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Accountable Care Organizations: Forcing Physician Self-Referrals to Improve Care?

The Patient Protection and Affordable Care Act of 2010 (PPACA) proposes several “innovations that attempt to improve both the quality and affordability of health care services.”¹ One way the Act seeks to accomplish this goal is through the establishment of Accountable Care Organizations (“ACOs”). ACOs are collaborations that integrate providers, such as hospitals, physicians, and others “around the ability to receive shared-saving bonuses from a payer by achieving measured quality targets and demonstrating real reductions in overall spending growth for a defined population of patients.”² ACOs are “a recognized legal entit[ies] under State law”³ that aim to improve accessibility and quality while lowering the costs of medical care.⁴ The coordination of healthcare providers is “achieved through initiatives such as creation of patient-centered medical homes, sharing of patient health information among providers, and implementation of care management programs designed to facilitate best practices and improve communication among providers and social services agencies throughout the community.”⁵

Proponents believe that “ACOs will change both the culture and practice patterns of providers and as these changes are institutionalized, all payers and all patients will benefit from the delivery of higher-quality, lower-cost, and better integrated services.”⁶ The Obama

¹ Mark Shields, MD, *From Clinical Integration to Accountable Care* 20 *Annals Health L.* 151 (2011).

² David Newman, *Accountable Care Organizations and the Medicare Shared Savings Program*, CONGRESSIONAL RESEARCH SERVICE (Nov. 4, 2010).

³ *Accountable Care Organization Overview*, CMS.GOV (March 11, 2010), <http://csm.gov/ACO>

⁴ N.J.S.A. 30:4D-8.1

⁵ N.J.S.A. 30:4D-8.1

⁶ David Newman, *Accountable Care Organizations and the Medicare Shared Savings Program*, CONGRESSIONAL RESEARCH SERVICE (Nov. 4, 2010). *citing* Karen Davis, Cathy Schoen, and Kristof Stremikis, *Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally, 2010 Update*, THE COMMONWEALTH FUND, Washington DC, June 23, 2010,

administration is looking toward ACOs to streamline healthcare and move away from a fragmented system towards an integrated system that focuses on quality care⁷ and cost performance instead of volume and intensity of provided services.⁸ Patients receive fragmented care when they see multiple unrelated providers. Fragmented care ends up being costly, “since provider payments are not linked to performance or outcomes and services can be duplicative, and of lower quality, since providers lack financial incentives to coordinate care.”⁹ This disputes the widely held assumption that increased medical services yields higher quality care.¹⁰

The Department of Health and Human Services (HHS) will establish goals for federally created ACOs established under the PPACA. Each ACO will be responsible for meeting or exceeding quality performance and cost-saving goals, as determined by HHS.¹¹ If the ACO is successful in meeting these goals, the potential savings will be returned to the ACO from the State and reinvested in patient care.¹² This concept is called gainsharing and allows physicians to share a portion of the realized savings by working with other physicians to make a patient’s healthcare more efficient.¹³ The gainsharing incentive structure is an overlay to the traditional fee-for-service model.¹⁴

<http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2010/Jun/Mirror-Mirror-Update.aspx?page=all>.

⁷ Walker, *supra* note 5.

⁸ *Accountable Care Organization Research Report*, AMERICAN HOSPITAL ASSOCIATION RESEARCH COMMITTEE, www.hret.org/accountable/resources/ACO-Synthesis-Report.pdf

⁹ CONGRESSIONAL RESEARCH SERVICE, *supra* note 2.

¹⁰ AMERICAN HOSPITAL ASSOCIATION RESEARCH COMMITTEE, *supra* note 8.

¹¹ *FAQs on ACOs: Accountable Care Organizations Explained*, KAISER HEALTH NET, <http://www.kaiserhealthnews.org/Stories/2011/January/13/ACO-accountable-care-organization-FAQ.aspx>

¹² Lilo Stainton, *Bill Would Expand “Accountable” Health Care in New Jersey: Accountable Care Organizations pull together doctors and bill payers to deliver better healthcare at lower cost to indigent patients*, NJ SPOTLIGHT, (March 14 2011)Healthcare <http://www.njspotlight.com/stories/11/0313/2353/>

¹³ *Id.*

¹⁴ Jorge Lopez, *Promise and Pitfalls: Health Reform’s Medicare ACO Shared Savings Program*, AKING GROUP, (March 12, 2012) <http://www.akingump.com/jlopez>:

In August 2011, New Jersey Governor Chris Christie signed A-3636/S-2443 into law, establishing the Medicaid Accountable Care Organization Project (“the project”).¹⁵ The law authorizes the creation of ACOs in New Jersey that will be overseen by the State, specifically the Department of Health and Senior Services.¹⁶ New Jersey ACOs plan to target patients covered by Medicaid,¹⁷ the publicly subsidized health insurance program for poor, blind, and disabled residents.¹⁸ Under the ACO Project, New Jersey’s Department of Health and Senior Services will be responsible for certifying ACOs as “nonprofit coalitions of local health care providers who organize themselves to improve care for a defined population of at least 5,000 Medicaid enrollees.”¹⁹ A defined population might include Medicaid enrollees living in a city or cluster of smaller municipalities.²⁰

Similar to federally created ACOs, the New Jersey ACO model “is centered on improving treatment of chronic conditions, like diabetes and high blood pressure, reducing emergency room visits and hospitalizations, and coordinating patient care among all providers in a geographic region, like Camden or Trenton.”²¹ The model also depends on technology, including good healthcare data that will help identify communities and patients in the most need.²² Enhanced technology will also allow electronic patient records to be immediately accessible to all hospitals and doctors treating a patient,²³ helping to coordinate care.

¹⁵ N.J.S.A. 30:4D-8.1

¹⁶ Derek Delia and Louise B. Russell, *Medicaid Accountable Care Organizations: Opportunities for Cost Control*, THE HASTINGS CENTER, (March 12, 2012) <http://healthcarecostmonitor.thehastingscenter.org/louiserussell/medicaid-accountable-care-organizations-opportunities-for-state-cost-control/>

¹⁷ *Id.*

¹⁸ Stainton, *supra* note 12.

¹⁹ Delia and Russell, *supra* note 16.

²⁰ *Id.*

²¹ *Id.*

²² KAISER HEALTH NET, *supra* note 11.

²³ *Id.*

As the New Jersey law stands today, it is, in some instances, in violation of New Jersey's physician self-referral law: the Codey Law.²⁴ A self-referral is "a referral to an entity or family member in which the physician has a financial interest."²⁵ Many legislators and policy makers have argued that health care costs and utilization inappropriately increase when physicians are able to obtain financial profits from their health care services referrals.²⁶ One argument is that if physicians are unable to financially benefit from their referrals, they will not be motivated by profit to make as many medically unnecessary referrals.²⁷

New Jersey enacted the Codey Law in 1989 to prohibit physicians from referring patients to health care services in which the physician has a significant beneficial interest.²⁸ The statute defines "significant beneficial interest" as "any financial interest except financial interests in leases and publicly traded securities."²⁹ There is a comparable federal law: the Physician's Self-Referral Law ("Stark Law"),³⁰ which is part of the Social Security Act.³¹ The Stark Law "prohibits physicians from referring Medicare and Medicaid patients for designated health services (including inpatient and outpatient services) to entities with which the physician has a financial relationship, unless the activity falls within a regulatory exception."³² Because the participating ACO physicians have a financial interest in the ACO, the physician will be violating the Stark Law or the Codey Law by referring to a physician or hospital within the ACO. However, a limitation on referrals within the ACO defeats the purpose of the project and will hinder the ACO's prospects of meeting its requirements.

²⁴ N.J.S.A. § 18A:71C-35

²⁵ KAISER HEALTH NET, *supra* note 11.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ New Jersey Appellate Court Holds Private Entities Lack Standing to Enforce Codey Law, HEALTH CAPITAL, (March 12, 2012) http://www.healthcapital.com/hcc/newsletter/12_09/Codey.pdf

³⁰ Social Security Act § 1887; 42 U.S.C. § 1395nn.

³¹ *Id.*

³² KAISER HEALTH NET, *supra* note 11.

Some of the referrals that will occur within the ACO will violate the Codey Law. In order to succeed in implementing ACOs in New Jersey, the Board of Medical Examiners (BME) under the authority of the State of New Jersey should issue an advisory letter which includes regulatory waivers that will exempt ACOs participants from violating the Codey Law while participating in the ACO and referring to fellow ACO physicians. In October 2011, the Center for Medicare and Medicaid Services (CMS) released the interim final Federal Regulations for ACOs.³³ The Regulations include a waiver to exempt ACOs participants from the Stark Law when³⁴ “the financial relationship is reasonably related to the purposes of the Shared Savings Program.”³⁵ However, these Federal waivers will not protect New Jersey ACO participants from the Codey Law. Yet, even though a referral may appear to be a self-referral within the ACO, closer scrutiny will show that not all self-referrals will violate the Codey Law. Thus, not all self-referrals within the ACO will require exemption from the Law.

The thesis of my Note is that New Jersey’s legislation enacting the Medicaid Accountable Care Organization Demonstration Project will violate New Jersey’s Codey Law because it encourages physician self-referrals that are prohibited by the Codey Law. By analyzing the federal government’s waivers to the Stark Law, New Jersey can establish regulations that will allow ACOs to optimize gainsharing without violating the law. Part II of this Note takes a detailed look at what an Accountable Care Organization is and why many view it as a promising way to lower health care costs. Next, I will explain the current New Jersey legislation authorizing the establishment of ACOs and the New Jersey law that prohibits self-

³³ *Id.*

³⁴ *Id.*

³⁵ 42 C.F.R. Chapter IV (2011).

referrals. I will also analyze the CMS's Federal Regulations for ACOs, which will exempt ACOs from certain provisions of federal physician self-referrals laws.

II. BACKGROUND

A. The ACO Concept

An ACO is an “integrated healthcare delivery system that relies on a network of primary care physicians, one or more hospitals, and sub-specialists to provide care to a defined patient population.”³⁶ The system would reward hospitals and physicians for reporting certain quality measures and “link payment to the attainment of performance goals,” such as achieving better clinical outcomes and lowering costs in order to yield increased value.³⁷ Under this model, the hospital and physician networks would be responsible for the quality of care delivered to patients and would receive bonuses for providing high-quality, low-cost care.³⁸ ACOs are modeled after entities regarded by the healthcare industry as quality leaders in health care, such as the Mayo Clinic, Kaiser Permanente, Geisinger Health System, and the Cleveland Clinic.³⁹

The groundwork for the shared accountability method emerged from a January 2007 *Health Affairs* article and a March 2007 report to Congress from the Medicare Payment Advisory Committee.⁴⁰ In the *Health Affairs* article, Elliot Fisher and colleagues argued that

Medicare beneficiaries receive most of their care from relatively coherent local delivery systems comprising physicians and the hospitals where they work or admit their patients. Efforts to create accountable care organizations at this level-the extended hospital medical staff-deserve

³⁶ Bill Asyltene, Paul DeMuro, Esq., Laura Jacobs, Paul Katz, Daniel Meron, Esq., Daniel Settelmayer, Es., Brian Silversteign, M.D., Julie Marder, Esq., *Accountable Care Organizations - Physician/Hospital Integration*, The Health Lawyer 21 Health Law. 1 2008-2009.

³⁷ *Id.*

³⁸ *Id.*

³⁹ CONGRESSIONAL RESEARCH SERVICE, *supra* note 2.

⁴⁰ Medicare Payment Advisory Commission, Report to the Congress: Assessing Alternatives to the Sustainable Growth Rate System 188 - 189 (March 2007), *available at* http://www.medpac.gov/documents/Mar07_SGR_mandated_report.pdf.

consideration as a potential means of improving the quality and lowering the cost of care.⁴¹

Furthermore, Dr. Fisher, who coined the term “ACO,” wrote that

these measures should rapidly move from the current generation of technical quality measures to focus on patient-level health outcomes and experience measures that reflect ACOs’ ability to deliver patient-centered care that is well coordinated across providers and improves outcomes for patients.⁴²

Promoting a more efficient use of care settings, providers, and use of treatments will theoretically allow ACOs to reach these goals.⁴³ There will be an emphasis on physicians instead of insurers or hospitals since physicians “control (directly or indirectly) 87% of all personal health spending.”⁴⁴

1. Patients

ACOs can benefit patients in many ways.⁴⁵ They provide patients with a greater role in guiding of their own care, offering incentives to prevent diseases, and reducing duplicative tests.⁴⁶ Patients receive much of their healthcare separately and many hope the ACO model will prove that this method works better than a patchwork of services and costs less in order to work.⁴⁷ However, patients are not required to participate in the ACO.⁴⁸ ACO providers are required to notify their patients, who then have the option to go to another doctor if the patient

⁴¹ *Id.*

⁴² Elliot S. Fisher, Mark B. McClellan, John Bertko, Steven M. Liberman, Julie J. Lee, Julie L. Lewis & Jonathan S. Skinner, *Fostering Accountable Health Care: Moving Forward in Medicare*, 28 HEALTH AFF. 219, 219 (2009).

⁴³ *Id.*

⁴⁴ RESEARCH SERVICE, *supra* note 2, citing Lawton Robert Burns and Ralph W. Muller, “Hospital-Physician Collaboration: Landscape of Economic Integration and Impact on Clinical Integration,” *Milbank Quarterly*, vol. 86, no. 3 (2008), p. 377, citing A. Sager and D. Socolar 2005. *Health Costs Absorb One-Quarter of Economic Growth 2000-2005*. Boston: Boston University School of Public Health.

⁴⁵ *Atlantic Health, with hospital in Summit, creates accountable care organization, linchpin in health reform*, NJ.COM (March 12, 2012)

http://www.nj.com/independentpress/index.ssf/2011/01/atlantic_health_with_hospital.html

⁴⁶ *Id.*

⁴⁷ KAISER HEALTH NET, *supra* note 2.

⁴⁸ *Id.*

does not want to participate in the ACO⁴⁹ without paying more.⁵⁰ The patient can decline to have his data shared within the ACO,⁵¹ but ideally the providers will track and share patient history electronically.⁵² Such data and history will allow the providers to develop ways together to control or prevent illness.⁵³ Physicians will be likely to want to refer patients to specialists and hospitals within the ACO network.⁵⁴

2. Gainsharing

As policymakers face the failure of fee-for-service medicine to properly align quality and efficiency standards, a shared accountability tactic to physician payment has emerged.⁵⁵ Under the current “fee-for-service” system, Medicaid providers are paid for services performed. Therefore, providers do not have an economic incentive to eliminate unnecessary services. Unlike the typical fee-for-service model, Medicaid will compensate ACO-participating providers not only for services performed, but also for “demonstrating improved clinical performance and increased efficiency through collaboration with other providers in the network”⁵⁶ through the concept of gainsharing as an incentive to increase care by lowering costs. Gainsharing refers to the “sharing of cost savings attributable to physicians’ efforts in controlling the costs of providing patient care.”⁵⁷ The Department of Health and Senior Services, while utilizing outcome evaluation data provided by the Rutgers Center for State Health Policy,

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *N.J. lawmakers advance bill on rewards for preventing, controlling illnesses among N.J. Poor*, NJ.COM (March 12, 2012) http://www.nj.com/news/index.ssf/2011/01/lawmakers_approve_bill_on_rewa.html

⁵³ *Id.*

⁵⁴ KAISER HEALTH NET, *supra* note 2.

⁵⁵ Jackson Williams, J.D., M.P.A., *The Shared Accountability Approach to Physician Payment: Four Options for Developing Accountable Care Organizations*, 7 Ind. Health L. Rev. 185 (2010)

⁵⁶ *Id.*

⁵⁷ Ellen V. Weissman, Esq., *Structuring Incentive Payment and Shared Savings Programs*, HEALTH LAWYERS, (March 12, 2012) <http://www.healthlawyers.org/Events/Programs/Materials/Documents/MM10/weissman.pdf>

shall approve only those gainsharing plans that promote: improvements in health outcomes and quality of care, as measured by objective benchmarks as well as patient experience of care; expanded access to primary and behavioral health care services; and the reduction of unnecessary and inefficient costs associated with care rendered to Medicaid recipients residing in the ACO's designated area.⁵⁸

ACOs will be rewarded for their efficiency relevant to their previous levels of efficiency.⁵⁹ If the ACO meets quality and savings requirements, it will qualify for a percentage of the savings.⁶⁰

Overall, doctors, hospitals, and insurance companies in New Jersey's poorest communities will receive financial rewards for preventing and controlling illnesses, instead of just treating them.⁶¹

Providers would get more money for keeping their patients out of the hospital and healthy, and not just for providing more procedures.⁶² However, there is also a penalty for being inefficient.⁶³

If an ACO does not save enough money, the ACO would have to pay the cost of the investments it made.⁶⁴ It could also have to pay a penalty if performance and savings benchmarks aren't met.⁶⁵

In order to control health care costs in general, doctors will need to stop providing costly medical services that are unlikely to help patients.⁶⁶

[A]lthough the reimbursement methodology used for hospitals creates an incentive to provide services cost effectively, the traditional reimbursement system for physicians creates an incentive for them to order more services: the greater the volume of services, the greater the reimbursement.⁶⁷

⁵⁸ N.J.S.A. 30:4D-8.5

⁵⁹ Lopez, *supra* note 4.

⁶⁰ Stainton, *supra* note 12.

⁶¹ *N.J. Lawmakers advance bill on rewards for preventing, controlling illnesses among N.J. poor*, NJ.COM, (Jan. 24, 2011) http://www.nj.com/news/index.ssf/2011/01/lawmakers_approve_bill_on_rewa.html

⁶² KAISER HEALTH NET, *supra* note 2.

⁶³ Lopez, *supra* note 4.

⁶⁴ KAISER HEALTH NET, *supra* note 2.

⁶⁵ *Id.*

⁶⁶ Stainton, *supra* note 12.

⁶⁷ *Id.*

Physician orders can drive up hospital costs.⁶⁸ This could arguably be restrained, though, because ACOs make providers jointly accountable so all participating providers will have a financial incentive to save money.⁶⁹ One way to save a significant amount of money is to avoid unnecessary tests and procedures, which drastically drive up costs.⁷⁰ Other ways that ACOs will be able to reduce costs is through lowering administrative costs, eliminating waste, and better patient care for the chronically ill.⁷¹

One concern from hospital and doctor groups is that they will be held accountable if patients go outside an ACO for care.⁷² These groups want less stringent standards of being held financially accountable for these patients and are resisting efforts to penalize them if they miss savings targets.⁷³ However, ACOs will be set up to reach cost savings goals because of its resources and capacities.⁷⁴ ACOs have deeper financial resources than fragmented care.⁷⁵ For example, ACOs will have access to better health records and data analysis.⁷⁶ This will make it easier to coordinate care. Also, ACOs will have better management expertise and greater capital.⁷⁷

B. MEDICARE AND CMS ACO REGULATIONS

1. Medicare ACOs and the Affordable Care Act

The PPACA “authorized Medicare to enter into contracts with ACOs in what is called the Medicare Shared Savings Program ... [and] ... left it to CMS to decide on the rules and

⁶⁸ *Id.*

⁶⁹ KAISER HEALTH NET, *supra* note 2.

⁷⁰ *Id.*

⁷¹ Implementing the Affordable Care Act: What Role For Accountable Care Organizations? Symposium, *ACOs and the Decline of Physician Autonomy*, Jessica Mantel, Seton Hall University School of Law (October 28, 2011).

⁷² *Id.*

⁷³ Jordan Rau, *Insurers, health-care providers at odds on rules for 'accountable care organizations*, KAISER HEALTH NEWS (January 9, 2011).

⁷⁴ Mantel, *supra* note 71.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

standards for this program, and the agency issued final regulations in October 2011.”⁷⁸ Prior to the PPACA, CMS conducted its own demonstration project from 2005 through 2010, the Medicare Physician Group Practice demonstration, which involved one physician-hospital organization and nine multispecialty group practices.⁷⁹ The ten organizations could retain a “portion of the savings they generated for Medicare, relative to a projected spending target, and they could increase their share of savings depending on how well they performed on a set of 32 quality measures.”⁸⁰ This project was considered to be the immediate predecessor to ACOs and the results “suggest that ACOs will be able to improve the quality of care they deliver (at least as measured by process-oriented clinical quality measures) but may have a harder time generating savings.”⁸¹ CMS projects that the Medicare Shared Savings Program will generate up to \$940 million in net federal savings in its first four years, assuming 270 ACOs sign up to participate.⁸² CMS expects better evidence about how to reduce costs using ACO-style payment arrangements and improve quality within the next few years.⁸³

2. Self-Referral Laws

Distributing bonus payments among providers and structuring an ACO presents challenging legal issues.⁸⁴ ACO “[p]rovider and practitioner collaboration may implicate a variety of federal and state healthcare program fraud and abuse laws.”⁸⁵ ACOs that are successful enough to earn “incentive bonuses or that receive partial capitation must find a mechanism to distribute the bonuses or partial capitation to participating providers in a manner

⁷⁸ *The Next Steps for ACOs*, HEALTH AFFAIRS (January 31, 2012), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=61

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ Glenn E. Soloman, Robert W. Lundy, David A. Hatch, *Future Models: The formation of affordable care organizations may revolutionize the concept of managed care*, 33 L.A. Law 34, 37 (2010-2011).

⁸⁵ *Id.*

that provides incentives for qualifying behavior but at the same time does not violate federal and state laws relating to patient referrals.”⁸⁶ Because of the financial incentives to keep an ACO patient within the ACO discussed above, ACO participants will likely violate Physician Self-Referral Laws.⁸⁷ Under these laws, “if a physician has any financial relationship with an entity that furnishes so-called designated health services, such as a hospital, the physician may not refer any [Medicaid] patients to that entity unless the relationship fits into an exception.”⁸⁸ As a result, “any shared savings program must be structured so that it fits within existing Stark exceptions—even though doing so may limit the ability of an ACO to recognize specific providers for their contributions to cost savings and higher quality care.”⁸⁹ Many legislators and policy makers have argued that health care utilization and costs increase inappropriately when physicians are able to reap financial profits from their referrals of health care services.⁹⁰ One argument of legislators and policy makers is that if physicians cannot benefit financially from their referrals, they will not only make fewer referrals, but the referrals they do make will be medically unnecessary and motivated solely by profit.⁹¹

The Federal Physician Self-referral Law (“Stark”) is found in the Social Security Act.⁹² It prohibits physicians from referring Medicare and Medicaid patients for designated health services (including inpatient and outpatient services) to entities with which the physician has a financial relationship, unless the activity falls within a regulatory exception.⁹³ This is enforced by CMS.⁹⁴ The Stark Law defines “referral” broadly, as a

⁸⁶ Soloman, *supra* note 84.

⁸⁷ Stainton, *supra* note 12.

⁸⁸ *Id.*

⁸⁹ Soloman, *supra* note 84.

⁹⁰ Stainton, *supra* note 12.

⁹¹ *Id.*

⁹² Social Security Act § 1887; 42 U.S.C. § 1395nn

⁹³ Stainton, *supra* note 12.

⁹⁴ *Id.*

request by a physician for an item or service payable under Medicare or Medicaid (including the request by a physician for consultation with another physician and any test or procedure ordered or performed by such other physician), or a request by a physician for the establishment of a plan of care that includes the provision of a DHS.⁹⁵

The definition of “referral” does not include services personally performed by a referring/ordering physician, but services furnished by employees of, or other members of the same group practice as, the ordering physician.⁹⁶ Accordingly, physicians who personally perform the service they order for their patients can structure arrangements without worrying about potential Stark violations.⁹⁷ In order to implement ACOs supported by PPACA, “new regulations clearly delineating permissible referral arrangements, incentive gainsharing arrangements, and cost-reduction mechanisms are essential.”⁹⁸

The New Jersey Legislature enacted the Codey Law in 1989 as New Jersey’s version of the federal Stark Law.⁹⁹ The law intended to “eliminate financial incentives to physicians and other practitioners licensed by the New Jersey Board of Medical Examiners (BME) to refer their patients to entities in which they held any financial interest.”¹⁰⁰

2. CMS Federal Regulations

Congress has realized that an ACO program implicates the Stark Law and as a result, the “PPACA gives authority to HHS to waive [this statute] for the purpose of implementing the ACO program.”¹⁰¹ Legislators and policymakers assume that the ACO will be “composed of providers that tend to refer to one another (either admitting to the same hospital or referring to a

⁹⁵ *Stark Law: Information on penalties, legal practices, latest news and advice (FAQs)*, STARKLAW.ORG, (March 12, 2012) <http://starklaw.org/>

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Audrey A. Hale, Kristy Hlavenka, *Sweeping Changes to New Jersey’s Codey Law*, DRINKER BIDDLE (April 23, 2009) <http://www.drinkerbiddle.com/files/Publication/755ab5ee-eb3f-475f-b881->

¹⁰⁰ *Id.*

¹⁰¹ Soloman, *supra* note 84.

common set of specialists.”¹⁰² On October 20, 2011, CMS issued its interim final version of federal regulations for ACOs established under the PPACA.¹⁰³ The regulations are important because an ACO’s success depends on the rules –¹⁰⁴ if the rules “give providers too much flexibility, savings could vanish – or ACOs could even end up becoming a fiscal burden.”¹⁰⁵ However, if the rules are too strict, provider groups fear that few doctors and hospitals may join the ACO.¹⁰⁶ The Secretary of Health and Human Services, Kathleen Sebelius, has determined, “based on consideration of public input and the Department’s own analysis, that it is necessary to waive certain provisions of the Physician Self-Referral Law.”¹⁰⁷ Section 1899(f) of the Act, as added by the Affordable Care Act, “authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act.”¹⁰⁸

There are five waivers listed in the regulations: ACO Pre-participation Waiver, ACO Participation Waiver, Shared Savings Distribution Waiver, Compliance with the Stark Law Waiver, Waiver for Patient Incentives.¹⁰⁹ The first four waivers protect arrangements involving “an ACO, its ACO participants, and/or its ACO providers/suppliers, if the ACO has a participation agreement and remains in good standing under that agreement.”¹¹⁰ The fifth waiver, the ACO pre-participation waiver, is available for start-up arrangements (as defined in the waiver) 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 all other conditions of the waiver

¹⁰² CONGRESSIONAL RESEARCH SERVICE, *supra* note 4.

¹⁰³ Glenn E. Soloman, Robert W. Lundy, David A. Hatch, *Future Models: The formation of affordable care organizations may revolutionize the concept of managed care*, 33 L.A. Law 34, 37 (2010-2011).

¹⁰⁴ *Id.*

¹⁰⁵ Jordan Rau, *Insurers, health-care providers at odds on rules for ‘accountable care organizations*, KAISER HEALTH NEWS (January 9, 2011).

¹⁰⁶ *Id.*

¹⁰⁷ 42 C.F.R. Chapter IV (2011).

¹⁰⁸ 42 C.F.R. Chapter IV (2011).

¹⁰⁹ *Federal Agencies Address Legal Issues Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, OFFICE OF INSPECTOR GENERAL U.S. DEPT. OF HEALTH AND HUMAN SERVICES, <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>

¹¹⁰ 42 C.F.R. Chapter IV (2011).

are satisfied.”¹¹¹ These five waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start-up and operating activities that further the purposes of the Shared Savings Program.¹¹² The waiver specifically for compliance with the physician self-referral law is intended to

ease the compliance burden on providers that might elect to use existing Physician Self-Referral Law exceptions for their ACO arrangements and to reassure those with existing arrangements that already fit in such an exception that they need not undertake a separate legal review under the Federal anti-kickback statute or Gainsharing CMP.¹¹³

Waivers are not always needed. A waiver of a “specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law.”¹¹⁴ Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Physician Self-Referral Law.¹¹⁵ Failure to fit in a waiver is not, in and of itself, a violation of the laws.¹¹⁶ Existing exceptions and safe harbors might apply to ACO arrangements, depending on the circumstances.¹¹⁷ These include, among others, Physician Self-Referral Law exceptions for “employment, personal services arrangements, in-office ancillary services, electronic health records (EHR) arrangements, risk-sharing, and indirect compensation arrangements (to the extent an ACO arrangement is an indirect financial relationship).”¹¹⁸

The waivers will be self-implementing. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required by

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ 42 C.F.R. Chapter IV (2011).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

parties in order to be covered by a waiver. Parties need not apply for an individualized waiver.¹¹⁹ Moreover, when a waiver requires that the terms of the arrangement be reasonably related to the purposes of the Shared Savings Program, “the arrangement need only be reasonably related to one enumerated purpose, although we would expect that many arrangements would relate to multiple purposes.”¹²⁰ Where a reasonable relationship exists, it should not be difficult for parties to “articulate clearly the nexus between their arrangement and the purposes of the Shared Savings Program.”¹²¹

The ACO pre-participation and ACO participation waivers will also require an “audit trail of contemporaneous documentation that identifies core characteristics of the arrangement (as listed in the waiver text), is maintained for 10 years, and is available to the Secretary, upon request.”¹²² There is also a transparency requirement that requires public disclosure of those who seek waiver protection arrangements.¹²³ The public disclosure will include the description of the arrangement, but shall not include the financial or economic terms of the arrangement.”¹²⁴ The Final ACO Waivers Rule represents a dramatic departure for the Agencies, especially with regard to enforcement of the Stark law.¹²⁵ By allowing compensation to physicians to incentivize more efficient and effective care, and by focusing on procedural requirements ... the Agencies are “relieving ACOs and their participants of substantial regulatory uncertainty and burdens that would otherwise interfere with effective participation in the Shared Savings Program.”¹²⁶

¹¹⁹ 42 C.F.R. Chapter IV (2011).

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *ACOs Get Broad Waivers from Fraud and Abuse Laws*, McDermott, Will & Emory, (Nov. 10, 2011)

<http://www.mwe.com/info/news/wp1111a.pdf>

¹²⁶ *Id.*

However, most states, like New Jersey, have their own versions of the federal self-referral laws, which are not covered by this waiver. ACO advocates, including hospitals and physicians, argued that the laws are legal barriers that would prevent organizational, group, and individual providers from forming legitimate ACOs under the current laws.¹²⁷ Stakeholders have expressed concern that the restrictions these laws place on certain arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the Shared Savings Program.¹²⁸ The New Jersey legislation allows for waivers of the physician self-referral law, but waivers have yet to be implemented. It authorizes the Commissioner of Human Services to

apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and to secure federal financial participation for State Medicaid expenditures under the federal Medicaid program, and shall take such additional steps as may be necessary to secure on behalf of participating ACOs such waivers, exemptions, or advisory opinions to ensure that such ACOs are in compliance with applicable provisions of State and federal laws related to fraud and abuse, including, but not limited to, anti-kickback, self-referral, false claims, and civil monetary penalties.¹²⁹

C. NEW JERSEY ACCOUNTABLE CARE ORGANIZATIONS FOR MEDICAID PATIENTS

1. New Jersey ACO Legislation

The New Jersey Legislation establishing the Medicaid Accountable Care Demonstration Project is “[a]ligned closely with the ACOs described in the federal Affordable Care Act,” as the legislation “would create multi-stakeholder, geographic Medicaid ACOs.”¹³⁰ The Medicaid ACOs will be similar to the Medicare ACOs discussed in the PPACA with regards to technology

¹²⁷ *Id.*

¹²⁸ 42 C.F.R. Chapter IV (2011).

¹²⁹ N.J.S.A. 30:4D-8.1

¹³⁰ Camden Coalition of Healthcare Providers – Medicaid ACO Demonstration Projects - <http://www.camdenhealth.org/data-research/medicaid-acos-in-nj/>

and clinical theory,¹³¹ however the key difference is which patients each ACO is targeting.¹³²

The New Jersey law authorizes a three-year Medicaid ACO demonstration project¹³³ and community-based, non-profit coalitions can apply for recognition by the State of New Jersey as a Medicaid ACO.¹³⁴ The applicants will need 100% of the acute care hospitals, 75% of the primary care providers, two behavioral health providers, and two community residents from that geography on the board of the organization.¹³⁵

The New Jersey Legislation establishing the Medicaid Accountable Care Demonstration project seeks to:

(1) increase access to primary care, behavioral health care, pharmaceuticals, and dental care by Medicaid recipients residing in defined regions; (2) improve health outcomes and quality as measured by objective metrics and patient experience of care; and (3) reduce unnecessary and inefficient care without interfering with patients' access to their health care providers or the providers' access to existing Medicaid reimbursement systems.¹³⁶

A major goal is also to reduce the inappropriate utilization of high-cost emergency care by Medicaid recipients and others, especially where an individual's need is more properly addressed through non-emergency primary care treatment.¹³⁷

While an ACO alters the coordination and delivery of care, it does not seek to change the reimbursement process: doctors, hospitals and other caregivers will continue to bill the state's Medicaid program, which is administered through private insurance providers.¹³⁸ Participating

¹³¹ Implementing the Affordable Care Act: What Role For Accountable Care Organizations? Symposium, *Lessons from ACO Implementation in New Jersey*, John Jacobi, Seton Hall University School of Law (October 28, 2011).

¹³² *Id.*

¹³³ *Medicaid ACO Demonstration Projects*, CAMDEN COALITION OF HEALTHCARE PROVIDERS (March 12, 2012) <http://www.camdenhealth.org/data-research/medicaid-acos-in-nj/>

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ N.J.S.A. 30:4D-8.1

¹³⁷ *Id.*

¹³⁸ Stainton, *supra* note 12.

providers will still receive their usual Medicaid payments.¹³⁹ Under the ACO Project, payment shall continue to be made to providers of services and suppliers participating for services provided to managed care recipients or individuals who receive services on a fee-for-service basis in the same manner as they would otherwise be made, except that the ACO is eligible to receive gainsharing payments in addition.¹⁴⁰

The law does not require the ACOs to focus on any particular region.¹⁴¹ However, the law does require an ACO to focus on a geographic region with at least 5,000 Medicaid patients and a hospital that treats a large number of so-called “charity care patients,” or those without insurance or an ability to pay.¹⁴² New Jersey is a state with socioeconomic segregation – the poor tend to live in cities while the wealthy are more likely found living in the suburbs.¹⁴³ Therefore, Medicaid ACOs will probably be implemented in New Jersey cities.

Many New Jersey State Legislators believe ACOs are necessary because the State is going broke.¹⁴⁴ New Jersey in particular is seen as an outlier in hospitalization and care.¹⁴⁵ The law is about “spending State health care dollars smarter, and improving care for people who depend on our State’s health care safety net for access to medical services,” said Senator Whelan, D-Atlantic, and a member of the Senate health panel.¹⁴⁶ Senator Whelan also stated, “[r]ight now, we lack the objective evaluation and cost-effective protections to make sure that

¹³⁹ CAMDEN COALITION OF HEALTHCARE PROVIDERS, *supra* note 133.

¹⁴⁰ N.J.S.A. 30:4D-8.12

¹⁴¹ CAMDEN COALITION OF HEALTHCARE PROVIDERS, *supra* note 133.

¹⁴² *Id.*

¹⁴³ Implementing the Affordable Care Act: What Role For Accountable Care Organizations? Symposium, *Lessons from ACO Implementation in New Jersey*, John Jacobi, Seton Hall University School of Law (Oct. 28, 2011).

¹⁴⁴ Helen Oscislowski, *ACO Pilots for New Jersey -- Will they “fly?”*, LEGAL HEALTH INFORMATION EXCHANGE, (Jan. 19, 2007) <http://www.legalhie.com/acos/aco-pilots-for-new-jersey----will-they-fly/>

¹⁴⁵ *Id.*

¹⁴⁶ Oscislowski, *supra* note 144.

we're getting the biggest bang for our buck, and providing the best care possible for people enrolled in the Medicaid system. It's time that we do better for New Jerseyans in need."¹⁴⁷

2. Medicaid in New Jersey¹⁴⁸

Legislators and policymakers conceived the New Jersey ACO model "as a way to achieve and reward high-quality, appropriately accessible and affordable patient care in communities in which these traits are most often and obviously lacking."¹⁴⁹ New Jersey's ACO Project will focus on Medicaid patients.¹⁵⁰ Although the PPACA does not confine ACOs to Medicaid patients, the ACOs established under this project will be restricted to the indigent.¹⁵¹ Medicaid provides health insurance to pregnant women, parents/caretakers and dependent children, and people who are aged, blind or disabled.¹⁵² Medicaid pay for hospital services, doctor visits, prescriptions, nursing home care and "other healthcare needs, depending on what program a person is eligible for."¹⁵³ The Medicaid program provides coverage for roughly 1.3 million people in New Jersey¹⁵⁴ and the State's Medicaid budget in fiscal year 2010 was \$10.7 billion.¹⁵⁵ The Governor, legislators and New Jersey taxpayers are concerned with the "affordability of the existing Medicaid program, let alone any expansions to the program."¹⁵⁶ The federal government provides over 50% of Medicaid funds,¹⁵⁷ but States are responsible for

¹⁴⁷ *Id.*

¹⁴⁸ "In 1995, New Jersey Medicaid began moving Medicaid clients from a traditional fee-for-service health insurance program, in which healthcare providers bill Medicaid directly, into managed care. Under managed care, clients enroll in an HMO, which manages their healthcare and offers special services in addition to the benefits to which Medicaid clients are entitled." *NJ Medicaid and Managed Care*, Department of Human Services. <http://www.state.nj.us/humanservices/dmahs/info/resources/care/>

¹⁴⁹ Elizabeth G. Litten, *ACOs: Getting More for Less?*, 204 N.J.L.J. 522, 524 (May 23, 2011).

¹⁵⁰ Lilo Stainton, *supra* at 12.

¹⁵¹ *Id.*

¹⁵² *NJ Medicaid*, Department of Human Services Division of Medical Assistance & Health Services (March 12, 2012) <http://www.nj.gov/humanservices/dmahs/home/>

¹⁵³ *Id.*

¹⁵⁴ Lilo Stainton, *supra* at 12.

¹⁵⁵ *Id.*

¹⁵⁶ Elizabeth G. Litten, *ACOs: Getting More for Less?*, 204 N.J.L.J. 522, 524 (May 23, 2011).

¹⁵⁷ Lilo Stainton, *supra* at 12.

finding solutions to Medicaid budgetary problems stemming from rising Medicaid costs.¹⁵⁸ Medicaid patients are two times more likely to go to the ER than their own doctor,¹⁵⁹ which leaves these patients without any coordinated care.¹⁶⁰ Because a hospital is always staffed, there is less incentive to go to a private physician's office and wait for care.¹⁶¹ Focusing on Medicaid makes particular sense in New Jersey because the State has a very fragmented marketplace of hospitals, providers, and payers.¹⁶² The high concentration of Medicaid patients in urban, impoverished cities, "with a high percentage covered by government-sponsored health plans ... will make the ACO implementation model easier."¹⁶³ Medicaid patients are frequent utilizers of emergency rooms, which dramatically increases health care costs.¹⁶⁴ Reducing unnecessary "ER and hospital use for complex, Medicaid patients [will be] is less disruptive to the existing business model of New Jersey's hospitals and healthcare providers."¹⁶⁵

New Jersey has dysfunctional care. Although New Jersey has high quality doctors, care is uncoordinated and it is often difficult for the most vulnerable patients – the poor, people with disabilities or poor housing, and re-entering prisoners – to get primary care treatment.¹⁶⁶ Vincent Polistina, R-Atlantic, a member of the Assembly Health & Senior Services Committee, explained that

[o]ur current health care delivery and payment system often fails to provide high quality, cost-effective health care to the most vulnerable patients, many of whom have limited access to primary care services. ... Typically, individuals who incur

¹⁵⁸ Delia, *supra* note 15.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ CAMDEN COALITION OF HEALTHCARE PROVIDERS, *supra* note 133.

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Implementing the Affordable Care Act: What Role For Accountable Care Organizations? Symposium, *The Prospect of Being Hanged: Focusing the Physician Mind on ACOs*, Hal Teitelbaum, Seton Hall University School of Law (October 28, 2011), (March 12, 2012)

¹⁶⁵ CAMDEN COALITION OF HEALTHCARE PROVIDERS, *supra* note 133.

¹⁶⁶ Implementing the Affordable Care Act: What Role For Accountable Care Organizations? Symposium, *Lessons from ACO Implementation in New Jersey*, John Jacobi, Seton Hall University School of Law (October 28, 2011).

the highest medical costs, those cycling in and out of the hospital, are the ones who usually receive the poorest care. These are patients who tend to delay care, underutilize preventive care, seek care in hospital emergency departments or are admitted to hospitals for preventable problems.¹⁶⁷

Polistina believes that “ACOs should help them better navigate the health care system, resulting in better care and lower costs for the state’s Medicaid program.”¹⁶⁸

The Demonstration Project would not change the way in which Medicaid claims are currently paid. Rather, it would “allow an additional payment to providers participating in the Medicaid ACO to the extent savings are achieved (and from the savings realized, not from additional or new revenue required to fund the Project) as a result of improvements in access to needed services, achievement of quality standards, and coordination and information-sharing among the various participating providers.”¹⁶⁹ The Medicaid ACO will “‘sit on top’ of the existing care delivery and payment system and function as an invisible (to the patient) cohesive layer.”¹⁷⁰ It would permit voluntary participation by a Medicaid managed care organization (MCO). In addition, the MCO would continue to receive premium payments from Medicaid and operate in accordance with its Medicaid contract.”¹⁷¹

3. Camden Coalition of Healthcare Providers

The groundwork of an ACO for the indigent has already been established in Camden, New Jersey.¹⁷² The Camden Coalition of Healthcare Providers is a non-profit organization committed to improving the quality, capacity, and accessibility of the healthcare delivery system

¹⁶⁷ A. Rep, *Atlanticare to Launch Polistina-Sponsored Accountable Care Organization to Aid Low Income Patients, Lower Costs*, POLITICKERNJ, (October 19, 2011) <http://www.politickernj.com/51823/atlanticare-launch-polistina-sponsored-accountable-care-organization-aid-low-income-patients-l>

¹⁶⁸ *Id.*

¹⁶⁹ Elizabeth G. Litten, *ACOs: Getting More for Less?*, 204 N.J.L.J. 522, 524 (May 23, 2011).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² Tom Moran, *Focus on ‘Super Users’ saves lives and dollars in New Jersey*, NJ.COM (Jan. 25, 2011) http://blog.nj.com/njv_editorial_page/2011/01/focus_on_super_users_saves_liv.html

in Camden, New Jersey.¹⁷³ The broad partnership includes primary care doctors, nurses, hospitals, mental health caregivers, patient advocates and insurance representatives.¹⁷⁴ Dr. Jeffrey Brenner, a family doctor, created the organization in 2002.¹⁷⁵ It focuses on a small group of “super users” who make frequent hospital visits and absorb a great share of medical spending.¹⁷⁶ By providing more care for this group, he is driving down costs by nearly half and creating better outcomes.¹⁷⁷ The Camden Coalition is the model that State Legislators and others used in creating demonstration projects across New Jersey.¹⁷⁸ Two similar citywide healthcare coalitions have been formed in the cities of Trenton and Newark.¹⁷⁹

Data mining helped shape the operation of the Camden Coalition.¹⁸⁰ The Coalition focused on gathering data on healthcare “hot spots,” city blocks with high concentrations of the most costly and sickest patients.¹⁸¹ The vast majority of these patients are covered by Medicaid.¹⁸² The Coalition examined seven years of patient records and found that “20 percent of patients absorbed 90 percent of the healthcare expenditures in Camden.”¹⁸³ Moreover, many of these patients live in the same area.¹⁸⁴ Members of the coalition realized that by focusing on these clusters of high-cost, chronically ill patients, they could have a real impact on the city’s overall healthcare picture.¹⁸⁵ So far, the Coalition is seeing positive results.¹⁸⁶ Patients are

¹⁷³ *Medicaid ACO Demonstration Projects*, CAMDEN COALITION OF HEALTHCARE PROVIDERS (March 12, 2012) <http://www.camdenhealth.org/data-research/medicaid-acos-in-nj/>

¹⁷⁴ Stainton, *supra* note 12.

¹⁷⁵ *Id.*

Tom Moran, *Focus on ‘Super Users’ saves lives and dollars in New Jersey*, NJ.COM (Jan. 25, 2011) http://blog.nj.com/njv_editorial_page/2011/01/focus_on_super_users_saves_liv.html

¹⁷⁷ *Id.*

¹⁷⁸ L. Stainton, *supra* note 12.

¹⁷⁹ CAMDEN COALITION OF HEALTHCARE PROVIDERS, *supra* note 133.

¹⁸⁰ Stainton, *supra* note 12.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ Stainton, *supra* note 12.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

healthier and happier and initial results show a 40 percent to 50 percent reduction in healthcare costs.¹⁸⁷

IV. Analysis

A. The Medicaid Accountable Care Demonstration Project established by New Jersey law violates the Codey Law.

The ACO gainsharing structure encourages referrals within the ACO. However, these will be seen as self-referrals, which are often considered suspect financial relationships.¹⁸⁸ ACOs will need to defy the idea that health care utilization and costs increase inappropriately when physicians are able to reap financial profits from their referrals of health care services. It may be optimal for physicians to refer within the ACO to meet the ACO's benchmarks and reap financial profits.¹⁸⁹ Conventional wisdom about referrals and financial incentives will not necessarily apply to ACOs. People have argued that if physicians cannot benefit financially from their referrals, they will make fewer referrals that are medically unnecessary and motivated solely by profit under typical health care structures.¹⁹⁰ While participating in an ACO, a physician's incentive is still motivated by profit because the physician is working towards a piece of the savings from the gainsharing financial structure. With an ACO, physician self-referrals do not necessarily imply selfish, personal profit motives, but an incentive to obtain more money for the ACO to put back into improving health care. The profit motive with ACOs is to make less unnecessary self-referrals instead of more, however, without an exception, these referrals could still violate the Codey Law.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ Stainton, *supra* note 12.

¹⁹⁰ *Id.*

In order for an ACO to meet its goals, there may be an incentive for self-referrals. When the ACO is evaluated, State officials will not only look to the providers who are part of the ACO, but those outside as well that are treating the ACO patient.¹⁹¹ A key part of the ACO concept is that even if a patient is participating in an ACO, that patient is able to get care anywhere outside of the ACO.¹⁹² Ultimately, the ACO is held accountable for costs and services outside of the ACO. Doctor and hospital groups also want to avoid being held financially accountable for patients who go outside an ACO for care.¹⁹³ Although the savings an ACO would receive for reaching certain benchmarks is above and beyond the traditional fee-for-service payments providers will continue to receive, ACOs that do not meet their goals will receive penalties.¹⁹⁴ This concern will naturally lead to self-referrals within the ACO. The ACO will be incentivized to make sure the care that its patient receives will not inhibit the strategy of the ACO.¹⁹⁵ If the patient goes outside the ACO for treatment, the ACO may be taking a risk. If the ACO refers to someone within the ACO – someone who is aware of and has agreed to the ACO’s goals – the ACO might be taking on less risk. Presumably, the ACO primary care doctor, “the gatekeeper,” will refer within the ACO to coordinate care.¹⁹⁶

However, to truly determine whether a physician self-referral law prohibits a particular arrangement, three questions must be answered.¹⁹⁷ First, does the arrangement involve a referral of a Medicaid patient by a physician?¹⁹⁸ Second, it must be determined if there is any significant beneficial interest between the referring physician or family member of a physician and the

¹⁹¹ Jorge Lopez, *Promise and Pitfalls: Health Reform’s Medicare ACO Shared Savings Program*, AKING GROUP, (March 12, 2012) <http://www.akingump.com/jlopez>:

¹⁹² *Id.*

¹⁹³ Jordan Rau, *Insurers, health-care providers at odds on rules for ‘accountable care organizations*, KAISER HEALTH NEWS (January 9, 2011).

¹⁹⁴ Lopez, *supra* note 14.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Making Sense of the Stark Law: Compliance for the Medical Practice*, Massachusetts Medical Society, 2005.

¹⁹⁸ *Id.*

entity to which the referral is being made.¹⁹⁹ If the answers to these questions are “yes,” then it must be determined whether it fits into an exception.²⁰⁰

There will be numerous referrals within ACOs, especially because there is an incentive to keep a patient within the ACO. However, the Codey Law states that “[a] practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner’s immediate family, or the practitioner in combination with the practitioner’s immediate family who had the significant beneficial interest prior to the effective date of” the law.²⁰¹ The Stark law broadly defines “referral” to “include a request by a physician for an item or service payable under Medicare or Medicaid (including the request by a physician for consultation with another physician and any test or procedure ordered or performed by such other physician), or a request by a physician for the establishment of a plan of care that includes the provision of a DHS.”²⁰² The ACO participants are responsible for meeting certain quality and cost goals and therefore, participants will have a natural incentive to refer to other members of the ACO who share the same goals.²⁰³

The Codey Law prohibits referrals certain referrals when there is “a significant beneficial interest.”²⁰⁴ To determine if there is a significant beneficial interest, one can examine the ownership and financial interests between the referring physicians. A financial relationship is defined as a direct or indirect ownership or investment interest in an entity through equity, debt, or other means, or a direct or indirect compensation arrangement involving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, between a physician (or immediate

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ N.J.S.A. 45:9-22.5

²⁰² *Stark Law: FAQs*. STARKLAW.ORG. <http://starklaw.org/stark-law-faq.htm>

²⁰³ Bill Asyltene, Paul DeMuro, Esq., Laura Jacobs, Paul Katz, Daniel Meron, Esq., Daniel Settelmayer, Esq., Brian Silversteign, M.D., Julie Marder, Esq., *Accountable Care Organizations - Physician/Hospital Integration*, The Health Lawyer 21 Health Law. 1 2008-2009.

²⁰⁴ N.J.S.A. 45:9-22.5

family member) and an entity.²⁰⁵ Because ACO participants are all part of the same ACO legal entity and will benefit financially from the success of the ACO, ACO participants could share a significant beneficial interest.

A straightforward example of a direct ownership and financial would be if a referring physician refers a Medicaid patient to a physical therapy business in which the referring physician has equity interest, either through direct ownership or shares of stock.²⁰⁶ As a result of the ACO, an ACO participant does not necessarily have direct ownership interest or shares of stock in the physician's business to which he is referring to nor does the referring position have a direct ownership interest or shares of stock in the ACO. New Jersey ACOs will be a non-profit legal entity. Therefore, referring ACO participants will not violate the Codey law because of direct ownership and financial interests.

However, an indirect ownership or financial interest can also violate the Codey law. For example, if a physician refers a Medicaid patient to a psychiatrist and the referring physician is a direct co-owner of an imaging licensing company, which provided a capital loan to the psychiatrist's practice, there would be a violation.²⁰⁷ This indirect ownership situation could happen, but not as a result of the ACO because the referring physician would not have a co-ownership interest of the imaging licensing business as a result of both being ACO participants. Also, as stated above, the referring physician could never be a direct co-owner of the ACO.

Direct compensation agreements can also lead to violations. For example, if the referring physician has an independent contractual relationship with a clinical lab and also makes referrals to it, there's a potential violation.²⁰⁸ A physician participating in the ACO would require some

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 8.

²⁰⁷ *Id.* at 9.

²⁰⁸ *Id.* at 11.

sort of contract that sets out the ACOs compensation guidelines if awarded money through gainsharing, which could be considered a direct compensation agreement. However, this contractual agreement is with the ACO and not the physician or entity to which the physician is referring to. The referring physician is technically not making referrals directly to the ACO but instead is making referrals to someone who also has a contractual relationship with the ACO. This sort of direct compensation agreement example applied to ACOs will probably not cause a violation.

However, an indirect compensation arrangement could pose a problem. ACOs do offer compensation arrangements to referring physicians. For example, two physicians are ACO participants and refer to each other. They are not co-owners of any business nor do they have any direct financial relationship as a result of the ACO. However, they both have a significant beneficial interest in the ACO itself because they can receive money through gainsharing. By referring to another physician who is an ACO participant instead of one who is not could significantly benefit the physician if it ultimately improves the quality measures of the ACO. Therefore, even if the traditional financial or ownership relationship does not exist, simply being a part of the ACO leaves no room to avoid violating the Codey Law if referring to another ACO participant.

The Codey Law also has exceptions, but they will not prevent self-referral violation. Specifically, the law says that “[t]he restrictions on referral of patients established in this section shall not apply to ... medical treatment or a procedure that is provided at the practitioner’s medical office and for which a bill is issued directly in the name of the practitioner or the practitioner’s medical office; ... renal dialysis; ... and ambulatory surgery or procedures requiring anesthesia performed at a surgical practice registered with the Department of Health

and Senior Services pursuant to subsection g. of section 12 of P.L.1971, c. 136 (C.26:2H-12) or at an ambulatory care facility licensed by the Department of Health and Senior Services to perform surgical and related services,” if certain conditions are met. In an ACO, these exceptions will not apply for the same reasons described above. Even if the referring physicians fall under one of these exceptions, as ACO participants, they will still violate the Codey law.

B. The Board of Medical Examiners can issue an advisory letter, which will excuse the Demonstration Project from provisions of the Codey Law.

Because the financial incentives that may influence self-referrals can actually provide an incentive for better care at lower costs in an ACO, participants should not be penalized for carrying out the goals of the ACO and the best interest of the patient, despite a potential conflict with the Codey Law. To ensure health care providers will be exempt from penalties for violating the Codey Law, New Jersey State Board of Medical Examiners (BME) should develop Codey Law waivers via an advisory letter for ACOs established in New Jersey. These waivers will prevent the ACOs from violating the law and ease the concerns of other physicians who might be hesitant to make referrals, even if they are not violating the law.

The BME’s responsibility includes the protection of the public’s health, safety, and welfare, which includes “licensing medical professionals, adopting regulations, determining standards of practice, investigating allegations of physician misconduct, and disciplining those who do not adhere to requirements - thereby assuring the public that the physicians are qualified, competent, and honest.”²⁰⁹ The State has given the Board of Medical Examiners the authority to

²⁰⁹ State Board of Medical Examiners, OFFICE OF THE ATTORNEY GENERAL, (March 12, 2012) <http://www.state.nj.us/lps/ca/bme/>

draft advisory letters, which have the power to provide regulatory waivers for health care providers.²¹⁰ The State BME has issued regulations in the past regarding the self-referral law.²¹¹

C. New Jersey can look to recent federal regulations providing exceptions to the federal self-referral law for guidance.

Because CMS and HHS's Office of the Inspector General ("OIG") have recognized the need for the Stark Waiver, New Jersey should follow the federal government's lead in waiving parts of the Codey Law for ACOs. First, the BME letter should include a pre-participation waiver, which will allow proper start-ups.²¹² Moreover, the waivers should be self-implementing. This will be especially important in New Jersey where it is somewhat unclear which relationships will violate the Codey Law. If the waivers are self-implementing, the health care providers will not need to worry about clarifying the relationship among themselves or soliciting advisory letters regarding their specific relationship before making the referral. This will foster an efficient system of making the best health care choices for patients.

However, for those relationships that do violate the Codey Law, it will also be important for New Jersey to require that the terms of the relationship be reasonably related to one enumerated principal of the ACO.²¹³ It is advisable, however, that the BME put in guidance as to what a reasonable relationship entails. Finally, in order to assess how reasonable the relationship is and in the spirit of the transparency of the Codey law, documentation should also be required if the BME so requests it. As ACOs are becoming more popular throughout the country, health care providers may experience greater scrutiny as to what the financial arrangements are within the ACO. Keeping accurate records will only protect the ACO in the future.

²¹⁰ *Id.*

²¹¹ *Board of Medical Examiners Regulation* (May 3, 2011) http://www.njconsumeraffairs.gov/laws/BME_Regs.pdf

²¹² 42 CFR Chapter IV

²¹³ 42 CFR Chapter IV

IV. Conclusion

New Jersey's legislation enacting the Medicaid Accountable Care Organization Demonstration Project may violate New Jersey's Codey Law because it encourages physician self-referrals that are prohibited by the Codey Law. However, a closer look at the different financial relationships within the ACO show that not all referrals will violate the Codey Law. By analyzing the federal government's waivers to the Stark Law, New Jersey can establish regulations that will allow ACOs to optimize gainsharing without violating the law. Nevertheless, ACOs are a transitional program and not a model that will last forever.²¹⁴ Because improvement and calculated savings are based on the ACOs previous performance, there will come a point where the ACO cannot meet the ACOs criteria without sacrificing patient care.²¹⁵

²¹⁴ Lopez, *supra* note 14.

²¹⁵ *Id.*