 160 primary care physicians with 400 participating specialist physicians.¹⁴² CMS classifies Genesys PHO as a partnership between a hospital system and medical practices.¹⁴³ Genesys PHO utilized an existing Michigan LLC to form its ACO.

Michigan Pioneer ACO is managed by the Detroit Medical Center PHO, a partnership of The Detroit Medical Center and its 1100 physicians, including employed physicians, faculty physicians, and private practice primary care physicians.¹⁴⁴ CMS classifies Michigan Pioneer ACO as a partnership between a hospital system and medical practices.¹⁴⁵ The Michigan Pioneer ACO created a new Michigan LLC to form its ACO.

The University of Michigan Health System includes the U-M Faculty Group Practice, part of the U-M Medical School, which consists of nearly 1,600 U-M faculty physicians who care for patients at the three U-M hospitals and 40 U-M health centers.¹⁴⁶ U-M partnered with IHA Health Services Corporation, an Ann Arbor-based healthcare provider group with 175 physicians in 32 practices.¹⁴⁷ CMS classifies the University of Michigan Health System as an integrated delivery system.¹⁴⁸ The University of Michigan Health System ACO utilized its existing structure to build on its work in the Medicare Physician Group Practice Demonstration.

Each of the three Pioneer ACOs started in the State of Michigan took a different approach to formation. However, despite these differences, each ACO was approved by CMS to participate in the Pioneer ACO Model. Therefore, each satisfied the legal structure, governance and operational requirements outlined by CMS. These ACOs demonstrate that there are numerous ways to develop an integrated healthcare system that will be eligible to participate in the MSSP.

CONCLUSION

While ACOs are poised to have a tremendous impact on the delivery of health care, the development of such organizations is still an emerging area. Therefore, it is likely – if not certain – that issues regarding Michigan law will arise which are not contemplated by this Whitepaper. Providers or attorneys with specific questions about ACOs should contact experienced health law counsel who will be able to advise on these issues.

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¹ Pub L. 111-148 (hereafter "ACA").

² ACA, § 3022(a)(1)(A).

³ ACA, § 3022(a)(1)(B).

⁴ 42 CFR § 425.20.

⁵ Centers for Medicare and Medicaid Services, Medicare Shared Savings Program Frequently Asked Questions. http://www.cms.gov/sharedsavingsprogram/Downloads/MSSP_FAQs.pdf.

⁶ 42 CFR § 400.202.

⁷ *Id.*

⁸ Physician Assistant is defined at 42 CFR § 410.74(a)(2).

⁹ Nurse Practitioner is defined at 42 CFR § 410.75(b).

¹⁰ Clinical Nurse Specialist is defined at 42 CFR § 410.76(b).

¹¹ 42 CFR § 425.20.

¹² Method II billing for CAHs is described in 42 CFR § 413.70(b)(3).

¹³ The Rural Health Clinic Services Act of 1977, Pub. L. No. 95-210.

¹⁴ Section 1861(aa) of the Social Security Act, as amended by Section 4161 of the Omnibus Budget Reconciliation Act of 1990.

¹⁵ 42 CFR § 425.108(c).

¹⁶ 42 CFR § 400.202.

¹⁷ 42 CFR § 425.108(d).

¹⁸ 42 CFR § 425.108(d)(1).

¹⁹ *Id.*

²⁰ 42 CFR § 425.108(d)(2).

²¹ 42 CFR § 425.104(a).

²² ACA, § 3022(b)(2)(C).

²³ 42 CFR § 425.104(a)(2).

²⁴ 42 CFR § 425.104(a)(3).

²⁵ 42 CFR § 425.104(a)(4).

²⁶ 42 CFR § 425.104(a); 42 CFR § 425.106(b)(5).

²⁷ 42 CFR § 425.106(b)(4).

²⁸ ACA, § 3022(b)(1).

²⁹ 42 CFR § 425.106(a).

³⁰ 42 CFR § 425.106(c)(1).

³¹ 42 CFR § 425.106(c)(3).

³² 42 CFR § 425.106(c)(2).

³³ Pioneer ACOs must also include a "Consumer Advocate" in its governing body. The Consumer Advocate requirement for Pioneer ACOs mirrors the Medicare Beneficiary requirement under the regular ACO discussed herein.

³⁴ 42 CFR § 425.106(c)(4).

³⁵ 42 CFR § 425.106(c)(5).

³⁶ Mich. Comp. Laws §450.1488.

³⁷ ACA, § 3022(b)(2)(F).

³⁸ 42 CFR § 425.108(b).

³⁹ *Id.*

⁴⁰ 42 CFR § 425.108(c).

⁴¹ *Id.*

⁴² 42 CFR § 425.108(e).

⁴³ ACA, § 3022(b)(2)(D).

⁴⁴ 42 CFR § 425.110(a)(1).

⁴⁵ 42 CFR § 425.110(a)(2).

⁴⁶ 42 CFR § 425.110(b).

⁴⁷ 42 CFR § 425.110(b)(1).

⁴⁸ 42 CFR § 425.110(b)(2).

⁴⁹ 42 CFR §§ 425.400(a)(1)(i)-(ii).

⁵⁰ 42 CFR § 425.400(a)(2)(i).

⁵¹ 42 CFR § 425.400(a)(2)(ii).

⁵² 42 CFR § 425.400(a)(2)(iii).

⁵³ 42 CFR § 425.402(a).

⁵⁴ *Id.*
⁵⁵ 42 CFR §§ 425.402(a)(1)(i)(A)-(B).
⁵⁶ 42 CFR §§ 425.402(a)(1)(ii)(A)-(B).
⁵⁷ 42 CFR § 425.402(a)(2).
⁵⁸ 42 CFR §§ 425.402(a)(2)(i)-(ii).
⁵⁹ 42 CFR § 425.400(b).
⁶⁰ ACA, § 3022(b)(2)(G).
⁶¹ 42 CFR § 425.112(a)(1)(ii).
⁶² 42 CFR § 425.112(a)(1)(iii).
⁶³ 42 CFR § 425.112(a)(3)(i).
⁶⁴ *Id.*
⁶⁵ 42 CFR § 425.112(a)(3)(ii).
⁶⁶ 42 CFR § 425.112(b)(1).
⁶⁷ *Id.*
⁶⁸ 42 CFR § 425.112(b)(2).
⁶⁹ 42 CFR § 425.112(b)(2)(i).
⁷⁰ 42 CFR § 425.112(b)(2)(ii).
⁷¹ 42 CFR § 425.112(b)(2)(iii).
⁷² 42 CFR § 425.112(b)(2)(iii)(A).
⁷³ 42 CFR §§ 425.112(b)(2)(iv)-(vi).
⁷⁴ 42 CFR § 425.112(b)(3).
⁷⁵ *Id.*
⁷⁶ 42 CFR § 425.112(b)(4).
⁷⁷ 42 CFR § 425.112(b)(4)(i).
⁷⁸ 42 CFR § 425.106(a).
⁷⁹ 76 Fed. Reg. 67805 (Nov. 2, 2011).
⁸⁰ 42 CFR § 425.106(d).
⁸¹ 42 CFR § 425.106(d)(1).
⁸² ACA, § 6301(a)(3).
⁸³ 42 CFR § 425.106(d)(2).
⁸⁴ 42 CFR § 425.106(d)(3).
⁸⁵ Mich. Comp. Laws § 450.1251(1) (Emphasis added).
⁸⁶ Mich. Comp. Laws § 450.1101 et seq.
⁸⁷ Mich. Comp. Laws § 450.221 et seq.
⁸⁸ Mich. Comp. Laws § 450.4101 et seq.
⁸⁹ Mich. Comp. Laws § 450.1251.
⁹⁰ MI Op. Att'y Gen. No. 6770 (Sept. 17, 1993).
⁹¹ 76 Fed. Reg. 67805 (Nov. 2, 2011).
⁹² Memorandum and Model Bulletin from National Association of Insurance Commissioners on Certain Types of Compensation and Reimbursement Arrangements Between Health Care Providers and Individuals, Employers and Other Groups to State Insurance Commissioners (Aug. 10, 1995).
⁹³ 42 C.F.R. § 425.604.
⁹⁴ 42 C.F.R. § 425.600.
⁹⁵ 42 C.F.R. § 425.606.
⁹⁶ Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,944 (Nov. 2, 2011).
⁹⁷ *Id.* at 67,945.
⁹⁸ *Id.* at 67,945.
⁹⁹ Mich. Comp. Laws § 500.7001.
¹⁰⁰ Mich. Comp. Laws § 500.3501(f).
¹⁰¹ Mich. Comp. Laws § 550.1105.
¹⁰² Mich. Comp. Laws § 333.17011.
¹⁰³ American Medical Association Code of Medical Ethics, Opinion 10.015 - The Patient-Physician Relationship.

¹⁰⁴ CMS and OIG previously jointly filed a notice with comment period for certain proposed waivers and other design waiver considerations. The Shared Savings Waiver and the Compliance with the Physician Self-Referral Law Waiver were first set out as proposed waivers. *See* 76 Fed. Reg. 19655 (April 7, 2011).

¹⁰⁵ 76 Fed. Reg. 67992 (November 2, 2011).

¹⁰⁶ 76 Fed. Reg. 67802 (November 2, 2011).

¹⁰⁷ This requirement applies only to the Pre-Participation Waiver and the Participation Waiver.

¹⁰⁸ 76 Fed.Reg. at 67994.

¹⁰⁹ 76 Fed.Reg. at 68008.

¹¹⁰ 42 U.S.C. § 1395nn

¹¹¹ Designated health services are defined in 42 CFR § 411.351 as: (i) clinical laboratory services; (ii) physical therapy, occupational therapy, and outpatient speech-language pathology services; (iii) radiology and certain other imaging services; (iv) radiology therapy services and supplies; (v) durable medical equipment and supplies; (vi) parenteral and enteral nutrients, equipment and supplies; (vii) prosthetics, orthotics, and prosthetic devices and supplies; (viii) home health services; (ix) outpatient prescription drugs; and (x) inpatient and outpatient hospital services.

¹¹² There are numerous exceptions to Stark which are set forth in 42 CFR §§ 411.355 – 411.357.

¹¹³ 42 U.S.C. § 1320a-7b(b)(1) and (2).

¹¹⁴ 42 U.S.C. 1320a-7a(a)(5) which is Section 1128A(a)(5) of the Social Security Act.

¹¹⁵ 42 U.S.C. 1320a-7a(b)(1) and (2) which are Sections 1128(b)(1) and (2) of the Social Security ACT.

¹¹⁶ 76 Fed. Reg. at 68000.

¹¹⁷ Examples of these “non-medical” items include consultant and professional support, market analysis for antitrust review, legal services, and financial and accounting services.

¹¹⁸ 76 Fed. Reg. at 68000.

¹¹⁹ The documentation must identify at least the following: (a) a description of the arrangement, its parties, date of the arrangement, the purpose of the arrangement, the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities or goods); and the financial or economic terms of the arrangement; and (b) the date and manner of the governing body’s authorization and the basis for concluding the arrangement is reasonably related to the purposes of the Shared Savings Program.

¹²⁰ 76 Fed.Reg. at 68000-68001.

¹²¹ 42 CFR §§ 425.106 and 425.108.

¹²² See endnote 125, *supra*.

¹²³ 76 Fed.Reg. at 68001.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ 42 CFR § 425.304(a)(1).

¹²⁷ Mich. Comp. Laws § 33.16221(e)(iv)(B). Disciplinary action may include a reprimand, fine, probation, suspension, revocation, limitation, community service, denial or restitution. Mich. Comp. Laws § 333.16226.

¹²⁸ 42 CFR § 411.357(d).

¹²⁹ 42 CFR § 411.357(l).

¹³⁰ 42 CFR § 411.357(p).

¹³¹ 42 CFR § 411.357(n).

¹³² This exception provides that “[c]ompensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.”

¹³³ Mich. Comp. Laws § 333.16221(d)(ii).

¹³⁴ Mich. Comp. Laws § 750.428.

¹³⁵ Mich. Comp. Laws §§ 752.1004-752.1004b.

¹³⁶ Mich. Comp. Laws §400.601 *et seq.*

¹³⁷ See, e.g., *People v. Motor City Hospital and Surgical Supply Inc.*, 227 Mich.App. 209 (1998); *People v. Vakilian*, No. 208352, 1998 WL 1986994 (Mich. App. December 29, 1998)(unpublished); *People v. Rodansky*, No. 208351, 1998 WL 1986977 (Mich. App. December 29, 1998) (unpublished).

¹³⁸ "Pioneer ACO Model," Center for Medicare & Medicaid Innovation.
<http://innovations.cms.gov/initiatives/aco/pioneer/>

¹³⁹ "Pioneer Accountable Care Organization Model: General Fact Sheet," Department of Health & Human Services. December 19, 2011. <http://innovations.cms.gov/Files/fact-sheet/Pioneer-ACO-General-Fact-Sheet.pdf>.

¹⁴⁰ *Id.*

¹⁴¹ "The Pioneer ACO Model: A Better Care Experience Through a New Model of Care," Department of Health & Human Services. December 19, 2011. <http://innovations.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf>

¹⁴² "Selected Participants in the Pioneer ACO Model," Center for Medicare & Medicaid Innovation. December 19, 2011. <http://innovations.cms.gov/Files/x/Pioneer-ACO-Model-Selectee-Descriptions-document.pdf>.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*