Considerations for the Development of Accountable Care Organizations in New York State

JUNE 2011

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Acknowledgements

The authors would like to extend their thanks to Laura Braslow for her contributions to the report.

Support for this work was provided by the New York State Health Foundation (NYSHealth). The mission of NYSHealth is to expand health insurance coverage, increase access to high-quality health care services, and improve public and community health. The views presented here are those of the authors and not necessarily those of the New York State Health Foundation or its directors, officers, and staff.

Introduction

The Patient Protection and Affordable Care Act (ACA) created a wide range of initiatives designed to transform how health care is provided and financed throughout the country. A key element of the ACA's health care delivery and payment reform agenda is the Medicare Shared Savings Program (MSSP). The MSSP provides a legal framework and a set of financial incentives for groups of providers—through participation in an Accountable Care Organization (ACO) —to collaborate in delivering higher-quality and more cost-effective care to Medicare beneficiaries. The program has lofty intentions. As Centers for Medicare and Medicaid Services (CMS) Administrator Donald Berwick wrote in *The New England Journal of Medicine*, "CMS believes with enhanced cooperation among beneficiaries, hospitals, physicians, and other health care providers, ACOs will be an important new tool for giving Medicare beneficiaries the affordable, high-quality care they want, need, and deserve."[1]

CMS is projecting that within a three-year period there will be 75-150 ACOs coordinating care for 1.5 million to 4 million Medicare beneficiaries nationwide. The Congressional Budget Office estimates that the savings to Medicare over 10 years will be $4.9 billion. A large portion of the savings from the program are expected to come from reduced hospital admissions, although the results of prior CMS demonstrations also indicate the potential for significant savings in outpatient services.

The issuance of a Proposed Rule implementing the MSSP by CMS is heightening the focus of health care organizations in New York and across the nation on whether ACOs offer a viable framework for changing the way health care is delivered and funded. Although the Proposed Rule will apply only to the MSSP, the ACOs that are created to participate in that program will inevitably seek to negotiate a variety of similar arrangements with private, third-party payers to generate additional revenue to cover the cost of maintaining the ACO's infrastructure. The Proposed Rule may also influence the way in which state Medicaid programs structure their own ACO initiatives.

New York State policymakers will need to assess the role ACOs should play in controlling runaway medical expenses and improving the quality of health care. Among other things, State policymakers will have to assess whether the marketplace should be allowed to adapt on its own to meet the demands of the ACO model, or whether government incentives and policies are necessary and appropriate to stimulate this transformation.

State policymakers will also need to reevaluate New York's existing health care regulatory structure. For example, when the traditional fee-for-service reimbursement model is augmented with government efforts for achieving cost and quality targets (including new types of compensation arrangements, such as bundled payments, episode of care payments, or partial or full capitation), priorities will shift. The typical fee-for-service policy concerns

[1] Donald M. Berwick, M.D., M.P.P., "Launching Accountable Care Organizations — The Proposed Rule for the Medicare Shared Savings Program." *The New England Journal of Medicine*. Published on March 31, 2011, at **www.nejm.org**.

regarding the incentives for overutilization of health care may be reversed, with the policy focus shifting to the risks associated with withholding or limiting care. In addition, to the extent providers are at risk for costs that exceed a defined budget, the financial solvency issues that have historically arisen in connection with the regulation of insurers will be relevant for providers as well. New types of financial relationships between hospitals and physicians may also implicate State fraud and abuse and antitrust laws that were designed for a different market environment.

This paper is designed to provide a framework for State officials and health care industry stakeholders to consider the policy issues raised by the development of ACOs in New York. Section II of the paper contains a high-level overview of recent Medicare ACO initiatives. Section III scans New York's health industry landscape, with an eye toward the potential role of ACOs in the market. Section IV discusses key issues for consideration by State policymakers.

Overview of Medicare ACO Initiatives

THE MSSP PROPOSED RULE

The MSSP Proposed Rule, published on April 7, 2011, sets forth the Federal legal framework for ACOs and has the potential, given the size and influence of the Medicare program, to play a major role in reshaping the relationship between payers and providers. In addition to issuing the Proposed Rule, the Federal government published companion policy guidance from the Federal Trade Commission (FTC) (regarding Federal antitrust enforcement policy), the Internal Revenue Service (IRS) (regarding financial relationships between tax-exempt organizations and other parties), and CMS and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) (regarding waivers of the Federal anti-kickback, self-referral, and civil monetary laws). Public comments are being solicited with the expectation that final rules and program notices will be released later this year. CMS has announced that it will enter into contracts with ACOs under the MSSP beginning on January 1, 2012. However, given the anticipated timeframe for responding to public comments on the Proposed Rule, a delay to sometime later in 2012 seems likely. ACOs will be required to enter into three-year contracts with CMS; these contracts will be awarded on an annual basis.

- **Who Is Eligible to Form an ACO?** The Proposed Rule defines an ACO as a legal entity recognized under state law that consists of Medicare-enrolled providers or suppliers (ACO participants) that work together to manage and coordinate care for Medicare fee-for-service beneficiaries. An ACO may be formed by physicians in group practice arrangements, networks of individual practices, partnerships or joint venture arrangements between hospitals and physicians, or hospitals and their employed physicians.

- **How Must ACOs Be Governed?** An ACO must demonstrate a mechanism of shared governance that provides all ACO participants with appropriate "proportionate control" over the ACO's decision-making process. The governing body must also include one or more Medicare beneficiary representatives served by the ACO.

- **How Are Medicare Beneficiaries Attributed to ACOs?** CMS proposes to attribute a beneficiary to an ACO if the beneficiary received a plurality of his or her primary care services from primary care physicians who are participants in the ACO. Beneficiary attribution would be carried out on a retrospective basis. At least 5,000 Medicare beneficiaries must be attributed to an ACO.

- **How Will ACOs Participate in Shared Savings?** In submitting its application, an ACO must choose a Track One or Track Two classification; these tracks represent two models of shared savings and losses. Under the "one-sided model," the ACO shares only in savings. Under the "two-sided model," the ACO also shares in losses. In Track One, the savings-only model applies for years one and two; for the third year of the three-year contract, ACOs must transition to the two-sided model. Under Track Two, the two-sided model applies for all three years. To determine whether an ACO saved the Medicare program money, CMS will compare

actual expenditures to an estimate of what Medicare would have paid for the care of the beneficiaries attributed to the providers in the ACO. ACOs are generally entitled to receive 50% of the savings under the one-sided model and 60% under the two-sided model. Payments of savings are contingent upon meeting the quality goals discussed below. The shared loss rate for an ACO is one minus the ACO's shared savings rate. The Proposed Rule establishes caps on the maximum amount of savings and losses for which an ACO is responsible each year.

- **What Type of Quality Standards Will Be Applied to ACOs?** CMS has proposed 65 quality measures falling into five domains. The domains are patient experience of care, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. In the first performance year, an ACO will be deemed to meet the quality standards by simply reporting the required data. Thereafter, performance will be measured at the level of an individual measure, an aggregate of all measures within each of five domains, and a single performance score across all measures and domains.

- **How Will the Fraud and Abuse Laws Be Applied to ACOs?** CMS and OIG have proposed a framework for granting waivers of the Stark Law, the Anti-Kickback Statute, and the "gainsharing" provision of the Civil Monetary Penalties Law.[2] All of these laws potentially restrict the type of financial arrangements between hospitals and physicians that are likely to be necessary to form and effectively operate many ACOs. To qualify for any of the proposed waivers, the ACO must participate in the MSSP. Under the waivers, an ACO's distribution of CMS shared savings payments to participating hospitals and physicians would be shielded from legal scrutiny. The proposed waivers would not cover the distribution of shared savings received by an ACO from payers other than Medicare. In addition, the waivers would not apply to financial arrangements other than shared savings distributions, such as those relating to the initial or ongoing financing of an ACO.

- **How Will the Antitrust Laws Be Applied to ACOs?** The antitrust laws restrict competing health care providers from jointly negotiating prices with third-party payers, an activity that is integral to the operation of an ACO. To comply with the antitrust laws, as an initial matter, providers jointly negotiating prices must be "financially integrated" (which means they share a substantial amount of financial risk) or "clinically integrated" (which means they have agreed to follow standard practice protocols, participate in care management activities, report quality data, and take other steps to deliver care as an integrated enterprise). If providers are financially or clinically integrated, their activities are then analyzed under a "rule of reason" test where the benefits of that integration are weighed against the potential anticompetitive effect of the arrangement. The Policy Statement issued by the FTC and the Department of Justice (DOJ) eliminates much of the uncertainty related to what constitutes "clinical

[2] The Anti-Kickback Statute prohibits any person from knowingly providing something of value to another person in return for the referral of Medicare or Medicaid patients. 42 U.S.C. § 1320a-7b. The Stark Law restricts the type of financial relationships that may be entered into by physicians with entities they refer to, including hospitals. 42 U.S.C. § 1395nn. The gainsharing provision of the Civil Monetary Penalties Law prohibits a hospital from making payments to induce a physician to limit services to Federal health care program beneficiaries under the physician's direct care. 42 U.S.C. § 1320a-7a(b).

integration" by providing that ACOs approved to participate in the MSSP will be deemed clinically integrated. The way in which the rule of reason analysis is applied to a clinically integrated ACO will depend on the market share of the ACO's participants. The Policy Statement requires ACOs to calculate their Primary Service Area (PSA) share for each service provided by ACO participants. Depending on the PSA share, there are three categories of possible antitrust review:

ACO PSA SHARE	REVIEW PROCESS
≤30 percent (with a rural exception)	**SAFETY ZONE:** No antitrust review necessary by the Antitrust Agencies.
>30 percent and ≤50 percent	**OPTIONAL REVIEW:** Comply with list of conduct restrictions or proceed without antitrust assurances.
>50 percent	**MANDATORY REVIEW:** ACO must seek review by the Antitrust Agencies to assess likelihood of anticompetitive effects and submit approval of Antitrust Agencies to CMS.

- **How Will the Tax Exemption Laws Be Applied to ACOs?** A notice issued by the IRS sets forth the terms under which tax-exempt organizations can participate in ACOs under the MSSP without running afoul of rules designed to prevent these organizations from impermissibly promoting private interests. Essentially, the notice requires tax-exempt organizations to enter into written agreements with ACOs that are negotiated at arm's length. These agreements must ensure that any benefits received by the tax-exempt organization are proportional to the contributions made by the tax-exempt organization to the business of the ACO. Simply stated, arrangements in which tax-exempt organizations subsidize or treat preferentially the interests of private parties, such as physicians, are likely to create tax issues.

THE PIONEER PROGRAM

On May 17, 2011, the Center for Medicare and Medicaid Innovation ("CMMI") announced the Pioneer ACO program, designed for organizations that are ready to "move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the Medicare Shared Savings Program."[3] The program is projected to fund as many as 30 Pioneer ACOs, saving Medicare up to $430 million over three years. The Pioneer ACO Model shares many common characteristics with its MSSP counterpart, including its focus on the Medicare fee-for-service program. Pioneer ACOs will also be eligible for waivers from the Federal Stark Law, Anti-Kickback Law, and gainsharing provisions, as well as for the protections being afforded by the new antitrust rules being developed in concert with the MSSP.

Despite similarities, there are a number of significant differences between Pioneer and proposed MSSP ACOs that have policy and regulatory implications. Pioneer ACOs require participants to enter into population-based reimbursement arrangements, or partial capitation. In fact, by the third year, these ACOs are expected to generate a majority of their revenue from

[3] http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco/.

outcomes-based payment arrangements. Notably, Pioneer ACOs are required to enter into outcomes-based contracts with other purchasers and are encouraged to contract with state Medicaid agencies for both Medicaid and dual eligible beneficiaries. Pioneer ACO composition, governance and assignment methodologies are also different. Federally Qualified Health Centers may form Pioneer ACOs, and beneficiary attribution is not exclusively PCP-based; ACO beneficiaries may be attributed based on relationships with certain specialty providers under certain conditions. Beneficiaries may be attributed to Pioneer ACOs either prospectively or retrospectively. Finally, Pioneer ACO governance must include both Medicare beneficiaries and consumer advocates.

OTHER CMS ANNOUNCEMENTS RELEVANT TO ACO DEVELOPMENT

The May 17 announcement included two additional notices. First, CMMI is seeking comment on an Advance Payment ACO Model. This development was triggered by early feedback suggesting that providers lack ready access to the capital needed to invest in infrastructure and staff for care coordination. Advance Payment would give certain ACOs participating in the MSSP access to shared savings upfront, which would be recouped through the ACOs' earned shared savings. CMMI also announced free Accelerated Development Learning Sessions, which will provide existing or nascent ACOs the opportunity to learn about essential ACO functions and ways to build capacity needed to improve care coordination and delivery.

ACOs and the New York Health Care Market

The extent to which ACOs succeed in controlling health care costs and improving quality in the New York market will likely depend on both the willingness of third-party payers (including commercial payers and Medicaid) to enter into alternative reimbursement arrangements with ACOs and the capacity of health care providers to collaborate in building clinically integrated care delivery systems. Thus, a consideration of policy issues must begin with an understanding of the current state of New York's payer and provider markets, and how these markets may need to change to make ACOs viable in the State.

THE PAYER MARKET

Consistent with the national average, nearly half of New Yorkers obtain their health insurance through employer-sponsored health plans.[4] New York has high rates of self-funded coverage (49%) and public employee coverage (roughly 25-30%) compared to other states.[5]

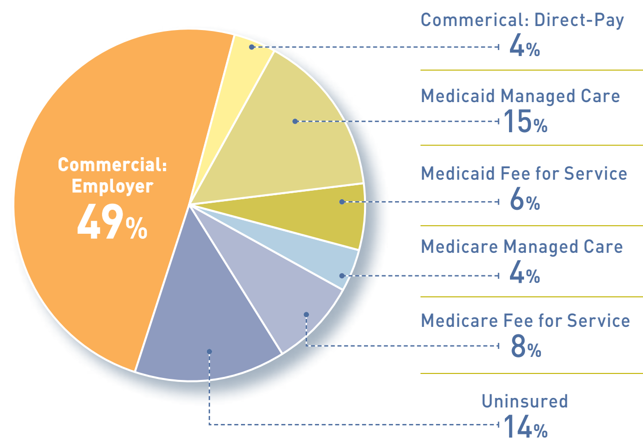
Unlike some markets that are dominated by a few large commercial payers, New York's commercial insurance market is highly fragmented. No commercial insurer controls more than 26% of the State's market (see **Table 1**).

Medicaid and Medicare account for another third of New York's insurance market (see **Figure 1**). Medicaid is increasingly provided through managed care plans. Family Health Plus and Child

TABLE 1: NYS COMMERCIAL MARKET SHARE, LARGEST INSURERS, 2006[6]

Insurer	Share
Empire HealthChoice	26%
GHI HMO / Group Health Inc.	15%
Excellus Health Plan	14%
Oxford	13%

FIGURE 1: HEALTH INSURANCE COVERAGE IN NEW YORK, 2008–2009



SOURCES: State Health Facts, Kaiser Family Foundation. Newell and Baumgarten, 2011. New York State Department of Health, Medicaid Quarterly Reports and Monthly Managed Care Enrollment Reports, Nov. 2010.

[4] The Kaiser Family Foundation, statehealthfacts.org. Data Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2009 and 2010 Current Population Survey (CPS: Annual Social and Economic Supplements).

[5] Peter Newell and Allan Baumgarten, "The Big Picture III: Private and Public Health Insurance Markets in New York, 2009." United Hospital Fund, April 2011; Peter Newell and Allan Baumgarten, "The Big Picture: Private and Public Health Insurance Markets in New York." United Hospital Fund, October 2009.

[6] Newell and Baumgarten, 2009. Table 2. Data include Individual, Group, and Healthy New York program enrollment in Article 44 HMOs and Article 42 Accident and Health Insurers, as well as enrollment in Article 43 Nonprofit Insurers.

Health Plus are administered entirely through managed care plans and together cover more than 800,000 members. Further, roughly two-thirds of traditional Medicaid beneficiaries are enrolled in managed care plans.[7] Medicare Advantage enrollment continues to grow in New York, currently comprising almost 40% of Medicare beneficiaries.[8]

In New York, Medicaid Managed Care—and, increasingly, Medicare Managed Care as well—is dominated by provider-sponsored prepaid health service plans (PHSPs). These plans, which reflect early efforts by providers to integrate the care delivery and payer functions, currently cover more than two-thirds of New York State Medicaid, Family Health Plus, and Child Health Plus enrollees statewide, and have an even more dominant market share in New York City.[9] Some of these plans have long had capitation and other risk-sharing arrangements with their provider sponsors. The Health Department has a long-established quality review and incentive system in place for managed care plans, called QARR (Quality Assurance Reporting Requirements).

With implementation of a health benefit exchange and Federal insurance subsidies authorized under the ACA beginning in 2014, New York's commercial health insurance market will experience significant shifts. Nearly 700,000 uninsured New Yorkers will become eligible for subsidies, and an additional 340,000 higher-income people who are uninsured will be able to access more affordable individual coverage through the exchange.[10] New York will also experience substantially increased Medicaid enrollment in 2014, and most of the enrollees will be required to join managed care plans.

Left alone, the current structure of the New York payer market, especially downstate, may present a barrier to ACO development. The market is highly fragmented and there do not exist policy or financial levers to encourage private commercial or Medicaid plans to contract with ACOs on a uniform basis. The absence of uniform quality measurements and other standards may make it difficult for ACOs to operate across multiple payers. As discussed below, Medicaid policy, the rules governing New York's health benefit exchange, and the recently passed New York ACO statute may create a different market dynamic, but at this time it is far too early to tell how these various initiatives may coalesce to affect new delivery and payment models. The significant portion of Medicaid beneficiaries enrolled in managed care plans also raises questions about the role of ACOs in that program.

[7] New York State Department of Health, Medicaid Quarterly Reports and Monthly Managed Care Enrollment Reports, November 2010.

[8] Newell and Baumgarten, 2011.

[9] New York State Department of Health, Medicaid Managed Care Monthly Enrollment Report and Child Health Plus Enrollment by Insurer, March 2011.

[10] Boozang, P., Dutton, M., Lam, A., Bachrach, D. "Implementing Federal Health Care Reform: A Roadmap for New York State," New York State Health Foundation, August 2010.

[11] Hospital Institutional Cost Reports, 2007. Data provided by HANYS Solutions. Count of hospitals based on unique Operating Certificate numbers.

[12] Commission on Health Care Facilities in the 21st Century. "Final Report of the Commission on Health Care Facilities in the 21st Century." December 2006.

THE PROVIDER MARKET

New York has more than 200 hospitals,[11] and is generally considered to be over-bedded, despite implementation of right-sizing efforts by the Berger Commission.[12] As of 2008, New York had 3.1 hospital beds per 1,000 residents, significantly higher than the national average of 2.6 per 1,000 residents. In New York City, where there is a high concentration of hospitals and perhaps the largest concentration of academic medical centers and other teaching hospitals in the world, that rate is more than twice the statewide average.[13]

New York State has 66,000 active physicians, of whom almost one-third (more than 20,000) are primary care providers. In New York State, 72% of physicians and 68% of primary care physicians[14] practice in the New York City metropolitan area.[15] Overall, New York has 105 primary care physicians per 100,000 residents, with a much higher rate in New York City (115 per 100,000 residents) than upstate (88 per 100,000).[16]

Unlike other areas of the country,[17] many physicians in New York State primarily practice in hospitals: 30% report hospitals as their primary practice setting, while 27% are in solo practice, 34% are in group practice, and 4% work in freestanding health centers. Physicians in the New York City metropolitan area are more likely to practice in hospital settings and less likely to be in group practices than physicians in the rest of the State.[18] It is likely, however, that the percentage of primary care physicians working for hospitals is substantially lower than the percentage of specialists.

Compared to physicians nationwide, workforce data suggest that New York physicians employed in office settings are more likely to work for small employers than for large employers, indicating a relatively diffuse market environment (see **Table 2**). Of physicians working in office-based practices, in New York 75% work in practices with fewer than 25 employees, as compared to 62% nationwide. More than half (51%) of New York State physicians work for employers with fewer than 10 employees, compared to 43% nationwide. Only 4% of New York State office-based physicians work for employers with 25-500 employees, compared to 23% nationwide, suggesting that very few New York State physicians work in the typical large group practice common in other states.

[13] Alan Sager and Deborah Socoloar. "Closing Hospitals in New York State Won't Save Money but Will Harm Access to Health Care." Committee of Interns and Residents, New York City, November 2006.

[14] Primary care physicians are defined as physicians reporting specialties of Family Medicine, General Internal Medicine, and General Pediatrics. This definition is similar to but not exactly the same definition of primary care physicians employed by CMS in the MSSP Proposed Rule.

[15] New York City metropolitan area includes the five boroughs of New York City, as well as Long Island and Westchester County.

[16] Armstrong, David P. and Forte, Gaetano J., "Annual New York Physician Workforce Profile, 2010 Edition." Center for Health and Workforce Studies, School of Public Health, SUNY Albany. December 2010.

[17] Survey data from the Center for Studying Health System Change indicate that nationally only 13% of physicians report hospitals as their primary practice site, with 32% reporting solo practice and 40% reporting group practice. Unfortunately, because of differences in the survey instrument and sampling methodology, these results are not directly comparable to the statistics available for New York State. SOURCE: 2008 Heath Tracking Physician Survey, Center for Studying Health System Change (HSC). 2011.

[18] Armstrong and Forte, 2010.

TABLE 2.
Distribution of Office-Based Physicians by Firm Size of Primary Employer, 2006–2008

Number of Employees in Firm	New York State (n=43)	U.S. (n=820)
Under 10	51%	43%
10 – 24	24%	19%
Total <25	**75%**	**62%**
25 – 99	2%	15%
100 – 499	2%	8%
Total 25 – 499	**4%**	**23%**
500 – 999	5%	2%
1000+	16%	13%
Total 500+	**21%**	**15%**

SOURCE: Bureau of Labor Statistics, 2006-2008 blend of Current Population Survey Annual Social and Economic Supplement, custom tabulation. Data reflect physicians and surgeons (SOC 29-1060) primarily employed in physician offices (2002 NAICS 6211).

Please note: estimates are not statistically reliable because of small sample size.

Although data are not available for New York State specifically, nationwide an increasing number of physician practices are owned by hospitals. According to the Medical Group Management Association, in 2003, 19% of practices reported that they were hospital-owned, compared to 36% in 2008.[19] In 2009, nearly two-thirds (65%) of established physicians were employed by hospital-owned practices, and almost half (49%) of new hires out of residency were placed within hospital-owned practices.[20]

Physicians in small practices are far less likely than physicians in large groups or hospital-based organizations to participate in ACOs. Physicians in small practices are more likely to lack the capital, staff support, and information technology infrastructure required for effective ACO participation. These physicians will also face a greater challenge in joining together with other providers to form an organized, clinically integrated enterprise. As is the case in the rest of the nation, New York may see a sharp decline in the number of small- and mid-sized physician practices as the complexity of private practice grows and its rewards diminish. While the pace of consolidation is hard to predict, large multispecialty practices and hospital ownership of physician practices are likely to help fuel interest in new delivery and payment models such as ACOs. What remains to be seen is whether New York policymakers take actions that accelerate physician consolidation by creating policies and financial incentives that reward those who join organized delivery systems.

[19] Kirchheimer, Barbara. "Physician Investors Feel Healthcare Industry's Economic Pressure." *Modern Physician*. January 12, 2009. **http://www.modernphysician.com/article/20090112/MODERNPHYSICIAN/301039981/1114#**.

[20] Medical Group Management Association. "MGMA Physician Placement Report: 65 percent of established physicians placed in hospital-owned practices." June 3, 2010. **http://www.mgma.com/press/default.aspx?id=33777**.

Implications for State Policymakers

While CMS and other Federal agencies will determine how ACOs will function in the Medicare program, state policymakers will have an important role to play in the outcome of the ACO experiment. Many health care providers are likely to refrain from forming ACOs if Medicare is the only payer willing to enter into alternative reimbursement arrangements with such entities. Indeed, in the short term, many organizations may be looking to test their ACOs in the commercial insurance market before participating in the MSSP. In the long term, providers will be hoping to spread the start-up and ongoing costs of operating an ACO over their entire patient base, leveraging incentive compensation to cover these costs not only from Medicare, but from Medicaid and private insurers as well. As a result, the success of ACOs in New York will likely be linked to the State's ability to create a market and regulatory environment conducive to these enterprises.

New York policymakers and other industry stakeholders will confront a diverse set of policy issues as they consider the appropriate role of ACOs in controlling health care costs and improving quality in this State. The key implications for State policymakers are discussed below.

CHANGES NECESSARY IN NEW YORK'S REGULATORY ENVIRONMENT TO SUPPORT ACO DEVELOPMENT

The MSSP Proposed Rule does not preempt state laws and regulations, and thus ACOs participating in the MSSP or Pioneer program must be organized and operated in a manner that complies with New York's existing statutes and regulations. In developing the MSSP, Federal regulators took care to propose simultaneous modifications to existing Federal laws that would remove or lessen the impact of those laws that were perceived to create barriers to ACO development.

As is the case on the Federal level, New York currently has its own complex framework of laws and regulations that might limit the ability of providers to form and operate ACOs. As the Federal implementation of the MSSP proceeds, New York lawmakers will need to assess which New York laws may negatively influence ACO development, either because the laws are inconsistent with the goals of ACOs or because they conflict with emerging Federal rules and thereby undermine the ability of providers to create a broad, multipayer ACO platform. In some cases, lawmakers may want to consider changes in law to better align State rules with Federal rules and to support more widespread development of ACOs.

ACOs typically perform a variety of functions that may be subject to New York laws and regulations governing the delivery and receipt of payment for medical care. These functions include serving as a contracting intermediary between third-party payers and health care providers, assuming financial risk for the cost and/or quality of health care services, and distributing compensation among participating providers. The key New York regulatory schemes potentially implicated by ACOs include the following:

- **Assumption of Financial Risk.** Various provisions in New York law regulate providers and provider-owned networks from assuming financial risk for the cost of health care services.[21] Insurance Department Regulation 164 and the Health Department's Provider Contract Guidelines authorize providers to assume risk from licensed insurers or HMOs if they adhere to certain safeguards.[22] But existing provisions in New York law are not likely to be sufficient to cover the full range of activities undertaken by ACOs. For example, currently, there is no clear legal framework in New York under which ACOs may accept financial risk from third-party payers other than licensed insurers or HMOs, such as self-funded employee health benefit plans or the Medicaid or Medicare fee-for-service programs. A clearer legal basis for these activities may be necessary to support all-payer contracting by ACOs.

- **Corporate Practice of Medicine/Arranging for Medical Care.** Long-standing case law prohibits the corporate practice of medicine in New York. The prohibition extends not only to the direct employment of physicians and other health care professionals by corporations (other than professional corporations or licensed health care facilities), but also to the receipt of payment and the arranging for medical care by an unlicensed entity.[23] Limited legal authority exists for Independent Practice Associations (IPAs) to arrange for care on behalf of HMOs, but the legal capacity of ACO-type entities to arrange for care on behalf of other payers is less clear. Because the purpose of ACOs includes assembling provider networks, coordinating the care received by patients in these networks, and receiving payment for services delivered by their participating providers, lawmakers and regulators should take the steps necessary to ensure that authorized ACO entities are not limited by the corporate practice doctrine in the range of payers with which they may contract.

- **Fee Splitting.** Closely related to the corporate practice bar is the prohibition on fee splitting. Subject to certain exceptions, physicians and other health care professionals are barred from sharing their professional fees with outside entities, including hospitals and other health care facilities.[24] A similar prohibition applies to the sharing of revenues or profits by hospitals.[25] Although IPAs as well as intermediaries authorized to assume risk under Regulation 164 are exempt from the fee-splitting bar, ACO arrangements that do not fit squarely within these exceptions may raise legal concerns. Making clear that fee-splitting rules do not apply to authorized ACO entities would make these initiatives more likely to advance.

- **Fraud and Abuse.** New York has adopted health care fraud and abuse laws that are modeled on Federal fraud and abuse statutes. New York's physician self-referral law, like the Federal Stark Law, prohibits physicians from referring patients for "designated health services" to entities with which they have a financial relationship, unless that relationship fits within

[21] N.Y. Ins. Law §§ 1101, 1102(a).

[22] 11 N.Y.C.R.R. § 101; **http://www.health.state.ny.us/health_care/managed_care/hmoipa/hmo_ipa.htm**.

[23] See, e.g., *State v. Abortion Information Agency, Inc.*, 37 A.D.2d 142 (1st Dept. 1971), aff'd 30 N.Y.2d 174 (1972).

[24] N.Y. Educ. Law § 6530(19); 8 N.Y.C.R.R. § 29.1(b)(4).

[25] 10 N.Y.C.R.R. § 600.9(c).

an exception. [26] Unlike the Stark Law, the New York statute applies to items or services covered by any payer, not only Medicare. New York has also adopted a kickback law that is similar to the Federal Anti-Kickback Statute but applies only to items or services covered by Medicaid. In connection with the Proposed Rule, CMS and OIG have proposed waivers that would insulate the distribution of shared savings by an ACO to its participating providers from prosecution under the Stark Law and Federal Anti-Kickback Statute. Providing similar protections under New York law would help advance ACO formation. This could be accomplished by creating exceptions to or waivers of New York's fraud and abuse statutes comparable to those being established under their Federal counterparts.

- **Antitrust.** There is likely to be similar uncertainty under State antitrust laws. New York law prohibits restraints on trade in a manner similar to Federal antitrust laws.[27] The joint negotiation of prices by competing providers through an ACO could constitute price-fixing under this statute. In connection with the Proposed Rule, the FTC and DOJ have proposed a framework under which ACOs participating in the MSSP would be protected from Federal antitrust claims. However, no similar protection is provided from claims under State antitrust laws. Thus, there may be uncertainty as to whether ACOs following the FTC/DOJ guidelines are still at risk of State law antitrust claims. New York lawmakers could support ACO development substantially by adopting the Federal antitrust framework for ACOs.

Recognizing the potential benefits of ACOs, the New York Legislature passed, as part of the budget adopted in April 2011, a new statutory scheme under which health care providers can be certified as an ACO.[28] An ACO is defined as "an organization of clinically integrated health care providers certified" by the Health Department. The law authorizes the Health Department to certify up to seven ACOs prior to December 31, 2015.

The law directs the Health Department to issue regulations establishing requirements for ACO certification. These regulations are supposed to address:

- ACO governance and management structures;
- the populations to be served by ACOs;
- the character, competence, and fiscal responsibility of the ACO and its principals;
- the adequacy of the ACO's provider network;
- the ACO's mechanisms for providing and coordinating high-quality medical care;
- the ACO's mechanisms for receiving and distributing incentive or other payments;
- the ACO's provider credentialing and acceptance standards;

[26] N.Y. Public Health Law § 238-a.

[27] N.Y. General Business Law § 340.

[28] N.Y. Public Health Law Articles 29-E and 29-F.

- the ACO's quality assurance and grievance procedures;
- the mechanisms used by the ACO to promote evidence-based medicine and patient engagement;
- standards for measuring the ACO's performance;
- ACO compliance obligations;
- data reporting requirements imposed on ACOs and their participants; and
- protection of patient rights.

The law authorizes certified ACOs to enter into alternative reimbursement arrangements, including full and partial capitation, with third-party payers. The term "third-party payer" is defined broadly, and presumably includes State-licensed insurers and HMOs, self-funded employee health benefit plans, State employee plans, and the Medicaid program. Certification by the Health Department as an ACO appears to confer two primary benefits on a provider network:

- **Waiver of State Law Restrictions.** State corporate practice of medicine, fee-splitting, self-referral, anti-kickback, and antitrust laws may serve as an impediment to certain ACO arrangements. Under the new statute, ACOs certified by the Health Department would be insulated from prosecution under these laws.
- **Authority to Contract With a Broader Range of Payers.** The existing State legal framework authorizes ACO-type entities to contract with and assume financial risk from only State-licensed insurers and HMOs. But there is no clear authority for ACOs to enter into similar arrangements with other payers, such as self-funded employee health benefit plans or the Medicaid program. Certification under the new statute would provide clear legal authority for ACOs to contract with these additional payers.

Much remains to be learned about the New York ACO law and how it will be implemented. Ideally, the new law will provide waivers from provisions in the existing State laws referenced above that are consistent with emerging Federal policies relating to ACOs. Were such consistency to evolve, the formation and operation of ACOs would be encouraged, especially if combined with policies that encourage commercial and Medicaid plans to contract with ACOs. That said, the fact that the New York ACO law authorizes only seven ACOs means that its impact is likely to be very limited. This limit may need to be increased, or changes to the existing laws referenced above may be necessary, to promote broader ACO development.

The 2011-12 budget contains a number of other health care reform initiatives potentially related to ACO development. These initiatives are summarized in the Appendix to this report.

THE ROLE OF ACOS IN THE MEDICAID PROGRAM

It is unclear whether or how the Medicaid program in New York will embrace an ACO strategy. New York's Medicaid program has long relied on mandatory managed care programs to improve quality and control costs. As indicated above, roughly two-thirds of Medicaid beneficiaries are enrolled in managed care plans,[29] and it is expected that this number will increase over the next few years as exemptions from managed care enrollment for certain populations are eliminated.[30] Unlike most Medicare beneficiaries, who remain in the largely unmanaged fee-for-service system, most Medicaid beneficiaries have long been subject to the utilization controls and network limitations imposed by managed care plans. ACOs have been positioned in the Medicare program as a politically palatable cost-saving alternative to more tightly controlled managed care plans. The political calculus is different for Medicaid.

From a policy perspective, a critical issue to assess is how the roles of Medicaid managed care plans and ACOs should be reconciled. For example, should ACOs be viewed primarily as downstream contractors to managed care plans or as direct contractors with the State? If the former, to what extent should managed care plans be incentivized or required to contract with ACOs? Does the State need to expand the range of the quality measurements currently applied to managed care plans to better capture the type of measures ACOs are well-positioned to affect?

The role of ACOs in Medicaid may depend on the type of population being served. The debate over what added value an ACO can provide beyond a managed care plan is likely to focus predominantly on models of care for beneficiaries with chronic illnesses and serious mental health issues. Significantly, new behavioral health legislation specially contemplates, by April 1, 2013, the emergence of provider delivery systems taking on responsibility for managing "the behavioral and physical health needs of [Medicaid] enrollees with significant behavioral health needs."

Whether Medicaid decides to view ACOs as a core part of the State strategy for improving quality and controlling costs will likely be a major factor in determining the overall rate at which ACOs develop in New York, especially downstate. In many areas in New York City, Medicaid and Medicare together cover close to 70-80% of the insured population. Any convergence by two such large payers around a specific model for organizing care would undoubtedly spur significant market activity.

CAPITAL SUPPORT FOR ACO DEVELOPMENT

ACOs and their participants will require substantial capital to develop the care management, health information technology, and contracting infrastructure needed to manage health services properly across the entire care continuum. While CMS estimated the total average start-up investment and first-year operating expenditures for a participant in the MSSP to be

[29] New York State Department of Health, Medicaid Quarterly Reports and Monthly Managed Care Enrollment Reports, November 2010.

[30] For example, the New York State Fiscal Year 2011-2012 budget expands the role of managed care in New York Medicaid by mandating that enrollees requiring more than 120 days of community-based long-term care services join a managed long-term care plan or other program model that supports coordination and integration of services.

approximately $1.7 million,[31] trade associations have estimated that the cost will be higher. A report prepared for the American Hospital Association, for example, estimates $5.3 million in start-up costs and $6.3 million in ongoing annual costs for an ACO developed by a one-hospital system and including 80 primary care physicians and 150 specialists.[32]

Given the relatively few large physician groups in New York State, it is unlikely that the required capital will come from doctors. There are several financially strong hospital systems that have the necessary resources, but many hospitals in the State are strapped for cash. The capital demands are likely to be particularly daunting for the State's safety net hospitals. Investor capital is likely to be unavailable because of the uncertain profitability of ACOs and the restrictions on investor ownership in the Proposed Rule.

One policy question is whether some type of State-sponsored capital program is necessary to stimulate ACO development. Through the HEAL (Health Care Efficiency and Affordability Law) Program, New York has been a national leader in using public funds to trigger hospital reengineering and health information technology adoption. Policymakers may need to consider whether a similar initiative is necessary for ACOs. Given current budget constraints, the willingness of elected officials to make funds available for ACO capital needs may hinge on their belief that the ACOs launched with State support will save the State money in the long run through reduced Medicaid and State employee health benefit expenditures.

A related issue for consideration is whether commercial payers should be incentivized to provide capital to the ACOs with which they contract. For example, the State might encourage insurers to make grants or loans to ACOs through preferable treatment of these arrangements under medical loss ratio or financial solvency rules. Alternatively, the State might consider creation of special grant and loan vehicles to support ACO development. There is a rich history in New York of using capital dollars to support social innovation, ranging from the Primary Care Development Corporation to the many HEAL-funded initiatives to create new types of delivery capacity and health IT infrastructure.

THE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE SUPPORTING ACOS

It is axiomatic that successful ACOs will need to develop an integrated set of systems and data where patient information is standardized and flows seamlessly across the care continuum. Especially because ACOs are unlikely to restrict where patients can choose to get care—indeed, the Proposed Rule prohibits ACOs from doing so—the need to have information flow across a large set of providers, including those who are part of an ACO and those who are not, will be critical to ACOs' success.

[31] 76 Fed. Reg. 19639.

[32] Keith D. Moore and Dean C. Coddington. McManis Consulting. "The Work Ahead: Activities and Costs to Develop an Accountable Care Organization." Prepared for the American Hospital Association. April 2011.

Fortunately, New York has embarked on building and operating the State Health Information Network of New York (SHIN-NY). The SHIN-NY is being designed to be a network of networks, one that allows clinicians to exchange patient information regardless of where the patient receives care, to support the delivery of the right care at the right time in a coordinated, patient-centered manner. While the SHIN-NY is still in an early stage of development, significant Federal and State grant dollars have been set aside to support its evolution. The development of the SHIN-NY will be an important enabler to ACOs in New York, both reducing the costs of building the infrastructure necessary to support the flow of information and ensuring that that information follows the patient across institutional settings.

State officials and the New York eHealth Collaborative, a public-private partnership charged with overseeing the SHIN-NY, have been evaluating for several years the type of data analytics and care management tools that should be integrated into the SHIN-NY to maximize the system's effectiveness at improving quality and controlling costs. These issues will take on even greater importance as policymakers consider how to leverage the SHIN-NY to support the emergence of ACOs in the State.

THE USE OF THE HEALTH BENEFIT EXCHANGE TO PROMOTE ACOS

By 2014, it is expected that more than 600,000 New Yorkers will purchase their health insurance through a health benefit exchange (HBE) created under the ACA. Only qualified health plans (QHPs) may participate in state HBEs. The ACA defines a QHP as "a health insurance issuer that is licensed in good standing to offer health insurance coverage in each state in which such issuer offers health insurance coverage...."[33] Accordingly, an ACO may not be offered as a coverage option in an HBE. However, an ACO may contract with a QHP and potentially even co-brand a product with a QHP.

The State is contemplating whether to employ a "passive HBE model" under which the State merely creates the marketplace but sets few rules, or an "active HBE model" under which the State winnows the number of plans participating in the exchange based on cost and quality factors. If the State adopts the active model, it might use the HBE to support ACO development.

The ACA requires HHS to develop HBE guidelines regarding the use of payment structures to improve health care outcomes, thereby setting the stage for states to qualify health plans for participation in the HBE based on their use of innovative payment methodologies and integrated delivery models, including ACOs. New York State has embraced medical homes as well as ACOs and has also developed an extensive quality framework for Medicaid managed care plans. Given these commitments, one can foresee a New York HBE leveraging its consumer base to require health plans to contract with ACOs. Indeed, the ACA encourages states to leverage broader health reform priorities through exchanges.

[33] ACA § 1301(a)(1)(C)(i).

Another potential use of the HBE relates to one of the major problems facing ACOs: the difficulty in accommodating different quality and data reporting standards mandated by multiple payers. This problem is likely to be a significant one in New York because of the absence of a dominant insurer that is big enough to establish an effective industry standard. The State might seek to address this issue, for instance, by incorporating into the HBE's selection process consideration of whether an insurer has agreed to use a State-approved standard set of quality and reporting measures for its ACOs. Other ways of simplifying the operation of ACOs through HBE policies may also be possible.

THE NEED FOR ADDITIONAL PRIMARY CARE CAPACITY

The ACO model is built on a foundation of robust primary care. Under the MSSP, patients are assigned to ACOs based on their relationship with one of the ACO's primary care providers. Primary care providers will typically serve as the patient's medical home, offering preventive care while coordinating and managing many other services. The ACO model does not work without a sufficient number of primary care providers.

In 2008, 11% of New York State residents—both upstate and in underserved communities in the New York City metropolitan area—lived in a Primary Care Health Professional Shortage Area.[34] New York has several initiatives underway to expand and enhance primary care capacity, including Doctors Across New York, which provides practice support and loan repayment for physicians who practice in primary care and other needed specialties in underserved areas of the State, and the medical home initiative discussed above. These initiatives are supported by New York's recent investment of $600 million in hospital clinics, community clinics, and physician fees.

THE NEED TO RECONSIDER HOSPITAL BED CAPACITY

It is likely that in many parts of New York, hospitals will play a key role in transitioning to new models of care. This transition may be difficult as the ACO model is premised, in part, on achieving cost savings by reducing hospital stays through preventive care, effective post-discharge planning, and the provision of care in the least costly appropriate setting. State policymakers will need to recognize hospital efforts to transition from one business model to another, including the need to consolidate inpatient services intelligently. In the past several years, planning efforts like those led by the Berger Commission, along with transition capital funding made available through the HEAL-NY program, have been important enablers of hospitals' ability to implement new business models. State policymakers will need to develop similar types of programs to continue the migration to new service delivery and payment models.

[34] The Kaiser Family Foundation, **statehealthfacts.org**. Data Source: Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration (HRSA), Special Data Request, April 2009; 2008 population data from Annual Population Estimates by State, July 1, 2008 Population, U.S. Census Bureau; available at **http://www.census.gov/popest/states/tables/NST-EST2008-01.xls**.

THE IMPACT OF ACOS ON ACADEMIC MEDICAL CENTERS

New York's teaching hospitals may be presented with special challenges relating to the development of ACOs. Historically, both the Medicare and Medicaid programs have recognized the special benefits provided by teaching hospitals in training the next generation of caregivers and in serving disadvantaged populations, and reimbursed them for these added costs, making their overall reimbursement higher than nonteaching hospitals. In the past, physicians deciding where to refer their patients had no economic stake in the costs of teaching hospitals. A referring physician's compensation was unaffected by the costs incurred by Medicare and Medicaid for direct graduate medical education (DGME), indirect medical education (IME), and disproportionate share hospital payments (DSH).

ACOs may present physicians with new considerations. If physicians in an ACO are being held accountable for the total cost of all services provided to their patients, they may have an incentive to refer patients to lower-cost community hospitals, which do not bear the costs of training. Indeed, certain private payers are already providing physicians with data about the costs of local hospitals to give physicians the capacity to comparison shop. State policymakers will need to evaluate whether the State's academic medicine infrastructure could become weakened by new ACO payment models, and establish the means to mitigate this unintended consequence by, for example, excluding IME, DGME, and DSH payments from ACO reimbursement benchmarks.

Conclusion

There is little debate that New York's health care system can and should generate better quality care at a lower cost. But State policymakers have to address the threshold issue of whether ACOs are the right vehicle for transforming the system. In theory, the ACO model holds great promise, particularly if implemented in concert with payment reform and statewide health IT initiatives. Linking payment for outcomes with improved coordination of care is a worthy goal to which policymakers should aspire. But for veteran watchers of health care, who have lived through multiple attempts to improve the delivery and payment system—including HMOs, physician management companies, and provider-sponsored organizations—the quote that may come to mind is Yogi Berra's: "This is like déjà vu, all over again." State policymakers will have to first evaluate whether the gains to be achieved in quality and potential cost improvement are sufficient to justify the bold changes in policy needed to truly advance the accountable care model. If the conclusion is reached that the gains can be achieved, then combining lessons learned from past failures with a new imperative for reform may make the ACO model viable in New York.

Appendix: Recent State Budget Initiatives

In addition to creating authority for State certification of ACOs, the FY 2011-12 New York State budget includes several additional provisions that may advance New York's commitment to payment and delivery system reform. Certain themes that run through the Federal ACO rules can be seen in the State reforms, most notably the adoption of payment structures and care models that emphasize primary care and care coordination and hold providers accountable for the efficient and effective delivery of services. These State budget provisions include:

- **Patient-Centered Medical Homes (Article 29-AA).** This Article authorizes the Commissioner of Health to establish medical home multipayer programs whereby certified primary care clinicians and clinics receive enhanced payment rates from public and private payers. Among other things, the Commissioner is authorized to test new models of payments to high-volume Medicaid medical homes that incorporate risk-adjusted global payments combined with care management and pay-for-performance adjustments.
- **Health Homes (Section 365-l).** Relying on the Federal health home option, this provision authorizes the Commissioner of Health to establish a program of health homes for chronically ill Medicaid beneficiaries. Intended to enhance coordination of medical and behavioral health services and reduce unnecessary and costly institutionalizations, hospitalizations, and emergency room visits, the Affordable Care Act requires health homes to provide comprehensive care management; care coordination; health promotion; comprehensive transitional care and follow-up; patient and family support; and referral to community and social support services. These requirements are reflected in the State legislation.
- **Potentially Preventable Negative Outcomes (Section 35-a).** The Commissioner is authorized to adjust rates of payment to hospitals based on potentially preventable readmissions and other potentially preventable negative outcomes by comparing the actual and risk-adjusted expected numbers of such events.
- **Administration and Management of Behavioral Health Services (Section 365-m).** The current carve-outs from Medicaid managed care of seriously mentally ill individuals and some behavioral health services have contributed to a fragmented system of care for Medicaid beneficiaries with significant behavioral health challenges. Recognizing this challenge, the Legislature authorized the Commissioners of Mental Health and Alcohol and Substance Abuse Services, in consultation with the Commissioner of Health, to contract with regional entities charged with approving and coordinating behavioral health services and facilitating the linkage of physical and behavioral health. Among other things, the regional entities are required to ensure that payments are consistent with "the efficient and economical delivery of quality care." By April 1, 2013, the legislation contemplates that these regional entities will be replaced by "special needs plans" or provider systems "capable of managing the behavioral and physical health needs of [Medicaid] enrollees with significant behavioral health needs."

Managed Long-Term Care (Sections 41 through 41-b). Today, most Medicaid beneficiaries requiring long-term home health or personal care services are in the fee-for-service system, where the care is neither managed nor coordinated. This provision changes that situation, mandating that enrollees requiring more than 120 days of community-based long-term care services join a managed long-term care plan or participate in another program that supports coordination and integration of services.

Episodic Payments for Certified Home Health Agencies (Section 4). Effective April 1, 2012, New York will replace its per-hour payment rates for certified home health agencies (CHHAs) with episodic payments using a statewide base price for each 60-day episode of care adjusted by a regional wage index, and an individual case mix index. By moving to risk-adjusted episodic payment rates, the CHHA becomes accountable for the delivery of efficient and effective care.

Several years ago, New York began an effort to reform its payment and delivery system to ensure that all New Yorkers have access to cost-effective, quality care, emphasizing transparency and accountability. That effort is reinforced by Federal health reform and most particularly by the new ACO rules.

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