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New Jersey's Medicaid ACO Pilot Program, Past and Future: A Baseline Report

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I. EXECUTIVE SUMMARY

New Jersey's Medicaid Accountable Care Organization Demonstration Project became law in 2011, representing a broad consensus that accountable care organizations ("ACOs") could improve the delivery of care in the Medicaid system. ACOs offer the promise of providing "the right care, at the right time, in the right place." The ACO law reflected a commitment to improve the care experience for Medicaid recipients, strengthen public health outcomes, and responsibly control the cost of care.

Several organizations comprising community representatives, advocates, and health and social service providers have taken up the call to examine the ACO form of community care. These organizations are active in their communities and have already had an impact on health care and outcomes. They are near a decision point: within weeks of this Report's release, the New Jersey Department of Human Services ("DHS" or "Department") is scheduled to release final regulations implementing New Jersey's Medicaid ACO law and providing the precise criteria by which applicants for certification as a New Jersey Medicaid ACO will be judged.

These organizations vary in many ways, but they are united in a core mission. They embody the belief that Medicaid-financed care can be excellent and cost-effective, and that vulnerable, high-risk patients can be engaged in care that improves their lives. They share a belief in transformational integration of a care system rooted in community, and in building links among housing, behavioral health, primary and specialty medical care, hospital care, nursing and community medicine care, and others devoted to improving health and lives. The regulations will start the clock for the organizations to apply for certification as a Medicaid ACO. Simultaneously, however, the organizations contemplating seeking ACO certification are facing

troubling sustainability issues. The difficulties arise from the changing structure of New Jersey Medicaid's finance system.

The Medicaid ACO law contemplated that Medicaid ACOs would have access to a revenue stream generated by "gainsharing," the award of a share in savings to Medicaid resulting from ACO efforts. The ACOs, under the law, would designate a geographic area in which at least 5,000 Medicaid recipients live. The ACOs would then provide community health services with the goal of improving care and reducing the rate of cost increase. If the ACOs could drive down the rate of Medicaid costs as compared with projected costs while establishing high standards of care and community engagement, they would share in the gain Medicaid realized from their efforts.

As the time for application for ACO certification nears, the path to financial sustainability is unclear. The gainsharing system described above is mandatory under the law only for fee-for-service ("FFS") Medicaid. Even in 2011, however, a minority of Medicaid recipients were served through Medicaid's FFS system. The majority were members of managed care organizations ("MCOs") that contract with Medicaid. Today, almost all Medicaid recipients in New Jersey are served through MCOs. But MCOs are not required to enter into gainsharing agreements with ACOs under the Pilot. If they do not voluntarily participate, the income stream earmarked by the law to sustain Medicaid ACOs will disappear. As of this writing, it is uncertain whether MCOs will enter into gainsharing agreements with ACOs.

This Report is the first of two that will examine the past and future of New Jersey's Medicaid ACO Pilot. This Report sets out the background and current status of the Pilot. The

second Report, to be released in April 2014, will reflect further discussions with stakeholders and further research and analysis on the sustainability of New Jersey's Medicaid ACOs.

This Baseline Report provides the following information:

- **Background and structure.** This Section describes the impetus for the New Jersey Medicaid ACO Pilot and sets forth the basic legal and organizational requirements contained in the Medicaid ACO law.
- **The business case for Medicaid ACOs in 2011.** The sense of mission that drove the passage of the Medicaid ACO law informed the business plans that emerged at that time. Early efforts of the organizations were grant-funded; sustainability was tied in substantial part to gainsharing.
- **Protections and guidance offered by the Medicaid ACO law on legal issues.** The health care delivery and finance system is in transition between a competitive, volume-driven, fee-for-service system, and an integrative, quality-driven system in which payments will be tied to results. Creating a Medicaid ACO requires navigating complex legal rules.
 - **Antitrust protections.** The Medicaid ACO law provides some legal protection to organizations that gain certification. The certification, then, has substantial value beyond access to gainsharing, as it permits collaborative activities necessary for the creation of linkages and clinical integration.
 - **Fraud & abuse guidance.** The Medicaid ACO law does not provide formal protections from the reach of a variety of fraud and abuse laws, but the structure created by the law and proposed regulations provides valuable guidance for Medicaid ACOs.
- **Common law liability of Medicaid ACOs.** This Section addresses the liability that can attach as ACOs actively manage health care. Possible liability traceable to unreasonably adopted care protocols, inadequately screened participating physicians, or improperly disclosed patient information is addressed.
- **Business plans redux: 2014.** In this Section, we describe the uncertainty in the relationship between MCOs and ACOs, set out some of the literature that treats

this relationship, and describe some alternative ventures that may be available to sustain ACOs.

We conclude this preliminary Report by describing our next steps. We will consult stakeholders and analyze developments elsewhere to provide additional assistance in furthering the mission of Medicaid ACOs. We will integrate that additional information into our Final Report, to be produced in April 2014. This benchmark Report contains several key takeaway points:

- **Health care delivery and finance are in the process of evolution from FFS financing and fragmented care delivery to some forms of global or case-based payment and integrated, patient-centered health care. This evolution offers the promise of moderated costs as well as improved patient care.**
- **The statutory mission of the Medicaid ACO Pilot project, to improve health care delivery to medically vulnerable Medicaid recipients through care improvement and coordination, has been embraced by many organizations around New Jersey.**
- **The business case for Medicaid ACOs was sound at the time of the 2011 passage of the Medicaid ACO Pilot statute, as many Medicaid recipients were in Medicaid FFS, and the State committed to sharing any financial gains realized through the efforts of Medicaid ACOs to improve care and reduce Medicaid costs.**
- **The approval of the Medicaid Global Waiver renders that business case more complex, as nearly all New Jersey Medicaid recipients are now out of the FFS system and enrolled in MCOs.**
- **Even without the promise of gainsharing, the Medicaid ACO Pilot statute offers value to organizations considering the formation of a Medicaid ACO.**
 - **The statute explicitly provides protection from challenges based on New Jersey's antitrust law to the operation of a Medicaid ACO.**

- **The draft regulations, crafted by New Jersey Medicaid after consultation with federal regulators, offer substantial guidance on how Medicaid ACOs may operate in compliance with federal antitrust law.**
- **The statute and draft regulations, crafted by New Jersey Medicaid after consultation with federal regulators, offer substantial guidance on how Medicaid ACOs may operate in compliance with federal and State fraud and abuse laws.**
- **New Jersey Medicaid has stated that certified New Jersey Medicaid ACOs will have access to substantial Medicaid data for the purpose of improving care quality and coordination for the patients they serve.**
- **These statutory benefits will permit community health care providers committed to serving the needs of Medicaid eligible patients and their communities to develop clinical and financial integration within a structure carrying the imprimatur of State law. This will add certainty and give a substantial comfort that doing the right thing – reducing the fragmentation of care and adopting cooperative, patient-centered delivery systems – will not be regarded by regulators as violating important health regulations.**
- **As organizations move from serving as community planners and cheerleaders for innovative care, and become coordinators of care for patients, they will be exposed to the liability perils to which all care providers and coordinators are subject. This exposure, while inevitable, is not a reason to shy away from the important mission of Medicaid ACOs. This Report describes some of the steps Medicaid ACOs can take, in consultation with their attorneys, to plan for exposure to liability for their conduct.**
- **The relationship between Medicaid MCOs and ACOs is now front and center in this Pilot, as any substantial gainsharing arrangements that can financially sustain Medicaid ACOs are now subject to negotiation with MCOs. That being said, there are commonalities of interest between ACOs and MCOs within Medicaid, and opportunities to collaborate that can redound to the benefit of all.**
- **The key takeaways, however, that will guide the authors as they move to the second phase of this analysis over the next several months are these:**
 - **The organizations that have formed around the idea of improving care for Medicaid-eligible residents in New Jersey remain committed to that**

important mission, notwithstanding changes in the structure of Medicaid financing.

- **The Medicaid ACO Pilot statute and draft regulations provide substantial benefit to any organization contemplating creating integrated care systems within New Jersey Medicaid, above and beyond the financial promise of gainsharing.**
- **The organizations remain committed to the mission of the 2011 statute; they need not, however, be constrained by the organizational vision that drove the drafting of the 2011 statute. They can and will explore alternative business models through which they may serve their communities.**

II. BACKGROUND AND STRUCTURE OF NEW JERSEY'S MEDICAID ACOS

The mission of New Jersey's Medicaid ACO Demonstration Project is to improve access to quality health care for the State's most vulnerable patients while also reducing inefficient costs.¹ The Legislature noted that many of the State's poorest patients lack access to coordinated, quality primary care and other appropriate medical care. As a result, many delay getting care, underutilize available preventive care, or rely on costlier care alternatives, such as hospital emergency departments ("EDs") or in-patient hospital care for preventable problems.² Dr. Jeffrey Brenner began highlighting these concerns more than a decade ago based on his experience as a primary care provider in Camden. Noting that one percent of patients accounted for thirty percent of medical costs, largely driven by costly emergency department visits for common primary care ailments, Dr. Brenner has been leading efforts in Camden to unite "local health care providers, hospitals, social service agencies, and patients to build a population-based model that improves care and controls costs for these ED 'super-utilizers.'"³ New Jersey's Medicaid ACO Pilot builds on Dr. Brenner's groundbreaking work in Camden by similarly focusing on regional collaboration and shared accountability to improve care for the State's most at-risk patients.⁴ The Demonstration's goals are to increase access to primary care, behavioral health care, pharmaceuticals, and dental care while improving health outcomes and quality, as

¹ See N.J. STAT. ANN. §§ 30:4D-8.1(a), (c).

² See *id.* § 30:4D-8.1(a).

³ Jeffrey Brenner & Nikki Highsmith, *An ACO Is Born In Camden, But Can It Flourish In Medicaid?*, HEALTH AFFAIRS BLOG (June 23, 2011), <http://healthaffairs.org/blog/2011/06/23/an-aco-is-born-in-camden-but-can-it-flourish-in-medicaid/>.

⁴ See N.J. STAT. ANN. §§ 30:4D-8.1(f).

measured by objective metrics and patient experience of care, and reducing unnecessary and inefficient care.⁵

New Jersey's Medicaid ACO Pilot chose the ACO model to achieve these goals, noting that this model of care delivery reform "has gained recognition as a mechanism that can be used to improve health care quality and health outcomes, while lowering the overall costs of medical care by providing incentives to coordinate care among providers throughout a region."⁶ Dr. Elliot Fisher, Director of Population Health and Policy at the Dartmouth Institute for Health Policy and Clinical Practice, reportedly coined the term, "accountable care organization," during a Medicare Payment Advisory Committee meeting in 2006.⁷ Because the FFS Medicare payment methodology incentivizes providers to provide a high volume of care regardless of its value to quality of care or health outcomes, Dr. Fisher and his colleagues proposed to make providers accountable for overall costs and quality of care for the population of patients they treat.⁸ The program would incentivize providers to provide appropriate, efficient care by permitting them to share in savings achieved if they also document improvements in the quality of the care they provide.⁹ Based on their research, they believed that ACOs could provide better health care at lower costs.¹⁰ Indeed, they found that in many instances, lower per beneficiary spending in Medicare was associated with increased quality and equal or better health

⁵ *Id.* § 30:4D-8.1(d); TRICIA MCGINNIS & DAVID MARC SMALL, CTR. FOR HEALTHCARE STRATEGIES, INC., POLICY BRIEF: ACCOUNTABLE CARE ORGANIZATIONS IN MEDICAID: EMERGING PRACTICES TO GUIDE PROGRAM DESIGN 15 (Feb. 2012), available at http://www.chcs.org/usr_doc/Creating_ACOs_in_Medicaid.pdf.

⁶ N.J. STAT. ANN. §§ 30:4D-8.1(b).

⁷ See Peggy Scanlan, *ACOs Not the Only Game in Town*, *American Hospital Assoc 'n*, HEALTH FORUM BLOG (Nov. 8, 2013), http://www.healthforum.com/aboutus/blogs/MarketingBlog/2013/November/1108MarketingBlog_SurveyACO.dhtml.

⁸ See Elliott S. Fisher *et al.*, *Fostering Accountable Health Care: Moving Forward in Medicare*, HEALTH AFFAIRS, at 222 (March/April 2009), <http://content.healthaffairs.org/content/28/2/w219.full.pdf+html>.

⁹ *See id.*

¹⁰ *See id.*

outcomes.¹¹ Thus in 2009, Dr. Fisher and others proposed a voluntary and incremental program to encourage Medicare ACO development as a means of addressing rising health care costs and increased fragmentation that threatened the fiscal sustainability of Medicare.¹²

The next year, Congress passed the Patient Protection and Affordable Care Act (“ACA”),¹³ Section 3022 of which added Section 1899 to Title XVIII of the Social Security Act to require the Secretary of the U.S. Department of Health and Human Services (“HHS”) to establish the Medicare Shared Savings Program (“MSSP”) by January 1, 2012.¹⁴ The MSSP encourages doctors, hospitals, and other health care providers involved in patient care to form Medicare ACOs “to facilitate coordination and cooperation among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs.”¹⁵ Similar in many respects to the voluntary program Dr. Fisher and his colleagues had proposed, a Medicare ACO voluntarily formed pursuant to the MSSP is held accountable for the care that it provides to a population of Medicare beneficiaries.¹⁶ As an incentive to improving care, a Medicare ACO that satisfies quality indicators may share in any savings it realizes through more efficient care delivery, as measured against a benchmark HHS must establish annually.¹⁷ Providers continue to receive Medicare FFS payments under the MSSP.¹⁸

¹¹ *See id.* at 220.

¹² *See id.* at 219, 222.

¹³ *See* The Patient Protection and Affordable Care Act, Pub. L. No. 111-48, § 3022, 124 Stat. 119 (2010); The Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-52, 124 Stat. 1029 (2010)).

¹⁴ *See* 42 U.S.C. § 1395jjj(a)(1); CENTERS FOR MEDICARE & MEDICAID SERVICES, *Statutory Basis for the Shared Savings Program*, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes_Regulations_Guidance.html (last visited Dec. 5, 2013).

¹⁵ CENTERS FOR MEDICARE & MEDICAID SERVICES, *supra* note 14.

¹⁶ *See* 42 U.S.C. § 1395jjj(a)(1).

¹⁷ *See id.* § 1395jjj(a)(1)(B).

¹⁸ *See id.* § 1395jjj(d)(1)(A).

The statute and implementing regulations¹⁹ establish a number of requirements for Medicare ACOs. For example, the ACO must have a formal legal structure and at least 5,000 beneficiaries attributed to it.²⁰ Under the Final Rule, HHS established two-tracks for Medicare ACOs, one in which the ACO may share in savings but bear no downside risk in its first three year agreement period, and another that provides a Medicare ACO a greater share of savings in exchange for assuming the downside risk of sharing the cost of care expenditures that exceed its benchmark.²¹ When the Centers for Medicare and Medicaid Services (“CMS”) finalized rules for the MSSP, CMS, the Federal Trade Commission (“FTC”), the U.S. Department of Justice (“DOJ”) Antitrust Division, and the Internal Revenue Service also issued guidance to explain how each would enforce aspects of the MSSP that implicate their regulatory jurisdiction.²² The goal of this extraordinary demonstration of inter- and intra-agency cooperation was to assuage stakeholder concerns about potential antitrust, fraud and abuse, and tax implications from participation in the MSSP and thereby to encourage Medicare ACO development.

While the federal government has focused on Medicare ACOs, New Jersey directed its attention to how ACOs could reform its Medicaid program. On August 18, 2011, New Jersey enacted the Medicaid ACO Demonstration Project²³ with support from a broad coalition of

¹⁹ See 42 C.F.R. Part 425.

²⁰ See 42 U.S.C. § 1395jjj(b)(2)(C)-(D).

²¹ See 42 C.F.R. §§ 425.600, 425.604, 425.606.

²² See Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011) [hereinafter “MSSP Antitrust Statement”]; Medicare Program, Final Waivers in Connection with the Shared Savings Program; Interim Final Rule, 76 Fed. Reg. 67,992, 68,009 (Nov. 2, 2011) [hereinafter “MSSP Waivers IFR”]; Internal Revenue Service Fact Sheet, *Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations*, FS-2011-11 (Oct. 20, 2011). See discussion of antitrust and fraud and abuse issues in Section IV, *infra*.

²³ See N.J. STAT. ANN. §§ 30:4D-8.1–8.15.

businesses, hospitals, healthcare providers, and consumer groups.²⁴ As is the case in the MSSP, participation in the Pilot is voluntary. Similar to health care providers who participate in Medicare ACOs, participating providers²⁵ will continue to receive Medicaid FFS or managed care reimbursements²⁶ for their professional services.²⁷ To incentivize increased care coordination and efficiency, providers who satisfy quality benchmarks will be eligible to share in savings generated by the Medicaid ACO. These gainsharing payments would be in addition to, and would not affect, Medicaid FFS or managed care reimbursements.²⁸

The similarities between New Jersey's Demonstration and the MSSP, however, do not overshadow significant distinctions between the two programs. Described as "unique in its ground-up, community-based approach,"²⁹ New Jersey's three-year Pilot focuses on combating fragmented care delivery by permitting only one Medicaid ACO in each designated area,³⁰ which the statute defines as a "municipality or defined geographic area in which no fewer than 5,000 Medicaid recipients reside."³¹ The MSSP, by contrast, attributes beneficiaries to a Medicare ACO based not on geography but rather on a retrospective analysis of the beneficiary's

²⁴ NAT'L GOVERNORS ASSOC'N, *Case Study: New Jersey Establishes Medicaid ACO Demonstration*, available at <http://statepolicyoptions.nga.org/sites/default/files/casestudy/pdf/New%20Jersey%20-%20Medicaid%20Accountable%20Care%20Organization.pdf>.

²⁵ Recognizing the evolving nature of primary practice, especially in under-resourced areas, the statute defines primary care provider to include licensed physician extenders, such as "physician assistants, advanced practice nurses, and nurse midwives whose professional practice involves the provision of primary care, including internal medicine, family medicine, geriatric care, pediatric care, or obstetrical/gynecological care." See N.J. STAT. ANN. § 30:4D-8.2.

²⁶ As discussed in more detail in Section VI, *infra*, managed care organizations (MCOs) that contract with the State are permitted but not required to participate in the Demonstration Project. See *id.* § 30:4D-8.7(a). MCOs that choose to participate must submit a separate Medicaid ACO gainsharing plan, and they are permitted to withdraw from the three-year pilot after one year. See *id.* § 30:4D-8.7(a) & (b). This is in contrast to non-MCO Medicaid ACO applicants, which must commit to being accountable for health outcomes, quality, cost, and access to care for at least three years after certification. See *id.* § 30:4D-8.4(c)(6).

²⁷ See *id.* §§ 30:4D-8.1(f), 8.12.

²⁸ See *id.* § 30:4D-8.5.

²⁹ MCGINNIS & SMALL, *supra* note 5, at 7.

³⁰ See N.J. STAT. ANN. § 30:4D-8.4(b).

³¹ See *id.* § 30:4D-8.2.

utilization of primary care services from an ACO provider in a given year.³² To further facilitate regional collaboration, each Medicaid ACO's application must have the support of one hundred percent of the general hospitals, at least seventy-five percent of the qualified primary care providers, and at least four qualified behavioral health care providers within the ACO's designated area.³³ The MSSP does not have similar requirements. In fact, guidance from the FTC and Antitrust Division of DOJ ("Antitrust Agencies") that established a safety zone for clinically integrated Medicare ACOs "that are highly unlikely to raise significant competitive concerns and, therefore, will not be challenged by the Agencies under the antitrust laws, absent extraordinary circumstances," also defined the outer boundary of this zone at 30 percent of each common service in each participant's primary service area,³⁴ far less than the Pilot's required participation percentages. The Demonstration also differs from the MSSP in that participating providers only share in savings and do not take on any downside risk.

Various intentional structural components of the Project complement and reinforce its community-focused design. Each Medicaid ACO must be a nonprofit corporation whose primary purpose is to improve "the quality and efficiency of care provided to Medicaid recipients residing in a given designated area."³⁵ The Pilot further requires the governing board to include representatives of a broad array of stakeholders in the designated area, "including, but not limited to, general hospitals, clinics, private practice offices, physicians, behavioral health care providers, and dentists; patients; and other social service agencies or organizations"³⁶ At least two consumer organizations with capacity to advocate for patients in the ACO's geographic area must have voting representation on the board, at least one of which must "have extensive

³² See 42 C.F.R. §§ 425.400, 425.402.

³³ See N.J. STAT. ANN. § 30:4D-8.4(c)(3).

³⁴ MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. at 67,028.

³⁵ N.J. STAT. ANN. § 30:4D-8.3(b).

³⁶ *Id.* § 30:4D-8.4(c)(2)(a).

leadership involvement by individuals residing within the designated area” and a physical location within the designated area.³⁷ In addition, at least one of the individuals on the board representing consumer organizations must live within the ACO’s defined area.³⁸

The Pilot also includes a number of mechanisms to regulate the activities of Medicaid ACOs and thereby ensure that they further the statutory aims of the Demonstration.³⁹ DHS, in consultation with the New Jersey Department of Health and Senior Services (“DHSS”), must review applications for certification to ensure proposed ACOs meet the minimum standards set forth in the statute.⁴⁰ DHS, again with input from DHSS, also must review certified Medicaid ACOs’ gainsharing plans, which will include “approv[ing] a methodology proposed by the Medicaid ACO applicant for calculation of cost savings and for monitoring of health outcomes and quality of care under the Demonstration Project.”⁴¹ The Department may only approve gainsharing plans that promote the statutory goals.⁴² Among the considerations the State must make when deciding whether to approve a gainsharing plan is whether the plan promotes care coordination through multi-disciplinary teams; expansion of medical homes; increased patient medication adherence; use of health information technology and sharing of health information; and use of open-access scheduling.⁴³ In performing this review, the Department must consider data regarding health outcomes and patient experience of care.⁴⁴ Each year, DHS, in consultation with DHSS, also must evaluate the Pilot to assess whether it has achieved

³⁷ *Id.* § 30:4D-8.4(c)(2)(b).

³⁸ *Id.*

³⁹ *Id.* § 30:4D-8.5(a).

⁴⁰ *Id.* § 30:4D-8.4(a), (c).

⁴¹ *Id.* § 30:4D-8.8(a)(3).

⁴² *Id.* § 30:4D-8.5(b).

⁴³ *Id.* § 30:4D-8.5(b)(1).

⁴⁴ *Id.* § 30:4D-8.5(b).

measurable cost savings or improvements in health outcomes or population health.⁴⁵ The Commissioners of DHS and DHSS must report the findings from these annual evaluations to the Governor and Legislature at the completion of the three-year Pilot, at which time they may recommend making the Demonstration Project permanent, if they find that it “was successful in reducing costs and improving health outcomes and the quality of care for Medicaid recipients . . .

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As discussed in more detail in Section IV below, the statute also includes provisions to make it less likely that Medicaid ACOs will face antitrust or fraud and abuse liability as a consequence of their participation in the Demonstration Project. The Legislature exempted Pilot activities from New Jersey antitrust laws and expressed its intent that the state action immunity doctrine would provide immunity to Medicaid ACOs from federal antitrust laws.⁴⁷ The statute also includes provisions aimed to guide Medicaid ACO conduct to comply with fraud and abuse laws.⁴⁸ These provisions are vital to the viability of the Pilot because the federal guidance establishing fraud and abuse waivers and antitrust protection for Medicare ACOs participating in the MSSP does not apply to Medicaid ACOs.⁴⁹

On April 12, 2013, the Division of Medical Assistance and Health Services in DHS issued proposed regulations to implement the Demonstration Project.⁵⁰ The public comment period closed on July 8, 2013, and it is expected that the State will finalize the regulations in

⁴⁵ *Id.* § 30:4D-8.9.

⁴⁶ *Id.* § 30:4D-8.14.

⁴⁷ *Id.* § 30:4D-8.1(g).

⁴⁸ *See, e.g., id.* § 30:4D-8.5(e); *see generally* discussion in Section IV.B, *infra*.

⁴⁹ *See* MSSP Waivers IFR, *supra* note 22, 76 Fed. Reg. at 68,007; MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. at 67,027.

⁵⁰ *See* Division of Medical Assistance and Health Services, *Medicaid Accountable Care Organization Demonstration Project Implementation of Demonstration Project Proposed New Rules: N.J.A.C. 10:79A*, Agency Control Number: 11-P-22, Proposal Number: PRN 2013-05445, N.J.R. 5(1) (May 6, 2013), <http://www.state.nj.us/humanservices/providers/ruleprop/RuleProposals/PRN2013054DHSDMAHS1079A.pdf> [hereinafter “N.J. Proposed Rule 10:79A-”].

early 2014. The proposed rules would require entities to submit their application for certification as a Medicaid ACO to the Department within 60 days of the effective date of the rules.⁵¹

III. THE BUSINESS CASE FOR MEDICAID ACOs IN 2011

Health care providers and community representatives, led by Dr. Jeffrey Brenner, were at the forefront encouraging the passage of New Jersey's Medicaid ACO law. Their mission was to advance the "Triple Aim" of "improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations"⁵² in poor areas of New Jersey in which Medicaid is the primary payer. Care in those areas had long suffered from significant barriers to the achievement of patient satisfaction, community health, and appropriate cost containment. Medicaid reimbursement has long been below other payers, with physician payment in New Jersey presenting particularly significant problems, and the shift from FFS Medicaid to managed care did nothing to redress that problem.⁵³ In addition, safety net hospitals in these areas faced another problem related to the passage of the ACA. The projected increase in the number of patients eligible for Medicaid and private insurance was certainly good news; the bad news was that the ACA, as a counterbalance to those gains, also phased in reductions in Disproportionate Share Hospital payments (in New Jersey distributed as "charity care"). Hospitals in many areas of New Jersey were concerned that the costs of caring for the residual

⁵¹ *Id.* 10:79A-1.5(b)(4). *Cf.* N.J. STAT. ANN. § 30:4D-8.4(a) ("The department shall accept applications for certification from demonstration project applicants beginning 60 days following the effective date of this act . . .").

⁵² Donald M. Berwick *et al.*, *The Triple Aim: Care, Health, And Cost*, 27:3 HEALTH AFFAIRS 759, 760 (2008).

⁵³ *See* Stephen Zuckerman *et al.*, *Trends In Medicaid Physician Fees*, 2003–2008, HEALTH AFFAIRS, Web Exclusive, at w510 (Apr. 28, 2009), available at <http://content.healthaffairs.org/content/28/3/w510.short>; Sandra L. Decker, *Two-Thirds Of Primary Care Physicians Accepted New Medicaid Patients In 2011-12: A Baseline To Measure Future Acceptance Rates*, 32:7 HEALTH AFFAIRS 1183 (2013) (noting that New Jersey physician participation lags due to historically low reimbursement rates); MARK DUGGAN & TAMARA HAYFORD, NAT'L BUREAU OF ECONOMIC RESEARCH, HAS THE SHIFT TO MANAGED CARE REDUCED MEDICAID EXPENDITURES? EVIDENCE FROM STATE AND LOCAL-LEVEL MANDATES, NBER Working Paper No. 17236 (July 2011), available at <http://www.nber.org/papers/w17236> (finding that Medicaid MCOs typically achieve cost savings by constraining reimbursement rates).

uninsured populations in their areas – undocumented persons, people for whom private coverage was unaffordable, and people not yet enrolled in available coverage – could overwhelm the gains realized by the increase in insured patients.⁵⁴

In addition to those fiscal difficulties, the nascent care organizations in these underserved areas also experienced the severe fragmentation that has long bedeviled health care delivery.⁵⁵ Robert Kane and colleagues, in an analysis of the benefits of increased coordination of care, have described the harm this fragmentation has done, particularly for vulnerable patients with chronic illness:

Rarely in a fragmented, poorly coordinated health care system is a single health care professional or entity responsible for a patient's overall care. . . . Imprecise clinician responsibility increases the chance that some services may conflict with others . . . and that still other needed services may not be provided at all. Among people with chronic conditions 71% report having no help in coordinating their care . . . and 17% say they have received contradictory medical information from health care professionals.

* * *

Patients with chronic conditions suffer from fragmented services . . . when they are treated not as persons but instead are segmented or compartmentalized into discrete organs or body systems. If health care professionals treat a malfunctioning system of the body rather than the person as a whole (i.e., treat the disease in the patient rather than treat the patient with disease), treatment can become a series of medical interventions that target only the disease and ignore the ill person.⁵⁶

⁵⁴ See Dennis P. Andrulis & Nadia J. Siddiqui, *Health Reform Holds Both Risks And Rewards For Safety-Net Providers And Racially And Ethnically Diverse Patients*, 30:10 HEALTH AFFAIRS 1830 (2011).

⁵⁵ See generally EINER ELHAUGE, ED., *THE FRAGMENTATION OF U.S. HEALTHCARE: CAUSES AND SOLUTIONS* (2010); Alain Enthoven, *Integrated Delivery Systems: The Cure for Fragmentation*, 15:10 AM. J. MANAGED CARE S284 (2009).

⁵⁶ ROBERT L. KANE, M.D., ET AL., *MEETING THE CHALLENGE OF CHRONIC ILLNESS* 50-51 (Johns Hopkins Univ. Press 2005).

In the target areas for Medicaid ACOs, the fragmentation problem was even graver, as their populations often needed a combination of social and medical services, and the task of adding an additional level of coordination to that presented by the health care system alone only made the task more daunting. The combination of medical resources stretched by tight reimbursement, the medical and socioeconomic fragility of the residents of the communities suffering high rates of chronic illness, and the deeply fragmented nature of the health care and social services systems were increasingly the focus of reform activity.

The business model of organizations seeking to form Medicaid ACOs followed the mission: to create and nurture organizations rooted in the community and dedicated to the transformational integration of services improving the health of residents in a cost-effective manner. The mission was both backward- and forward-looking. It reflected dissatisfaction with the missed opportunities for “right care, right time, right place” in communities reliant on their service providers for comprehensive and comprehensible care. It also reflected the knowledge that the health care finance system is changing, and that social service and health providers, particularly in vulnerable communities, needed to anticipate and plan for change. It was broadly agreed that the health finance and care delivery system is undergoing dramatic changes, and that dramatically different payment, and perhaps organizational, systems were on their way – perhaps including case and global payments, regional integrated systems, partnerships between care providers and finance entities, or not-yet-imagined combinations. The existing, fragmented care system, coupled with FFS and traditional managed care financing, would not be the future, and providers intent on serving their communities needed to prepare for change. That preparation included generating ideas for efficient, effective care delivery, and the means by which more effective methods of care could be financially sustained. The methods for creating viable

organizations include directing attention to community engagement, integrating care, empowering providers to transform the delivery system in primary care and chronic care management, implementing health information technology, and embracing gainsharing as a financing vehicle.

Under New Jersey’s Pilot, Medicaid ACOs must encompass a wide range of partners and be formed as “nonprofit corporations organized with the voluntary support and participation of local general hospitals, clinics, pharmacies, health centers, qualified primary care and behavioral health care providers, and public health and social services agencies.”⁵⁷ Their governing boards must include

[V]oting representation from at least two consumer organizations capable of advocating on behalf of patients residing within the designated area of the ACO. At least one of the organizations shall have extensive leadership involvement by individuals residing within the designated area of the ACO, and shall have a physical location within the designated area. Additionally, at least one of the individuals representing a consumer organization shall be an individual who resides within the designated area served by the ACO.⁵⁸

Organizations forming Medicaid ACOs recognized the humbling nature of attempting to improve the structure of care for vulnerable populations, and sought community engagement as a necessary element. The robust inclusion of community representatives and outreach was consistent with the literature on the creation of Medicaid ACOs. The Center for Health Care Strategies has produced many thoughtful studies guiding states and community organizations toward success in the mission of improving Medicaid care. The steps that it recommended in

⁵⁷ N.J. STAT. ANN. § 30:4D-8.3(a).

⁵⁸ *Id.* § 30:4D-8.4(b).

achieving a sound community partnership were consistent with those adopted by New Jersey organizations:

- Requiring ACO governance structures to include meaningful community and patient representation;
- Asking ACO applicants to provide a detailed community engagement strategy;
- Requiring community and social services participation in care teams; and
- Using community-level metrics to assess ACO performance.⁵⁹

Success was seen as possible only with community engagement, and the organizations as well as the legislation proceeded accordingly.

The organizations also accepted as a basic tenet the integration of health and social service providers. This integration includes governance responsibility, as reflected by the board composition required by the Medicaid ACO law. For less vulnerable populations, the integration of social services and health care may be a minor concern, but for the Medicaid population, social services, including housing and behavioral health services, “can provide critical support and much larger opportunities for coordination and cost reduction.”⁶⁰ In addition, the organizations saw the opportunity to address the service fragmentation in their communities by building relationships across and among service lines. The Medicaid ACO form is, then, an opportunity to improve the coordination of care. “Conceptually, ACOs are seen as a vehicle for

⁵⁹ MCGINNIS & SMALL, *supra* note 5, at 4.

⁶⁰ S. Lawrence Kokot *et al.*, *Early Experiences with Accountable Care in Medicaid: Special Challenges, Big Opportunities*, 16 POPULATION HEALTH MANAGEMENT S4, S10 (Suppl. 1 2013).

encouraging providers to build connectivity and collaboration across the full spectrum of health services that rests on a strong primary care foundation.”⁶¹

Primary care is in many ways the foundation of the ACO model, and the organizations therefore accepted the goal of linking primary care with community services.⁶² The linkages in the ACO model allow the provider of services, and in particular primary care physicians, to take leadership in the process. Through engaged provider leadership and sound linkages among participating providers and community members, the goal was to develop methods of outreach, creative patient engagement, and improved service delivery. “Building high-performing, cross-functional teams – in which all partners have well-defined roles and responsibilities and work closely with the primary care team – is essential.”⁶³

The organizations embraced New Jersey’s development of Health Information Exchanges as key components in this integrative model. The use of electronic health records and the exchange of information through Health Information Exchanges were accepted as basic tools to permit collaborative health providers to maintain consistent treatment plans as patients moved throughout the ACO service system.⁶⁴ The integration of sound health information technology not only permitted the improvement of care coordination, particularly for patients with chronic illness, but also allowed the identification of high-utilizing patients who might benefit from

⁶¹ TRICIA MCGINNIS & AMANDA VAN VLEET, CTR. FOR HEALTH CARE STRATEGIES, INC., CORE CONSIDERATIONS FOR IMPLEMENTING MEDICAID ACCOUNTABLE CARE ORGANIZATIONS 3 (Nov. 2012), *available at* http://www.chcs.org/publications3960/publications_show.htm?doc_id=1261462.

⁶² See MICHAEL STANEK, NATIONAL ACADEMY FOR STATE HEALTH POLICY, FEDERAL AND STATE POLICY TO PROMOTE THE INTEGRATION OF PRIMARY CARE AND COMMUNITY SERVICES 3 (Aug. 2013), *available at* <http://www.nashp.org/publication/federal-and-state-policy-promote-integration-primary-care-and-community-resources>.

⁶³ MCGINNIS & SMALL, *supra* note 5, at 3.

⁶⁴ See SHARON SILOW-CARROLL & JENNIFER N. EDWARDS, THE COMMONWEALTH FUND, EARLY ADOPTERS OF THE ACCOUNTABLE CARE MODEL: A FIELD REPORT ON IMPROVEMENTS IN HEALTH CARE DELIVERY 16 (March 2013), *available at* <http://www.commonwealthfund.org/Publications/Fund-Reports/2013/Mar/Early-Adopters-Accountable-Care-Model.aspx>.

outreach and coordinated care services.⁶⁵ Dr. Brenner and the Camden Coalition of Healthcare Providers used analysis of the data from their health information technology resources to identify “hotspots” of high use, and to fashion interventions that improved care and permitted efficient use of resources.⁶⁶

The organizations can take some comfort in the legal guidance and protection offered by the New Jersey Medicaid ACO law, as is described more fully below.⁶⁷ The organizational efforts necessary to compose a Medicaid ACO can acquire some protection from antitrust scrutiny through compliance with the ACO law. In addition, the guidance and requirements in the ACO law, and in the proposed regulations, will assist Medicaid ACOs as they navigate the strictures of various fraud and abuse laws.

The business plan, then, contemplated a reimagining of service delivery in New Jersey’s poorest neighborhoods. It was premised on community engagement, collaborative governance and service delivery among health and social services providers, and the use of technology to connect providers and permit the analysis of the needs of the population served. All of this would take money. Much of the seed money was provided by New Jersey’s Nicholson Foundation.⁶⁸ Sustainable Medicaid ACOs, however, needed a revenue source on a more permanent footing. The Medicaid ACO model is such that it has no subscribers, no patients of its own. Instead, the patients it touched were to be insured by New Jersey Medicaid, either

⁶⁵ *Id.*

⁶⁶ See Atul Gawande, *The Hot Spotters: Can We Lower Costs by Giving the Neediest Patients Better Care?*, THE NEW YORKER (Jan. 24, 2011), available at http://www.newyorker.com/reporting/2011/01/24/110124fa_fact_gawande.

⁶⁷ See Section IV, *infra*.

⁶⁸ See NICHOLSON FOUNDATION REPORT: IMPROVING HEALTHCARE FOR VULNERABLE POPULATIONS, available at http://www.thenicholsonfoundation-newjersey.org/programs/sub/Improving_Healthcare_for_Vulnerable_Populations.pdf.

directly or through the intermediation of a commercial MCO contracting with New Jersey Medicaid.

The vision of New Jersey Medicaid ACOs contemplated funding on an ongoing basis through “gainsharing,” a mechanism used in several settings pursuant to which a provider or an entity obtains compensation by reducing the cost of care experienced by an upstream provider or insurer.⁶⁹ In other words, gainsharing is available for demonstrated value added in health care delivery and finance arrangements. The Medicaid ACO law describes a process by which a Medicaid ACO could be entitled to payment from New Jersey Medicaid if it could demonstrate that it had provided high-quality care to FFS Medicaid enrollees within its geographic area at a lesser cost than trends predicted.⁷⁰ It also permitted, but did not require, that HMOs participating in Medicaid strike similar arrangements with Medicaid ACOs whereby the ACO could be contractually entitled to gainsharing proceeds from the MCO based on savings realized for that MCO’s Medicaid subscribers within the ACO’s geographic area.⁷¹

The goal of the nascent Medicaid ACO organizations, then, was to improve care and reduce costs by creating community-based organizations that could facilitate coordination among health and social service providers for the benefit of Medicaid-eligible persons in a particular geographic area. The business plans implementing that goal contemplated income streams from gainsharing arrangements with New Jersey Medicaid, and, at the option of the MCOs, with Medicaid-participating MCOs. The creation and maintenance of such an organization faced some legal difficulties, not dissimilar from those faced by Medicare ACOs permitted by the ACA. Like Medicare ACOs, New Jersey’s Medicaid ACOs faced the cognitive dissonance that

⁶⁹ See Nicole Martingano-Reinhart, Comment, *Gainsharing and the Patient Protection and Affordable Care Act*, 43 SETON HALL L. REV. 1325, 1325 (2013).

⁷⁰ N.J. STAT. ANN. § 30:4D-8.5.

⁷¹ *Id.* § 30:4D-8.7.

confronts all new health care ventures straddling the divide between the past (FFS, competitive, and volume-dependent care delivery) and the future (collaborative or integrated, quality-driven care delivery). The following Sections describe those issues and the means by which the organizations hoped to achieve the level of integration and collaboration needed to become a Medicaid ACO.

IV. ANTITRUST AND FRAUD AND ABUSE PROTECTIONS

ACOs form a bridge between an old health system and a new one. As is described above in Section III, the FFS system is keyed to isolated encounters and therefore tends toward fragmented care delivery. Newer systems are likely to focus on care integration and quality outcomes, with global payments, partial capitation, and as-yet-unknown innovative and case-based reimbursement tools. As care entities evolve, they will tend toward financial and clinical integration to respond to these new payment systems. As they do so, they must be aware that regulators are steeped in a history of “collaborative” undertakings serving as vehicles for maximization of market share, extraction of unwarranted payments, and diminution of care quality. Caregivers, then, must move toward exciting new organizational forms cognizant of regulatory skepticism and concern for old forms of fraud and abuse.

The New Jersey Medicaid Pilot’s statute and draft regulations (created in consultation between State and federal regulators) can help in the transition for Medicaid caregivers. They contain legal protections and structural guidance that can help organizations move to patient-centered, collaborative care without being tripped up by the many federal and State regulations to which they are subject. The Pilot’s protections and guidance are not entirely comprehensive, and the organizations should seek independent counsel on their integrative efforts. The

protections and guidance are extremely valuable components of the Pilot, permitting important organizational development within a structured framework. This Section describes some of the most important health regulations implicated by Medicaid ACOs' organization and operation, and the protections and guidance encompassed by the Pilot's statute and draft regulations.

A. Responding to Anticompetitive Concerns⁷²

Despite their mission of expanding coverage, improving quality, and controlling costs, Medicaid ACOs can implicate antitrust laws⁷³ because their call for increased regional coordination may threaten competition. Collaboration among competitors can lead to less competition,⁷⁴ which antitrust law strives to preserve in the belief that consumer choice can lead to quality and value.⁷⁵

The ACO model raises a number of anticompetitive concerns. If ACOs lead to greater integration, that could reduce the number of competitors and thus increase the market power of ACOs.⁷⁶ As market power increases, so does the potential that prices will reach uncompetitive

⁷² This discussion draws from a previous article, see Tara Adams Ragone, *Structuring Medicaid Accountable Care Organizations to Avoid Antitrust Challenges*, 42 SETON HALL L. REV. 1443 (2012).

⁷³ See Sherman Antitrust Act, 15 U.S.C. §§ 1-7 (Section 1 makes illegal every contract, combination, or conspiracy in restraint of trade); New Jersey Antitrust Act, N.J. STAT. ANN. § 56:9-1 *et seq.*

⁷⁴ See JAMES C. COSGROVE, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-291R, FEDERAL ANTITRUST POLICY: STAKEHOLDERS' PERSPECTIVES DIFFERED ON THE ADEQUACY OF GUIDANCE FOR COLLABORATION AMONG HEALTH CARE PROVIDERS 2 (Mar. 16, 2012), available at <http://www.gao.gov/assets/590/589393.pdf> [hereinafter "GAO"].

⁷⁵ TAYLOR BURKE ET AL., ALIGNING FORCES FOR QUALITY, HEALTH SYSTEM REFORM AND ANTITRUST LAW: THE ANTITRUST ASPECTS OF HEALTH INFORMATION SHARING BY PUBLIC AND PRIVATE HEALTH INSURERS 1 (July 2009), available at <http://www.stateinnovation.org/Publications/All-Publications/Report-2009-AligningForcesforQuality-HealthSystemR.aspx>. Although there are three primary federal antitrust laws, the Sherman Act, 15 U.S.C. §§ 1-7, the Clayton Act, 15 U.S.C. §§ 12-27, and the Federal Trade Commission Act, 15 U.S.C. §§ 41-58, Section 1 of the Sherman Act is most relevant for purposes of ACO antitrust analysis.

⁷⁶ See Richard M. Sheffler *et al.*, *Accountable Care Organizations and Antitrust*, 307 JAMA 1493 (2012); Thomas L. Greaney, *Regulators as Market-Makers: Accountable Care Organizations and Competition Policy* 16 (Aug. 4, 2012) (Working Paper), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2124097 [hereinafter "Greaney, *Regulators as Market-Makers*"]; cf. JULIE BRILL, COMM'R, FED. TRADE. COMM'N, REMARKS BEFORE THE NORTH CAROLINA BAR ASSOC'N'S ANTITRUST AND TRADE REGULATION SECTION 5 (Feb. 9, 2012), available at <http://www.ftc.gov/speeches/brill/120209nc-cle.pdf> (noting that ACOs participating in the MSSP could "interface with the antitrust laws in the future" because "as these integrated groups begin to act in the marketplace, they could potentially gain market power and reduce competition").

levels.⁷⁷ If Medicaid ACO health care providers negotiate their reimbursement rates as a block with Medicaid MCOs, for example, they could increase their market power and drive prices to uncompetitive levels. Even where FFS Medicaid prices are set by government and therefore are not susceptible to anticompetitive collusion,⁷⁸ reduced competition could have a negative effect on non-price elements, such as output, quality of services, and innovation.⁷⁹ Thus, it could raise antitrust concerns if Medicaid ACO providers agreed to limit business hours or restrict access to certain services to reduce costs, or if two hospitals agreed to specialize in different fields so that neither would compete with the other in these specialties.⁸⁰

Antitrust regulators also could be concerned that ACOs will negatively impact competition outside of the Medicaid markets. For example, while Medicaid ACO participants may collaborate to decide how to divide shared savings earned by reducing costs while meeting quality benchmarks, it almost certainly would violate antitrust laws if these potential competitors

⁷⁷ *Antitrust Issues for Accountable Care Organizations: Revised Agency Guidance Spotlights Possible Concerns*, ADVISORY (ARNOLD & PORTER LLP) 2, Nov. 2011, available at http://www.arnoldporter.com/resources/documents/Advisory%20Antitrust_Issues_Accountable_Care_Organizations_Revised_Agency_Guidance_Spotlights_Possible_Concerns.pdf; see generally Austin Frakt, *Simply Put: Market Power*, INCIDENTAL ECONOMIST (Mar. 18, 2011, 5:00 AM), <http://theincidentaleconomist.com/wordpress/excerpts-from-health-reform-and-market-competition-by-leibenluft-and-luft/> (discussing concept of market power for purposes of antitrust law).

⁷⁸ See, e.g., Kevin Outterson, *Do ACOs with Market Power Need Relaxed Antitrust Rules?*, INCIDENTAL ECONOMIST (Dec. 2, 2010, 1:00 PM), <http://theincidentaleconomist.com/wordpress/do-acos-with-market-power-need-relaxed-antitrust-rules/> (“Medicare-only ACOs should get a stay-out-of-jail free card as well, since the sole customer is a price-fixer.”).

⁷⁹ See BURKE ET AL., *supra* note 75, at 6; cf. Ken Glazer & Catherine A. LaRose, *Accountable Care Organizations: Antitrust Business as Usual*, THE ANTITRUST SOURCE, at 2 (Dec. 2011), http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/dec11_glazer_12_21f.authcheckdam.pdf (noting that “although Medicare reimbursements are subject to set fees for services, which eliminates the possibility that [a MSSP] ACO might conspire to fix prices for various services it provides to beneficiaries, the government will still be alert to anti-competitive schemes regarding non-price elements of competition”); see generally DEP’T OF JUSTICE & FED. TRADE COMM’N, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION* 4 (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> [hereinafter “DOSE OF COMPETITION”] (“Non-price competition can promote higher quality and encourage innovation.”).

⁸⁰ Glazer & LaRose, *supra* note 79, at 7-8.

jointly discussed contracting outside of the ACO context.⁸¹ ACO arrangements might also “make it easier for physicians to exclude potential competitors from entry into the local market.”⁸²

Antitrust concerns are heightened in New Jersey’s Pilot because the statute permits only one Medicaid ACO in each defined region, and that ACO must have the support of all of the hospitals and at least seventy-five percent of the primary care providers in that region, a level of exclusivity and concentration that sets off antitrust alarms.⁸³ Thus, antitrust regulators are likely to scrutinize New Jersey’s Demonstration Project to ensure collaboration in its Medicaid markets will not reduce quality, innovation, and choice for both Medicaid and commercial patients. Fear of this scrutiny may discourage entities from participating in the Pilot.

Fortunately, the New Jersey Legislature anticipated these antitrust issues when it designed the Pilot. The authorizing legislation expressly exempts Medicaid ACOs from State antitrust liability.⁸⁴ With respect to federal law, the statute and its proposed implementing regulations structure the Demonstration to mitigate the risks of anticompetitive conduct and thus federal antitrust liability.

⁸¹ Austin Frakt, *Excerpts from “Health Reform and Market Competition,”* by Leibenluft and Luft, *INCIDENTAL ECONOMIST* (Oct. 25, 2010), <http://theincidentaleconomist.com/wordpress/excerpts-from-health-reform-and-market-competition-by-leibenluft-and-luft/> (quoting Leibenluft and Luft article).

⁸² *Id.*; see generally *Antitrust Laws and Their Effects on Healthcare Providers, Insurers and Patients: Hearing before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 2d Sess. (2010), available at http://judiciary.house.gov/hearings/printers/111th/111-157_62658.PDF (testimony of Sharis A. Pozen, Chief of Staff and Counsel to the Assistant Att’y Gen. Antitrust Div., U.S. Dep’t of Justice) (noting that antitrust regulators want to ensure “that coordination and integration among health care providers encourage innovation and efficiency without harming competition”).

⁸³ *Cf.* Thomas L. Greaney, *Accountable Care Organizations—The Fork in the Road*, *NEW ENG. J. MED.* 2 (Dec. 22, 2010), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1013404> (warning of the risks of “‘overinclusive’ ACOs . . . composed of an unduly large proportion of the hospitals or physicians in their markets” and suggesting the federal government not certify ACOs for the MSSP “that are likely to inhibit the development of competing ACOs or that will otherwise impede competition in the private insurance market,” which, among other things, “would constrain large hospitals [in most regions of the country] from forming ACOs with rival hospitals”).

⁸⁴ See N.J. STAT. ANN. § 30:4D-8.1(1)(g).

For one, New Jersey's Demonstration requires clinical integration as a means of achieving the goal of improved quality of care at lower costs, which reduces the anticompetitive threat from collaboration. The FTC and Antitrust Division of DOJ, as the federal agencies with overlapping authority to enforce the nation's antitrust laws,⁸⁵ have recognized that clinical integration of care delivery among potential competitors may survive an antitrust challenge.⁸⁶ Rather than threatening competition, such collaboration may realize significant procompetitive efficiencies, including lowering prices or improving quality.⁸⁷ When an arrangement achieves substantial clinical integration such that it is likely to produce significant efficiencies that benefit consumers, and when it is reasonably necessary to realize the pro-competitive benefits of the integration, the Antitrust Agencies will not presume that the agreement is per se illegal.⁸⁸ Instead, they will apply the rule of reason to review the legality of the arrangement:

A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws.⁸⁹

⁸⁵ GAO, *supra* note 74, at 2; MAKING HEALTH REFORM WORK: ACCOUNTABLE CARE ORGANIZATIONS AND COMPETITION, CTR. FOR AMERICAN PROGRESS 20 n.1 (Feb. 2011), http://www.americanprogress.org/issues/2011/02/pdf/aco_competition.pdf.

⁸⁶ See GAO, *supra* note 74, at 5-7. Although the Antitrust Agencies have recognized that financial integration also has procompetitive potential, New Jersey's ACO Demonstration Project does not include financial integration, and thus it is beyond the scope of this rReport.

⁸⁷ See, e.g., *Statements of Antitrust Enforcement Policy in Health Care*, Dep't of Justice & Fed. Trade Comm'n (Aug. 1996), <http://www.justice.gov/atr/public/guidelines/0000.pdf>; ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS, DEP'T OF JUSTICE & FED. TRADE COMM'N (2000), *available at* <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; Letter from Fed. Trade Comm'n on TriState Health Partners, Inc. Advisory Op. to Christi J. Braun, Esq. (Apr. 13, 2009), *available at* <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf>; DOSE OF COMPETITION, *supra* note 79, ch. 2, 36-41; MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. 67,026.

⁸⁸ GAO, *supra* note 74, at 6-8.

⁸⁹ MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. at 67,026, 67,027.

New Jersey’s statute and proposed regulations emphasize several care approaches and techniques that would promote clinical integration, including plans to use multi-disciplinary teams to coordinate patient care, to expand the use of medical home and chronic care models, to use health information technology and share health information, and “to improve service coordination to ensure integrated care for primary care, behavioral health care, dental, and other health care needs, including prescription drugs.”⁹⁰ The proposed regulations also would expressly require New Jersey Medicaid ACOs to “include sufficient clinical integration”⁹¹ and echo the Antitrust Agencies’ guidance by requiring that any shared savings agreements are “necessary to improve care for Medicaid beneficiaries by incentivizing the integration of care between multiple distinct entities.”⁹²

The Antitrust Agencies recently recognized that the eligibility criteria for the MSSP “are broadly consistent with the indicia of clinical integration” identified in previous agency advice and guidance.⁹³ Thus, because organizations that meet the MSSP eligibility requirements “are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants’ joint efforts,”⁹⁴ the Antitrust Agencies will afford rule of reason treatment to Medicare ACOs in the MSSP.⁹⁵ Although this guidance only applies to ACOs participating in the MSSP and does not

⁹⁰ N.J. Proposed Rule 10:79A-1.6(d)(1); *see also* N.J. STAT. ANN. § 30:4D-8.5(b)(1); *cf.* GAO, *supra* note 74, at 12 (noting that the FTC in a recent advisory opinion, Fed. Trade Comm’n, Advisory Opinion for Greater Rochester Independent Practice Association, Inc. (2007), found that the use of evidence-based practice guidelines and electronic health records constituted evidence of clinical integration); *see also* TAYLOR BURKE & SARA ROSENBAUM, ALIGNING FORCES FOR QUALITY, ACCOUNTABLE CARE ORGANIZATIONS: IMPLICATIONS FOR ANTITRUST POLICY 5 (Mar. 2010), <https://folio.iupui.edu/bitstream/handle/10244/810/57509.pdf?sequence=1> (summarizing key indicia of clinical integration recognized by the Antitrust Agencies).

⁹¹ N.J. Proposed Rule 10:79A-1.3(b).

⁹² *Id.* The Department also notes in its proposed rules that it views the Demonstration Project as pro-competitive because it “does not impact the negotiated fee schedules between payers, hospitals, and providers.” *Id.*

⁹³ MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. at 67,027.

⁹⁴ *Id.* at 67,027-28.

⁹⁵ *Id.* at 67,028.

directly apply to New Jersey's Demonstration,⁹⁶ several similarities between the MSSP and New Jersey's Pilot may lead the Antitrust Agencies to similarly apply rule of reason analysis to Medicaid ACOs. Given the patent legislative intent behind the Medicaid ACO Demonstration to encourage clinical integration in the name of quality improvement at reduced costs, the Antitrust Agencies likely would find that the procompetitive advantages to consumers of New Jersey's Medicaid ACO Pilot outweigh its potential harm to competition, and that the anticompetitive aspects of the collaboration are necessary to realize its benefits.⁹⁷

Even if the Antitrust Agencies do not find that New Jersey's Medicaid ACOs are sufficiently clinically integrated to balance the threat to competition or that the degree of market concentration is too high to survive rule of reason analysis,⁹⁸ the Legislature also expressed its intent to cloak Medicaid ACOs with the protection from federal antitrust liability provided by the state action immunity doctrine, provided their activities do not "constitute per se violations of State or federal antitrust laws."⁹⁹ The state action doctrine shields private market participants from federal antitrust liability for actions undertaken pursuant to a state regulatory scheme when two elements are satisfied. First, the state must articulate a clear and affirmative policy to allow

⁹⁶ *Id.* at 67,027.

⁹⁷ *Cf.* Letter dated Feb. 13, 2013 from Markus H. Meier, Assistant Director, Bureau of Competition, Health Care Division, Fed'l Trade Comm'n, to Michael E. Joseph, Esq. Re: Norman PHO Advisory Opinion, at 1 (advising that FTC is unlikely to challenge proposed joint contracting activities of a multiprovider network joint venture, noting that its "proposed clinical integration program offers the potential to create a high degree of interdependence and cooperation among its participating physicians and to generate significant efficiencies in the provision of physician services" and that its "proposed joint contracting . . . appears to be both subordinate to the network's integrative activities and reasonably necessary to implement the proposed program and achieve its efficiency benefits").

⁹⁸ As discussed in Section II, *supra*, there are several differences between the MSSP and the New Jersey Pilot, some of which may impact the rule of reason balancing. In particular, the Project's requirement that all 75 percent of primary care providers and 100 percent of hospitals in the defined geographic area participate and its prohibition on more than one Medicaid ACO in a region may tip the rule of reason balancing despite the strong indicia of clinical integration built into New Jersey's design. *See generally* Ragone, *supra* note 72, at 1453-Pilot61 (highlighting similarities and differences between New Jersey's Demonstration and the MSSP and how these factors may impact the antitrust analysis of the). *Cf.* BURKE & ROSENBAUM, *supra* note 90, at 7 (observing that "even if an arrangement is clinically integrated, it can still be condemned under the rule of reason if it has market power").

⁹⁹ *See* N.J. STAT. ANN. § 30:4D-8.1(g); *see generally* MCGINNIS & SMALL, *supra* note 5, at 5 (noting that "anti-trust issues in Medicaid may be easier [than in the MSSP context] due to the state-action doctrine").

the anticompetitive conduct to ensure that the state's goals, and not simply self-serving goals, are furthered.¹⁰⁰ Second, the state must provide active supervision of anticompetitive conduct undertaken by private actors.¹⁰¹ Not surprisingly, the doctrine is not favored because it permits anticompetitive behavior that otherwise would violate federal policy.¹⁰²

New Jersey's Medicaid ACO legislation almost certainly satisfies the first element of the state action test because the Legislature specifically expressed its intent for private participants to enjoy immunity from federal antitrust liability "through the state action doctrine."¹⁰³

With respect to the active supervision prong, the statute establishes numerous mechanisms through which the State can supervise and monitor Medicaid ACO activities. As summarized in Section II above, the Department has the authority to deny certification as a Medicaid ACO to an applicant that does not meet the statutory requirements.¹⁰⁴ It also has to approve the gainsharing plan submitted by the Medicaid ACO before the ACO may receive or distribute shared savings.¹⁰⁵ To fulfill these duties, DHS, with input from DHSS, also will collect and review data from participants.¹⁰⁶ The Department, again in consultation with DHSS, also must oversee an annual evaluation of the program to assess whether there are cost savings

¹⁰⁰ California Retail Liquor Dealers Ass'n v. Midcal Aluminum, 445 U.S. 97, 105 (1980).

¹⁰¹ *Id.*

¹⁰² FTC v. Ticor Title Ins. Co., 504 U.S. 621, 636 (1992); *see generally* DOSE OF COMPETITION, *supra* note 79, at 28 (warning that "[i]nappropriately broad interpretations" of the state action doctrine can "chill or limit competition in health care markets").

¹⁰³ *See* N.J. STAT. ANN. § 30:4D-8.1(g); *see generally* F.T.C. v. Phoebe Putney Health System, Inc., 133 S. Ct. 1003, 1011 (2013) ("[T]o pass the 'clear articulation' test," a state legislature need not 'expressly state in a statute or its legislative history that the legislature intends for the delegated action to have anticompetitive effects.' Rather, we explained in *Hallie* [*v. Eau Claire*, 471 U.S. 34, 43 (1985)] that state-action immunity applies if the anticompetitive effect was the 'foreseeable result' of what the State authorized.") (internal citation omitted).

¹⁰⁴ N.J. STAT. ANN. § 30:4D-8.4(a).

¹⁰⁵ *See id.* §§ 30:4D-8.4(c)(4), 30:4D-8.5(a).

¹⁰⁶ *See id.* §§ 30:4D-8.5(b) & (h), 30:4D-8.8(1) & (2).

and health improvements¹⁰⁷ and then must report these findings at the completion of the three-year Demonstration to the Governor and Legislature.¹⁰⁸

Though this statutory framework provides a number of ways for the State to supervise Medicaid ACOs, it may not require sufficiently meaningful ongoing state oversight to satisfy the active supervision prong required for state action immunity. The Supreme Court has explained that the active supervision requirement “requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy.”¹⁰⁹ The statute requires annual review of the program as a whole, but it does not expressly require ongoing review of each ACO’s continued eligibility and compliance with the Pilot’s objectives.¹¹⁰ The statute also does not specify any duty on the State to monitor potential anticompetitive spillover effects into other markets from the ACO’s activities nor require ACOs to notify the State of any material changes in their qualifications to be an ACO. In addition, although active supervision requires the State to disapprove of anticompetitive private party conduct that fails to comply with State policy,¹¹¹ the statute is not clear whether the State has any remedial options other than approving or disapproving ACO applications and gainsharing plans, such as suspending or revoking a previously granted certification.¹¹²

DHS’s proposed regulations include several provisions that would address these antitrust concerns directly and with greater specificity. For one, consistent with recent guidance from the

¹⁰⁷ See *id.* § 30:4D-8.9.

¹⁰⁸ See *id.* § 30:4D-8.14.

¹⁰⁹ *Ticor Title Ins. Co.*, 504 U.S. at 634 (internal quotation marks and citation omitted).

¹¹⁰ See N.J. STAT. ANN. § 30:4D-8.9.

¹¹¹ See *supra* note 109 and accompanying text (quoting *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 634 (1992)).

¹¹² See N.J. STAT. ANN. §§ 30:4D-8.4(a), 8.5(b).

federal Antitrust Agencies in the MSSP context,¹¹³ the proposed rules would expressly forbid Medicaid ACOs from negotiating reimbursement rates for clinical services performed by its participating providers, as distinguished from gainsharing plans, which may be negotiated.¹¹⁴ The proposed rules also would clarify that, in carrying out the statutorily required assessment “of the expected impact of revenues on hospitals that agree to participate,”¹¹⁵ ACO members would not be allowed to “share confidential revenue and rate information among themselves”¹¹⁶ They also would prohibit Medicaid ACOs from “conduct that may facilitate collusion among Medicaid ACO participants affecting the commercial health care marketplace, including but not limited to, discussions among ACO participants about rates negotiated with commercial payers,” and would require them to implement safeguards against such collusive behavior.¹¹⁷ Further, the proposed rules would require Medicaid ACOs to include an antitrust compliance statement in their bylaws,¹¹⁸ with which participating health care providers must agree to comply.¹¹⁹

In addition to laying out clear rules to prohibit anticompetitive behavior, the proposed regulations also would provide more detail regarding the State’s responsibilities to ensure the State oversight is meaningful and independent. To this end, an express goal of the rules would be to establish the Department’s ongoing “exercise of independent judgment and control in its

¹¹³ See MSSP Antitrust Statement, *supra* note 22, 76 Fed. Reg. at 67,029 (recommending that ACOs avoid the “improper exchanges of prices or other competitively sensitive information among competing participants [that] could facilitate collusion and reduce competition in the provision of services outside the ACO”); BURKE ET AL., *supra* note 75, at 12.

¹¹⁴ N.J. Proposed Rule 10:79A-1.3(d); *see also* N.J. Proposed Rule 10:79A-1.5(c)(9) (requiring ACO to certify its agreement not to negotiate rates in its application for certification and noting that failure to comply with this requirement constitutes grounds for decertification of the ACO); N.J. Proposed Rule 10:79A-1.7(c) (requiring ACO to renew this certification in its annual report). *Cf.* Letter dated Jan. 16, 2013 from William J. Baer, Assistant Attorney General, U.S. Dep’t of Just., Antitrust Div., to Colin R. Kass, Esq., at 7 (explaining that DOJ’s intention not to challenge a voluntary hospital gainsharing program is based in part on the fact that program participants will not exchange “competitively sensitive information”).

¹¹⁵ N.J. STAT. ANN. § 30:4D-8.5(h).

¹¹⁶ N.J. Proposed Rule 10:79A-1.6(d)(1)(x) & (6).

¹¹⁷ *Id.* 10:79A-1.3(a).

¹¹⁸ *Id.* 10:79A-1.5(c)(3)(i)(1)(C).

¹¹⁹ *Id.* 10:79A-1.5(c)(4)(ii)(7).

oversight and regulation of the conduct of the Medicaid ACOs in the Demonstration Project . . . to safeguard against violations of Federal laws.”¹²⁰ The proposed rules would call for the Department to consult with the New Jersey Office of the Attorney General in carrying out its oversight responsibilities.¹²¹ Consistent with FTC recommendations,¹²² the proposed rules also would spell out what the State would have to do to satisfy the statutory requirement to review certification applications, gainsharing plans, and annual reports. For example, rather than permitting a passive, rubber stamp review, the proposed rules would require the Department to actively review all submitted materials, including attachments, and to request additional documentation or explanations when necessary to facilitate its review.¹²³ The proposed rules also would require the State to issue a written decision approving or denying each ACO certification application and gainsharing plan and to accept or reject in writing each Medicaid ACO’s annual report.¹²⁴ ACOs would have to advise the State of any material changes to their

¹²⁰ *Id.* 10:79A-1.2(a) & (c).

¹²¹ *Id.* 10:79A-1.2(c).

¹²² *See generally* TODD J. ZYWICKI *ET AL.*, OFFICE OF POLICY PLANNING, REPORT OF THE STATE ACTION TASK FORCE 55 (Sept. 2003), *available at* <http://www.ftc.gov/os/2003/09/stateactionreport.pdf> (identifying three elements that the FTC considers when deciding if the active supervision prong has been satisfied: development of an adequate factual record, including notice and opportunity to be heard; a written decision on the merits; and “a specific assessment—both qualitative and quantitative—of how the private action comports with the substantive standards established by the state legislature”); *see, e.g.*, ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT IN IND. HOUSEHOLD GOODS AND WAREHOUSEMEN, INC., File No. 021-0115, at 4 (F.T.C. Apr. 5, 2003), *available at* <http://www.ftc.gov/os/2003/03/indianahouseholdmoversanalysis.pdf> [hereinafter “IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER”] (requiring that states engage in a “‘pointed re-examination’ of the private conduct.” “One asserting the state action defense must demonstrate that the state agency has ascertained the relevant facts, examined the substantive merits of the private action, assessed whether that private action comports with the underlying statutory criteria established by the state legislature, and squarely ruled on the merits of the private action in a way sufficient to establish the challenged conduct as a product of deliberate state intervention rather than private choice.”).

¹²³ N.J. Proposed Rules 10:79A-1.5(d)(3), 10:79A-1.6(e)(2), 10:79A-1.7(d)(2); *see, e.g.*, IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 122, at 6 (noting that the state should obtain “reliable, timely, and complete” data as part of developing an adequate factual record so that it may evaluate whether the private conduct is furthering the legislative objectives); Letter from Joseph J. Simons, Dir., Bureau of Competition, Fed. Trade Comm’n, on Alaska S.B. 37 to Lisa Murkowski, Chair, H. Labor & Commerce Comm., Alaska H.R. (Jan. 18, 2002), *available at* www.ftc.gov/be/v020003.htm (criticizing a proposed regulatory scheme for not permitting the state to require submission of additional information needed to facilitate pointed re-examination).

¹²⁴ N.J. Proposed Rules 10:79A-1.4(a)(1)-(3), 10:79A-1.5(d), 10:79A-1.6(e), 10:79A-1.7(c)(7), 10:79A-1.7(d)(3); *see generally* IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note

certification materials, and the Department would have authority to act in response to these changes, including decertifying a previously approved ACO.¹²⁵ The Department also would have the power to decertify an ACO if it violates the prohibition on negotiating rates for services with a public or private payer.¹²⁶

The proposed regulations also would directly respond to concerns about potential anticompetitive spillover into commercial markets by requiring DHS, as part of its statutorily required annual review of the Pilot, to include consultation with the State Department of Banking and Insurance “to assess potential anticompetitive effects on commercial rates for clinical services in the ACO’s designated area.”¹²⁷ Again, this review would need to be reduced to writing and should recommend termination of the ACO if it appears the Demonstration is causing commercial rates to increase more quickly than in comparable markets that lack an ACO.¹²⁸

To facilitate monitoring of potential anticompetitive effects from the Demonstration, the proposed rules also would require the Department to provide a mechanism for payers, non-ACO providers, and other parties who could be affected by the Demonstration to complain “about any

122, at 7 (explaining that, “[t]hrough not essential, the existence of a written decision is normally the clearest indication that the [state entity] (1) genuinely has assessed whether the private conduct satisfies the legislature’s stated standards and (2) has directly taken responsibility for that determination”).

¹²⁵ N.J. Proposed Rules 10:79A-1.5(e), 10:79A-1.6(f)(1)-(2); *see, e.g.*, IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 122, at 6 (emphasizing that the state should conduct periodic reviews of ongoing private conduct with updated data and not just to permit an initial approval to justify continued immunity).

¹²⁶ N.J. Proposed Rules 10:79A-1.5(c)(8), 10:79A-1.7(c)(7).

¹²⁷ *Id.* 10:79A-1.4(a)(5). *Cf., e.g.*, Greaney, *Regulators as Market-Makers*, *supra* note 76, at 28, 29 (noting that several commenters on the MSSP Proposed Rule suggested “ways to improve detection and analysis of competitive conditions such as collaborative data collection by CMS and the antitrust agencies, mandating public reporting on the cost and price of care, and close monitoring of provider pricing in commercial markets” and suggesting “CMS could make more explicit that it is likely to deny renewal of authority for ACOs to participate in the MSSP where it finds evidence of spillovers in the form of price increases and cost shifting to the private sector resulting from market power”).

¹²⁸ N.J. Proposed Rule 10:79A-1.4(a)(5).

anticompetitive activity by ACOs and their participants.”¹²⁹ The ACO would need to certify in its application that it and its participants will provide the State with all requested data to permit monitoring and oversight, including, but not limited to, data to monitor any potential impact of the ACO’s operations on commercial rates.¹³⁰

These details in the proposed rules would flesh out the scope and mechanics of the oversight required by the statute and the state action immunity doctrine. Given that New Jersey consulted the Antitrust Agencies throughout the drafting of these proposed regulations, Medicaid ACOs that comply with the statute and rules should be immune from antitrust liability.

B. Guarding against Fraud and Abuse Liability

Depending on how they are structured, ACOs also may implicate various fraud and abuse laws that exist to protect consumers from higher costs from overutilization and improper referrals and to preserve access to medically appropriate care. The Federal Gainsharing Civil Monetary Penalty Provisions (CMP), for example, generally prohibit direct or indirect hospital payments to physicians to induce them to reduce or limit their services to Medicare or Medicaid patients in their direct care.¹³¹ The Beneficiary Inducements CMP provision generally prohibits remuneration to beneficiaries of Medicare or Medicaid that are likely to influence the beneficiary

¹²⁹ *Id.* 10:79A-1.4(a)(6).

¹³⁰ *Id.* 10:79A-1.5(c)(10); *see also id.* 10:79A-1.7(c) (detailing what an ACO must report to the State annually, including quality performance and patient experience findings at the ACO and practice level and information regarding complaints received); *id.* 10:79A-1.7(c)(8) (requiring ACO to certify in annual report that it complied with any requests for data necessary for monitoring impact on commercial rates).

¹³¹ *See* 42 U.S.C. § 1320a-7a(b)(1) and (2); 42 C.F.R. § 1003.100 *et seq.* The CMP applies by its terms to all payments, even those inducing physicians to curtail medically unnecessary care. The U.S. Department of Health and Human Services, Office of the Inspector General (“OIG”), however, has approved a number of specific gainsharing arrangements when those arrangements were determined to include safeguards against inappropriate reductions in patient care. The OIG noted that approved arrangements included several protective features, including transparency of design; evidence that the arrangement did not adversely affect patient care; a basis in objective clinical measures; disclosure of the arrangement to patients; and reasonable limitations in the duration and scope of the arrangement. *See, e.g.,* Department of Health and Human Services, Office of the Inspector General, OIG Advisory Opinion No. 08-21 (Dec. 8, 2008), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf>. We recommend that any ACO contemplating the implementation of such an arrangement consult counsel before doing so.

to order or receive an item or service from a particular provider;¹³² however, the ACA amended the CMP law to exempt any incentive that “promotes access to care and poses a low risk of harm to patients and Federal healthcare programs.”¹³³ The Anti-Kickback Statute (AKS) makes it a felony under federal law to knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward referrals.¹³⁴ Federal and New Jersey law prohibit physician referrals in various situations where there is a financial relationship.¹³⁵ These laws reflect the policy judgment that care decisions should be driven by what care is medically appropriate for a given patient and not by financial inducements to stint on care or by financial incentives to drum up business that will line providers’ pocket. Relatedly, these laws seek to protect beneficiaries so they may choose a provider and make treatment decisions without the distraction of gifts or other remuneration. They also seek to protect against increased costs to public programs and consumers from self-interested conduct.

There are various ways the actions of Medicaid ACO participants could implicate fraud and abuse laws. The Pilot, like many ACO models, includes provisions for gainsharing of savings achieved. The Office of Inspector General (“OIG”) at HHS has opined that gainsharing arrangements between hospitals and physicians violate the CMP provision prohibiting hospitals from paying a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician’s direct care—even “where there is no adverse

¹³² See 42 U.S.C. § 1320a-7a(a)(5).

¹³³ *Id.* § 1320a-7a(i)(6)(F) (creating exemption from the CMP prohibition in 42 U.S.C. § 1320a-7a(a)(5)).

¹³⁴ See 42 U.S.C. § 1320a-7b(b)(1) and (2). The AKS contains numerous statutory exceptions and regulatory safe harbors. See 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952.

¹³⁵ See Physician Self-Referral Law (“Stark Law”), 42 U.S.C. § 1395nn; 42 C.F.R. § 411.350 *et seq.*; Codey Act, N.J. STAT. ANN. § 45:9-22.5 *et seq.* The federal Stark Act applies only indirectly to Medicaid, but courts have accepted the Department of Justice’s argument that a self-referral violating Stark’s terms can form the basis of a claim under the False Claims Act. See *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*, No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147 (M.D. Fla. Mar. 19, 2012), *cited in* Renee M. Howard, AMERICAN HEALTH LAWYERS ASSOCIATION, *What the Courts Are Saying About the Stark Law*, at 8-9 (April 2012) available at http://www.healthlawyers.org/Members/PracticeGroups/FA/Newsletters/Documents/Fraud_April13.pdf.

impact on the quality of care received by patients”—and may implicate the federal AKS and federal and state Physician Self-Referral laws.¹³⁶ The Pilot also encourages greater coordination, which in many instances will include referrals within the ACO, and therefore could implicate the Physician Self-Referral Laws and AKS. Patient-centered health delivery models, which ACOs often incorporate, may seek to provide beneficiaries with tools to help them better manage their health, such as scales or blood pressure monitors, which may constitute remuneration under the Beneficiary Inducements CMP.

Thus, to avoid violating fraud and abuse laws, it is critical to ensure any gainsharing payments do not reward or induce inappropriate referrals or reductions in appropriate medical care. The Demonstration statute requires the Commissioner of DHS to “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.”¹³⁷ Absent assurance that ACOs and their members will not face potential fraud and abuse liability for their participation in the Pilot, it is an open question whether potential ACOs will risk liability.¹³⁸

To date, the federal agencies charged with enforcing these laws have not issued any formal waivers or guidance specific to New Jersey’s Demonstration. As authorized by the

¹³⁶ Department of Health and Human Services, Office of the Inspector General, *Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries* (July 1999), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

¹³⁷ N.J. STAT. ANN. § 30:4D-8.10(a).

¹³⁸ Cf. MSSP Waivers IFR, *supra* note 22, 76 Fed. Reg. at 68,009 (noting CMS’s belief, based on comments submitted to proposed fraud and abuse waivers, “that a significant number of ACO applicants for the [Medicare] Shared Savings Program would forego applying to participate . . . until final waivers have become effective”).

ACA, CMS released an interim final rule on November 2, 2011 establishing five “waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified arrangements involving accountable care organizations (ACOs)” participating in the MSSP so that the fraud and abuse “laws do not unduly impede development of beneficial ACOs.”¹³⁹ Despite similarities between New Jersey’s Medicaid ACO Demonstration and the MSSP, as discussed above, these waivers apply only to the MSSP ACOs and do not apply to New Jersey’s Pilot.¹⁴⁰ New Jersey officials, however, have consulted with federal authorities during the drafting of the regulations implementing the Pilot. Thus, the Demonstration Project’s statute and its proposed implementing regulations try to address many of these fraud and abuse concerns by including provisions directed at minimizing the risk that Medicaid ACOs and their members will violate applicable fraud and abuse laws by participating in the Pilot.

For example, the statute prohibits the State from approving any “gainsharing plan that provides direct or indirect financial incentives for the reduction or limitation of medically necessary and appropriate items or services provided to patients under a health care provider’s clinical care in violation of federal law.”¹⁴¹ The proposed regulations similarly would emphasize that the purpose of the Demonstration Project is to encourage appropriate care and not to reduce care.¹⁴² They also would specifically prohibit gainsharing plans that “provide direct or indirect financial incentives for provider self-referrals in violation of Federal law (42 U.S.C. § 1395nn)

¹³⁹ See *id.* at 67,992, 67,993.

¹⁴⁰ See *id.* at 68,007.

¹⁴¹ N.J. STAT. ANN. § 30:4D-8.5(e). *But see supra* note 131 (discussing the application of the federal CMP law to inducements to reduce patient care).

¹⁴² See N.J. Proposed Rules 10:79A-1.2(b); 10:79A-1.6(d)(7)(v)(5); *see, e.g.*, N.J. Proposed Rule 10:79A-1.4(a)(4) & (c) (requiring Department to annually review Demonstration Project to assess, among other things, if there have been improvements in outcomes).

or State law (N.J.S.A. 45:9-22.5) or reward providers based on the volume of referrals.”¹⁴³ Letters of support required from health care providers in the ACO’s designated geographic area would have to acknowledge, among other things, that “the provider shall retain responsibility for medically appropriate treatment and referral decisions, document the basis for such decisions, and not limit treatment and referrals to providers participating in the ACO if treatment or referral to outside providers is medically indicated.”¹⁴⁴ Providers also would have to acknowledge that they will not organize care delivery “to reduce access to care or increase costs, but instead shall work to improve health outcomes and quality while reducing unnecessary and inefficient spending”¹⁴⁵ As part of its application for certification as a Medicaid ACO, an individual with legal authority to bind the ACO would need to affirm that the ACO will comply with all federal and State laws and regulations, including those “designed to protect Medicaid beneficiaries’ ability to access necessary care”¹⁴⁶

To verify that the Demonstration is improving health outcomes and quality, the legislation requires “objective metrics and patient experience of care.”¹⁴⁷ To be certified, the proposed rules would require an ACO to demonstrate, among other things, that it is capable of collecting data and reporting “quality measures, efficiency measurements, patient safety measurements, and patient satisfaction findings.”¹⁴⁸ The proposed regulations also would require the ACO to identify in its gainsharing plan at least five quality performance measures,

¹⁴³ *Id.* 10:79A-1.6(d)(7)(v)(5).

¹⁴⁴ *Id.* 10:79A-1.5(c)(4)(ii)(5).

¹⁴⁵ *Id.* 10:79A-1.5(c)(4)(ii)(6).

¹⁴⁶ *Id.* 10:79A-1.5(c)(7)(v).

¹⁴⁷ N.J. STAT. ANN. § 30:4D-8.1(1)(d).

¹⁴⁸ N.J. Proposed Rule 10:79A-1.5(c)(8).

from those approved by the Department,¹⁴⁹ that it will use and report on to measure its health and quality outcomes.¹⁵⁰ These five measures would need to “provide a valid mix of preventative measures, at-risk population measures, and appropriate use of providers and access to care measures”¹⁵¹ The Department then would be charged with reviewing and analyzing “the ACO’s quality measurement plan and annual performance to ensure the ACO is helping to facilitate improvements in health care access and quality while protecting the provision of medically necessary care.”¹⁵² Being eligible to share in any gains is dependent on the ACO demonstrating satisfaction of these quality measures.¹⁵³

In addition to reporting objective quality measures, the proposed rules would require an ACO to identify in its gainsharing plan how it will collect, analyze and act on patient experience findings.¹⁵⁴ Finding that “[c]ollecting and analyzing patient and consumer feedback is the best mechanism to detect and remediate any potential improper limitations in care,”¹⁵⁵ the proposed regulations would require ACOs to “[p]rovide a clear and easy way for patients or consumers to make complaints or speak up regarding a possible improper self-referral, or reduction or limitation of services by a participating ACO member,” which could include on-line feedback forms, telephone hotlines, or hard copy forms.¹⁵⁶

¹⁴⁹ See *NJ Medicaid ACO Demonstration Project: Quality Metrics*, available at http://www.state.nj.us/humanservices/dmahs/info/NJ_Medicaid_ACO_Demonstration_Project_Quality_Metrics_5-13-13.pdf (last visited Dec. 5, 2013).

¹⁵⁰ N.J. Proposed Rule 10:79A-1.6(d)(3); see also N.J. Proposed Rule 10:79A-1.7(c) (detailing what ACO must report to the State annually, including quality performance and patient experience findings at the ACO and practice level and information regarding complaints received).

¹⁵¹ N.J. Proposed Rule 10:79A-1.6(d)(3)(i)(2).

¹⁵² *Id.* 10:79A-1.6(d)(3)(ii)(4).

¹⁵³ See N.J. STAT. ANN. §§ 30:4D-8.4(c)(4), 30:4D-8.5(a).

¹⁵⁴ N.J. Proposed Rule 10:79A-1.6(d)(4).

¹⁵⁵ *Id.* 10:79A-1.6(d)(5).

¹⁵⁶ *Id.* 10:79A-1.6(d)(5)(i).

The statute's requirement that the ACO's board include voting consumer representatives provides an additional mechanism for consumer concerns to come to the fore.¹⁵⁷ Similarly, the statute also requires the ACO to have "a process for engaging members of the community and for receiving public comments with respect to its gainsharing plan,"¹⁵⁸ which provides another means for smoking out consumer concerns.¹⁵⁹ The proposed regulations would include several provisions that would implement these statutory requirements.¹⁶⁰

The proposed rules would require an ACO to implement a timely process for reviewing and addressing complaints and to report annually to the Department and public the number, type, and resolution of complaints.¹⁶¹ An ACO would have to notify the Department within three business days of learning about "a material concern regarding patient safety and/or satisfaction"¹⁶² Where "a provider improperly reduces care, limits services, or engages in inappropriate self-referral," the ACO must take appropriate disciplinary action, such as withholding gainsharing or excluding a practice from the ACO.¹⁶³

¹⁵⁷ See N.J. STAT. ANN. § 30:4D-8.4(c)(2)(a).

¹⁵⁸ *Id.* § 30:4D-8.4(c)(5); see also N.J. Proposed Rule 10:79A-1.6(d)(9) (providing additional details about the public comment process).

¹⁵⁹ See, e.g., IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 122, at 7 (providing notice and an opportunity to comment to affected communities "are powerful engines for ensuring that relevant facts—especially those facts that might tend to contradict the proponent's contentions—are brought to the state decisionmaker's attention").

¹⁶⁰ See, e.g., N.J. Proposed Rule 10:79A-1.5(c)(5) (requiring ACO to demonstrate in its application that it has a process for engaging the community, such as designating an individual in its leadership structure to be responsible for engaging the public, providing public comment opportunity at annual public ACO board meetings, and making Certificate of Incorporation, bylaws, and gainsharing plans available for public inspection and copying); *id.* 10:79A-1.5(c)(8)(ii) (requiring ACO's management structure to include quality committee, medical director, or governance structure "responsible for setting and evaluating standards of care, receiving and addressing patient complaints, and conducting ongoing monitoring to ensure access to quality care and to prevent inappropriate provider self-referrals, reductions in care, or limitations on services").

¹⁶¹ *Id.* 10:79A-1.6(d)(5) & (d)(5)(ii), 10:79A-1.7(c)(6)(i).

¹⁶² *Id.* 10:79A-1.7(c)(6)(i).

¹⁶³ *Id.* 10:79A-1.6(d)(5)(iv).

These statutory and proposed regulatory provisions guide Medicaid ACOs to help ensure their conduct complies with federal and State fraud and abuse laws while pursuing innovative reforms that may improve access to and the quality of care and reduce inefficient health care costs. New Jersey's statute and proposed regulations, however, do not seem to address potential liability under the Beneficiary Inducements CMP. As Medicaid ACOs explore innovative tools to support preventive health care and patient compliance with treatment, such as providing blood pressure monitoring devices or mobile medical applications to monitor patient medication adherence and chronic diseases,¹⁶⁴ they should be aware of this law, consider whether an existing exception applies, such as the exception to promote delivery of preventive care,¹⁶⁵ and consider seeking an advisory opinion from OIG before providing anything at no cost or below fair market value to beneficiaries.¹⁶⁶ Consultation with CMS and OIG would be wise to see if additional precautions are necessary, such as the transparency and audit trail requirements contained in some of the MSSP waivers.¹⁶⁷

V. THE COMMON LAW LIABILITY RISKS CONFRONTING ACOs

ACOs confront the risk of legal liability for medical malpractice, ordinary negligence, breach of contract, and other common law claims. Just as ACOs are, to varying degrees,

¹⁶⁴ See, e.g., Andrew Kitchenman, *Accountable Care Organization's Innovative Approach Gets Results*, NJ SPOTLIGHT, Dec. 9, 2013 (reporting that HackensackAlliance ACO provided some patients with tablet computers to remind them to take their medications as part of its innovations that resulted in savings of approximately \$10 million while reportedly improving the quality of care provided to 12,000 Medicare patients between April 2012 and April 2013).

¹⁶⁵ See 42 C.F.R. § 1003.101.

¹⁶⁶ Cf. MSSP Waivers IFR, *supra* note 22, 76 Fed. Reg. at 68,007 (promulgating a waiver of AKS and Beneficiary Inducements CMP "to address arrangements pursuant to which ACOs, ACO participants, and ACO providers/suppliers provide beneficiaries with free or below-fair market value items and services that advance the goals of preventive care, adherence to treatment, drug, or follow-up care regimes, or management of a chronic disease").

¹⁶⁷ See *id.* at 68,003-04.

“clinically and financially accountable for a population of patients,”¹⁶⁸ they also may be legally accountable to them. This Section provides an overview of ACOs’ exposure to common law liability and then discusses steps organizations can take to reduce and manage the risks they face.

A New Jersey statute specifically provides for liability

for economic and non-economic loss that occurs as a result of [a] carrier's or organized delivery system's negligence with respect to the denial of or delay in approving or providing medically necessary covered services, which denial or delay is the proximate cause of the covered person's: (1) death; (2) serious and protracted or permanent impairment of a bodily function or system; (3) loss of a body organ necessary for normal bodily function; (4) loss of a body member; (5) exacerbation of a serious or life-threatening disease or condition that results in serious or significant harm or requires substantial medical treatment; (6) a physical condition resulting in chronic and significant pain; or (7) substantial physical or mental harm which resulted in further substantial medical treatment made medically necessary by the denial or delay of care.¹⁶⁹

This statute will only apply to ACOs that approve or provide medical services and that meet the definition of a “carrier” or of an “organized delivery system.” The statute defines “carrier” as

an insurance company, health, hospital or medical service corporation, or health maintenance organization authorized to issue health benefits plans in this State or a dental service corporation or dental plan organization authorized to issue dental benefits plans in this State.¹⁷⁰

“Organized delivery system” is defined as

¹⁶⁸ Sandra L. Berkowitz, *Accountable Care Organizations: Operational Risk and Financial Responsibility*, WILLIS HEALTHTREK (March 2012).

¹⁶⁹ N.J. STAT. ANN. § 2A:53A-33.

¹⁷⁰ *Id.* § 2A:53A-32.

an organization with defined governance that: a. is organized for the purpose of and has the capability of contracting with a carrier to provide, or arrange to provide, under its own management substantially all or a substantial portion of the comprehensive health care services or benefits under the carrier's benefits plan on behalf of the carrier, which may or may not include the payment of hospital and ancillary benefits; or b. is organized for the purpose of acting on behalf of a carrier to provide, or arrange to provide, limited health care services that the carrier elects to subcontract for as a separate category of benefits and services apart from its delivery of benefits under its comprehensive benefits plan, which limited services are provided on a separate contractual basis and under different terms and conditions than those governing the delivery of benefits and services under the carrier's comprehensive benefits plan.¹⁷¹

An ACO that is not covered under the statute might nonetheless be found directly liable for common law claims such as medical malpractice, “corporate negligence,” and breach or implied breach of contract or warranty.¹⁷² In New Jersey and elsewhere, HMOs and other MCOs have faced liability for harm caused by actions such as screening and selecting physicians, developing and promulgating care pathways, and authorizing or denying payment for care.¹⁷³ Health law attorneys Mark Mattioli and Stephanie Barr have concluded that “[w]hile the corporate negligence doctrine has not yet been extended to ACOs, it would not be much of a stretch for it to apply.”¹⁷⁴

¹⁷¹ *Id.* § 17:48H-1.

¹⁷² *Id.* See also Anne B. Claiborne *et al.*, *Legal Impediments to Implementing Value-Based Purchasing in Healthcare*, 35 AM. J. OF LAW & MED. 442, 468 (2009) (“[T]he corporate negligence theory has been extended in many courts to apply to those MCOs that are similar to hospitals in many ways - *i.e.*, MCOs composed of individuals who work collaboratively to arrange for and provide healthcare services to subscribers.”).

¹⁷³ In New Jersey, the Health Maintenance Organizations Act protects certain HMO employees from suit, but allows suits against an HMO itself to go forward. *Dunn v. Praiss*, 139 N.J. 564, 568-69 (1995) (finding that the facts of the case did not support a negligence claim against the defendant HMO but did support a contractual claim).

¹⁷⁴ Mark L. Mattioli & Stephanie M. Barr, *Accountable Care Organizations: From Theory to Practice*, THE LEGAL INTELLIGENCER 3 (Mar. 19, 2013).

In order to be found liable for negligence, the defendant must have breached a duty owed to the plaintiff. The New Jersey Supreme Court has explained that “[t]he question of whether a duty to exercise reasonable care to avoid the risk of harm to another exists is one of fairness and policy that implicates many factors[,]” including whether the harm was foreseeable.¹⁷⁵ As cases are brought against ACOs, courts will grapple with the question of what duties ACOs owe and to whom.

An ACO could potentially be liable on a contractual or corporate negligence theory based upon negligent screening and selection (this is termed “credentialing” when done by hospitals) of its participating physicians.¹⁷⁶ An ACO’s exposure would depend on, among other things, its legal form, the extent to which it undertakes to perform the screening and selection function, and the representations it makes to the public and to participating patients about its participating physicians. An ACO could also face liability for failing to exercise control over the physicians once selected. Liability for negligent selection and control of care coordinators, health coaches, or other non-physicians who work for or with the organization also is a possibility.¹⁷⁷ If an ACO directs a care coordinator or health coach to reduce visits to the emergency room, for example, or

¹⁷⁵ *Carvalho v. Toll Bros. and Developers*, 143 N.J. 565, 572 (1996).

¹⁷⁶ *Claiborne et al.*, *supra* note 172 (“The theory of corporate negligence . . . was established by an Illinois Supreme Court case, where it was found that a hospital owes a duty of care to its patients related to credentialing independent of that owed by the individual physicians at the hospital. At issue in the case was the hospital’s failure to review a physician’s care adequately and to require physicians to procure consultations under certain circumstances. The doctrine of corporate negligence has since been expanded to include a hospital’s responsibility to screen physician applicants adequately for hospital privileges, to select and retain competent doctors, and to oversee practitioners providing care in the hospital.”).

¹⁷⁷ *See, e.g.*, David J. Shulkin, *Building an Accountable Care Organization for All the Wrong Reasons*, 87 MAYO CLINIC PROCEEDINGS 721-22 (Aug. 2012) (explaining that the Medicare ACO created by Atlantic Health System in New Jersey relies on “a network of clinical navigators who collaborate with primary care physician offices to identify patients with short-term and long-term care needs and guide them through planned pathways of care” as well as “case managers [who] work with high-medical acuity patients who require intensive assistance with care planning”); Gawande, *supra* note 66 (describing a model of coordinated care, adopted in Atlantic City, New Jersey, that relies heavily on “health coaches,” lay people who “work[] with patients—in person, by phone, by e-mail—to help them manage their health”).

to lower admission or readmission rates, the ACO might face liability if a patient in need of hospital care does not receive it.

ACOs also face potential liability arising out of their role in selecting or developing, and then implementing, care pathways, clinical practice guidelines, and treatment protocols.¹⁷⁸ As Erin Zuena Bartolini of the New England Healthcare Institute explains, “[m]any ACOs have created review boards to assess the evidence and ultimately decide if and when current and new drugs, devices, and procedures should be used and for which patients.”¹⁷⁹ If a protocol that an ACO adopts results in sub-standard care that causes patient harm, the ACO could be sued for medical malpractice or ordinary negligence.¹⁸⁰ Importantly, courts “do not consider . . . cost containment goals when determining whether a medical decision was appropriate.”¹⁸¹ As professor Nadia Sawicki has explained, whether the ACO would in fact be liable would turn in part on the degree of influence the protocol had on physicians’ treatment decisions. While physicians participating in a Medicaid ACO would be unlikely to be “absolutely bound” by a

¹⁷⁸ H. Benjamin Harvey & I. Glenn Cohen, *The Looming Threat of Liability for Accountable Care Organizations and What to Do About It*, 310 JAMA 141, 142 (2013) (“[I]f a poor outcome occurs in a patient with congestive heart failure (CHF), a plaintiff could challenge an ACO’s more stringent CHF hospital admissions criteria, asserting a prioritization of cost savings over patient care.”); *see also* Connolly v. Aetna United States Healthcare, 286 F. Supp. 2d 391, 401-02 (D.N.J. 2003) (alleging that the defendant HMO promulgated a policy that “encouraged, pressured, and/or directly or indirectly required that participating physicians prescribe Home Uterine Palpation for a pregnant woman [such as the plaintiff]” and that “[i]n adopting and implementing this policy [the defendant] acted without adequate consideration of whether this policy was medically appropriate, and thus acted negligently and without due care for the health and safety of its members and their children”).

¹⁷⁹ *How Will ACOs Share Liability Risk?*, CALIFORNIA HEALTHLINE (August 12, 2013); *see also* Shulkin, *supra* note 177 (explaining that Atlantic Health System’s Medicare ACO uses “planned pathways of care” and giving as an example the organization’s Cardiac Success program, which “has achieved 4% to 6% 30-day all-cause readmission rates by incorporating protocol-based approaches that rely on nurse practitioners and home care nurses coordinating with heart failure specialists and referring physicians”).

¹⁸⁰ *Acosta v. HealthSpring of Fla., Inc.*, 118 So. 3d 246, 248 (Fla. Dist. Ct. App. 3d Dist. 2013) (“[T]he distinction between ordinary negligence and medical negligence “is fundamentally fact dependent. . . . Administrative delays and refusals in the authorization of medical care have been characterized . . . as ordinary contract or negligence claims rather than claims for medical malpractice.”).

¹⁸¹ Harvey & Cohen, *supra* note 178, at 141.

protocol, they might face financial or professional repercussions for choosing to deviate from it.¹⁸²

Plaintiffs might also seek to hold ACOs liable for medical malpractice or ordinary negligence based on the organizations' establishment of financial incentives designed to influence physician decision making. Liability based on the ACO's role in facilitating the adoption and use of electronic health records (EHRs) also is a concern. A legal guide to ACOs prepared for North Carolina's Toward Accountable Care Consortium provides that "[c]orporate liability involving [health information exchange] could be triggered by premature or inadequate deployment of EHRs or [health information technology] that results in errors, possibly resulting from inadequate staff training, erroneous data entry, flawed applications, or inadequate [information technology] infrastructure."¹⁸³ Attorney Christopher DiGiacinto and his colleagues predict that "in the ACO setting, the sheer breadth of the material required to be maintained will likely increase the chances for liability that have traditionally resulted from [paper-based health] records."¹⁸⁴ DiGiacinto also believes that "the very existence of all this documentation pertaining to any given patient will likely create a duty for providers within the continuum of the patient's care to be fully familiar with all of the patient's documentation, no matter its source, before undertaking any treatment."¹⁸⁵

¹⁸² Nadia Sawicki, *Standards of Care and Patient Advocacy in Religiously Affiliated Hospitals*, BILL OF HEALTH (Dec. 3, 2013) (discussing the United States Conference of Catholic Bishops' ethical directive on pregnancy termination and its effect on physicians' treatment decisions and noting that the question of whether the Conference of Bishops could be liable for those decisions will turn on whether the directive "could be deemed to 'interfere with,' 'override,' or 'render powerless' physicians' independent medical decision-making").

¹⁸³ TOWARD ACCOUNTABLE CARE CONSORTIUM, ACCOUNTABLE CARE LEGAL GUIDE 13 (2013), http://www.ncmedsoc.org/non_members/legislative/ac/AC%20Legal%20Guide_022113_reduced%20file%20size.pdf.

¹⁸⁴ Christopher E. DiGiacinto *et al.*, *Potential Liability Risks and Solutions for Accountable Care Organizations*, AHRMNY RISK MANAGEMENT QUARTERLY JOURNAL 2 (Summer 2013).

¹⁸⁵ *Id.*

An ACO's role as a facilitator of data-driven healthcare could also lead to liability in the event of a data breach.¹⁸⁶ As one commenter put it, “[w]hen a healthcare provider endures a data breach, monetary damages quickly follow. Whether they’re receiving a fine as a result of a federal [Health Insurance Portability and Accountability Act (HIPAA)] violation or patients seek state-level damages in a class-action suit, these organizations are likely to take some type of financial hit.”¹⁸⁷

New Jersey has a statute that sets forth the duties that businesses and other entities owe to their customers when there is a data breach.¹⁸⁸ At least one court has held, however, that private plaintiffs cannot sue to enforce the State's breach notification statute.¹⁸⁹ Plaintiffs may bring suit under New Jersey's Consumer Fraud Act,¹⁹⁰ but to prevail they must show that they sustained an “ascertainable loss of moneys or property.”¹⁹¹ This is likely to be a difficult showing for most victims of a data breach to make.¹⁹²

In addition to being directly liable for its own actions as described above, an ACO could also be held vicariously liable for the negligence of its employees and, under certain circumstances, the independent contractors with which it works.¹⁹³ Attorneys Mattioli and Barr

¹⁸⁶ See Jeremy Chang, *Data Breach and Corporate Liability*, COLUMBIA BUS. L. REV. ONLINE (Oct. 10, 2013); Alan Charles Raul *et al.*, *Developments in Data Breach Liability*, PRIVACY & DATA SECURITY LAW JOURNAL (Sept. 2009).

¹⁸⁷ Patrick Ouellette, *Determining Insurance Liability After a Health Data Breach*, HEALTH IT SECURITY (Dec. 3, 2013).

¹⁸⁸ N.J. STAT. ANN. § 56:8-163.

¹⁸⁹ Holmes v. Countrywide Fin. Corp., 2012 U.S. Dist. LEXIS 96587, at *38 (W.D. Ky. July 12, 2012) (“Insofar as the Court can tell, [N.J. STAT. ANN.] § 56:8-163 does not provide a private right of action for citizens to enforce its provisions.”).

¹⁹⁰ N.J. STAT. ANN. § 56:8-1, *et seq.*

¹⁹¹ *Id.* § 56:8-19.

¹⁹² Holmes, 2012 U.S. Dist. LEXIS 96587, at *38-41.

¹⁹³ See Lau v. Lara, 2013 N.J. Super. Unpub. LEXIS 1058, at *10-11 (App. Div. May 6, 2013) (citing Carter v. Reynolds, 175 N.J. 402, 408-09 (2003) for the proposition that “an employer can be found liable for the negligence of an employee causing injur[y] to a third part[y] if, at the time of the occurrence, the employee was acting within the scope of his or her employment”); N.J. STAT. ANN. § 2A:53A-33(a) (“Under the provisions of this section, a carrier or organized delivery system shall be liable for the health care treatment decisions of its employees, agents or

also suggest that because the ACO model makes each provider accountable for a patient's overall care, it "could give rise to liability of ACO participants for the care provided by other ACO participants."¹⁹⁴ There could also be vicarious liability based on apparent or ostensible agency, to the extent that a reasonable person in the patient's position would have concluded that the negligent provider was employed by or acting on behalf of the ACO.¹⁹⁵

It is not expected that New Jersey's Medicaid ACOs will employ the physicians that choose to participate, at least not in the near term. They might employ nurses and health coaches to aid in the coordination and delivery of care, however. Even if they do not have an employer-employee relationship, attorney Christopher DiGiacinto and colleagues argue that because ACOs' structure "explicitly integrates administrative and patient care functions," it will be "much more difficult" for ACOs "to distance themselves from individual providers by arguing that they are independent contractors."¹⁹⁶

Some observers believe that ACOs have even more exposure to legal liability than do other MCOs such as health maintenance organizations (HMOs), independent practice

other representatives over whom the carrier or organized delivery system has the right to exercise influence or control, or has actually exercised influence or control"); *Basil v. Wolf*, 193 N.J. 38, 63 (2007) ("Liability may be imputed to a principal for the actions of independent contractors: (1) where the principal retains control of the manner and means of doing the work that is the subject of the contract; (2) where the principal engages an incompetent contractor; or (3) where the activity constitutes a nuisance per se."); *see also, e.g.*, *Jackson v. Fauver*, 334 F. Supp. 2d 697, 744 (D.N.J. 2004) (holding that the defendant Correctional Medical Services, a prison health management company, could be subject to vicarious liability for the negligence of its subcontractor physicians). *But see Scott-Neal v. N.J. State Dept. of Corr.*, 366 N.J. Super. 570, 574 (App. Div. 2004) (noting that the court had previously ordered the dismissal of a claim against Correctional Medical Services on the basis of vicarious liability because it did not exercise authority over the practice of medicine by physicians retained to provide care to inmates).

¹⁹⁴ *Mattioli & Barr, supra* note 174, at 3.

¹⁹⁵ *Basil v. Wolf*, 193 N.J. at 63 ("If a principal cloaks an independent contractor with apparent authority or agency, the principal can be held liable as if the contractor were its own employee if it held out the contractor to the plaintiff as its own servant or agent.").

¹⁹⁶ *DiGiacinto et al., supra* note 184, at 3.

associations (IPAs), and physician hospital organizations (PHOs).¹⁹⁷ For one, when such plans are employer-provided, they benefit from expansive preemption of state claims under the Employee Retirement Income Security Act of 1974 (ERISA).¹⁹⁸ Even when HMOs and other MCOs are not employee-provided, ACOs may have more exposure than they do, because, as noted above, ACOs are more involved in and accountable for clinical care. On the other hand, there are also aspects of ACOs, and of New Jersey's Medicaid ACOs in particular, that will reduce their exposure to liability.

ACOs occur on a continuum from less to more involvement in clinical care and from less to more financial risk. ACOs that are less involved in clinical care and that do not bear financial risk are protected to some extent from legal liability. Mark Hall and colleagues “found no indication that disease management or case management, as currently practiced by managed care entities, creates major liability risks, and 2 other research teams that have studied case management and disease management recently found no indication that liability is a major problem.”¹⁹⁹ The Toward Accountable Care Consortium's *Accountable Care Legal Guide* provides that “[i]t is relatively easy to create care coordination contractual language to avoid the ACO crossing over the line from guidelines to directing care delivery. The language is called the ‘Wickline’ provision, named after a famous case from the early days of managed care.”²⁰⁰ On the other hand, ACOs that are more involved in clinical care and are able to deploy effective financial incentives have advantages, too. They will have concomitantly greater control over the

¹⁹⁷ *Id.* at 1 (predicting that “claims for malpractice against ACOs and ACO-affiliated providers . . . will be enhanced” because ACOs “implement patient care standards” and “participate directly in increasing the quality and efficiency of patient care”).

¹⁹⁸ *Yodzis v. Tilak*, 2009 N.J. Super. Unpub. LEXIS 490, at *33 (App. Div. Feb. 26, 2009).

¹⁹⁹ Mark A. Hall, *et al.*, *Liability Implications of Physician-Directed Care Coordination*, 3 ANNS. FAM. MED. 115, 117 (2005).

²⁰⁰ TOWARD ACCOUNTABLE CARE CONSORTIUM, *supra* note 183, at 15; *see also* Brian Liang, *Cost Containment and Physician Obligations: Mandates for Patient Advocacy*, 8 AMA VIRTUAL MENTOR 157-161 (2006) (discussing *Wickline v. State of California*, 192 Cal. App. 3d 1630 (1986)).

quality of care and will be better able to implement an effective system-wide risk management program.

In a July 2013 article in *JAMA*, Benjamin Harvey and Glenn Cohen make three recommendations for ACOs seeking to reduce or mitigate their risk of liability.²⁰¹ First, they recommend that ACOs secure managed care errors and omissions insurance. ACOs can insure against, among other things, the risk of direct and vicarious medical malpractice liability, the risk of liability for financial incentives that distort medical necessity decisions, and the risk of liability for a data breach.²⁰² Attorneys Mattioli and Barr advise participating providers to “ensure that the ACO has sufficient liability coverage to prevent the participants from being brought in under alternative theories for the care provided by another ACO participant.”²⁰³ Determining whether an ACO’s coverage is “sufficient” may not be entirely straightforward, however. Writing in 2012, Sandra Berkowitz of the insurance broker Willis North America noted that there are hurdles related to the fact that some underwriters believe that ACOs have direct medical malpractice exposure, while others believe they will only face vicarious liability for the actions of their providers.²⁰⁴

Harvey and Cohen also recommend that ACOs match their care pathways and treatment protocols “to published guidelines or evidence-based medicine.”²⁰⁵ In addition to improving

²⁰¹ Harvey & Cohen, *supra* note 178, at 142.

²⁰² Berkowitz, *supra* note 168, at 3.

²⁰³ Mattioli & Barr, *supra* note 174, at 3.

²⁰⁴ Berkowitz, *supra* note 168, at 4.

²⁰⁵ Harvey & Cohen, *supra* note 178, at 142.

quality of care and thereby reducing the incidence of malpractice, hewing to published guidelines can also serve as a defense in litigation.²⁰⁶

Harvey and Cohen's final recommendation is that ACOs "be cautious when implementing incentive-based compensation that ties a substantial portion of physicians' income to their ability to reduce patient care costs."²⁰⁷ Christopher Smith makes a similar point, arguing that ACOs have an advantage over MCOs in this regard, to the extent that "physicians in the MCO context face possible termination if they do not achieve cost cutting goals, whereas physicians and providers in the ACO context . . . lose shared bonuses[.]"²⁰⁸ The Toward Accountable Care Consortium's *Accountable Care Legal Guide* also flags physician incentives as a concern, but states that because "[t]he ACO incentivizes both quality and efficiency," it "takes away a plaintiff lawyer's favorite argument that the physician short-changed care for the sake of 'the almighty dollar.'"²⁰⁹ That providers who participate in New Jersey's Medicaid ACOs will continue to be compensated on a FFS or per capita basis, and that neither New Jersey's Medicaid ACOs nor its participating providers will bear any downside risk both weigh in favor of a finding that decisions about patient care, whether made at the level of the ACO or at the level of the provider, were driven by quality concerns and not an imperative to save money.

Finally, New Jersey's non-profit Medicaid ACOs may be able to take advantage of the state's charitable immunity law.²¹⁰ The law provides as follows:

²⁰⁶ *But see* Ronen Avraham, *Private Regulation*, 34 HARV. J. L. & PUB. POL'Y 543, 586 (2011) ("The information available, however, suggests that the use of guidelines within medical malpractice law can be characterized as largely incoherent and inconsistent.").

²⁰⁷ Harvey & Cohen, *supra* note 178, at 142.

²⁰⁸ Christopher Smith, *Between the Scylla and Charybdis: Physicians and the Clash of Liability Standards and Cost Cutting Goals within Accountable Care Organizations*, 20 ANN. HEALTH L. 165, 193-94 (2013).

²⁰⁹ TOWARD ACCOUNTABLE CARE CONSORTIUM, *supra* note 183, at 14.

²¹⁰ Note that non-profit accountable care organizations need to be mindful of (1) the need to maintain their tax-exempt status, and (2) the need to avoid improper inurement. *Id.* at 10.

No nonprofit corporation, society or association organized exclusively for religious, charitable or educational purposes or its trustees, directors, officers, employees, agents, servants or volunteers shall, except as is hereinafter set forth, be liable to respond in damages to any person who shall suffer damage from the negligence of any agent or servant of such corporation, society or association, where such person is a beneficiary, to whatever degree, of the works of such nonprofit corporation, society or association; provided, however, that such immunity from liability shall not extend to any person who shall suffer damage from the negligence of such corporation, society, or association or of its agents or servants where such person is one unconcerned in and unrelated to and outside of the benefactions of such corporation, society or association.²¹¹

The act does not afford immunity to health care providers who work for non-profit organizations.²¹² It also provides only limited immunity to hospitals, in the form of a \$250,000 cap on damages.²¹³

To benefit from charitable immunity, an ACO will need to demonstrate that it was organized exclusively for charitable purposes. Importantly, non-profit status does not equate to charitableness. In determining whether charitable immunity applies, courts must undertake a fact-intensive determination that includes “a source of funds assessment.”²¹⁴ A non-profit ACO

²¹¹ N.J. STAT. ANN. § 2A:53A-7. The act’s protections do not apply to: “(1) any trustee, director, officer, employee, agent, servant or volunteer causing damage by a willful, wanton or grossly negligent act of commission or omission, including sexual assault and other crimes of a sexual nature; (2) any trustee, director, officer, employee, agent, servant or volunteer causing damage as the result of the negligent operation of a motor vehicle; or (3) an independent contractor of a nonprofit corporation, society or association organized exclusively for religious, charitable, educational or hospital purposes.” *Id.*

²¹² *Id.*

²¹³ N.J. STAT. ANN. § 2A:53A-8.

²¹⁴ *Ryan v. Holy Trinity Evangelical Lutheran Church*, 175 N.J. 333, 346 (2003).

is unlikely to qualify for charitable immunity unless it receives private charitable contributions.²¹⁵

VI. THE BUSINESS CASE FOR MEDICAID ACOs IN 2014: THE RELATIONSHIP BETWEEN ACOs AND MCOs

As was described in Section III above,²¹⁶ the organizations developing New Jersey Medicaid ACOs have business plans that flow from their strong sense of mission. That mission hasn't changed since 2011: advancing the Triple Aim (improved care experience, improved public health, and reductions in cost pressure) in areas of New Jersey where Medicaid is a primary payer and the population contains low-income, vulnerable people. New Jersey's Medicaid ACO law continues to offer some legal protection and guidance for organizations planning to apply for certification as Medicaid ACOs.²¹⁷ The organizations, however, are grappling with changes in the financial structure of New Jersey Medicaid, and with uncertainty regarding the extent to which gainsharing, as envisioned in the Medicaid ACO statute, will serve as a viable funding source going forward.

The organizations' business plans, therefore, are being reconsidered. This necessary reconsideration must remain forward-looking, advancing the shared mission of improving care for New Jersey's most vulnerable patients. Serving that mission will require organizational creativity and flexibility. The evolution of New Jersey's Medicaid financing structure will entail changes in sustainability planning for Medicaid ACOs. Having been galvanized into action by

²¹⁵ Parker v. St. Stephen's Urban Development Corp., 243 N.J. Super. 317, 326-27 (App. Div. 1990) (explaining that the requirement that an entity receive private charitable contributions arises out of "the fact that the essence of the public policy favoring charitable immunity is the preservation of private charitable contributions for their designated purposes").

²¹⁶ See Section III, *supra*.

²¹⁷ See Section IV, *supra*.

the 2011 passage of the Medicaid ACO Pilot, they cannot be tied to the 2011 vision of Medicaid ACOs in their structure and operation.

New Jersey organizations are awaiting the final Medicaid ACO regulations as this Report goes to press. The organizations are taking stock, and many are preparing to file to participate in the Medicaid ACO Project. It is clear that the creation of Medicaid ACOs is a work in progress for both the State and the organizations themselves. There is no “best way to proceed with accountable care” in the Medicaid context.²¹⁸ Several observations about the current status of New Jersey’s Medicaid ACO experiment are, however, in order. First, organizations are at different levels of organizational sophistication. Some have built significant infrastructure, and have the organizational pieces in place to permit them to change care delivery for the better. Others are at a more formative stage, in agreement on goals but still building their structures. Still others are observing the development of Medicaid ACOs, and have not yet chosen whether to adopt the ACO model for care delivery.

In New Jersey and elsewhere, MCOs have served as fiscal intermediaries between the State’s Medicaid agency and Medicaid beneficiaries. Medicaid MCOs serve important functions in Medicaid, including forming and maintaining provider networks and evaluating reimbursement claims from providers. Medicaid ACOs are designed to improve health outcomes through coordination and improvement of care. The MCO and ACO functions can be complementary, although meshing their organizational missions may not be a simple task.

²¹⁸ Kokot *et al.*, *supra* note 60, at S4, S9.

Some states have required their Medicaid MCOs to participate in the development of Medicaid ACOs.²¹⁹ New Jersey's Medicaid ACO Pilot permits but does not require MCOs to contract with the new ACOs.²²⁰ This leaves the relationship between Medicaid ACOs and MCOs open, subject to negotiation. This uncertainty was built into Medicaid ACOs when the Pilot was enacted in 2011. The uncertainty looms even larger with the 2012 approval of New Jersey's Global Medicaid Waiver,²²¹ pursuant to which nearly all Medicaid-eligible people in New Jersey will be in Medicaid ACOs.²²² Gainsharing as a financing mechanism for ACOs is, after the approval of the Global Waiver, entirely subject to the voluntary actions of Medicaid MCOs.

As Marsha Gold and others have recently observed,

Failure to anticipate questions about how the ACOs will work within the context of existing managed care programs may slow implementation of ACO initiatives. . . . [New Jersey] wished to retain its extensive network of risk-based MCOs, which have the authority to specify the terms of provider contracts (including any gain-sharing component). Though the state envisioned that the MCOs would contract directly with the ACOs, the legislation did not address the structure of these contractual relationships in detail. The forthcoming regulations will likely make MCO participation in the initiative voluntary, but the state expects that the intensive

²¹⁹ See MCGINNIS & VAN VLEET, *supra* note 61, at 6-7 (noting that while Medicaid MCO contracting with ACOs is mandatory in Minnesota, it is voluntary in New Jersey).

²²⁰ N.J. STAT. ANN. § 30:4D-8.7.

²²¹ See Letter from Marilyn Tavenner, Acting Administrator, Centers for Medicaid & Medicare Services, to Commissioner Jennifer Velez, New Jersey Department of Human Services, dated Oct. 2, 2012, *available at* http://www.state.nj.us/humanservices/dmahs/home/CMW_approval_letter.pdf (granting New Jersey's Global Medicaid waiver).

²²² See ROBERT HOUSTON & TRICIA MCGINNIS, CTR. FOR HEALTH CARE STRATEGIES, INC., ADAPTING THE MEDICARE SHARED SAVINGS PROGRAM TO MEDICAID ACCOUNTABLE CARE ORGANIZATIONS 5 (March 2013), *available at* http://www.chcs.org/publications3960/publications_show.htm?doc_id=1261489#.UUx4MhfktLc (observing that 97 percent of New Jersey Medicaid subscribers are enrolled in MCOs).

case management envisioned in ACOs will be attractive to at least some MCOs.²²³

There is, then, important work to be done in clarifying the relationship between the Medicaid MCOs and the Medicaid ACOs. This Section addresses some of the barriers to be overcome in achieving contractual arrangements between ACOs and MCOs, and how creative thinking may allow a programmatic relationship within the Medicaid system between the two types of organizations to accommodate arrangements by which ACOs provide various services to add value for Medicaid patients and MCOs.

A. Barriers to MCO-ACO Collaboration

Organizations contemplating the formation of Medicaid ACOs embrace their mission of improving care coordination and quality for Medicaid-eligible people. The Medicaid ACO Pilot statute codifies some of the components of that mission: engaging and educating patients, fostering patient self-management, improving primary and behavioral services, and coordinating and integrating care.²²⁴ These functions are not cost-free; the statute includes gainsharing provisions to sustain the ACOs' mission. The statute sets stringent eligibility requirements for ACO entitlement to gainsharing proceeds for services rendered to patients in the Medicaid FFS system,²²⁵ but clearly makes the remission of gainsharing payments mandatory once an ACO complies with the requirements and establishes requisite cost savings.²²⁶ The approval of the Global Waiver, however, establishes that very few Medicaid recipients will remain in the FFS system. Gainsharing revenue will flow to the ACOs, then, only if Medicaid MCOs choose to

²²³ MARSHA GOLD *ET AL.* KAISER FAMILY FOUNDATION, EMERGING MEDICAID ACCOUNTABLE CARE ORGANIZATIONS: THE ROLE OF MANAGED CARE 4-5 (May 2012), *available at* <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8319.pdf>.

²²⁴ N.J. STAT. ANN. § 30:4D-8.1(e).

²²⁵ *Id.* § 30:4D-8.5.

²²⁶ *Id.* § 30:4D-8.6.

voluntarily participate in the Pilot.²²⁷ Voluntary participation might seem a natural for MCOs, as they would gain a share of the benefit, if any, of the cost-saving activities of ACOs, and owe the ACOs nothing if no savings appear. There are, however, two reasons for MCOs to hesitate.

First, should ACOs perform well at the task of managing the care of complex, high-utilizing patients, the MCOs contracting with those ACOs would seem to realize a benefit, but might paradoxically face a disadvantage. The benefit, of course, would be the reduction in the cost of care for the complex, high-utilizing patients served by the ACOs, as the management of the medical care and social services can reduce utilization of services while improving outcomes and patient satisfaction. The disadvantage might arise as a result of subscriber selection behavior: if one MCO were to contract with an ACO that is successful at managing the care for complex and expensive patients, other complex and expensive patients might opt to be covered by that MCO to obtain that superior service. If the Medicaid risk adjustment methodology does not fully compensate an MCO for the resulting increase in its member risk profile, it could become a “sick person magnet” and suffer financially for gaining a reputation for good care.

The second concern is that MCOs might have only a limited financial interest over time in reducing the cost of care to high-utilizers:

If ACOs achieve savings over projected costs, the MCO automatically retains a portion of savings from the annual capitation payment, net the savings paid to the ACO. But, if the ACO program is effective at reducing total Medicaid costs, MCOs receive lower rates in subsequent years because capitation rates are adjusted to reflect actuarial soundness.²²⁸

²²⁷ *Id.* § 30:4D-8.7.

²²⁸ TRICIA MCGINNIS *ET AL.*, CTR. FOR HEALTH CARE STRATEGIES, INC. THE BALANCING ACT: INTEGRATING MEDICAID ACCOUNTABLE CARE ORGANIZATIONS INTO A MANAGED CARE ENVIRONMENT 4 (Nov. 2013), *available at* http://www.chcs.org/publications3960/publications_show.htm?doc_id=1261583.

An MCO voluntarily contracting with ACOs, then, may face a reduction in its subsequent years' capitation payments as a result of the success of its ACO partner that may at least in part offset any gain in the year of service. New Jersey Medicaid would, however, realize reduced costs going forward as a result of successful ACO activity.

These two reasons for possible Medicaid MCOs' reluctance to contract with Medicaid ACOs are contestable, but should be taken seriously. First, the concerns presented by the selection issues should not be dismissed lightly.²²⁹ It is possible that an MCO's reputation for improved care for high-risk persons could draw historically poorly served, but high need patients to a high-performing MCO. To the extent New Jersey Medicaid's risk adjustment methodology creates disincentives for this improved service, it might be reexamined. Similarly, the concern that Medicaid MCOs will lose in future years' premiums the gain they achieve through partnering with ACOs in reducing utilization should be examined carefully. Both the selection issue and the premium adjustment issue suggest that MCOs have a disincentive to contract with ACOs to improve care and reduce utilization.

Without disturbing the place of MCOs in New Jersey Medicaid, then, the State could create financial incentives and contractual requirements that could facilitate the beneficial development of accountable care efforts in New Jersey. For example, the State could "develop incentives that encourage voluntary MCO participation,"²³⁰ or require such interventions as

²²⁹ The selection problem is at least in part a result of New Jersey's Medicaid ACO law permitting, but not requiring, MCOs to contract with ACOs, *see* N.J. STAT. ANN. § 30:4D-8.7, thereby creating the possibility of some but not all of the MCOs in a region contracting with an ACO. Were all New Jersey Medicaid MCOs required to contract with ACOs, as is the case, for example, in Minnesota, the selection problem would be largely eliminated. *See* MCGINNIS & VAN VLEET, *supra* note 61, at 6-7 (noting that while Medicaid MCO contracting with ACOs is mandatory in Minnesota, it is voluntary in New Jersey).

²³⁰ MCGINNIS *ET AL.*, *supra* note 228, at 3.

“face-to-face care management to high-risk patients, a responsibility that could be delegated to ACOs.”²³¹

The risk selection and premium catch-up problems should, then, be examined to ascertain whether they present unwarranted barriers to the success of the Medicaid ACO Pilot. The complex interaction of ACOs’ community care model and the premium-adjustment principles to which MCOs are subject should not, however, be regarded narrowly as a barrier to the success of the Medicaid ACO Pilot. Rather, if factually borne out, these interactions suggest a technical flaw in New Jersey Medicaid’s contractual relationship with its MCO partners, creating perverse disincentives for them to innovate and form partnerships beneficial to Medicaid and Medicaid participants. It is therefore in the interest of the MCOs and the ACOs to examine these two issues and to discuss sensible solutions with New Jersey Medicaid. A programmatic fix would not only clarify Medicaid ACOs’ sustainability, but also correct a possible disincentive on the part of MCOs from pursuing beneficial innovations.

B. The Programmatic Relationship between ACOs and MCOs

How can the pursuit of Medicaid ACOs’ mission mesh with MCOs’ important Medicaid role? The ACOs’ mission – to improve health outcomes for Medicaid participants through the coordination and improvement of care – is within the broader charge of Medicaid ACOs. The question is the best means by which the two organizations can cooperate under current New Jersey Medicaid practice. States have differently mixed and matched the care coordination function of ACOs and the broader mission of MCOs in their Medicaid programs. Some have integrated community engagement and case management functions directly into existing MCOs;

²³¹ *Id.*

others have set out a scope of service that defines the relevant obligations of MCOs and ACOs; others have empowered ACOs without disturbing the preexisting Medicaid landscape.²³² New Jersey is in the third camp.

The relationship between ACOs and MCOs may work most easily in New Jersey if ACOs fill gaps, or supplement, the central services provided by MCOs. MCOs' principal functions include forming and maintaining a network of providers sufficient and appropriate to serve the needs of their subscribers, and receiving and adjudicating claims for reimbursement from their network providers. MCOs play other roles, of course, but if those are the two principal functions, then ACOs could appropriately fill the gap by,

[M]oving clinical care management activities to the point of care and aligning incentives more effectively at the provider level. [They can also] knit together medical and social service financing at the community level and deploy those resources more effectively to improve outcomes.²³³

Under this formulation of the relationship, MCOs would be free to focus attention on their finance and network maintenance obligations, with ACOs performing specialized, localized services to address the needs of particularly vulnerable populations in return for a share of the reduction realized in the anticipated Medicaid costs.

Some in the developing Medicaid ACO organizations are considering the range of services that might fill out this bare-bones description of their mandate. They might take on intensive case management of high-risk patients; train and coach MCO network providers to assist in the integration of appropriate community care management techniques; develop data-

²³² See Kokot *et al.*, *supra* note 60, at S7 – S9; MCGINNIS & VAN VLEET, note 61, at 6-7.

²³³ MCGINNIS & VAN VLEET, *supra* note 61, at 1.

driven outreach projects on behalf of MCOs; and develop evidence-based guidelines for the care of vulnerable subpopulations among MCOs' patient panel.²³⁴

These efforts must be explored in the broader context of the relationship between the MCOs and ACOs within New Jersey's Medicaid program. The structural discussions, including the rectification of disincentives on the part of the MCOs to undertake partnerships to apply accountable care techniques, can be cooperative and a "win-win for the MCOs, ACOs and the state,"²³⁵ and can be pursued jointly by the MCOs and ACOs. Regardless of the outcome of those efforts, however, targeted, task-oriented contractual arrangements between the MCOs and ACOs can be explored. These arrangements hold the promise of advancing cost containment, care improvement, and community engagement without unduly disrupting important financial relationships.

VII. CONCLUSIONS AND NEXT STEPS

New Jersey's Medicaid ACO Project was generated by Dr. Brenner's and others' desire to build community-based organizations of health care and social service providers to improve care and reduce cost in New Jersey's poorest communities. The Pilot was codified in the Medicaid ACO law signed in 2011, and since that time several non-profit organizations have gathered, consulted with their communities, and taken action to improve community health outcomes. The Pilot is now at a pivotal point, as these organizations await the release of the final regulations from the Department of Human Services, and evaluate the steps necessary for certification as a Medicaid ACO. The ACO law has already produced benefits in the form of

²³⁴ See MCGINNIS *ET AL.*, *supra* note 228, at 6-7.

²³⁵ *Id.* at 4.

these community organizations, peopled by dedicated professionals and community members engaged in the process of improving the health care system. The law promises more, including a degree of legal protection from antitrust scrutiny in the operation of Medicaid ACOs, and a degree of guidance on avoiding running afoul of the dense web of federal and state fraud and abuse rules and common law obligations.

Coordination is necessary to create the clinical integration central to improved care, to encourage clinicians to adopt evidence-based treatments, and to guide patients to healthy choices. The ACO law provides some protection and guidance, and therefore facilitates movement away from fragmented care and toward patient-centered coordinated care. As this Report also describes, however, the transition to new models of care delivery do not always harmonize with health regulatory law. It therefore recommends that all organizations obtain qualified counsel to steer them through the shoals of regulatory compliance. Similarly, ACOs are intended to engage in the coordination of care, and therefore must contemplate the possibility that they may face tort liability if their actions cause patient injuries. As this Report describes, maintaining appropriate insurance and following evidence-based guidance in care coordination will assist in minimizing the effects of such liability. Perhaps most critically, however, the organizations considering Medicaid ACO status are faced with a sustainability puzzle. The ACO law anticipated that Medicaid ACOs achieving reductions in the cost of Medicaid FFS care in their region would share in the savings generated. In addition, the law permitted, but did not require, Medicaid MCOs to contract with ACOs for similar gainsharing plans. Since the time of the ACO law's passage, however, Medicaid's FFS program has nearly disappeared, and Medicaid MCOs have not committed to creating gainsharing agreements with ACOs.

Medicaid ACOs will require revenue streams to support their transformational integrative work. This Report describes some of the alternative avenues that might be available if the gainsharing program does not prove feasible. In addition, it describes the possibility that MCOs and potential ACOs have a common interest in forging agreements on gainsharing programs, or more targeted contractual arrangements. Discussions among the MCOs, ACOs, and New Jersey Medicaid may reveal mutually satisfactory means by which MCOs and ACOs can collaborate to improve care and constrain costs in Medicaid.

This preliminary Report sets a baseline of information regarding New Jersey's Medicaid ACO Pilot. In the coming months, the authors will engage in further discussions, research, and analysis, and we will publish our Final Report in April 2014.