Structuring Medicaid Accountable Care Organizations to Avoid Antitrust Challenges

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I. INTRODUCTION

Faced with increasingly inefficient, costly, poor quality, fragmented medical care for their citizens,[1] several states are adopting accountable care organization (ACO) models of care delivery to improve access to quality health care while trying to bend the cost curve.[2] ACOs are not one-size-fits-all delivery systems,

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[1] *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 1 (Mar. 16, 2012), *available at* http://www.gao.gov/assets/590/589393.pdf [hereinafter "GAO"].

[2] *See, e.g.*, TRICIA MCGINNIS & DAVID MARC SMALL, CTR. FOR HEALTHCARE STRATEGIES, INC., POLICY BRIEF: ACCOUNTABLE CARE ORGANIZATIONS IN MEDICAID: EMERGING PRACTICES TO GUIDE PROGRAM DESIGN 1 (Feb. 2012), *available at* http://www.chcs.org/usr_doc/Creating_ACOs_in_Medicaid.pdf (noting that ACOs "are gaining momentum in Medicaid"); ANN MARIE MARCIARILLE ET AL., BERKELEY L. CHIEF JUSTICE EARL WARREN INST. ON L. & SOC. POLICY, POLICY BRIEF: BREAKING DOWN BARRIERS TO CREATING SAFETY-NET ACCOUNTABLE CARE ORGANIZATIONS: STATE STATUTORY AND REGULATORY ISSUES 16–19 (Dec. 2011), *available at* http://www.law.berkeley.edu/files/chefs/FINAL_assembled_SafetyNetACO.0817-1.pdf (describing accountable care-related reform efforts in California, Colorado, Connecticut, Florida, Illinois, Indiana, Iowa, Massachusetts, Montana, New Jersey, New York, Vermont, and Washington); KITTY PURINGTON ET AL., NAT'L ACAD. FOR STATE HEALTH POLICY, ON THE ROAD TO BETTER VALUE: STATE ROLES IN PROMOTING

however, and states are testing different models to see what works best for their needs.[3] Some states are focusing their efforts on developing Medicaid ACOs, which may "offer a useful framework through which payers, providers, and communities can radically restructure care delivery to improve care for low-income patients and reduce system costs."[4]

New Jersey is on the forefront of state efforts to develop safety net ACOs to provide essential health care to their most vulnerable populations. On August 18, 2011, New Jersey enacted the Medicaid Accountable Care Organization Demonstration Project.[5] Although this pilot project shares some features with other ACOs developed at the state and national level, it has been described as "unique in its ground-up, community-based approach"[6] pursuant to which a single ACO serves a defined geographic area. While this approach brings the community together to address entrenched, systemic fragmentation, the degree of market share and collaboration among potential competitors raises antitrust concerns.[7]

This Article explores two possible responses to these antitrust concerns: (1) clinical integration and (2) the state action doctrine. New Jersey is presently drafting regulations to implement its demonstration project. By structuring Medicaid ACOs to reflect these doctrines, the State should be able to mitigate anticompetitive threats and avoid federal antitrust liability. Failure to do so, however, could jeopardize the success of the pilot because providers are less inclined to seek to form an ACO if they face potential or even uncertain antitrust liability.[8] ACOs and antitrust regulation share the

ACCOUNTABLE CARE ORGANIZATIONS, (Feb. 2011), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2011/Feb/On%20the%20Road%20to%20Better%20Value/1479_Purington_on_the_road_to_better_value_ACOs_FINAL.pdf (examining the development of ACO models in Colorado, Massachusetts, Minnesota, North Carolina, Oregon, Vermont, and Washington "to promote better value in health care spending").

[3] CTR. FOR HEALTHCARE STRATEGIES, *supra* note 2, at 1.

[4] *Id.* at 1 (outlining essential requirements for safety-net ACOs and reviewing Medicaid-focused ACO programs in process throughout the country, including Colorado, Minnesota, New Jersey, Oregon, and Utah).

[5] *See* N.J. STAT. ANN. §§ 30:4D-8.1–8.15.

[6] CTR. FOR HEALTHCARE STRATEGIES, *supra* note 2, at 7.

[7] This Article focuses on federal antitrust law because New Jersey exempted activities undertaken pursuant to the Medicaid ACO demonstration from State antitrust laws. *See* N.J. STAT. ANN. § 30:4D-8.1(g).

[8] *See, e.g.*, Jonathan M. Grossman, et al., *Alert: House Judiciary Hearing Provides Few Answers*, HEALTH CARE ANTITRUST AND LEGISLATIVE UPDATE (Cozen O'Connor), Dec. 13, 2010, http://www.cozen.com/admin/files/publications/antitrust-121310.pdf

common goal of controlling costs while improving quality, and thus New Jersey should be able to harmonize its pilot with antitrust principles.

II. OVERVIEW OF NEW JERSEY'S MEDICAID ACO LEGISLATION

New Jersey's Medicaid ACO demonstration project, which garnered support from a broad coalition of businesses, hospitals, healthcare providers, and consumer groups, is a three-year pilot to test multi-stakeholder, geographic-based Medicaid ACOs.[9] The statutory aims include increasing access to care while improving health outcomes and quality, as measured by objective metrics and patient experience of care, and reducing unnecessary care.[10] Participating providers will continue to receive Medicaid fee-for-service or managed care reimbursements for their professional services.[11] As an incentive to coordinate care, the ACO will be eligible to share in any savings that it generates above a certain threshold, if it meets certain quality benchmarks.[12]

The statute establishes several eligibility requirements.[13] A non-profit coalition of providers from a given geographic area, with a governing board that includes community input, will apply to the State for recognition as a Medicaid ACO.[14] To ensure regional collaboration, each ACO's application must have the support of one hundred percent of the general hospitals and at least seventy-five percent of the primary care providers within the ACO's designated area.[15] Although participating providers may collaborate with other ACOs,[16] only one Medicaid ACO is permitted in each geographic area.[17] The statute requires each ACO to submit quality improvement

(reporting that health care providers recently testified before Congress "that clear guidance from federal agencies is urgently required to reduce the cost, complexity, and uncertainty that have stymied ACO formation to date and impede potential participants' willingness to join these organizations in the future").

[9] *Research and Advocacy: Medicaid ACO Demonstration Projects*, CAMDEN COALITION OF HEALTH CARE PROVIDERS, http://www.camdenhealth.org/data-research/medicaid-acos-in-nj/.

[10] N.J. STAT. ANN. § 30:4D-8.1(d); CTR. FOR HEALTHCARE STRATEGIES, *supra* note 2, at 15.

[11] *See* N.J. STAT. ANN. §§ 30:4D-8.1(f), 8.12.

[12] *See* § 30:4D-8.5.

[13] §§ 30:4D-8.4–8.5.

[14] §§ 30:4D-8.3–8.5.

[15] § 30:4D-8.4(c)(3).

[16] § 30:4D-8.3(a).

[17] § 30:4D-8.4(b).

and gainsharing plans to the State that advance the statutory goals of improving "quality and accessibility while reducing or stabilizing the costs of medical care throughout a region."[18] To this end, the State is only permitted to approve "gainsharing plans that promote: improvements in health outcomes and quality of care, as measured by objective benchmarks as well as patient experience of care; expanded access to primary and behavioral health care services; and the reduction of unnecessary and inefficient costs associated with care rendered to Medicaid recipients residing in the ACO's designated area."[19] The statute identifies a variety of criteria for the State to consider in conducting this review, including 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.[20]

III. ANTITRUST CONCERNS

Increased regional coordination and shared accountability are central to the goals of New Jersey's demonstration project. Collaboration, however, can lead to less competition.[21] But a commitment to protecting competition is the heart of antitrust law—a conviction that competition provides consumers with choices that can lead to quality and value.[22] As then U.S. Assistant Attorney General Christine Varney described:

> [t]he ultimate goal of health care reform is to harness the power of competition, together with regulation, to expand coverage, improve quality, and control the cost of health care for all Americans. The role of antitrust is to ensure that competition is preserved and protected, so that it is there to be harnessed.[23]

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[18] § 30:4D-8.1(c); *see also id.* § 30:4D-8.4(c)(4).

[19] § 30:4D-8.5(d).

[20] § 30:4D-8.5(b)(1).

[21] GAO, *supra* note 1, at 2.

[22] 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.

[23] Christine A. Varney, Remarks as Prepared for the American Bar

Thus, although ACOs and antitrust regulation share the goals of expanding coverage, improving quality, and controlling costs, aspects of the ACO model can raise anti-competitive concerns. The Federal Trade Commission (FTC) and Antitrust Division of the United States Department of Justice (DOJ), as the Federal agencies with overlapping authority to enforce the nation's antitrust laws ("Agencies"),[24] want to ensure "that coordination and integration among health care providers encourage innovation and efficiency without harming competition."[25]

There is some concern that the integration that ACOs encourage will lead to fewer competitors in the markets, which could then increase the market power of ACOs.[26] With increased market power comes the potential to raise prices to uncompetitive levels.[27]

Association/American Health Lawyers Association Antitrust in Healthcare Conference 3 (May 24, 2010), *available at* http://www.justice.gov/atr/public /speeches/258898.htm (quoted in Ken Glazer & Catherine A. LaRose, *Accountable Care Organizations: Antitrust Business as Usual*, THE ANTITRUST SOURCE (Dec. 2011), http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/dec11_glazer_12_21f.authcheckdam.pdf).

[24] GAO, *supra* note 1, 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.

[25] *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).

[26] *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 Federal Medicare Shared Savings Program (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").

[27] *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).

Even where prices are set by government programs, as they are in Medicare and fee-for-service Medicaid,[28] and are therefore not subject to anticompetitive collusion,[29] antitrust regulators may worry about the impact of reduced competition on output, quality of services, and innovation.[30] For example, it could run afoul of antitrust law for doctors participating in an ACO to agree to limit business hours or restrict access to certain services as a means of cost-savings, or for two hospitals to agree that each would specialize in different fields and neither would compete with the other in these spheres.[31] Similarly, the Agencies could object to arrangements among potential competitors that reduce consumer choice or lead to a decrease in the

[28] Most New Jersey Medicaid recipients get care through Medicaid managed care plans (HMOs) rather than fee-for-service Medicaid. *See* STATE OF NEW JERSEY, DEP'T OF HUMAN SERVS., DIV. OF MEDICAL ASSISTANCE & HEALTH SERVS., *NJ Medicaid and Managed Care*, http://www.state.nj.us/humanservices/dmahs/info/resources/care/; NATIONAL ALLIANCE ON MENTAL ILLNESS NEW JERSEY, *Frequently Asked Questions (FAQs) for Medicaid Clients*, 4 (Aug. 19, 2011), http://www.naminj.org/advocacy/enews /MedicaidClientFAQsAug192011.pdf; THE HENRY J. KAISER FAMILY FOUNDATION, STATEHEALTHFACTS.ORG, *New Jersey: Medicaid Managed Care,* http://www.statehealthfacts.org/profileind.jsp?cat=4&sub=56&rgn=32. The State pays the HMO a capitation rate, and then the HMO negotiates fee levels with providers. *See generally* CONTRACT BETWEEN STATE OF NEW JERSEY DEPARTMENT OF HUMAN SERVICES DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES AND _____, CONTRACTOR 3, *available at* http://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf (defining capitation as "a contractual agreement through which a contractor agrees to provide specified health care services to enrollees for a fixed amount per month"). If providers were to negotiate their reimbursement rates as a block with the HMOs, they could increase their market power and drive prices to uncompetitive levels. Thus, as recommended below, New Jersey should prohibit Medicaid HMO providers in an ACO from colluding to set prices with Medicaid HMOs.

[29] *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.").

[30] *See* BURKE ET AL., *supra* note 22, at 6; *cf.* Glazer & LaRose, *supra* note 23, at 2 (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.").

[31] Glazer & LaRose, *supra* note 23, at 7–8.

quality of health care.[32]

The Agencies also may worry about the impact New Jersey's Medicaid ACOs will have on competition outside of the Medicaid markets. While it does not violate antitrust law for Medicaid ACO participants to collectively decide how to divide shared savings earned by reducing costs while meeting quality benchmarks, it would raise serious antitrust issues if these potential competitors jointly discussed contracting outside of the ACO context.[33] In addition, the ACO arrangement could "make it easier for physicians to exclude potential competitors from entry into the local market."[34]

To be sure, aspects of New Jersey's Medicaid ACO collaborations trigger antitrust concerns. In particular, only one Medicaid ACO is permitted 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.[35] The Agencies may scrutinize New Jersey's demonstration project to ensure collaboration in the Medicaid markets will not reduce quality, innovation, and choice for both Medicaid and commercial patients.

IV. RESPONSES TO ANTITRUST CONCERNS

New Jersey has strong responses to the antitrust concerns raised by its Medicaid ACO pilot project. For one, collaboration is a means to an end—improved quality of care at lower costs. The pilot requires clinical integration to achieve these goals, which, as discussed in Section IV.A below, reduces the anticompetitive threat from collaboration. Further, even if the Agencies do not find that New Jersey's Medicaid ACOs are sufficiently clinically integrated to balance the threat to competition, the State specifically intended that

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[32] *Antitrust Issues for Accountable Care Organizations*, *supra* note 27.

[33] 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).

[34] *Id.*

[35] *Cf.* Thomas L. Greaney, *Accountable Care Organizations—The Fork in the Road*, NEW ENG. J. MED. 2 (Dec. 22, 2010), 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").

the state action doctrine would immunize the ACOs' conduct in furtherance of the pilot, as discussed in Section IV.B below. This section reviews the requirements for clinical integration and state action immunity and identifies ways New Jersey may structure its Medicaid ACOs to mitigate the risks of anticompetitive conduct and thus antitrust liability.

A. Clinical Integration

Not all collaboration among competitors triggers antitrust alarms.[36] Indeed, some increased transparency among competitors regarding quality and pricing, for example, has the potential to increase competition.[37] The Agencies have issued guidelines to help distinguish which types of collaboration are permissible and which pose too great a threat to competition.[38]

One form of collaboration among potential competitors that may survive an antitrust challenge is when competing health care providers clinically integrate their care delivery. The Agencies have recognized that clinical integration of health care providers has the potential to result in significant procompetitive efficiencies, such as lowering prices or improving quality.[39] In the Statements of Antitrust

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[36] BURKE ET AL., *supra* note 22, at 1.

[37] *Id.* at 3. Rather than a problem, some scholars believe integration is "an important solution for improving quality and cost in the fee-for-service health system." David Balto, Sr. Fellow, Ctr. for American Progress, *The Need for a New Antitrust Paradigm in Health Care*, Statements before the H. Judiciary Comm., Subcomm. on Courts and Competition Policy (Dec. 1, 2010), *available at* http://www.americanprogressaction.org/issues/2010/11/pdf/new_antitrust_paradigm_healthcare.pdf.

[38] *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 [hereinafter *Health Care Statements*]; 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) [hereinafter "TriState Health Partners"], *available at* http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf; DOSE OF COMPETITION, *supra* note 30, ch. 2, 36–41; 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"].

[39] *See* GAO, *supra* note 1, at 5–7. Although 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 Article. Some states and the Federal government are including forms of financial integration in their ACO models, such as risk-sharing. *See, e.g.*, CTR. FOR HEALTHCARE STRATEGIES, *supra* note 2, at 6, 13–14 (describing Minnesota's Medicaid ACO demonstration that includes risk-

Enforcement Policy in Health Care ("Health Care Statements"), most recently updated in 1996, the Agencies broadly described examples of activities in which physician joint ventures might engage to demonstrate sufficient clinical integration.[40] For example, the joint venture could implement "an active and ongoing program to evaluate and modify practice patterns . . . and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[41] Specifically, such a program could include, for example:

> (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and ensure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.[42]

Through these indicia of clinical integration, the Agencies assess whether a joint venture's structure has the capacity and whether individuals participating in the program have sufficient motivation to work toward the shared efficiency goals even though there is no shared financial risk to incent behavior.[43]

The Agencies made clear in the Health Care Statements that the examples provided were illustrative and not exhaustive.[44] In a recent advisory opinion, for example, the FTC also found that the use of evidence-based practice guidelines and electronic health records constituted evidence of clinical integration.[45]

When an arrangement achieves substantial clinical integration

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sharing); *see generally* Greaney, Regulators as Market-Makers, *supra* note 26, at 19 (noting "that although the FTC has been broadly supportive of efforts to form networks relying on clinical integration, some within the agency hold the view that financial integration offers a more reliable incentive to produce efficiencies necessary to justify enhanced opportunities to exercise market power").

[40] *See Health Care Statements*, *supra* note 38, at 90–91.

[41] *See id.*

[42] *See id.*

[43] *See* TriState Health Partners, *supra* note 38, at 15.

[44] *Id.* at § B.1, Statement 8.

[45] GAO, *supra* note 1, at 12 (citing FED. TRADE COMM'N, ADVISORY OPINION FOR GREATER ROCHESTER INDEPENDENT PRACTICE ASSOCIATION, INC. (2007)); *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 Agencies).

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 Agencies will not presume that the agreement is per se illegal.[46] 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.[47]

As its name suggests, reasonableness is at the core of this fact-intensive analysis.

The FTC and DOJ recently concluded in a joint Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("MSSP Antitrust Statement") that the eligibility criteria for the Medicare Shared Savings Program (MSSP) authorized by the Affordable Care Act "are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements" and other agency advice.[48] Thus, as Kevin Outterson summarized, "[i]f a provider is clinically integrated enough to qualify as a Medicare ACO, that's good enough for antitrust law too."[49] As discussed below, the Agencies' MSSP Antitrust Statement is instructive for New Jersey because there are significant similarities, albeit some striking differences as well, between New Jersey's Medicaid ACO pilot and the MSSP.

The MSSP promotes the formation of ACOs serving Medicare

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[46] GAO, *supra* note 1, at 6–8.

[47] MSSP Antitrust Statement, 76 Fed. Reg. 67,026, 67,027 (Oct. 28, 2011).

[48] *Id.*; *see generally* Greaney, Regulators as Market-Makers, *supra* note 26, at 18 (describing DOJ and FTC's MSSP Antitrust Statement as "a modest relaxation of antitrust standards previously announced by the agencies").

[49] Kevin Outterson, *The Substance of the ACO Antitrust Rules*, INCIDENTAL ECONOMIST (Nov. 29, 2011, 10:00 AM), http://theincidentaleconomist.com /wordpress/the-substance-of-the-aco-antitrust-rules/; *see also* Greaney, Regulators as Market-Makers, *supra* note 26, at 20 (observing that "the agencies' deference to Centers for Medicare & Medicaid Services ("CMS") regulatory standards [on the issue of clinical integration] marks a striking departure from their customary practice of evaluating competitive issues based on the specific conditions obtaining in individual circumstances and a general aversion to administrative regulation of markets").

fee-for-service beneficiaries.[50] Like New Jersey Medicaid ACOs, MSSP ACOs share a portion of cost savings they realize if the ACO satisfies quality performance standards established by the Secretary of Health and Human Services.[51] The MSSP has a number of eligibility requirements, including that the ACO have:

> (1) a formal legal structure that allows the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote evidence-based medicine and patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care for beneficiaries.[52]

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,"[53] the Agencies will not presume that joint price negotiations or other anticompetitive conduct by these joint ventures are per se illegal. Instead, they

> will treat joint negotiations with private payers as reasonably necessary to an ACO's primary purpose of improving health care delivery, and will afford rule of reason treatment to an ACO that meets [the MSSP] eligibility requirements for, and participates in, the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in commercial markets.[54]

Thus, even though the MSSP only involves the Medicare markets, the Agencies recognized "that ACOs may generate opportunities for health care providers to innovate in both the Medicare and commercial markets and achieve for many other consumers the benefits Congress intended for Medicare beneficiaries

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[50] *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).

[51] *See* 42 U.S.C. § 1395jjj(a)(1)(B).

[52] MSSP Antitrust Statement, 76 Fed. Reg. at 67,027 (citing The Patient Protection and Affordable Care Act, Pub. L. No. 111-48, § 3022, 124 Stat. 119, 395–99 (2010); Medicare Shared Savings Program: Accountable Care Organizations, 42 C.F.R. § 425 (2011)).

[53] MSSP Antitrust Statement, 76 Fed. Reg. at 67,027–28.

[54] *Id.* at 67,028.

through the [MSSP]."[55] Thus, their guidance outlined how health care providers could "form procompetitive ACOs that participate in both the Medicare and commercial markets."[56]

In doing so, however, the Agencies indicated that they would be evaluating data regarding cost, utilization, and quality metrics for each MSSP ACO to assess "whether the [MSSP] eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements."[57] The Agencies also signaled their willingness to consider alternative indicia of clinical integration.[58]

The most striking difference between the MSSP and New Jersey's Medicaid ACO arguably is market concentration. The MSSP Antitrust Statement established a safety zone for clinically integrated MSSP 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."[59] To come within the safety zone,

> independent [MSSP] ACO participants that provide the same service (a "common service") must have a combined share of 30 percent or less of each common service in each participant's [primary service area "PSA"], wherever two or more [MSSP] ACO participants provide that service to patients from that PSA.[60]

This is in sharp contrast to New Jersey's requirement that one hundred percent of hospitals and at least seventy-five percent of primary care providers in the ACO's designated area support the Medicaid ACO.[61] In addition, the MSSP requires that any hospital or ambulatory surgery center (ASC) that participates in an MSSP ACO

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[55] *Id.* at 67,026.

[56] Brill, *supra* note 26, at 5; *accord* SHARIS A. POZEN, ACTING ASSISTANT ATT'Y GEN., ANTITRUST DIV., DEP'T OF JUSTICE, COMPETITION AND HEALTH CARE: A PRESCRIPTION FOR HIGH QUALITY, AFFORDABLE CARE, REMARKS AS PREPARED FOR THE WORLD ANNUAL LEADERSHIP SUMMIT ON MERGERS AND ACQUISITIONS IN HEALTH CARE 16 (Mar. 19, 2012), *available at* http://html.documation.com/cds/HEALTH12/Support/PDFs/3-10.pdf.

[57] MSSP Antitrust Statement, 76 Fed. Reg. at 67,028.

[58] *Id.*

[59] *Id.* Even MSSP ACOs falling within the safety zone could face antitrust challenges based on extraordinary circumstances, "such as collusive behavior or exchanges of pricing or other competitively sensitive information with respect to the sale of competing services outside the ACO." *Id.* at 67,028 n.24.

[60] *Id.* at 67,028. The Final Antitrust Statement provides additional instructions on how to define and calculate PSAs and common services. *Id.*

[61] N.J. STAT. ANN. § 30:4D-8.4(c)(3).

must be non-exclusive to the ACO to fall within the safety zone, regardless of its share of the PSA.[62]

The MSSP Antitrust Statement also identifies conduct ACOs should avoid to mitigate antitrust concerns. For one, it recommends that all ACOs, regardless of market share or other indications of market power, should 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."[63]

The Agencies also identified the following four types of conduct that ACOs with market shares above the safety zones (or other indications of possible market power) may wish to avoid because they could raise competitive concerns[64]:

> (1) Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "anti-tiering," "guaranteed inclusion," "most-favored-nation," or similar contractual clauses or provisions.
> (2) Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the private payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO should not require a purchaser to contract with all of the hospitals under common ownership with a hospital that participates in the ACO).
> (3) Contracting on an exclusive basis with ACO physicians, hospitals, ASCs, or other providers, thereby preventing or discouraging those providers from contracting with private payers outside the ACO, either individually or through other ACOs or analogous collaborations.
> (4) Restricting a private payer's ability to make available to

[62] MSSP Antitrust Statement, 76 Fed. Reg. at 67,028–29. The Final Antitrust Statement provides guidance on what it means for an ACO participant to be non-exclusive to the ACO. *Id.* at 67,028. The Agencies also outlined exceptions to the safety zone requirements when an ACO's PSA share exceeds thirty percent in rural areas, or because a dominant provider performs a service that no other MSSP ACO participant provides in that PSA. *Id.* at 67,029. These exceptions also include non-exclusive participation requirements. *Id.*

[63] *Id.*

[64] While these activities could have anticompetitive effects, the Agencies recognized that they also could be competitively neutral or even procompetitive, and thus the antitrust analysis will depend on the particular facts of the situation. *Id.* at 67,029–30.

> its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency, and performance measures used in the Shared Savings Program.[65]

Although the MSSP Antitrust Statement does not directly apply to New Jersey's Medicaid ACOs,[66] its analytical principles should. Consistent with their desire "to maximize and foster opportunities for ACO innovation and better health for patients," the Agencies specifically acknowledged that "[t]he analytical principles underlying the Policy Statement also would apply to various ACO initiatives undertaken by the Innovation Center within [the Center for Medicare & Medicaid Services in HHS] as long as those ACOs are substantially clinically or financially integrated."[67] While New Jersey's pilot is not sponsored by the Innovation Center, the Agencies have indicated that they "support and applaud physicians, hospitals, and other providers when they find precompetitive, innovative ways to control costs and improve the quality of health care" and "encourage[] legitimate endeavors among health care providers to improve quality and control costs."[68] Relatedly, in recent interviews by the General Accounting Office, Agency officials defended the sufficiency of their guidance on clinical integration in part because they do not want to be "overly prescriptive."[69] Rather, they recognized that there are numerous and evolving ways to clinically integrate, and they intentionally "made the guidance sufficiently broad to account for new types of clinically integrated collaborative arrangements."[70] These comments suggest the Agencies will treat New Jersey's innovative approach to helping its most vulnerable patients similarly to how they treat federal pilots and innovations.[71]

Applying the principles in the MSSP Antitrust Statement, there

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[65] *Id.* at 67,029 (internal footnote omitted).

[66] *Id.* at 67,027.

[67] *Id.* at 67,026 & n.7.

[68] POZEN, *supra* note 56, at 1–2, 12.

[69] GAO, *supra* note 1, at 11.

[70] *Id.* at 11–12; *see generally* A DOSE OF COMPETITION, *supra* note 30, at 21 (recommending that private payers, governments, and providers experiment with payment methods to align "providers' incentives with consumers' interests in lower prices, quality improvements, and innovation").

[71] *See also* BURKE & ROSENBAUM, *supra* note 45, at 5 (observing that "the ACO model aligns with longstanding antitrust policies, the aim of which has been to not stand in the way of innovative and adequate health care financial and clinical integration arrangements").

is a strong basis to conclude that the Agencies will apply rule of reason analysis to New Jersey's demonstration project, as there are a number of similarities between the programs. Both involve independent providers collaborating with the goal of improving care while reducing costs. These providers continue to receive reimbursement for their services and potentially receive only a portion of any shared savings they realize through efficiencies. Both systems require clinical integration to achieve these efficiencies and measure quality and patient satisfaction to ensure neither suffers as a result of the economic savings. Indeed, the MSSP eligibility requirements, which the Agencies found to be broadly consistent with their clinical integration standards, mirror to a large degree those that apply to New Jersey Medicaid ACOs. The New Jersey pilot, like the MSSP, requires ACOs to have, among other attributes: (1) formal legal structures that allow the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care.[72] In addition, New Jersey's Medicaid ACOs include a number of features that should improve clinical collaboration, such as using electronic health records, electronic prescribing, and a range of specialists to address a broad range of medical issues.[73] Thus, the Agencies should conclude that New Jersey Medicaid ACOs warrant rule of reason review because they "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."[74]

There are differences between the programs, however, that may impact the rule of reason balancing. Perhaps the most challenging feature of New Jersey's demonstration project, from an antitrust perspective, will be its requirement that all hospitals and at least seventy-five percent of primary care providers in the ACO's defined region support the ACO.[75] Although the New Jersey law is non-exclusive to the extent that providers may associate with other ACOs, it permits only one Medicaid ACO in each geographic region.[76] Thus, the Medicaid ACO will have one hundred percent of the

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[72] *See* N.J. STAT. ANN. §§ 30:4D-8.4–8.5.

[73] *See* §§ 30:4D-8.4(c), 8.5(b).

[74] MSSP Antitrust Statement, 76 Fed. Reg. 67,026, 67,027–28 (Oct. 28, 2011).

[75] *See* N.J. STAT. ANN. § 30:4D-8.4(c)(3).

[76] *See* § 30:4D-8.4(b).

hospital market share and at least seventy-five percent of the primary care provider market share for Medicaid patients in a designated area. Despite the strong indicia of clinical integration built into New Jersey's design, "even if an arrangement is clinically integrated, it can still be condemned under the rule of reason if it has market power."[77] New Jersey thus should be prepared to demonstrate that its network of providers is not over-inclusive.

New Jersey can respond that the market share requirements in its legislation are ancillary to the main goal of improving coordination and care while reducing costs. The Medicaid markets in New Jersey are broken. There are inadequate numbers of providers, and there is little to no coordination among them.[78] As the Camden Coalition of Health Care Providers has maintained, Medicaid ACOs make sense for New Jersey because there is a "very fragmented provider, hospital, and payer marketplace. Medicaid patients are highly concentrated in urban, impoverished cities, with a high percentage covered by government-sponsored health plans . . . ."[79] There is a strong argument that the market share requirements are necessary to bring fragmented providers together to try to improve access to and the quality of care while realizing efficiencies.[80]

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[77] BURKE & ROSENBAUM, *supra* note 45, at 7.

[78] *See generally* LEGAL SERVS. OF N.J. POVERTY RESEARCH INSTITUTE, POVERTY BENCHMARKS 2012: ASSESSING NEW JERSEY'S PROGRESS IN COMBATING POVERTY 88 (May 2012), *available at* http://www.lsnj.org/PDFs/budget/Benchmarks2012.pdf ("Because [New Jersey Medicaid physician reimbursement] rates are so low, very few physicians participate as Medicaid providers. This means that, while many Medicaid recipients theoretically have health care coverage, they practically have no health care access."); Phil Galewitz, *Study: Nearly A Third Of Doctors Won't See New Medicaid Patients*, KAISER HEALTH NEWS, Aug. 6, 2012, http://www.kaiserhealthnews.org/stories /2012/august/06/third-of-medicaid-doctors-say-no-new-patients.aspx (reporting that a recent survey by the U.S. Centers for Disease Control and Prevention found that only forty percent of New Jersey office-based physicians will accept new Medicaid patients, the lowest rate in the nation); N.J. STAT. ANN. § 30:4D-8.1(c)(3) (identifying among the legislative findings in support of New Jersey's Medicaid ACO demonstration project that "[t]he current health care delivery and payment system often fails to provide high quality, cost-effective health care to the most vulnerable patients residing in New Jersey, many of whom have limited access to coordinated and primary care services and, therefore, tend to delay care, underutilize preventive care, seek care in hospital emergency departments or be admitted to hospitals for preventable problems").

[79] *Medicaid ACO Demonstration Projects*, CAMDEN COALITION OF HEALTH CARE PROVIDERS (Apr. 19, 2012), http://www.camdenhealth.org/?s=Medicaid%20ACO %20Demonstration%20Projects.

[80] *See generally* Sheffler, *supra* note 26, at 1493 (noting "potential efficiency benefits to exclusivity," such as that "[i]ncreased internal referrals and

The State also can emphasize that its Medicaid ACOs will develop in geographically contained regions, most likely those that have high concentrations of Medicaid patients. The quality measures, if well-crafted in the regulations, should ensure that the high market shares do not result in anticompetitive effects on non-price features of the market, like quality, output, or innovation. Although there is the risk of spillover of anticompetitive effects into commercial markets, the risk arguably is less than between Medicare and commercial markets. The pilot also is for a limited duration, which should cabin anticompetitive risks from this experiment.

New Jersey should structure its pilot through its regulations to account for antitrust concerns. Thus, it should implement safeguards to prevent anticompetitive effects from the ACO's activities. As suggested by the MSSP Antitrust Statement, the State should limit access among and between independent providers to competitively sensitive information by, for example, prohibiting collusion over price or other competitively sensitive terms and implementing firewalls to prevent collusion in the sale of competing services outside of the ACO.[81] Given the market share of New Jersey Medicaid ACOs, the regulations also should prohibit the four types of behavior that the Agencies flagged in the MSSP Antitrust Statement as potentially anticompetitive, to the extent such behavior is relevant to Medicaid markets.[82] The State could consider requiring training of ACO leadership and staff about antitrust concerns and clarifying how the Medicaid ACO will be able to discipline a non-complying provider. The State may want to collect data on the commercial markets where

communication among dedicated physicians is expected to facilitate coordinated, clinically integrated, and high-quality care"); CTR. FOR HEALTHCARE STRATEGIES, *supra* note 2, at 10 ("Other interviewees questioned whether anti-competitive behavior is of primary concern within Medicaid, given purchasing dynamics and cost drivers for low-income populations. Given low-levels of Medicaid reimbursement, for-profit, high-cost hospitals and health systems may be less likely to serve Medicaid beneficiaries in the first place. Patterns of high, inappropriate hospital and emergency department utilization are likely the biggest driver of avoidable Medicaid costs, rather than high per-unit costs. Collaboration among providers may be more effective in solving what is fundamentally a utilization issue related to unmet health and social needs, not a cost issue."). *Cf.* S. 1580 § 20, 76th Leg. Assemb., Reg. Sess. (Or. 2012), *available at* https://cco.health.oregon.gov/Documents/sb1580.intro.pdf (permitting more than one coordinated care organization to serve a geographic area if necessary to optimize access and choice).

[81] *See* MSSP Antitrust Statement, 76 Fed. Reg. 67,026, 67,029 (Oct. 28, 2011); BURKE, *supra* note 22, at 12.

[82] *See supra* note 62 and accompanying text.

ACOs operate to monitor for evidence of anticompetitive spillover.[83] In general, the State should endeavor to implement an "active and ongoing program to evaluate and modify practice patterns by the [ACO]'s providers and to create a high degree of interdependence and cooperation among the providers to control costs and ensure quality."[84]

Given the clear legislative intent behind the Medicaid ACO demonstration to encourage clinical integration in the name of quality improvement at reduced costs, it seems likely that the Agencies will 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. The result of the rule of reason analysis may well depend on how New Jersey structures its pilot in forthcoming regulations. New Jersey should use this opportunity to craft its regulations, ideally with Agency input, to make it more likely and verifiable that procompetitive effects dominate, which may convince the Agencies that Medicaid ACOs are a worthy innovation that they want to encourage.

B. State Action Doctrine

Even if the Medicaid ACO does not survive antitrust scrutiny under the rule of reason analysis, New Jersey specifically intended to extend its state action immunity from federal antitrust law to its Medicaid ACOs.[85] Other states also are invoking this doctrine to protect ACOs from federal antitrust challenges.[86]

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[83] *Cf., e.g.,* Greaney, Regulators as Market-Makers, *supra* note 26, 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").

[84] MSSP Antitrust Statement, 76 Fed. Reg. at 67,027; *see, e.g.*, H.B. 3650, 76th Leg. Assemb. (Or. 2011) (may not "solicit, share, or discuss pricing information" at joint survey or meetings); WASH. REV. CODE ANN. § 70.54.420 (West 2009) (may not agree "among competing health care providers or health carriers as to the price or specific level of reimbursement for health care services").

[85] *See* N.J. STAT. ANN. § 30:4D-8.1(g); *see generally* CTR. FOR HEALTHCARE STRATEGY, *supra* note 2, at 5 (noting that "anti-trust issues in Medicaid may be easier [than in the MSSP context] due to the state-action doctrine").

[86] *See, e.g.,* OR. REV. STAT. ANN. § 646.735(1) (West 2011) (declaring legislative

A state and its officers and agents generally are not subject to federal antitrust liability when they act to implement state legislation, even when their actions have anticompetitive effects.[87] This immunity from antitrust liability, often referred to as the *Parker* immunity doctrine, is based on principles of federalism and applies when the state is acting as a sovereign, but not when it is a mere "participant in a private agreement or combination by others for restraint of trade."[88]

Federalism concerns, however, do not reach private actors. Thus, where private actors seek shelter from antitrust liability for their involvement in a state regulatory scheme, courts require proof that the private actors are acting at the behest of the state and not simply as a result of private, anticompetitive agreements. The Supreme Court has a created a "state action doctrine" to define circumstances in which private market participants are shielded from federal antitrust laws for otherwise questionable conduct undertaken pursuant to a state regulatory scheme. Specifically, the Supreme Court has identified two elements that must be satisfied before private actors may invoke immunity from antitrust liability. First, the state must articulate a clear and affirmative policy to allow the anticompetitive conduct to ensure that the state's goals, and not simply self-serving goals, are furthered.[89] Second, the state must provide active supervision of anticompetitive conduct undertaken by private actors.[90] Given that the doctrine permits anticompetitive behavior that otherwise would violate federal policy, it is not surprising that its application is disfavored.[91]

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intent to provide immunity from federal antitrust laws to coordinated care organizations through the state action doctrine); WASH. REV. CODE ANN. § 70.54.420 (West 2011); N.Y. PUB. HEALTH LAW § 2959-a (McKinney 2011) (establishing multi-payer patient centered medical home program with state action immunity); NY CLS Pub. Health § 2999-r (adopting state action immunity for ACO demonstration); *see generally* PURINGTON ET AL., *supra* note 2, at 8–9 (noting that Vermont and Washington included language in legislative ACO proposals to provide antitrust protection to participants); BURKE, *supra* note 22, at 8–12 (summarizing health-related legislation in various states that relies on the state action doctrine).

[87] Parker v. Brown, 317 U.S. 341, 350–51 (1943) (finding no congressional intent for the federal antitrust laws "to restrain a state or its officers or agents from activities directed by its legislature"); *see also* FTC v. Ticor Title Ins. Co., 504 U.S. 621, 632–33 (1992) (stating that "federal antitrust laws are subject to supersession by state regulatory programs").

[88] *Parker*, 317 U.S. at 351–52.

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

[90] *Id.*

[91] *Ticor Title Ins. Co.*, 504 U.S. at 636; *see generally* DOSE OF COMPETITION, *supra* note 30, at 28 (warning that "[i]nappropriately broad interpretations" of the state

Applying the state action doctrine to New Jersey's demonstration project, it is likely that New Jersey's Medicaid ACO legislation satisfies the first element of the state action test. The Legislature specifically exempted private Medicaid ACO participants from State antitrust liability and expressed its intent for private participants to enjoy immunity from federal antitrust liability "through the state action doctrine."[92] Whether private participants in New Jersey's regulatory scheme will enjoy federal antitrust immunity therefore will depend on the second element: whether the State actively supervises, through mechanisms included in the State's statute and forthcoming regulations, the potentially anticompetitive private conduct.

As the Supreme Court of the United States has explained, 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."[93] By requiring the state to exercise sufficient independent judgment and control, courts ensure that private actors advance the state's regulatory agenda and not simply their private interests. "Immunity is conferred out of respect for ongoing regulation by the State, not out of respect for the economics of price restraint."[94]

What does not satisfy the active supervision requirement is clearer from case law than what does. It is not enough for the state to have a veto over private agreements or just to check the math on the private conduct.[95] Nor is it sufficient for the state to have the ability to supervise the private conduct if it does not actually engage in active supervision. The state also may not rely on state judicial review, at least where the court cannot reach the merits of the private action.[96] It likely is insufficient for the state to passively review contracts among competitors, especially if the system for state review essentially establishes "a presumption in favor of approval."[97]

Rather, the state must get into the "specific details" of the private behavior; "[a]ctual state involvement, not deference to private

action doctrine can "chill or limit competition in health care markets").

[92] *See* N.J. STAT. ANN. § 30:4D-8.1(g).

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

[94] *Id.* at 633.

[95] *Id.* at 638.

[96] *Id.* at 638–39.

[97] BURKE, *supra* note 22, at 11 (quoting FEDERAL TRADE COMM'N, IN RE MINNESOTA HOUSE BILL H.F. NO. 120 & SENATE BILL S.F. NO. 203 ADVISORY OPINION (Mar. 18, 2009), http://www.ftc/opp/advocacy/V090003.pdf).

[anticompetitive] arrangements under the general auspices of state law, is the precondition for immunity from federal law."[98] The development and administration of Medicaid ACOs may involve cooperation among entities that are otherwise competitors in matters such as business practices and referrals. The cases reviewing the state action doctrine as applied to some types of potential anticompetitive behavior provide an indication as to the degree of state oversight courts will expect of states in the supervision of other types of behavior.

While the Supreme Court to date has not identified specific procedural or substantive standards that states must adopt to satisfy the active supervision requirement,[99] the FTC has identified three elements that it will evaluate in deciding whether the active supervision prong has been satisfied in a given case:

> (1) Development of an adequate factual record, including notice and opportunity to be heard.
> (2) A written decision on the merits.
> (3) "[A] specific assessment—both qualitative and quantitative—of how the private action comports with the substantive standards established by the state legislature."[100]

Although the Supreme Court has not adopted these elements, the FTC regularly applies them;[101] it would be prudent, then, to anticipate that these elements will guide evaluation of applications of the state action doctrine.

In fleshing out the substance of these requirements, the FTC requires that states engage in a "'pointed re-examination' of the private conduct":

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[98] *Id.*

[99] Supreme Court guidance may be forthcoming because, for the first time in nearly twenty years, the Court will hear a case this term that concerns the scope of the state action doctrine, this time in the hospital merger context. *See* Fed. Trade Comm'n v. Phoebe Putney Health Sys., 2012 U.S. LEXIS 4852, 80 U.S.L.W. 3707 (Jun. 25, 2012); Questions Presented, 11-1160 Federal Trade Commission v. Phoebe Putney Health System, Inc., http://www.supremecourt.gov/qp/11-01160qp.pdf.

[100] 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.

[101] *See In re* N.C. State Bd. of Dental Exam'rs, F.T.C. Docket No. 9343 (F.T.C. Nov. 20, 2008), *available at* http://www.ftc.gov/os/adjpro/d9343/110208commopinion .pdf (noting that "[a]lthough no single one of these elements is necessarily a prerequisite for active supervision, the Board has presented no evidence that any of these elements are satisfied here" and that the Sixth Circuit affirmed the FTC's application of these elements in *Kentucky Household Goods Carriers Ass'n v. FTC*, 199 F. App'x 410 (6th Cir. 2006)).

> 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.[102]

Developing an adequate factual record facilitates this pointed re-examination. Thus, the FTC has emphasized the need for the state to obtain "reliable, timely, and complete" data to permit the state to evaluate if the private conduct is furthering the Legislative objectives.[103] The FTC similarly has emphasized the need for the state to conduct periodic reviews of ongoing private conduct with updated data and not just to permit an initial approval to justify continued immunity.[104] In the FTC's view, providing notice and an opportunity to comment to affected communities is integral to this process of assembling the factual record. As the FTC has stated, "[t]hese procedural elements . . . 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."[105] It is noteworthy that the FTC on several occasions has criticized a proposed regulatory scheme for not permitting the state to require submission of additional information needed to facilitate pointed re-examination.[106]

The FTC also places high value on the state supervisor issuing a

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[102] 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"].

[103] *Id.* at 6.

[104] *Id.* at 6; *see also* Letter from Susan S. DeSanti, Dir., Office of Policy Planning, Fed. Trade Comm'n, to Elliott Naishtat, Rep., Tex. H.R.*et al.* (May 18, 2011), *available at* http://html.documation.com/cds/HEALTH12/Support/PDFs/7-1.pdf (noting lack of required review after health care cooperative's first year in finding party seeking immunity had not carried heavy burden).

[105] IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 102, at 7.

[106] *See, e.g.*, 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 [hereinafter "FTC Letter on Alaska S.B. 37"].

written decision. As it has explained, "[t]hough 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."[107] Whether the state is approving or denying proposed private anticompetitive conduct, the FTC favors a written decision that provides "analysis and reasoning, and supporting evidence [regarding whether] the private conduct furthers the legislature's objectives."[108]

Whether reduced to writing or not, the FTC's third active supervision element looks for a qualitative and quantitative assessment by the state in considering whether to approve the private anticompetitive conduct. The FTC looks for evidence of the "steps the State took in analyzing" the proposed private conduct and "the criterion it used in evaluating" that proposed conduct.[109] Among the evidence the FTC will consider is "whether the State independently verified the accuracy of financial data submitted and whether it relied on accurate and representative samples of data. There should be evidence that the State has a thorough understanding of the consequences of the private parties' proposed action."[110] The FTC also looks for evidence that the state reviewed "particular contracts and fee arrangements . . . to assess whether they comport with State policy goals . . . and to remedy on an ongoing basis situations that may violate those goals."[111] This type of review can be rather intensive, and the FTC often expresses its concern that states lack the requisite resources and time to complete the hands-on oversight necessary.[112] For example, it has criticized proposals imposing thirty- and ninety-day time periods for state review, noting that they did not permit the state to extend the time for good cause.[113]

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[107] IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 102, at 7.

[108] *Id.*; *see also* Letter from Joseph. J. Simons, Dir., Bureau of Competition, Fed. Trade Comm'n on Ohio H.B. 325 to Dennis Stapleton, Chairman, Ins. Comm., Ohio H.R. (Oct. 16, 2002), *available at*: http://www.ftc.gov/os/2002/10/ohb325.htm.

[109] IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 102, at 8.

[110] *Id.*

[111] Letter from Susan S. DeSanti, Dir., Office of Policy Planning, Fed. Trade Comm'n to Senators Eric D. Coleman & John A. Kissel, Representatives Gerald Fox and John W. Hetherington, Conn. Gen. Assemb. (June 8, 2011), *available at* http://www.ftc.gov/os/2011/06/110608chc.pdf.

[112] *Id.*

[113] *See, e.g.*, Letter to Lisa Murkowski, *supra* note 106; Letter from Susan DeSanti,

New Jersey's Medicaid ACO legislation expressly intends for the State to have oversight over Medicaid ACOs and builds features of State oversight into the statute. Proposed ACOs must apply to the State Department of Human Services (DHS) "for certification and participation in the project," and DHS must "consult with the Department of Health and Senior Services (DHSS) with respect to establishment and oversight of the demonstration project."[114] DHS is empowered to deny certification to any applicant that it determines does not meet the various statutory eligibility requirements.[115] Once certified, a Medicaid ACO must further seek DHS approval of its gainsharing plan before it may receive and distribute any shared savings.[116] The statute requires DHS, with input from DHSS, to obtain and review data, including patient experience of care, and consider various criteria in deciding whether to approve an ACO's gainsharing plan, which include substantive standards as well as whether the plan was "developed with community input and will be made available for inspection by members of the community served by the ACO."[117] The statute also empowers DHS to approve amendments to an ACO's gainsharing plan.[118] The State is further charged with responsibility for designing and implementing the ACO application process, collecting data from ACO participants, and approving a methodology for calculating cost savings and monitoring health outcomes and quality of care under the pilot.[119] Each year, DHS, in consultation with DHSS, shall evaluate the pilot to assess whether there are cost savings and improvement in the rates of health screening, the outcomes and hospitalization rates for persons with chronic illnesses, and the hospitalization and readmission rates.[120] At the completion of the three-year demonstration project, DHS and DHSS shall provide an evaluation of the pilot to the Governor and to the Legislature, including an assessment of whether it should be made a permanent program.[121] The statute further directs DHS, with input

supra note 111.

[114] N.J. STAT. ANN. § 30:4D-8.3(a).

[115] § 30:4D-8.4.

[116] §§ 30:4D-8.5(a) & § 30:4D-8.7(a).

[117] § 30:4D-8.5(b) & (h).

[118] § 30:4D-8.5(a).

[119] § 30:4D-8.8(a).

[120] § 30:4D-8.9; *cf.* TEX. INS. CODE ANN. art. 848.060 (West 2011) (requiring annual renewal of health care collaborative certificate of authority and determination of approval).

[121] N.J. STAT. ANN. § 30:4D-8.14.

from DHSS, to promulgate regulations establishing, among other things, "the standards for gainsharing plans submitted by Medicaid ACOs . . . [and] governing the ongoing oversight and monitoring of the quality of care delivered to Medicaid recipients in the designated areas served by the Medicaid ACOs."[122]

While the statute establishes a framework for State oversight of the demonstration project, it may not be sufficient to satisfy the demanding state action standards. Based on the Agency guidance reviewed above, there are a number of issues for the State to consider as it finalizes draft regulations to implement the Medicaid ACO pilot. A high priority is addressing the need for ongoing monitoring and oversight. Although the statute requires annual review of the program as a whole, it does not expressly require ongoing review of each ACO's continued eligibility and compliance with the pilot's objectives.[123] The State needs to be able to monitor the performance of ACOs after they are certified and their gainsharing plans are approved or amended to ensure that they continue to comply with the program's objectives. To facilitate this oversight, for example, the State could require ACOs to report annually on the amount, distribution, and use of savings achieved; quality performance measures; and patient satisfaction reports. This oversight could keep an eye on whether there have been any anticompetitive spillover effects into other markets from the ACO's activities. The State may also want to impose an ongoing obligation on ACOs to notify the State in a timely fashion if they experience any material changes from what they represented in their applications or gainsharing plans so the State, as overseer, can evaluate whether these changes affect the ACO's eligibility for the pilot.

The state action doctrine not only requires the State to review the actions of non-state actors, but it also must disapprove of anticompetitive private party conduct that fails to comply with State policy.[124] The statute is not clear, however, whether the State has any option other than to approve or disapprove ACO applications and gainsharing plans.[125] The State should clarify the bases on which and at what points it may take action if a participant or ACO is not complying with the program's requirements. For example, the State

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[122] § 30:4D-8.15.

[123] § 30:4D-8.9.

[124] *See supra* note 93 and accompanying text (quoting FTC v. Ticor Title Ins. Co., 504 U.S. 621, 634 (1992)).

[125] *See* N.J. STAT. ANN. §§ 30:4D-8.4(a), 8.5(b).

may consider whether and in what circumstances it may suspend or revoke a previously granted certification, impose a remediation plan, require reapplication, and/or reconsider a previous decision.

Although not necessarily required to, the State also may wish to adopt some or all of the three factors that the FTC has said it will consider when analyzing if the active supervision prong has been satisfied.[126] To ensure that it develops an adequate factual record, the State could require applicants to submit information it will need to perform qualitative and quantitative assessments, which may include, for example, information regarding the ACO's contracts and fee arrangements and copies of the ACO's certificate of incorporation and bylaws. At a minimum, the State should include language giving it the authority to require applicants to provide additional information needed to perform its oversight functions. Although the statute contemplates some opportunity for the public to have notice of and to comment on ACO formation, the State could clarify what stages of the ACO formation and approval processes require notice and comment from the public and how the process will work at each stage.

The State also should decide whether to require any of its decisions regarding Medicaid ACOs to be in writing, such as its decisions regarding the ACO's application for certification, gainsharing plan, amendment of the plan, and, if implemented, annual review of the ACO's certification. It also would be useful for the State to require any decision to articulate the reasons and supporting evidence for its conclusion.

To demonstrate that the State performs a qualitative and quantitative assessment of the private conduct, the regulations could require the State to independently verify and analyze the information supplied by the ACOs. The regulations also could address how, logistically, the State will implement its oversight obligations. For example, it could establish the time frames for each stage in the process. In doing so, the State will have to balance the desire to keep the ACO certification process moving swiftly with both the reality of limited State resources and the Agencies' skepticism that the State can meaningfully fulfill an oversight function in limited time frames. The regulations could permit the State to extend the time periods for good cause.

While there are a variety of options available to the State to

[126] *See supra* note 100 and accompanying text.

improve the chances that the Agencies and, ultimately the courts, will find that the state action doctrine applies, it is unclear how much the State *must* do to satisfy the active supervision requirement. It is notable that the vast majority of available FTC guidance on this prong involves fact patterns that are distinguishable from Medicaid ACOs and much more akin to classic price fixing, like doctors seeking to band together to renegotiate fee schedules or movers collectively setting rates.[127] It is an open question how the FTC and DOJ will apply these standards to New Jersey's demonstration project. As discussed above, the Federal government has signaled its support of similar programs that look to bend the cost curve by improving quality while trimming costs. The pilot includes quality measures and consumer input, which should facilitate State oversight.[128] Thus, to the extent possible, New Jersey should seek input from the Agencies during the regulatory drafting process to inform its decisions about how to structure its oversight of the pilot.

V. CONCLUSION

New Jersey's Medicaid ACO Demonstration Project raises significant federal antitrust issues. But it also proposes an innovative reform that seeks to increase access to better quality health care for vulnerable populations while reducing costs. The federal antitrust Agencies share these goals and have committed to working with innovators to test these proposals. As Sharis A. Pozen, former Acting Assistant Attorney General of the Antitrust Division, recently said, "[t]he ultimate objective is that ACOs and ACO participants commit to the necessary changes in leadership, management, and clinical structures and procedures that will lead to real cost containment and quality improvements."[129] New Jersey's Medicaid ACO pilot challenges providers and the community to make this commitment.

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[127] *See, e.g.*, FTC Letter on Alaska S.B. 37, *supra* note 106 (commenting on State bill seeking to permit "competing physicians to engage in collective bargaining with health plans over fees and other terms"); IND. HOUSEHOLD GOODS AND WAREHOUSEMAN ANALYSIS OF PROPOSED CONSENT ORDER, *supra* note 102 (involving allegations that an association of seventy movers in Indiana established collective rates for the transportation of household goods within the State that were agreed upon by all of its members).

[128] *Cf.* GAO, *supra* note 1, at 16 (explaining that a "key reason" that the MSSP safety zone is more generous than in the 1996 Health Care Statements was that, "unlike collaborative arrangements in the private market, ACOs in the [M]SSP are subject to quality and cost reporting requirements and monitoring that do not exist for arrangements outside this program").

[129] POZEN, *supra* note 56, at 17.

New Jersey should work with the FTC and DOJ to structure its Medicaid ACO Demonstration Project to minimize the threat of anticompetitive conduct while maximizing these shared goals.