State Actions to Promote and Restrain Commercial Accountable Care Organizations

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Abstract

Accountable Care Organizations (ACOs), originally developed as part of the Affordable Care Act (ACA), have grown in both the public and private sectors. Commercial ACOs have the potential to improve healthcare quality and patient outcomes while achieving cost savings. However, they may also present risks—including those related to solvency and anticompetitive pricing—to providers, patients, and payers. Part 1 of this report draws on evidence from the literature and four case studies to outline tools that state governments can use to promote the potential benefits of ACOs while mitigating their potential risks. In Part 2, we apply these lessons to a large state with a rapidly growing ACO market: California. This part outlines policy guidelines for regulators and antitrust enforcement agencies in the state seeking to promote or restrain ACOs.

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CONTENTS

EXECUTIVE SUMMARY

Since 2010, interest in the Accountable Care Organization (ACO) model has grown considerably. ACOs have developed and proliferated in part as the result of intentional government policy, both from the Centers for Medicare and Medicaid Services and the Affordable Care Act. In turn, this has stimulated growth in the commercial sector.

According to Leavitt Partners, there are now over 300 payers with commercial ACO contracts, which cover more than 12 million lives nationwide. California alone now has 67 commercial ACOs, which cover over one million lives statewide. Commercial ACOs have the potential to improve healthcare quality and patient outcomes while achieving cost savings. However, they may also present risks—including those related to solvency and anticompetitive pricing—to providers, patients, and payers.

Aiming to inform states' roles in this fast-growing market, Part 1 of this report investigates how state governments may promote the responsible development of commercial ACOs. We first describe actions taken by state governments to realize varying policy goals. These goals are:

1. Support and Encourage Integrated Care
2. Support Alternative Payment Methodologies
3. Support Strong Networks of Primary Care
4. Protect the Public from Anticompetitive Behavior
5. Ensure Providers Responsibly Assume Risk
6. Develop and Support Comprehensive Databases
7. Encourage Public Reporting of Cost and Quality Performance Data

We then use a case study approach to present a variety of policy tools that state regulators and antitrust enforcers are using to achieve these goals. We focus on four states with significant development in this area: Rhode Island, New York, Massachusetts, and Texas. Dividing these tools into those that aim to regulate providers and those that aim to regulate payers, we identify:

<u>Tools that regulate providers</u>

1. Risk Certificates
2. Certificates of Authority or Licensing
3. Antitrust Enforcement
4. Antitrust Exemptions
5. Restrictions on the Range of Permissible Contracts
6. Support and Funding

<u>Tools that regulate payers</u>

7. Cost Caps and Benchmarks
8. Population-Based Contracting Targets
9. Primary Care and Primary Care Medical Homes Targets
10. Targets for Alternative Payments

We map these tools onto the policy goals identified earlier by state. A summary of this analysis appears in Table A.

TABLE A. PROMOTING THE RESPONSIBLE DEVELOPMENT OF COMMERCIAL ACOS

	Tools that Support and Regulate Providers						Tools that Support and Regulate Payers			
Potential State Roles	Risk Certificates	Certificates of Authority or Licensing	Antitrust Enforcement	Antitrust Exemptions	Restrict Range of Permissible Contracts	Support and Funding	Cost Caps and Benchmarks	Population-Based Contracting Targets	Primary Care Targets	Targets for Alternative Payments
Support and Encourage Integrated Care		NY		NY			RI	RI		
Support Alternative Payment Methodologies		NY				X		RI		RI
Support Strong Networks of Primary Care									RI	
Protect the Public from Anticompetitive Behavior		TX	X		MA					
Encourage Providers to Responsibly Assume Risk	MA	TX								RI
Develop and Support Comprehensive Databases						X				
Encourage Public Reporting of Cost and Quality Data		NY				X				

Source: Authors' Analysis

Notes: The state abbreviations refer to existing activities. "X" refers to activities that are possible, but have not been pursued in the context of these case studies. The state abbreviations in this table are illustrative, not exhaustive.

In Part 2 of this report, we consider whether California, a large state that has witnessed a remarkable proliferation of ACOs, should take additional actions to promote or restrain these organizations. In particular, drawing from lessons learned in Part 1, we compare California's actions in this area to those taken by the four case study states. To a policy-oriented audience, we provide guidance on three potential actions: certificates of authority, antitrust enforcement and exemptions, and risk certificates. While this section focuses on California, the implications of our analysis go beyond California, given the proliferation of ACOs across the United States.

Throughout this report, we discuss potential tradeoffs inherent in these policy goals. For example, financial and clinical integration may promote better quality or cost-effective healthcare, but also may present risks of anticompetitive behavior. States must consider and balance these goals when pursuing state action around ACOs. We conclude with a discussion of these tradeoffs and in the context of the state tools included in this report.

Part 1: State Case Studies

INTRODUCTION AND BACKGROUND

Accountable Care Organizations (ACOs) are voluntary partnerships between payers, physicians, hospitals, and other healthcare providers that are accountable for quality, cost, and often outcomes for a defined population of patients. Under the most formal of these models, if a provider is successful in controlling patient costs while meeting quality targets, the provider is able to share in the generated savings. However, if the provider delivers inefficient or low-quality care, the payer may require it to take responsibility for some of the incurred cost. As a result, many proponents believe ACOs may align payer and provider incentives, improving healthcare quality and patient outcomes while also achieving cost savings.

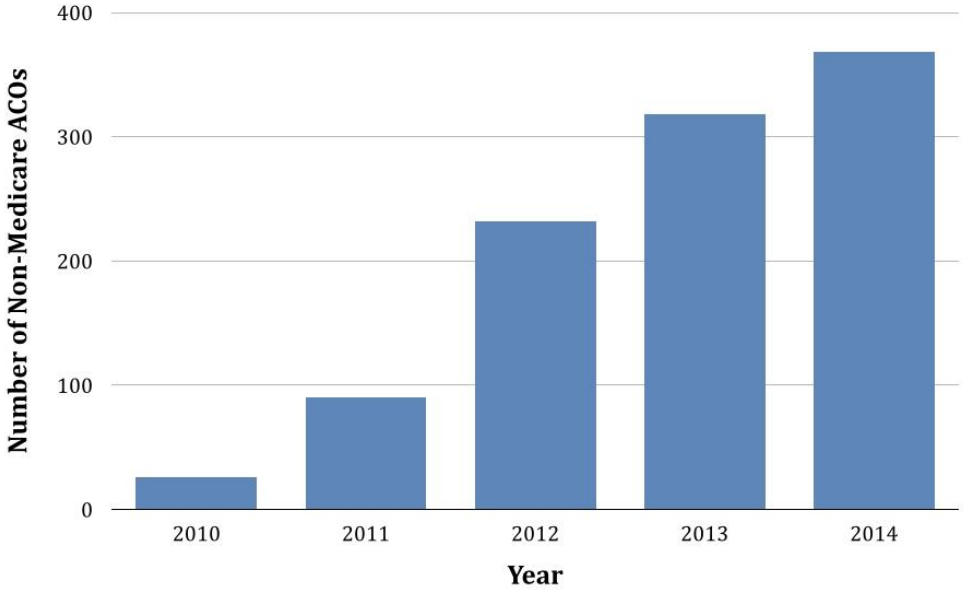
Since 2010, interest in the ACO model has grown considerably. ACOs have developed and proliferated in part as the result of intentional government policy, both from the Centers for Medicare and Medicaid Services (CMS) and the Affordable Care Act. CMS sponsors several types of ACOs, including the Medicare Pioneer ACO Model, Medicare Shared Savings Program (MSSP), Physician Group Practice Demonstration, Advance Payment ACO Model, Medicaid ACOs, and the recently announced Next Generation ACO Model for providers with significant experience managing risk. In all of these models, providers share in varying degrees of savings if they meet pre-determined quality metrics.

While they are less-explored and cited, numerous forms of ACOs have become prevalent in the commercial market. According to Leavitt Partners, there are nearly 300 payers with commercial ACO contracts, which cover about 12.4 million lives. Figure 1 below shows the number of non-Medicare ACOs nationally between 2010 and 2014, which according to Leavitt Partners have grown from 26 in 2010 to 368 at the end of 2014. Importantly, however, many ACOs have both public and private contracts.

States may play a pivotal role in pushing healthcare reform and promulgating the ACO model by exercising their role as payers in the Medicaid program. However, this report explicitly focuses on the regulation of commercial ACOs, defined as Accountable Care Organizations where a commercial payer, rather than a public one, is the entity providing cost and quality incentives for the associated provider organizations. We limit the scope of our analysis in this way because the existing literature does not adequately address or define the role of the state in this domain. Several studies have addressed government's role and best practices in supporting and developing public ACOs (McGinnis and Small 2012; Kocot et al. 2013; Stanek and Takach 2014). There is a dearth of literature, however, on how government action, in particular action on the state level, may support or restrain commercial ACOs.

Aiming to fill this gap, we seek to inform the state's role in this fast-growing market with this report. Specifically, we investigate how and why state government may support the responsible development of commercial ACOs. We first describe potential state roles to realize policy goals states may have around commercial ACOs. Focusing on both enabling and restraining strategies, we then present tools that state regulators are currently using to balance the potential benefits of ACOs against their potential risks. We map these tools onto the policy goals identified earlier. We conclude with a discussion of the inherent tradeoffs involved in these tools as states witness continued ACO growth. In this report, we do not address challenges with the implementation of these tools, in part because states' experiences with these tools are too recent to robustly analyze.

FIGURE 1. NUMBER OF NON-MEDICARE ACOS NATIONWIDE, 2010-2014



Sources: Authors' Analysis and data from Leavitt Partners, LLC

Commercial Accountable Care Organizations

In the private sector, payers and providers can forge diverse types of ACOs. Similar to Medicare ACOs, commercial ACO payers generally use their existing payment model—often fee-for-service—that they have with their providers. However, they then set a global budget for the total cost of care, the basis for calculating shared savings and shared losses among the ACO partners (Goroll and Schoenbaum 2012). Generally, commercial ACOs are not held to the same initial approval process, quality metrics, financial measures, or reporting requirements that are compulsory for ACOs sponsored by CMS. Although, like public ACOs, commercial ACOs do have a "triple aim" of improving patient outcomes and care quality while decreasing costs.

Commercial ACOs can take on a wide range of organizational attributes, sizes, payment arrangements, levels of integration, and relationships with payers. They can include many different types of provider organizations and can offer differing ranges of services to specific patient populations. They can represent large integrated delivery systems or non-integrated, but affiliated, provider networks. In their taxonomy of ACOs based on a national survey, Shortell et al. (2014) identify three distinct clusters of ACOs: (1) large, integrated delivery systems that tend to offer a large range of services; (2) smaller physician-led ACOs, which offer a narrower scope of services; and (3) hybrids that tend to be jointly hospital- and physician-led and offer a moderate scope of services.

Potential Advantages of Commercial ACOs

ACOs aim to lower healthcare costs while improving quality, care coordination, and patient outcomes. There is some evidence that ACOs and other similar financial risk sharing models have led to expenditure reductions by reducing health service utilization and achieving greater coordination of care (CMS 2015; Song et al. 2014; McWilliams et al. 2015: Markovich 2012; Toussaint et al. 2013; Melnick et al. 2014). Other studies have failed to find evidence of these effects (Mukherji 2014). As

more commercial ACOs form and as existing ACOs evolve, there will be more evidence on their benefits (Larson et al. 2012).

Potential Disadvantages of Commercial ACOs

ACOs pose two major risks to the public interest. First, the financial incentives within the ACO contract may be associated with anticompetitive behavior and pricing (Ramirez 2014). This may directly conflict with their promised benefits of controlling costs.

Second, providers entering into ACOs can encounter solvency issues. ACOs assume varying degrees of financial responsibility and risk, ranging from shared savings with bonus-only methods to global payments (fixed prepayments made to a group of providers or healthcare system). With some of these arrangements, ACOs may take on as much risk as a traditional payer (see Figure 2). However, some providers forming ACOs do not have the "infrastructure, clinical or financial experience required to take on and manage risk successfully" (Delbanco et al. 2011). Providers that take on too much risk may encounter solvency issues. Solvency concerns could disrupt physician-patient relationships, and in rural areas or areas with low-penetration of providers, could impede healthcare access.

SHOULD STATES PROMOTE COMMERCIAL ACOS? SHOULD THEY RESTRAIN THEM?

There is an on-going debate about the appropriate role of the federal and state governments in the healthcare sector, from being a single payer at one end of the continuum to taking a *laissez faire* approach that leaves market forces unimpeded at the other. This report investigates actions state governments have taken to promote the responsible development of commercial ACOs, which may involve promotion, restraint, or both. As such, we do not directly present our judgement on this debate. Rather, we present the available options to regulators and, in this section, present considerations for state governments as they decide where to position themselves on this continuum.

Some of the activities discussed in this report follow from a well-established role of government. For example, states have a responsibility to protect the public from anticompetitive conduct that can lead to monopoly or above market pricing. Other regulatory actions are new for provider organizations, but grounded in historic state actions for other organization types. For example, ensuring providers do not take on excessive risk advances from the common state role in regulating the solvency of the insurance market. Other activities presented here are newer, and not necessarily based on a solidified role for state government.

This analysis is positive not normative. We are agnostic about whether existing and planned state action squarely addresses a clearly motivated role for government—for example a real or perceived market failure or unacceptable distributional outcomes—or whether it overreaches. We do, however, discuss the potential tradeoffs inherent in these policy goals.

There are some goals and actions outside of the scope of this report. For example, ACOs require clearly defined financial structures to avoid problems related to the allocation of gains and losses among various entities. Large, integrated delivery system ACOs require a variety of physician, physician assistant, and nursing disciplines available to patients and new staff to help with administration and monitoring of the budget structure. A common challenge to the formation of ACOs is the difficulty hospitals and physicians often face in forging new partnerships. This analysis focuses on state actions, either realized or under consideration,

from a case study approach. As a result, we do not discuss all of the potential actions states could take to address the formation or restraint of ACOs.

TRADEOFFS IN POLICY GOALS

The policy goals that motivate the actions listed below often compete or conflict. States must carefully balance these pros and cons when pursuing regulatory action around ACOs. We discuss some of the major tradeoffs in this section explicitly, and then refer to these tradeoffs throughout the remainder of the report.

One of the most challenging tradeoffs is around the benefits and risks of integration. On the one hand, regulators may want to allow or even promote integration so that ACOs can achieve the scale required to improve coordination of care and realize lower costs. On the other hand, this coordination may present issues related to anticompetitive behavior and regulators may want to constrain ACOs' size and market coverage to ensure a competitive marketplace. Moreover, redesigning the financial model to align incentives is likely to be more successful if the provider organization also changes its payment structure (Bacher et al. 2013), which means that alternative payment methodologies may also interface with these concerns.

TABLE 1. ADVANTAGES AND DISADVANTAGES OF ALTERNATIVE PAYMENT MODELS

Payment Model	Advantages	Disadvantages
Fee-for-Service (No Shared Savings)	• Encourages productivity and delivery of care. • Relatively flexible in terms of provider size or structure, type of care provided, place of service or geographical location of care. • Has a straightforward payment model.	• Creates misaligned incentives between payers and provider. • Does not include provider accountability. • Creates incentives for providers to provide unnecessary care.
Fee-for-Service with Bonus Payments	• Has some incentives to cut costs and increase efficiency.	• May lead to misaligned incentives; can reward organizations that were previously inefficient and punish cost-efficient providers. • If an individual provider's share of pool is small relative to its FFS reimbursement, financial incentive to improve efficiency may be weak.
Per-Episode (Bundled Payments)	• Encourages coordination among multiple caregivers. • Supports flexibility in care delivery. • Creates incentive to efficiently manage episodes. • Creates clear accountability of care for single episodes. • Has a simple billing procedure.	• Defining boundaries of an episode can be difficult. • May increase barriers to patients' choice of provider and/or geographic availability. • Does not have incentives to reduce unnecessary episodes.
Global Payments/ Partial Capitation	• Includes incentives to avoid over-utilization and coordinate care among multiple providers or replace inappropriate care settings. • Includes incentives for providers to try new and non-traditional methods.	• Solvency is a real risk. • May not incorporate quality metrics or result in better patient outcomes.
Alternative Quality Contracting	• Has similar advantages in terms of cost controls and over-utilization as global payments and capitation. • May promote better patient outcomes and healthcare quality.	• Solvency is also a risk.

Sources: Authors' Analysis based on Song et al. (2012) and American Academy of Actuaries (2011)

States must also confront tradeoffs between promoting robust alternative payment models that improve incentives and mitigating against potential solvency concerns. For example, shared savings programs may not remove incentives for overutilization while global payments may introduce solvency concerns (American Academy of Actuaries 2011) while providing more powerful incentives for providers to control spending (Rosenthal and Cutler 2011). Table 1 above discusses some of these tradeoffs for each payment type.

While it is not explicitly listed in Table 1, quality of care is also an important dimension of this discussion. To the extent that these models improves quality of care while lowering costs, they could have additional benefits from the state's perspective. For example, because per-episode payments encourage coordination among multiple providers they may improve patient quality, particularly for specialized treatments that involve multiple provider types. Take ProvenCare, a performance-based bundled payment system that reimburses providers for coronary artery bypass graft surgery, which achieved notable quality improvements. These included a 10 percent reduction in readmissions, shorter average length of stay, and reduced hospital charges (Delbanco 2014). States must also balance these quality of care benefits against concerns related to cost and risk.

STATE POLICY GOALS

For the successful development of the ACO model, providers must exhibit a variety of characteristics. Specifically, providers' success in ACO arrangements depends on their ability to coordinate care delivery and meet performance and cost measurements. These, in turn, may depend on the level of the provider's integration, the network of primary care, and the provider's data and information technology infrastructure. On the other hand, too much integration or risk may present anticompetitive behavior or solvency concerns, which could introduce risks to the public.

In this section, we present seven actions state governments can take to promote or restrain ACOs to meet a variety of policy goals. We created these categories based on existing state activity in the four case study states and informed our framework with the five key components of state activity identified in Purington et al. (2011).[1] This list does not exhaustively cover all policy goals that states may wish to pursue.

Support and Encourage Integrated Care

Commercial ACOs vertically integrate providers to increase care coordination. There is a spectrum of organizational integration in ACOs, ranging from those led by hospitals to those led by physician groups, with integrated delivery systems in between. Improved clinical organization can result in better coordination and connection of inputs, delivery, management, and organization of healthcare services to provide diagnosis, treatment, follow-up care, and health promotion.

Integrated care systems may also promote high levels of communication and collaboration among health professionals, encouraging continuity of care. Continuity of care can occur in four aspects: (1) provider continuity where patients interact with the same professional for each visit; (2) continuity between primary care physicians and specialists; (3) continuity of hospital and ancillary services; and (4) continuity of information through shared information and records.

However, in some instances, existing laws may create barriers to full integration. For instance, states with a ban on the corporate practice of medicine, such as California and New York, prohibit general business corporations from practicing medicine or directly employing physicians. In some instances, this doctrine may inhibit various types of integration, including the formation of ACOs among multiple provider types. As a result, these doctrines may upset the goal of ACOs to promote efficiency and better outcomes through collaboration and integration. States looking to support integration in the commercial ACO sector may consider creating exemptions to or protections from this ban.

State and federal antitrust agencies may also prohibit some ACOs from forming or fully integrating to prevent harm to consumers and competition. Increased ACO formation could further exacerbate the growing trend toward consolidation of healthcare markets. The Federal Trade Commission (FTC) and the Department of Justice (DOJ) have offered guidance on antitrust enforcement policy for ACOs participating in the Medicare Shared Savings Program, but this guidance relies on CMS's ACO approval process to insure the appropriate level of integration needed to substantiate the ACOs procompetitive benefits (FTC and DOJ 2011). Therefore, these protections offered to CMS-approved ACOs do not apply to ACOs solely on the commercial market.

[1] Purington et al. (2011) identify five areas of state activity that correlate with the key components of the ACO model. They are: data, designing and promoting new payment methods, accountability measures, identifying and promoting systems of care, and supporting a continuum of care and the medical home model.

As a result, uncertainties and concerns over antitrust liability may discourage some health insurers and providers from forming commercial ACOs. States may consider promoting the development of ACOs by removing these barriers to entry either by creating an antitrust exemption or safe harbor for prospective ACOs. However, they should do so with the understanding that any such action increases the risk of anticompetitive behavior and conflicts with federal antitrust enforcers.

Support Alternative Payment Methodologies

Alternative payment methodologies (APMs) are payments to providers structured to shift economic incentives from volume of services provided to delivering care in a manner that improves quality, improves population health, reduces costs, or improves patient experiences. States can encourage the adoption of APMs either by removing barriers to them that exist in state law or directly encouraging them with targets.

There are some legal barriers to APMs. First, both the federal and state governments maintain self-referral laws and anti-kickback laws that prohibit physicians from referring patients to a person or entity with which the physician has a financial relationship. While these laws are meant to control healthcare costs and prevent fraud, the provider collaboration and financial integration inherent in ACOs may violate certain provisions in them (Lundy et al. 2010).

On the federal level, CMS established waivers to certain federal fraud and abuse laws, including: the self-referral law (or Stark Law), anti-kickback statute, and certain civil monetary penalties that are relevant for ACOs participating in the Shared Savings Program (CMS 2014).[2] However, these barriers can still exist on the state level, which in many cases are broader than the federal law and may apply to a greater range of healthcare services (Schaff, Leone, and Mack 2015). States seeking to remove this barrier to APMs may wish to grant exemptions or flexibility to these rules.

Many states also have fee splitting laws that prohibit the sharing of fees obtained from providing professional services with persons not licensed to provide the same or similar services. Due to the nature of shared savings, these laws may be implicated by payments made to suppliers and providers who participate in an ACO (Schaff, Leone, and Mack 2015). Again, states seeking to give more flexibility to ACOs as they move away from fee-for-service payment models may wish to grant exemptions to these rules.

Support Strong Networks of Primary Care

Both strong networks of primary care and primary care medical homes are important to the success of ACOs. Primary care teams operating under ACO structures serve as the initiation point for integrated patient management. These primary care teams also coordinate care with hospitals, jointly planning transitions between types of care—from inpatient and emergency rooms to outpatient care. To ensure comprehensive care options for patients, ACOs require a strong presence of medical homes and broader home health services.

There are over 6,000 primary care Health Professional Shortage Areas in the United States, making it difficult to form robust primary care services (Kaiser Family Foundation 2014). At the physician level, part of the reason for primary care shortages is their relatively low pay as compared to their specialist

[2] These waivers will expire on November 2, 2015, unless extended or CMS issues the waivers as a final rule.

counterparts. Some states already provide incentives for physicians to work in primary care, particularly in underserved areas.

There are emerging models that may enhance access to primary or preventative care that may also be used in tandem with ACOs. These include telemedicine, increasing nurse-physician ratios, expanding providers' scopes of practice, and pharmacy clinics, such as those in Walmart or CVS. To the extent that these models may benefit the public by increasing access to preventative medicine services, states may also consider implementing actions that promote or enhance these models or provide additional flexibility for ACOs to implement them.

Protect the Public from Anticompetitive Behavior

In the absence of proper oversight and enforcement, coordination of care and integration have the potential to adversely affect competition in healthcare markets (Bacher et al. 2013). Integration may provide ACOs with market power and leverage over insurers. For example, horizontal integration—which occurs when physicians join group practices or existing practices merge—may allow providers to obtain pricing power over insurers. Meanwhile vertical integration—when physicians align with non-physician partners, such as hospitals and health plans— may increase market leverage and enable participants in ACOs to inhibit competition by depriving their rivals of referrals (Bacher et al. 2013). Each of these situations could lead to cost increases.

Evidence is mounting that increased market concentration leads to higher prices and, possibly, lower quality of care. In a systematic review of the literature, Gaynor and Town (2012) found consistent evidence that concentrated hospital markets lead to higher hospital prices. Several of the studies they examined found price increases exceeded 20 percent when mergers occurred in concentrated markets. Further, Baker et al. (2014) associate the tightest form of vertical integration, hospital ownership of physician practices, with higher hospital prices and spending. They find that, in many markets, large integrated delivery systems are able to demand higher prices for all of their services due to the market leverage created by a few. The authors conclude that hospitals in concentrated markets have fewer incentives to compete on price or quality, particularly because quality can be difficult to measure.

While state attorneys general can bring antitrust enforcement actions to protect the public from anticompetitive behavior, it is not reasonable or feasible for these offices to use litigation as a full substitute for regulation. As such, state legislators and regulators may have a role to play by preemptively protecting the public from the potential anticompetitive behavior associated with ACOs through regulation and legislation.

Ensure Providers Responsibly Assume Risk

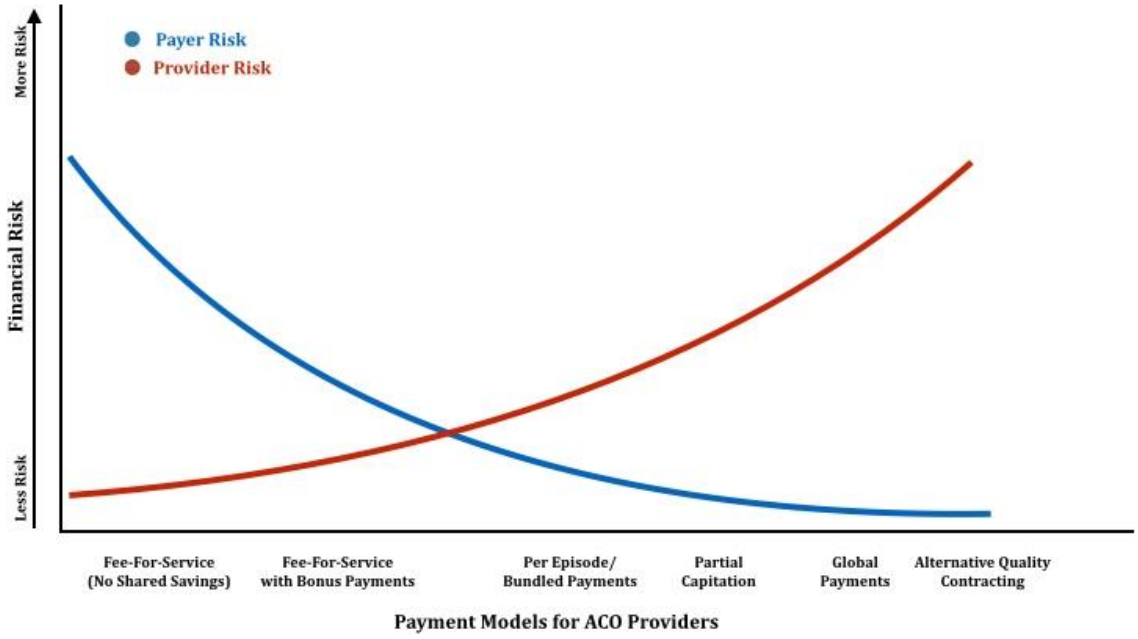
An ACO can assume varying degrees of financial responsibility and risk depending on how aggressively it pursues an alternative payment methodology. From a regulator's traditional view, the insurer—not the provider—is ultimately responsible to the consumer. However, within ACOs, providers take on risk ranging from shared savings with bonus-only methods to global payments (see Figure 2). High levels of provider risk can affect solvency, potentially impacting consumers' access to medically-necessary healthcare services.

At the lowest end of the spectrum, with bonus payments to providers that are built on top of a fee-for-service payment system, there is little provider risk. On the other hand, at the highest end of the spectrum, for example with global payments, some providers assume as much risk as a traditional insurer

or health plan. Higher levels of risk for providers, such as aggressive shared savings and shared losses with global budgets and alternative quality contracting, may present solvency concerns for providers. These types of problems even led to some bankruptcies of physician organizations in California during the 1990s. According to a report from the Catalyst for Payment Reform, "providers do not currently have the infrastructure, clinical or financial experience required to take on and manage risk successfully, though some payers are providing infrastructure and other support to providers" (Delbanco et al 2011).

A provider's vulnerability to solvency risks can present problems for the public, particularly in rural areas where small numbers of providers have high levels of market concentration. If these highly-concentrated providers are also financially integrated, increases in their risks of insolvency could threaten healthcare access for the surrounding population.

FIGURE 2. FINANCIAL RISK FOR PAYERS AND PROVIDERS, BY PAYMENT MODEL



Definitions

Fee-for-Service (No Shared Savings): Providers receive reimbursement for provision of individual services.
Fee-for-Service with Bonus Payments: Providers are eligible to receive a portion of savings if they meet quality of care standards while providing care at lower-than-projected costs.
Per-Episode / Bundled Payments: Providers receive a single payment for all the services a patient requires for an entire episode of care.
Partial Capitation: Under partial capitation, a provider is at financial risk for some, but not all, of the items and services provided to patients.
Global Payments: Under these arrangements, ACOs set budgets for health care services and providers receive a specified monthly or annual payment regardless of the services rendered or costs incurred.
Alternative Quality Contracting: Based on a global budget, providers receive pay-for-performance reimbursements for achieving certain quality benchmarks.

Sources: Authors' Analysis based on Becker (2015), Song et al. (2012), American Academy of Actuaries (2011)

In short, the amount of risk that a provider takes on should be comparable to its ability to manage and absorb risk. The American Academy of Actuaries (2011), for example, recommends that providers within ACOs taking on "significant amounts of risk should be subject to financial requirements consistent with

risk-based capital principles." Though insurers will need to ensure their collaborating providers have the appropriate levels of financial ability and network capacity, states can also play a role in regulating solvency.

Develop and Support Comprehensive Databases

To support the complex business and clinical processes associated with the ACO model, participating providers need access to health information technology infrastructure. Specifically, in order to meet performance metrics and financial targets, ACOs need timely access to multiple databases, including electronic medical records, past claims experience and claims-based data, and disease registry data (McGinnis and Small 2012).

Other information technology solutions that support effective ACOs include: health information exchange services, connectivity across the care continuum, predictive and retrospective analyses, quality reporting and measurement tools, and tools that engage patients in managing their care (Robinson and Associates 2011). All of these capabilities are important for eliminating service silos and improving integrated care.

Often, developing new information technology systems, secure data retention practices, and methods for tracking and measuring data against efficiency and quality standards can form a barrier to entry for prospective ACOs (American Academy of Actuaries 2011). These types of networks are characterized by high fixed costs and economies of scale. As such, state government may want to fund or provide some of these support services. States could either do this directly, or through a public-private partnership, for example an infrastructure bank.

Encourage Public Reporting of Cost and Quality Performance Data

Some policymakers and academics have promoted the idea of public measuring and reporting of provider cost and performance information. They note that this reporting would (1) provide consumers with information they need to choose providers with high-value care, and (2) spur reductions in cost and improvements in quality over time. Public reporting may also reinforce the ACOs' ability to improve quality while reducing costs.

Several states have established all payer claims databases (APCDs) to gather healthcare price information for analysis and dissemination. For example, Colorado's APCD includes data from commercial health plans, Medicare, and Medicaid. Policymakers and healthcare researchers can access aggregated pricing data to inform, monitor, and validate research and policy initiatives. Further, patients, providers, and community members can access price estimates for specific providers and procedures through Colorado Medical Price Compare. Improved access to healthcare price information will help states evaluate ACO impacts on healthcare costs and inform patient decision-making. However, whenever possible, states should report price and quality data together (Catalyst for Payment Reform 2012). Kessell et al. (2015) review quality measures used by Medicare, Medicaid, and commercial carriers, and discuss how they can be adapted for ACOs.

Notwithstanding, there is a concern that price transparency could adversely affect consumers, depending on how providers use this information (Sinaiko and Rosenthal, 2011; Cutler and Dafny 2011). If price information is not coupled with quality information, then consumers may infer that a higher price is a proxy for higher quality. On the supply side, for example, a low-cost provider may realize it can increase prices, but still be a low-cost provider; or, it may cause high-cost providers to settle on even higher prices.

The ideal scenario is one in which prices are transparent to buyers, but not transparent to sellers; however, this scenario is hard to practically implement.

Several studies have found possible benefits associated with public, transparent reporting of performance data by provider organizations. Marshall et al. (2000) summarize the empirical evidence on public disclosure of performance data to discuss its potential advantages. They find that, in a limited number of studies, publication of performance data is associated with an improvement in health outcomes. A more recent descriptive study by Werner and Bradlow (2010) finds that "hospital process performance improved and was associated with better patient and quality outcomes" in the three years following public reporting for U.S. hospitals by CMS. Although this relationship cannot be interpreted as causal, the authors note these results are "encouraging, since improving process performance may improve quality more broadly."

STATE POLICY TOOLS

In this section, we introduce and discuss the tools that state regulators, lawmakers, and antitrust enforcers are using—or considering using—to achieve the policy goals listed above. As such, these tools include both enabling strategies that seek to support or promote the development of commercial ACOs and restraining strategies that seek to mitigate their potential risks.

To form this list, we rely on a case study approach of those states that have taken the most action in this domain: New York, Massachusetts, Rhode Island, and Texas. According to 2015 estimates from Leavitt Partners, there are currently 48 commercial ACOs in Texas, 34 in New York, 27 in Massachusetts, and five in Rhode Island. We picked these four states for two reasons. First, according to several experts we contacted, these states are the most advanced in terms of their laws related to commercial ACOs. Second, these states represent a diversity of approaches in regulation, both in terms of tools used and policy objectives.

We spoke with regulators in each state's department or office that is responsible for overseeing the actions described. For example, we interviewed representatives from the Health Policy Commission and Department of Insurance in Massachusetts, the Texas Department of Insurance, the Rhode Island Office of the Health Insurance Commissioner, and the New York Department of Health. For additional context, we also spoke with researchers at the Texas Institute for Health Care Quality and Efficiency and the New York State Health Foundation.

Table 2 below maps each of these tools onto the seven state policy goals discussed above.

TABLE 2. PROMOTING THE RESPONSIBLE DEVELOPMENT OF COMMERCIAL ACOS

	Tools that Support and Regulate Providers						Tools that Support and Regulate Payers			
Potential State Roles	Risk Certificates	Certificates of Authority or Licensing	Antitrust Enforcement	Antitrust Exemptions	Restrict Range of Permissible Contracts	Support and Funding	Cost Caps and Benchmarks	Population-Based Contracting Targets	Primary Care Targets	Targets for Alternative Payments
Support and Encourage Integrated Care		NY		NY			RI	RI		
Support Alternative Payment Methodologies		NY				X		RI		RI
Support Strong Networks of Primary Care									RI	
Protect the Public from Anticompetitive Behavior		TX	X		MA					
Encourage Providers to Responsibly Assume Risk	MA	TX								RI
Develop and Support Comprehensive Databases						X				
Encourage Public Reporting of Cost and Quality Data		NY				X				

Source: Authors' Analysis

Notes: The state abbreviations refer to existing activities. "X" refers to activities that are possible, but have not been pursued in the context of these case studies. The state abbreviations in this table are illustrative, not exhaustive.

We divide these tools into those that support and restrain providers and those that support and restrain payers based on the authority of the relevant regulating agency. We should note, however, that many of these tools may ultimately regulate both providers and payers. For example, Rhode Island's Office of the Health Insurance Commissioner places cost caps on payer contracts, but ultimately payers may pass the onus of this regulatory burden onto providers. These constructs therefore reflect the direct authority of each state agency, not the ultimate aim of the policy tool.

TOOLS THAT PROMOTE AND RESTRAIN PROVIDERS

In this section, we describe a list of tools that states may use or are currently using to regulate and support healthcare providers.

Risk Certificates

In Massachusetts, the Division of Insurance established a process for certifying providers that take on "downside risk" or "risk-bearing provider organizations." These organizations, including ACOs, must obtain a risk certificate or risk certificate waiver from the Division of Insurance in order to enter into or continue "downside risk" contracts. This allows DOI to ensure carriers and provider organizations are prepared when they move into a risk arrangement and to prevent 'potential hiccups' to the healthcare delivery system.

DOI has found that different providers have varying levels of sophistication regarding risk management. Part of the DOI's role is to help all organizations—especially smaller or less sophisticated organizations—establish systems that may prevent them from getting into financial difficulties with risk assumed through alternate payment contracts. DOI has made and will continue to make their staff available for consultations with providers to assist with their applications, as well as with taking steps to manage their risks. In part, this system helps ensure smaller providers do not fall behind large players as they make agreements.

Certificates of Authority or Licensing

In regulations and other official policy statements, states can set forth specific entry requirements for ACOs, including licenses and certifications. These certifications and licenses can help states achieve a variety of policy goals. For example, they can include patient protection requirements, price and performance disclosure requirements, antitrust reviews, exemptions from other state laws, and solvency reviews.

Three of our case study states have an ACO-related certificate of authority process: Massachusetts, New York, and Texas. In Massachusetts, the Health Policy Commission has the authority to create regulations to guide the state's ACO certification program. In New York, the Commissioner of Health is responsible for issuing Certificates of Authority to entities that meet the conditions for ACO certification. In Texas, the Texas Department of Insurance (TDI) has the authority to certify Health Care Collaboratives (HCCs), which are Texas' version of an ACO. Each state certificate processes is different and aims to achieve specific goals. We describe each of these certification processes in more detail below.

Massachusetts

Massachusetts has a voluntary certification process for ACOs established by Chapter 224 of the Acts of 2012: *An Act Improving the Quality of Health Care and Reducing Costs through Increased Transparency, Efficiency, and Innovation*. Chapter 224 sets forth ten minimum standards for certification. For example, these standards require the certified ACO to be a separate legal entity, provide patient or consumer representation, move toward accepting more APMs in its contracts, and engage patients in shared decision-making.

The Massachusetts Health Policy Commission (HPC) has the authority to reject an application based on an entity's ability to meet certification criteria and the entirety of the application submitted. ACOs must apply for re-certification every two years to ensure compliance. The HPC's certification program is still under development and, to date, does not yet include specific reporting requirements to track performance or outcomes. In the short run, the HPC plans to leverage existing data sources to measure an ACO's clinical quality, health outcomes, patient experience and engagement, cost, and utilization.

From the ACO perspective, there are two benefits to certification: first, an ACO receives a brand and recognition through a potential "seal of approval" by the Commonwealth. According to staff members at the HPC this "is a meaningful distinction in a competitive marketplace such as Massachusetts." Second, HPC-certified ACOs will have the opportunity for preferential contracting with state-funded insurance programs. The certification does not involve an antitrust safe harbor or exemptions from any other laws.

New York

New York's *Chapter 59 of the Laws of 2011* enacted Public Health Law Article 29-E, which authorized the creation of an ACO demonstration program under the guidance of the New York Department of Health (DOH). This demonstration program became a full certification program in 2012. Under state law, no new certificates of authority may be granted after December 31, 2016.

New York's voluntary process certifies ACOs that do not take on downside risk.[3] Among other requirements, ACOs must demonstrate they are fiscally responsible, have a sufficient network, have a mechanism for distributing payments to participating providers, meet some quality benchmarks, and protect patient rights. The certification process does not include a solvency review.

The certification program includes a focus on quality assurance. New York certified ACOs are required to develop and implement quality management and improvement programs to "identify, evaluate and resolve issues related to quality." ACOs are also required to report to the DOH with data related to quality assurance and demonstrate quality performance equal to or above statewide and/or national benchmarks. These data will eventually be published on DOH's public website.

New York's certification process encourages integrated care by shielding ACOs from prosecution under the state's ban on the corporate practice of medicine if they meet certain conditions. It also

[3] Organizations that bear insurance risk must become licensed insurers with New York's Department of Financial Services and organizations that manage care must seek a managed care license under the public health law. The ACO certification process does not change or provide an exemption from these requirements.

removes barriers to entry by creating an antitrust safe harbor for ACOs that seek the exemption, and exempts participants from the state's prohibitions on fee splitting and self-referrals.

New York does not have a formal requirement for recertification, although certified ACOs are required to submit data and other necessary information annually. DOH's Commissioner also has the authority to limit, suspend or terminate the certificate of authority of an ACO after written notice, an opportunity for review, or a hearing.

Texas

As mentioned previously, TDI has the authority to certify HCCs, which are Texas' version of an ACO. The application process in Texas is focused on antitrust review and solvency. The certification process is not required for groups of doctors and hospitals to operate together, but rather triggers when a group takes on a certain amount of risk and potential antitrust issues arise. For example, groups can collaborate and use a fee-for-service payment structure without applying for the license. To date, no provider organization has pursued HCC certification in Texas.

The application involves two major parts: a solvency review, which is fairly light, and an in-depth antitrust review. After the solvency review, an expert would assemble the antitrust review and submit it to TDI. TDI would then make a recommendation and the Attorney General's office would peer review the application and remit it back to TDI if there are any issues. TDI has the final approval on the certification.

The HCC certification process in Texas involves expenses for the applicant. First, an applicant must fund its own antitrust review. Depending on its complexity and extent, the cost of this review could range from $25,000 - $250,000. Second, the applicant also must pay TDI to review the application on an annual basis, which may cost as much as $10,000 per year.

Texas also requires HCCs to develop, compile, evaluate, and report statistics on performance measures relating to the quality and cost of healthcare services and the HCCs must submit those cost and quality data as part of their recertification requirements (Tex. Ins. Code § 848.057). However, HCCs in Texas do not have any public reporting requirement associated with this collection effort.

Summary

Table 3 below summarizes the characteristics of certificates of authority and risk certificates, by these three case study states that use these tools. Across the parameters shown in the table, certificates have a wide range of requirements and even applicable organizations. Texas' requirement is the most stringent according to these criteria, while Massachusetts's certification requirement is the least restrictive.

TABLE 3: CHARACTERISTICS OF CERTIFICATES OF AUTHORITY AND RISK CERTIFICATES

	Massachusetts		Texas	New York
Characteristics of Certification	ACO Certification	Risk Certificates[1]	HCC Certification[2]	ACO Certification[3]
Voluntary or Mandatory	Voluntary	Mandatory	Mandatory	Voluntary
May Create a Safe Harbor or Safety Zone	No	N/A	Yes	Yes
Provides Protections from Other Laws or Requirements	No	N/A	No	Yes[4]
Includes a Solvency Review	No	Yes	Yes	No
Requires Public Reporting of Cost and Quality Data	Yes	N/A	No	Yes
Includes a Re-Certification Requirement	Yes	Yes	Yes	No

Source: Authors' Analysis

Notes
[1]Applies to Risk Bearing Provider Organizations
[2]Applies to Health Care Collaboratives that assume downside risk
[3]Applies to Accountable Care Organizations that do not assume downside risk
[4] Other exemptions include: ban on corporate practice of medicine, fee splitting, and self-referral laws

Antitrust Enforcement

States with concentrated healthcare markets may wish to engage in active enforcement of state and federal antitrust laws to prevent certain ACOs from harming competition and increasing prices. State attorneys general can either act independently or partner with federal agencies to bring antitrust enforcement actions. States maintain their own antitrust laws that would also apply to ACOs, unless a specific exception was granted (see 5.1.4). Forty-nine states have their own antitrust laws[4] and state attorneys general have been particularly determined in enforcing those laws in the healthcare industry (Mahinka et al. 2011).

State and federal antitrust enforcement officials generally have the opportunity to evaluate the formation of an ACO around the time of its creation. This is generally the case regardless of whether the ACO results from a formal horizontal or vertical merger, a contract, a joint venture, or some other alliance. Typically, antitrust enforcers analyze any type of provider collaboration through a similar lens because the resulting harm to competition is largely the same. The key concerns include: (1) whether the collaboration offers any efficiencies such as consumer cost savings or quality improvements; and (2) whether the proposed integration is bona fide or simply a mechanism to enhance market leverage (FTC 2014). If the enforcement agency finds that these initial concerns are satisfied, then it will evaluate the collaboration under a Rule of Reason analysis.

Under a Rule of Reason analysis examining the formation of an ACO, antitrust enforcers must determine the relevant product and geographic markets, the market concentration, and whether the efficiency benefits of the integration outweigh the risk to competition (FTC 2014). General appeals

[4] Pennsylvania is the only state without a separate antitrust law. Instead, this state enforces competition under its Unfair and Deceptive Practices statute.

to cost reductions and quality improvements are unlikely to outweigh any legitimate concerns over potential anticompetitive effects. Claimed efficiencies should be specific to the type of collaboration sought, explicit, and cognizable (FTC 2014). These questions regarding the potential benefits and anticompetitive effects of a particular integration proposal also apply to other provider collaborations, like affiliations.

Enforcement agencies generally consider whether the claimed efficiencies could be obtained through a structure that was less harmful to competition. For instance, is a merger required to achieve the specified quality improvements and cost reductions? In *Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System*, the 9th Circuit Court of Appeals found that the quality benefits obtained from sharing electronic medical records, standardizing treatment protocols, and integrating physicians across practices did not require a formal merger.

Ultimately, antitrust enforcers must determine whether a particular collaboration is likely to benefit consumers through particular initiatives designed to reduce costs and improve quality, or harm consumers through increased costs and reduced competition.

Once antitrust enforcers determine that a merger or collaboration is anticompetitive, they must decide upon a remedy. Antitrust remedies aim to restore the opportunity for the competitive market to function without the illegal conduct. Structural and conduct remedies are the most common antitrust enforcement actions related to mergers and collaborations like ACOs. Depending on the timing of the action and the market conditions, states may use structural and conduct remedies in isolation or in combination. We discuss each of these remedies in turn.

Structural Remedies

Structural remedies prevent the formation or eliminate the existence of an anticompetitive entity. They often require the violator to divest a portion of its business or even dissolve into smaller entities. If a potentially anticompetitive ACO has not yet or only recently formed, structural remedies offer a fairly simple solution to prevent the collaboration and restore the status quo by unwinding the integration. Antitrust enforcers have expressed a strong preference for structural remedies when possible, as research has shown that addressing anticompetitive concerns pre-consolidation is far more successful than post (Tenn 2008).

Antitrust enforcers have most commonly used structural remedies to prevent horizontal integration between competitors. They are not as frequently used to prevent vertical integration, which has generally not been viewed as anticompetitive (Ramirez 2011). However, in healthcare markets, vertical integration can harm competition by creating provider organizations with substantial leverage that can demand price increases for all entities in the system (Baker 2014). Academics have begun to call for antitrust enforcers to consider using structural remedies when a proposed vertical integration between healthcare entities with substantial market share threatens harm to competition (King 2015).

Not all ACOs will form by uniting previously separate entities. Existing large, integrated delivery systems may apply to become an ACO with little structural change. In these instances, conduct remedies may generally be more favorable. However, states should strongly consider structural remedies as options for healthcare entities that have acquired substantial market share and aggressively used it to drive up healthcare costs. In other industries, antitrust enforcers have won

monopolization and attempted monopolization claims resulting in a court-ordered full or partial divestiture of assets, which greatly increased competition and lowered costs (*United States v. AT&T* 1982).

Conduct Remedies

Conduct remedies are used to stop anticompetitive behavior, prevent its reoccurrence, and restore competition to the market. Instead of requiring a structural change, conduct remedies impose affirmative duties and restrictions on offending entities, sometimes for many years. Conduct remedies recently used for healthcare organizations included court-appointed monitors, price caps, limits on health expenditures, contract limitations, mandatory preservation of existing services, and government approval of further acquisitions.

Federal antitrust enforcers typically reject requests for conduct remedies when reviewing potentially anticompetitive healthcare integration for several reasons (Ramirez 2011). First, they do not restore the status quo with respect to competition, and enforcers view their restrictions as an inferior substitute for competition. Second, conduct remedies often create monitoring requirements that are expensive, burdensome, difficult to enforce, and often outside of the expertise of state officials. Third, conduct remedies are time-limited, leaving open the possibility of anticompetitive harms once monitoring concludes. Finally, conduct remedies may create consequences that may harm market dynamics in unforeseen and unintended ways.

State attorneys general appear to be more willing to use conduct remedies in the healthcare context than federal antitrust enforcers. Attorneys general in Massachusetts, Pennsylvania, and New York have recently agreed to use conduct remedies to regulate proposed healthcare mergers. Their willingness to do so may reflect a greater knowledge of the key actors and market dynamics within the state, a reluctance to engage in litigation, or the power of particular healthcare entities within the state.

However, in situations where the FTC or the state has concerns about competition, but does not want to engage in full litigation, conduct remedies can provide an effective means of regulating anticompetitive conduct (Ramirez 2011). Conduct remedies are preferential to structural remedies once the entities have fully integrated and the challenge of unwinding the entities increases substantially. Further, conduct remedies can preserve any procompetitive effects of integration that a structural remedy would eliminate, while still attempting to address the anticompetitive harms caused by the integration.

Antitrust Exemptions

While states can use antitrust enforcement to discourage anticompetitive integration (5.1.3), they can also encourage procompetitive integration by protecting healthcare entities from enforcement. Specifically, states wishing to promote ACO formation can pass legislation that exempts healthcare providers that engage in certain kinds of collaborative activity from antitrust review.

The FTC and DOJ have coordinated with CMS to exempt ACOs participating in the MSSP from certain antitrust enforcement actions (FTC 2011). For example, the Federal Trade Commission (FTC) created a "safety zone," based primarily on market shares. This safety zone shields providers that intend to form an ACO to participate in the MSSP from federal antitrust enforcement that

would otherwise prohibit their collaboration. ACOs that do not qualify for safety zone protection can request an expedited review to ensure their activities are lawful.

In a similar vein, states may exempt non-sovereign entities from state and federal antitrust laws to promote goals that may harm competition via the state action doctrine. To do so, the state must have an expressly stated intent to sacrifice competition for an alternative goal, and in the case of non-sovereign entities, the state must actively supervise the entity's activities (*North Carolina Board of Dental Examiners v. FTC* 2015).

In an effort to promote integration in healthcare, several states currently exempt healthcare collaborations, like ACOs, from antitrust enforcement. Ten states offer health-related collaborations antitrust immunity through certificates of public advantage. Three states have created a specific antitrust exemption for certain ACOs. For example, in New York, ACOs that receive certification by the Department of Health receive an equivalent state antitrust safe harbor as certification by CMS for the Federal MSSP (Nixon Peabody 2013). Other states have proposed legislation that would exempt certain healthcare providers that engage in collaborative activity from antitrust review (Ramirez 2014).

States may offer state action immunity because of the belief that provider integration and collaboration on price in the context of an ACO would otherwise violate antitrust laws. ACOs and other forms of vertical integration in healthcare designed to promote efficiency, improve quality and control costs, however, are generally viewed as efficiency enhancing. On the other hand, use of the state action doctrine in the ACO context has garnered opposition from the DOJ and FTC (Ramirez 2014). In April 2015, the FTC sent a letter to New York stating that it opposed the use of the state action doctrine to protect healthcare entities from antitrust enforcement. The Commission expressly stated that it would not target healthcare collaborations that benefited competition through lower costs and quality improvements. As a result, state action immunity in the ACO context would benefit only those entities that used leverage or market power gained from the integration in anticompetitive ways that harmed consumers. States considering the use of an antitrust exemption to encourage integration should place clear boundaries on the scope of antitrust immunity granted and engage in careful monitoring of the exempted entities, or be prepared to receive federal opposition.

Restrictions on the Range of Permissible Contracts

Some states have sought to enact legislation to make it more difficult for incumbents with market power to exclude competitors or to secure a competitive advantage without undermining the value of integration. Common restrictions on contract provisions include bans on most favored nations clauses, all or nothing provisions, anti-tiering or anti-steering provisions, non-disclosure agreements (gag clauses), and exclusivity provisions. Each of these provisions enables an entity with market leverage to either charge higher prices or exclude competitors in anticompetitive ways.

Most favored nations (MFN) clauses prevent a provider from giving any other insurer a deeper discount than the contracting insurer. MFN clauses most often occur when a large insurer agrees to pay a "must have" provider organization a higher than market rate to have it in their network (Muir, Alessi, and King 2013). To remain competitive, insurers need to negotiate a lower rate than their competitors, not the lowest rate possible. Once a large insurer has contracted with a "must have" provider at a supracompetitive rate, all other plans must pay an even higher rate to include the

provider in their network. As a result, MFN clauses enable providers to drive up costs across the board.

All-or-nothing clauses require an insurance plan that wants to include some providers and services in a particular health system in its network to agree to cover all providers and services in that health system. All-or-nothing clauses enable vertically integrated entities to charge supracompetitive prices for many of their providers and services.

Anti-tiering or anti-steering provisions prevent insurers from providing incentives for beneficiaries to select lower cost or higher value providers. For example, Massachusetts has sought to prevent providers from using their market power to inhibit benefit designs intended to create incentives for cost-conscious patient choices. In this domain, Massachusetts passed § 9A Chapter 176O, which makes it illegal for a provider to refuse to deal with an insurer in response to the insurer's offering of a tiered network.

Non-disclosure agreements or gag clauses prohibit providers and insurers from disclosing the negotiated healthcare prices to third parties (Muir, Alessi, and King 2013). These provisions and other similar agreements have greatly limited access to healthcare price information. Seeking to prevent providers from using their market power to inhibit price transparency, Massachusetts, for example, prohibits plans from entering into agreements with providers that limit either party's ability to disclose information on costs (amendment to § 9A of Chapter 176O).

Exclusivity provisions require an exclusive relationship between parties. In the ACO context, an ACO could use an exclusivity provision to ensure that a desirable provider does not affiliate with any other ACO. The FTC and DOJ limited ACO eligibility for the "safety zone" based on certain providers' exclusivity. ACOs seeking "safety zone" protections cannot exclusively contract with hospitals, ambulatory surgical centers, rural providers, and dominant providers (FTC 2011).

Each of these provisions promotes competition in healthcare markets and can help control healthcare prices. Antitrust enforcers often use these provisions as part of conduct remedies to regulate anticompetitive behavior. However, when passed as legislation, they apply to all market actors creating a more egalitarian environment.

Support and Funding

States can fund the development of key infrastructure needed for delivery system transformation. They can also provide support services or technical assistance, for example by funding information technology, providing staff support and data feedback loops, and convening stakeholders for collaboration.

Higgins et al. (2011) identify technical assistance to providers as one of the key requirements for ACO success. For example, providers may require assistance around identifying and developing capabilities needed to enter into ACO arrangements or assistance with effectively managing the care of their patients to achieve performance targets. The state could provide some of these roles by funding information technology solutions or providing technical assistance.

None of the states that we interviewed are actively pursuing this role, although Massachusetts does plan to offer technical support in some capacity. However, some other states are providing support

for infrastructure for CMS-sponsored ACOs. For example, according to Stanek and Takach (2014) "Vermont is planning to produce an integrated health data system in the state to support ACOs and other delivery system innovations."

States could also use a supportive role, rather than a regulatory role, to help build provider capacity to assume risk. For example, Rhode Island's Alternative Payment Advisory Committee has noted that to accomplish this goal, the state could provide targeted learning collaboratives, seminars for provider leaders, and technical assistance to providers with identified need for support.

TOOLS THAT SUPPORT AND REGULATE PAYERS

In addition to regulating providers, states can pursue the responsible development of ACOs with state actions that address healthcare payers. This discussion is based on the largely unique set of state actions in Rhode Island. In contrast to other states that have pursued regulations around providers, Rhode Island has leveraged its health insurance authority to push healthcare reform in the commercial ACO system. These actions include cost caps and benchmarks, which regulate insurer contracts, and several targets for payers, including (1) targets for population-based contracting, (2) targets for primary care and primary care medical homes, and (3) targets around adopting alternative payment structures. We discuss each of these in more detail below.

Cost Caps and Benchmarks

In Rhode Island, the Office of the Health Insurance Commissioner (OHIC) regulates insurer contracts by placing caps on cost growth. These include both hospital price increase limitations and ACO budget increase limitations.

These limitations arise from a set of hospital contracting standards for insurers, titled the *Hospital Contracting Conditions* that OHIC designed in 2010. The contracting standards limit the average annual effective rates of price increases for inpatient and outpatient hospital services to "no more than a weighted amount equal to increases in the CMS National Prospective Payment System Input Price Index (IPPS) plus 1% for all contractual years" (OHIC 2015). These cost caps are firm limitations on the terms insurers can agree to in their contract. If, for some reason, an insurer failed to meet these terms, they would face consequences ranging from fines to denial of rate filings.

While ultimately this regulatory action places a burden on providers, not payers, OHIC can only exercise its authority on payers and not directly on providers. Other states seeking to adopt similar authority would vest it with the state's insurance regulator or commissioner. As a result, we classify this tool as one that regulates payers.

This indirect approach does raise a question of effectiveness. There have not been any formal or scientific evaluations of the effectiveness of these cost caps on keeping prices low. It is unclear whether regulating provider market power or pricing through payers is an effective means of reducing prices or costs among providers.

Targets

Rhode Island's OHIC has developed three types of targets for payers that affect the development of ACOs. These are: (1) targets for population-based contracting, (2) targets for primary care and primary care medical homes, and (3) targets around adopting alternative payment structures. While

these targets are not legally binding, insurers must prove they made a good faith effort to comply with the standard.

Population-Based Contracting Targets

A population-based contract is a "provider reimbursement contract that uses a reimbursement methodology that is inclusive of the total, or near total medical costs of an identified, covered-lives population" (OHIC 2015). The core feature of this model is the payment of a single risk-adjusted global payment per capita for all health services required by a group of people over a fixed period of time. Rhode Island's goal is to move 80 percent of Rhode Island's population into contracts that are defined as capitated risk over the next five years.

In 2014 OHIC enacted the *Affordability Standards* to strengthen the state's primary care infrastructure, increase integrated care, and restrain growth in rates that insurers pay to providers. In these *Standards*, OHIC has set the following targets to promote population-based contracting: "by the end of 2015, at least 30% of lives will be subject to population-based contracts with upside risk, and by the end of 2016, at least 45% of insured lives will be subject to population-based contracts with 10% upside risk and downside risk. By the end of 2017, at least 60% of insured covered lives shall be subject to population-based contracts with 20% upside and downside risk" (OHIC 2015). In population-based contracts, "health insurers must limit increases to the ACO's annual risk-based budget for total medical expenses to the U.S. CPI-Urban less Food and Energy" (OHIC 2015).

Primary Care and Primary Care Medical Homes Targets

OHIC aims for at least 80 percent of contracted primary care practices to function as primary care medical homes (PCMHs) by December 31, 2019.

To achieve this target, the OHIC convened a Care Transformation Advisory Committee in April of 2013 to develop the State Healthcare Innovation Plan. OHIC also established the following targets for insurers, requiring them to "direct at least 10.7% of total medical payments toward primary care spending and at least 9.7% of total medical payments to Direct Primary Care Spend, defined as payment that directly benefits primary care practices" (OHIC 2015).

Targets for Alternative Payments

The *Affordability Standards* also recognize the goals to reduce the power of fee-for-service volume incentives and move toward alternative payment methodologies that provide incentives for better quality and efficient service delivery. Those regulations require each health insurer to submit a schedule to annually increase its use of APMs that mitigate fee-for-service volume incentives for hospital services, medical and surgical services, and primary care services.

Rhode Island's *Hospital Contracting Conditions* also requires that insurers' contracts with hospitals include a quality incentive program, which places "a portion of hospitals' annual rate increases at risk for performance on quality measures" (OHIC 2015). Specifically, 50 percent of any rate increase that insurers give hospitals must be earned on the basis of quality. OHIC's principal enforcement mechanism for this requirement is the rate review process. However, in the recent past OHIC has enforced this requirement through a contract audit in which plans must provide the language and terms written in contracts to demonstrate compliance.

DISCUSSION

While it is outside of the scope of this report to critique the tools currently under use, we can discuss their tradeoffs and potential advantages. Among the case studies, the most common and expansive tool was the certificate of authority. Three of the case study states—New York, Massachusetts, and Texas—have developed certification processes for ACOs that have widely different goals and structures.

For example, in Texas, a state with policymakers and citizens that are generally skeptical about role of government in promoting commercial organizations, the certification process is focused on restraint and protection—namely in antitrust and solvency. The Texas certifications are mandatory and do not involve any additional exceptions from state law. With high up-front costs for applicants, including the cost of an expert antitrust review, this certification process may even effectively discourage ACO formation.

New York, on the other hand, grants several benefits from its certification process, including shields from state prohibitions on fee splitting and corporate practice of medicine. These actions may serve to promote integration and alternative payment methodologies and may even encourage the formation of ACOs.

The Massachusetts certification process for ACOs, neither grants exemptions to any existing law nor requires participation. As such, its benefits to applicants are the least clear. On the other hand, the Massachusetts DOI risk certificates could play a significant role in supporting providers to take on responsible risk, particularly for small organizations with less sophistication regarding risk management.

As such, these certificates appear to be an adaptable and flexible tool that states can individualize depending on how they weigh competing policy objectives.

Part 2: Policy Guidance for California

POLICY GUIDANCE FOR CALIFORNIA

Building on its long history of managed care, California has witnessed a remarkable growth in Accountable Care Organizations (ACOs) in the last few years. In less than two years, between August 2012 and February 2014, the number of lives covered by ACOs in California increased from 514,100 to 915,285. This represents 2.4 percent of California's population, including 10.6 percent of California's Medicare fee-for-service beneficiaries and 2.3 percent of California's commercially insured lives (Fulton et al. 2015). With this growth, California now has more ACOs than any other state in the country (Shortell et al. 2015).

Does this market change demand policy action? In this Part, we consider whether California should take additional state actions to promote or restrain ACOs. In particular, drawing from lessons learned in Part 1, here, we compare California's actions in this area to those taken by the four case study states: Massachusetts, New York, Rhode Island and Texas. While we focus on California, the implications of our analysis go beyond California, given the proliferation of ACOs across the United States.

While we aim to produce useful policy guidance in this Part, we do not offer explicit recommendations. As Scheffler (2015) points out, the evidence is generally promising, but "the full potential of ACOs to improve the healthcare delivery system is still uncertain." As such, in this section we avoid making strong, declarative statements about the merits or risks of ACOs or, for that matter, firm policy recommendations. Instead, we present this section as "policy guidance" to aid policymakers interested in pursuing one or a combination of policy goals. As such, we will discuss the merits and risks of three policy options for regulating or promoting ACOs and discuss how each might function in California.

CALIFORNIA'S CONTEXT

In this section, we describe the regulatory and legal context and basic market characteristics for ACOs in California.

Growth of ACOs in California

In the past several years, California has significantly increased the number of ACOs (Fulton et al. 2015; Shortell et al. 2015). As of early 2015, there 1.1 million lives covered in 67 commercial ACOs and another 0.5 million lives covered in 40 Medicare ACOs (Fulton, Hollingshead, and Scheffler 2015). Anthem Blue Cross and Blue Shield of California account for the vast majority of commercial ACOs in the state.

California's Experience with Integrated Healthcare Delivery Systems

California's history with the delegated model, Kaiser Permanente, Medi-Cal managed care, and other forms of managed care has set the stage for both interest in and concern over the ongoing growth and development of ACOs in the state. The delegated model has aimed to put decision-making in the hands of physicians, with the goal of creating a more organized, coordinated, and cost-saving system (Shifting Ground 2009). Kaiser Permanente has provided Californians with one-stop shopping for integrated care (including primary, specialty, and hospital care) and financially-incentivized physicians with goals related to quality, access, and service. California's Medicaid program, Medi-Cal, has increasingly emphasized managed care plans.

Regulating Agencies

A dual regulatory structure, comprised of the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI), governs the California health insurance arena. California's Governor appoints the Director of the DMHC, while the Insurance Commissioner, who oversees CDI, is elected by statewide ballot every four years. The DMHC has jurisdiction over approximately 80 percent of the commercial insurance enrollment, leaving CDI with jurisdiction over about 20 percent of enrollment (California Health Care Foundation 2013). This dual regulatory structure can create a complex legal, and enforcement environment for health insurance in California.

With the passage of Senate Bill 260 (SB 260) in 1999, the California Legislature established the DMHC to oversee and regulate healthcare service plans in California and enforce the Knox-Keene Act (see Section 2.3). In addition, SB 260 created the Financial Solvency Standards Board, a committee tasked with outlining solvency standards for DMHC affiliated providers and advising the DMHC director, to protect patients who rely on physician organizations for care (California Health and Safety Code § 1347.15). SB 260 also authorized provider groups to contract with healthcare service plans as risk bearing organizations (RBOs) that deliver, arrange for, or provide healthcare services, but that need not be licensed as a health plan (Health & Saf. Code, § 1375.4.).

The DMHC regulates HMOs and some PPOs by issuing Knox-Keene licenses. These licenses require applicants to ensure timely access to care, demonstrate financial solvency, and monitor healthcare quality (Insurance Markets 2003; Accountable Care Organizations: Oversight Implementation 2010; Keslo 2001). Meanwhile, the DMHC does not regulate RBOs directly, but Health and Safety Code sections 1375.4, 1375.5, and 1375.6 establish standards and requirements for capitation and risk-shifting agreements between health plans and RBOs. The DMHC solvency regulations require RBOs to submit confidential financial information to the Department to ensure compliance with solvency grading criteria (28 Cal. Code Regs, §§ 1300.75.4-1300.75.4.8.).

CDI has jurisdiction over insurers that offer health insurance policies, including most PPOs and indemnity policies, but does not regulate financial risk assumed by providers (Insurance Markets 2003; Roth and Kelch 2001). CDI requires insurers to obtain a certificate of authority, whereby it reviews applicants' financial health, reinsurance arrangements, and potential hazards to policy holders. CDI does not have a corollary to the DMHC's Financial Solvency Standards Board to enforce solvency standards for providers.

Knox-Keene Act

The Knox-Keene Health Service Plan Act of 1975 (hereafter, Knox-Keene Act) was established to increase efficiency, cost-effectiveness, and high-quality healthcare coverage in the state of California (Health and Safety Code § 1340 et seq.). To promote high-quality, stable health plans, and with some exceptions, the Knox-Keene Act requires healthcare service plans to obtain a license, in a process overseen by the DMHC (§ 1345, 1349). In this case, a healthcare service plan is "any person who undertakes to arrange for the provision of healthcare services to subscribers or to pay for or to reimburse any part of the cost for those services, in return for a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees" (California Health and Safety Code § 1345 (f) (1)).

The licensing requirement allows the DMHC to enforce one of the most fundamental aspects of the Act: (1) that all basic health services are readily available at reasonable times to all enrollees, and (2)

that services are furnished in a manner providing for continuity of care and ready referral of patients to other providers consistent with good professional practice (§1367 Knox-Keene Act).

The DMHC awards two types of Knox-Keene licenses to full-service health plans: full and restricted. Any entity that assumes global financial risk for the provision of healthcare must first obtain a full license. Providers that accept global risk from a health plan must apply for a restricted or 'limited' license. The restricted licensees are subject to all financial requirements and periodic monitoring outlined in the Knox-Keene Act, but cannot directly market their plans to employers or consumers (Fulton et al. 2015).

Other Laws and Regulations

While the Knox-Keene Act outlines the DMHC's authority with respect to healthcare service plans and providers participating in ACOs, specific sections of the California Insurance Code govern CDI's actions for insurers participating in ACOs (Insurance Code § 740-742.1). Insurance Code § 740-742.1 first outlines the jurisdiction of CDI over any person or entity providing health insurance coverage unless that entity is "subject to the jurisdiction of another agency" (§ 740 (a) (g) (h) (i)). As noted earlier, those health insurance entities that fall under CDI's jurisdiction are subject to a thorough examination by the Commissioner to determine financial solvency and compliance with the provisions established by the Insurance Code.

Other laws that may impact the development of ACOs in California include the Physician Ownership and Referral Act (PORA), which prohibits physician self-referrals, and the California Ban on the Practice of Corporate Medicine (CPM), which bars hospitals from directly employing physicians (Bernstein et al. 2011). ACOs in California are also subject to governance requirements, anti-kickback laws, antitrust provisions, and data sharing and privacy requirements (Bernstein et al. 2011).

PORA is California's version of the Federal Stark Law. It prohibits physician self-referrals, although it provides an exception for self-referrals to hospitals if "the hospital does not compensate the licensee [the doctor] for the referral" (Lundy et al. 2010). The Knox-Keene Act provides a limited exception from PORA that allows plans to solicit or advertise for the cost of subscription or enrollment, facilities, and services rendered. As we noted in Part 1, in the context of an ACO payment structure, this law could be problematic for the development of ACOs if the saving distribution plan is tied to referrals (Lundy et al. 2010; Bernstein et al. 2011). If, however, the payment distribution is tied to outcomes or quality of care it is unclear how PORA will apply (Kim 2007).

CPM bans corporations from practicing medicine. This statute was put in place to prevent unlicensed non-medical professionals from influencing medical decisions. Effectively, it precludes corporations and hospitals from directly employing physicians. (Kim 2007; Shortell, Casalino, and Fisher 2010; 1971 CA Attorney General Opinion). Notably, there are a few exceptions to this ban, including medical schools, teaching hospitals, and non-profit community clinics. The ban on CPM, more rigorously enforced in California than other states with similar laws, does suggest that ACOs will be unable to employ physicians directly (Kim 2007). However, in general hospitals have been able to get around this ban by forming medical foundations that contract with physician organizations (California Health Care Foundation 2009).

California's antitrust laws include the Cartwright Act, the Unfair Practices Act (UPA), and the Unfair Competition Law (UCL) (CA Bus. and Professions Code §16600 et seq.). The Cartwright Act prohibits agreements between two or more parties that may hinder or restrain trade or commerce. The UPA prohibits sales below cost, unearned discounts, locality discrimination and secret rebates that injure competition. The UCL prohibits "unlawful, unfair, or fraudulent" business practices, and is the most easily accessible statute for plaintiffs. Although California's antitrust laws are not derived directly from the federal antitrust acts, the Sherman Act, the Clayton Act, and the Federal Trade Commission Act, California courts tend to view federal antitrust precedents as persuasive authority. Importantly for ACOs, California has traditionally aggressively enforced its antitrust laws and viewed horizontal collusion between competitors more harshly than vertical restraints on trade (Varner and Nevins 2003). In addition to the antitrust laws, three managed care immunity or safe harbor statutes provide that combinations or groups of providers formed as "efficient-sized contracting units" should be treated as presumptively legitimate enterprises for antitrust purposes. (Bus. & Prof. Code, § 16770(g); Ins. Code, § 10133.6; Health & Saf. Code, § 1342.6.). These safe harbors may also offer additional protection for ACOs.

CALIFORNIA'S POLICY GOALS

Following from Part 1, this section outlines two policy goals relevant to ACOs that regulators and policymakers in California, in particular, may wish to pursue. These two goals inform the policy options we outline and discuss in Section 5.

In general, these goals focus on restraining—rather than promoting—ACO development in California. We do not adopt this focus out of a resistance toward the ACO model, but rather to address the policy and market environment in California. As described previously, ACOs are developing and expanding rapidly in this state. With the state's long history with managed care, the market does not seem to require government intervention to promote an already growing industry.

Protect the Public from Anticompetitive Behavior

As we discussed in Part 1, in the absence of proper oversight and enforcement, coordination of care and integration have the potential to adversely affect competition in healthcare markets. These adverse effects may eventually undermine the ability of ACOs to meet their goals of reducing costs while improving quality (Scheffler et al. 2015).

California, in particular, may be concerned about the potential for rapidly growing and expanding ACOs to adversely affect competition. While California's market for health plans is more competitive than many other states (Kaiser Family Foundation 2011), provider market power is a concern for many insurers in California. ACO formation in California may exacerbate these underlying market dynamics.

Ensure Providers Responsibly Assume Risk

As we discussed in Part 1, a provider's vulnerability to solvency risks can present problems for the public. This can be particularly true in rural areas where there are small numbers of providers have high levels of market concentration. If these highly-concentrated providers are also financially integrated, their solvency could threaten healthcare access for the surrounding population.

The development of ACOs in California has increased the amount of financial risk placed on providers. The DMHC Financial Solvency Standards Board is designed to protect consumers from

excessive risk by health plans by regulating physician organization risk bearing. The absence of a similar organization or function at the CDI leaves questions about solvency standards and systemic risk for those providers that contract with insurers that fall under CDI's jurisdiction. As we noted earlier, the DMHC has jurisdiction over approximately 80 percent of the commercial health plan enrollment, while CDI has jurisdiction over 20 percent of enrollment (California Health Care Foundation 2013). This distribution suggests an expansion of the DMHC Financial Solvency Standards Board jurisdiction is feasible.

POLICY OPTIONS AND GUIDANCE

Part 1 of this report introduced a variety of tools that state regulators in Texas, New York, Massachusetts, and Rhode Island are using to balance potential benefits and risks of ACOs. These included: risk certificates, certificates of authority or licensing, antitrust exemptions, restrictions on the range of permissible contracts, support and funding, and regulations on payer contracts. In this section, we introduce three policy options that legislators in California might consider pursuing in the context of regulating or promoting commercial ACOs in the state.

We do not consider all of the policies from Part 1 because some tools used in other states would not be appropriate in the California context. For example, Rhode Island has promoted healthcare reform by leveraging its role as a health insurance regulator. This approach is appropriate for a small state with strong rate review regulations in place, but would not be appropriate in the populous state of California with relatively weaker statutory authority in rate review. Texas' strategies—which generally reflect the state's political skepticism around the role of government in promoting commercial organizations—may not align politically with California's regulatory approach.

Three of the policy options listed in Part 1, however, may be appropriate for California's context. These are: (1) certificates of authority, (2) antitrust enforcement activities and exemptions, and (3) risk certificates. In this section, we discuss each of these policy options and present some guidelines for a policymaker interested in pursuing that alternative.

Certificates of Authority

Among the case studies examined in Part 1, the most common and expansive tool was the certification of authority. Three of these case study states—New York, Massachusetts, and Texas—have developed certification processes for ACOs that have widely different goals and structures.

Under the Knox-Keene Act, entities that assume global financial risk already must obtain a license from the DMHC. Under this policy option, ACOs in California would acquire a certificate of authority from the DMHC on either a voluntary or a mandatory basis. This would form an additional requirement above what is already required under the Knox-Keene Act.

California could establish this certificate in the pursuit of many different policy goals and—like the certificates in other states—these tools could carry with them a variety of requirements. However, in this report, we focus on their potential as a regulatory intervention for protecting the public from anticompetitive behavior.

If the certificates of authority were mandatory, it would provide a clear opportunity for California to preemptively protect the public from anticompetitive behavior. While this role can be fulfilled by the

California's Attorney General through antitrust enforcement actions (see below), it is not reasonable or feasible for the office to use litigation as a full substitute for regulation. As such, California's regulators also may preemptively protect the public from the potential anticompetitive behavior associated with ACOs through regulation and legislation.

To meet this goal, California could include an antitrust review in the certificate of authority process. In this process, the ACO would have to demonstrate that the efficiency benefits of integration outweigh the risk to competition in those markets. Like Texas, California could require the applicant to hire an expert to complete the antitrust review and submit that external review to the DMHC. The DMHC would make a recommendation and California's Attorney General's office could have the authority to peer-review the application and remit it back to the DMHC if there are any issues. To avoid conflicts of interest, the DMHC, rather than the AG's office, would have the final approval on the certification.

California enforces its ban on the corporate practice of medicine more rigorously than other states with similar laws, suggesting one potential barrier to the effective development of commercial ACOs in California. Like the certificate of authority in New York, an ACO-specific certificate of authority in California could provide an exception to this ban. However, as noted earlier, hospitals have generally been able to get around this ban by forming medical foundations that contract with physician organizations (California Health Care Foundation 2009). As the formation and growth of ACOs in the state suggest, this ban does not form a significant barrier to the formation of ACOs in California. As such, while a certificate of authority may include an exemption to this ban, it is likely not a key consideration.

To ensure continuity and consistent oversight, policymakers should consider including a recertification requirement, perhaps on an annual or semi-annual basis. This requirement would follow from the example set in both Massachusetts and Texas.

Identifying commercial ACOs is one challenge to establishing certificates of authority. In short, the key attributes of an ACO contract—providers sharing financial savings tied to total cost of care and quality measures—also exist in contracts outside of ACO entities. For example, Anthem Blue Cross Vivity and the California Pay for Performance Program also exhibit these characteristics. As a result, the certificate of authority should apply to contracts with specific attributes rather than entities that call themselves ACOs.

Antitrust Enforcement and Exemptions

Given the proliferation of commercial ACOs in California and the FTC's general disapproval of use of the state action doctrine for ACOs, antitrust exemptions do not appear to be necessary or advisable.

However, antitrust enforcement may. In California's heavily consolidated healthcare market, some ACOs may be created to increase provider market leverage and impede competition. Both horizontal and vertical integration can harm competition and increase costs. As noted above, California could use certificates of authority to monitor the formation and behavior of ACOs for potential anticompetitive effects. If it does so, the DHMC and CDI should collaborate with the California Attorney General (AG) for antitrust enforcement purposes. If California opts against the use of

certificates of authority, then the AG's office should carefully monitor ACOs for potential antitrust violations.

The AG's office should consider establishing a review process for commercial ACOs that examines ACOs at the time of formation and on an ongoing basis. At the time of formation, which could be linked to the Knox-Keene licensing application or a notice of material modification to an existing license, the AG's office could examine the collaboration for anticompetitive risks due to increases in market share or leverage. If the potential harm to competition appeared to outweigh the procompetitive benefits of the integration, the AG's office could seek a structural remedy that would prevent the ACO formation. After an ACO has formed, the AG's office could address ongoing antitrust concerns through use of conduct remedies that target the specific violations. As with any conduct remedy, the AG's office should remain cognizant of the administrative burdens of oversight and the enforcement limitations. Finally, if the AG's office recognizes consistent patterns of anticompetitive behavior from a highly concentrated entity, it should consider a more permanent structural remedy to restore competition to the healthcare market.

Risk Certificates

As described above, the DMHC regulates healthcare service plans and CDI regulates health insurers. Furthermore, the DMHC's Financial Solvency Standards Board oversees risk bearing provider organizations to help ensure that they remain solvent. Specifically, the Board advises the Director of the DMHC about financial solvency issues in general, and explores provider alternative payment methodologies and their effect on the market. The DMHC reviews RBOs' financial status and enforces claims payment requirements (28 Cal. Code Regulations, §§ 1300.75.4-1300.75.4.8). However, CDI lacks a mechanism to regulate providers affiliated with its insurers, even if they accept risk-based payments. This gap in oversight could result in excessive financial risk, similar to the troubling practice in the late 1990s with providers bearing too much financial risk (Hammelman et al. 2009).

As such, providers' financial risk within ACOs should be studied. If the risk is systemically excessive, the California Legislature may wish to expand the regulatory power of CDI in order to better protect the public from the solvency risk of growing ACOs. A natural place for government regulation, the California Legislature could expand the role of CDI to mirror the solvency review the DMHC is currently doing for providers affiliated with its health plans. This action would serve to better protect consumers from providers bearing excessive risk and potential defaults.

Alternatively, California could expand the role of CDI, based on the approach taken in Massachusetts, by requiring risk-bearing provider organizations (RBPOs) to apply for risk certificates. Under Massachusetts' risk certificate process, a provider organization that (1) manages the treatment of a group of patients and (2) bears the downside risk of the cost of treating those patients according to the terms of an Alternative Payment Contract, must obtain a risk certificate from the Division of Insurance. These certificates demonstrate that the RBPO has satisfied the certification requirements, including demonstrating that the provider's Alternative Payment Contracts are not expected to threaten its financial solvency.

DISCUSSION

States pursuing regulation or promotion of ACOs must carefully consider competing policy goals. For example, integration may improve quality, but also lead to anticompetitive behavior and higher prices. Alternative payment methodologies may improve patient outcomes or reduce costs, but may also result in solvency concerns that threaten healthcare access. State regulation should carefully weigh the benefits against the risks and—in the context of its own preferences and values—create a systematic regulatory structure that addresses each of these concerns.

As California and other states around the nation pursue state action around ACOs, they must consider and balance these competing outcomes. As discussed in Part 1, certificates of authority may be one potential avenue to accomplish this objective. These certificates appear to be an adaptable and flexible tool that a state can individualize depending on how it weighs different competing objectives.

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