Accountable Care Organizations in California: Programmatic and Legal Considerations

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CALIFORNIA HEALTHCARE FOUNDATION

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I. Executive Summary

The Affordable Care Act (ACA) authorizes the federal government to test new health care payment and delivery models through Accountable Care Organizations (ACOs). New federal rules have been proposed for two ambitious ACO programs—the Medicare Shared Savings Program (MSSP) and the Pioneer program. These proposed rules, together with a companion framework for granting waivers under federal Stark and antikickback laws, and gain-sharing provisions of the Civil Monetary Penalties Law, present a bold framework for care delivery and payment.

Federal laws relating to these new initiatives do not preempt state law; thus, California policymakers will need to consider how the state’s legal framework for regulating health care insurers and providers either supports or inhibits the federal goals. This paper provides an overview of the issues, both programmatic and legal, that will need to be assessed by California policymakers.

Consider application of Knox-Keene and other state laws. The threshold issue that lawmakers must consider is whether ACOs are regulated through the Knox-Keene Health Care Service Plan Act of 1975 and its accompanying regulations. Under Knox-Keene, any entity that assumes global financial risk for the provision of health care must obtain a license from the California Department of Managed Health Care (DMHC). MSSP ACOs will likely not be considered risk-bearing under Knox-Keene, as these entities assume no capitated, prepaid, or periodic charges. Pioneer ACOs, on the other hand, will be required to enter into population-based prepayment arrangements with the federal government and commit to enter into outcomes-based contracts with other purchasers. As such, entities participating in the Pioneer program are more likely to be considered risk-bearing and subject to some state regulation.

ACO participants and policymakers will also need to consider state “corporate practice of medicine” provisions, which prohibit entities that are not owned and controlled by health care providers from directing health care providers in the provision of care. Depending on how they are structured, ACO care coordination and quality guidelines could be considered directing the provision of care, invoking the ban on corporate practice.

Promote multipayer initiatives. Another important public policy issue that will need to be assessed by California policymakers is how to harmonize emerging federal, state, and private ACO models to promote multipayer initiatives instead of more costly, complex, and siloed delivery system reforms. As the MSSP ACO rules have been developing, the commercial purchaser and provider market in California has been launching ACO-type programs (commercial ACOs), leveraging existing managed care networks. Commercial ACO initiatives are necessary to help spread the substantial administrative and operational costs necessary to establish ACO governance and care management processes. If commercial ACO efforts are not harmonized with federal ACO efforts, there is substantial risk that special-purpose ACO governance vehicles will emerge, greatly complicating the ACO landscape. In turn, this would undermine the ability of ACOs to create a single, uniform set of information systems, clinical guidelines, and care management programs to better coordinate care delivery and to achieve more cost-effective,
higher quality outcomes. In addition, establishing myriad ACO governance structures has the potential to confuse beneficiaries. As a result, additional consumer protections may be warranted to ensure individuals are well informed of their choices.

Ultimately, the success of MSSP and Pioneer ACOs in California will be determined by alignment with a number of state activities: commercial ACO initiatives, Medi-Cal ACO pilots targeting high-cost populations through its managed care program, and emerging health information exchange and health benefit exchange initiatives that can, if harmonized with ACOs, greatly enhance their effectiveness. Like many states, how California chooses to develop these new programs has the potential to create an environment that is either conducive to ACO formation or resistant to it.
II. Introduction

The federal Accountable Care Organization (ACO) programs represent an unprecedented opportunity for providers, purchasers, and the federal government to improve care coordination and patient outcomes while testing new reimbursement models and sharing in savings. The new federal programs, introduced in the wake of the Affordable Care Act (ACA), reflect an effort to shift reimbursement policy from paying for the provision of services to paying for the delivery of cost-effective outcomes.

As many as 180 federal ACOs facilitating care for 5 million Medicare fee-for-service (FFS) beneficiaries nationwide may save Medicare $1.5 billion over three years. Due to the size and influence of the Medicare program, ACOs have the potential to play a major role in reshaping the relationship between payers and providers. The program’s success depends in large part on whether the private market and state Medicaid agencies adopt similar models.

The stakes are high—health care expenditures are currently in excess of 16% of gross domestic product (GDP).\(^1\) If left unchecked, expenditures are expected to exceed 25% of GDP by 2035.\(^2\)

The federal legal framework for ACOs is set forth in the Medicare Shared Savings Program (MSSP) Proposed Rule\(^3\) and the Pioneer Request for Application\(^4\) (see sidebar below). ACOs created as a result of the MSSP may negotiate new payment and care delivery arrangements with other payers, including those in the commercial sector and within other publicly funded programs. The goal of this collaboration is to offer more transparent, effective, and efficient care, and to share in resulting savings or losses. The success of the MSSP, as well as other ACA initiatives, in helping to slow the rate of growth in health care costs will be carefully monitored.

<table>
<thead>
<tr>
<th>ACO Basics</th>
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<tr>
<td>ACOs are groups of providers that are jointly held accountable for improving quality and reducing cost of care. ACOs can take many forms, but every ACO will share the following features:</td>
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<tr>
<td>1. Be a provider-led organization that is collectively accountable for quality and costs of inpatient and outpatient care for a specific population.</td>
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<td>2. Receive payments linked to quality improvements and cost reductions.</td>
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<table>
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<th>ACO Models</th>
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<tr>
<td>This brief distinguishes three types of ACOs:</td>
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<tr>
<td>The MSSP ACO is described in the Proposed Rule and allows entities to enter into new contractual arrangements with CMS.</td>
</tr>
<tr>
<td>The Pioneer ACO is described in the Innovation Center announcement and allows entities to enter into contracts with CMS. See Table 2 on page 10 for differences between MSSP and Pioneer ACOs.</td>
</tr>
<tr>
<td>When described together, these models are referred to as “federal ACOs.”</td>
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<tr>
<td>The commercial ACO is a catch-all for current pilot programs being undertaken in California, which are designed to advance delivery system improvements in quality and efficiency through innovative payment arrangements.</td>
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Along with these announcements, several federal government agencies published companion regulation and policy guidance:

- Federal Trade Commission (FTC) and Department of Justice (DOJ) regarding federal antitrust enforcement policy
- Internal Revenue Service (IRS) regarding participation of tax-exempt organizations
- Centers for Medicaid and Medicare Services (CMS) and the Health and Human Services Office of the Inspector General regarding waivers for federal self-referral and civil monetary laws

Public comments are being solicited on all the proposed programs and rules, with the expectation that final rules and program notices will be released later this year. See Table 1.

MSSP ACOs will augment FFS reimbursement with payments for achieving quality and efficiency targets. In some cases, providers will also bear downside financial risk for the cost and quality of health care services. As a result, typical FFS policy concerns regarding incentives for overutilization of health care may be reversed, with focus shifting instead to risks associated with withholding or limiting care. Alternatively, Pioneer ACOs have escalating levels of financial accountability, including a transition from FFS to population-based payment.

To succeed in managing the cost and quality of health services, MSSP and Pioneer ACO models contemplate the creation of new forms of provider

<table>
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<th>Table 1. Federal Proposals and Rules</th>
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<tr>
<td><strong>PURPOSE</strong></td>
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<tr>
<td>IRS Notice 2011-20</td>
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<tr>
<td>Medicare Shared Savings Program (MSSP) Proposed Rule</td>
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<td>Accelerated ACO Developmental Learning Sessions</td>
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<tr>
<td>Advance Payment Initiative</td>
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<td>Medicare Pioneer Request for Application</td>
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organizations and networks that use common information systems and care management programs to achieve better coordinated, more cost-effective, patient-centered care.

As with many other health reform initiatives, policy decisions and regulations adopted at the state level will have a large impact on whether the federal MSSP program lives up to its potential. The ACA does not preempt state law, so state regulations covering a host of matters (from licensing and oversight requirements for risk-bearing organizations to restrictions on the corporate practice of medicine to rules about fraud, abuse, and antitrust to regulations concerning the privacy and security of health information) may significantly influence whether and how ACOs emerge. State policy actions regarding Medicaid, as well as newly emerging health benefit exchange (HBE) and health information exchange (HIE) infrastructure, may also play a key role in determining the success of ACOs.

As California’s state lawmakers and stakeholders examine the ACO marketplace, they will need to reach their own judgment as to whether ACOs present an attractive model for improving quality and controlling costs, both in government health care coverage programs and in the commercial insurance market. If so, then lawmakers and stakeholders must assess whether the state’s policy and regulatory framework supports or hinders ACO growth, as well as considering potential changes that would enable ACOs to thrive.

This paper provides a starting point for the identification and discussion of policy and regulatory issues likely to arise in connection with MSSP, Pioneer, and commercial ACO analogs in California. First, it provides a brief synopsis of the MSSP Proposed Rule and the ACO Pioneer program, along with limited background on the California marketplace. Second, it identifies past and current efforts to launch delivery system reforms with goals similar to the federal ACO initiatives. Third, it assesses how California’s existing statutes and regulations may influence ACO development. Finally, the paper identifies policy issues that will need to be addressed should lawmakers decide to support and foster ACOs.
III. Transitioning to Accountable Care: The MSSP Proposed Rule

In the MSSP Proposed Rule, an ACO is defined as a legal entity recognized under state law that consists of Medicare providers that manage and coordinate care for Medicare FFS beneficiaries. Several types of providers may form an MSSP ACO, including physicians in group practice, networks of individual providers, partnerships or joint venture arrangements between hospitals and providers, or hospitals employing providers. Federally qualified health centers (FQHCs) and rural health centers (RHCs) may participate in an MSSP ACO, but cannot independently form their own; Medicare beneficiaries will not be assigned to an MSSP ACO on the basis of care received at an FQHC or RHC. ACOs must also be capable of receiving and distributing shared savings, repaying shared losses, and ensuring compliance with other federal requirements.

Requirements set forth in the MSSP Proposed Rule are extensive. ACOs must, among other things, establish a defined process to promote evidence-based medicine and patient engagement, report on 65 cost and quality measures, and use remote monitoring, telehealth, registries, and electronic health records (EHRs) to coordinate care. Also, at least 50% of an ACO’s primary care physicians (PCPs) must be federally qualified meaningful users of EHRs. MSSP ACO care management requirements are intended to help ACO networks more effectively coordinate care and control costs.

Governance requirements are similarly extensive. For example, MSSP ACOs must demonstrate a mechanism of shared governance that provides all ACO participants with appropriate “proportionate control” over the ACO’s decisionmaking process. Additionally, ACO participants must hold at least 75% of control of the ACO’s governing body. Finally, there must be at least one Medicare beneficiary on the governing board.

Once an MSSP ACO is successfully formed, it will enter into a three-year contract with CMS to participate in the shared savings program. In the MSSP Proposed Rule, CMS outlines two models of risk sharing: the one-sided model, where the ACO shares only in savings, and the two-sided model, where the ACO shares in savings and losses. ACOs may participate in either the two-sided model for all three years of the agreement, or the one-sided model for years one and two and the two-sided model for year three.

Unlike managed care plans, there is no enrollment process through which patients join or enroll in an MSSP ACO. Instead, CMS proposes to assign beneficiaries to the ACO based on their utilization of primary care services provided by a PCP who was an ACO participant during the performance year. PCPs must sign exclusive contracts with ACOs, agreeing that all Medicare beneficiaries who meet assignment criteria will become members of the ACO, unless the beneficiaries elect to opt out of participation. Beneficiary assignment is performed on a retroactive basis at the end of each contract year.

To calculate shared savings or losses, CMS would first calculate the benchmark (i.e., what Medicare would have paid for the care of beneficiaries attributed to the ACO). The benchmark is calculated by tallying the total cost of patient care that would have been attributed to the ACO in each of the three prior years, and then risk- and inflation-adjusting that cost. For each performance year of the contract,
CMS would compare actual expenditures to the benchmark. If savings meet a specified minimum savings/loss rate, then the ACO would share in some portion of the savings or losses. An ACO’s share of the savings would be based in large part on how it scores on various quality initiatives — higher quality scores will lead to higher portions of shared savings — as well as a small bonus for beneficiary use of FQHCs and RHCs. Under the one-sided model, an ACO’s shared savings or shared loss is the lesser of 52.5% of savings or 7.5% of benchmark; under the two-sided model, the maximums are 65% of savings or 10% of benchmark.

The federal government has also proposed a framework for granting waivers under the federal Stark and antikickback laws, and the gain-sharing provision of the Civil Monetary Penalties Law. Specifically, the federal government proposes waiving those fraud and abuse laws for shared savings payments distributed to ACO participants. This waiver extends only for shared savings distributed through the MSSP program, and only for savings distributed in support of activities relating to the MSSP. Waivers would not apply to financial arrangements relating to the establishment or ongoing financing of an ACO.

Finally, the federal antitrust enforcement agencies — DOJ and FTC — issued an antitrust policy statement that applies to collaborations among otherwise independent providers and provider groups formed after March 23, 2010 that seek to participate in the MSSP. DOJ and FTC propose a bright-line test for establishing clinical integration — any ACO that meets CMS criteria is likely to constitute a bona fide arrangement that will allow the ACO to conduct joint negotiations with private sector payers in the commercial market. Recognizing that providers are more likely to integrate their health care delivery for Medicare beneficiaries through ACOs if they can also use them for commercially insured patients, the agencies would apply a rule of reason analysis to an MSSP ACO — not only to the Medicare market, but to the commercial market as well, so long as it uses the same leadership and governance structure and the same clinical and administrative processes.
IV. Pioneer ACOs

On May 17, 2011, the Center for Medicare and Medicaid Innovation (CMMI) announced the Pioneer ACO program, designed for “advanced organizations ready to participate in shared savings.” CMMI anticipates that it will fund as many as 30 Pioneer ACOs, saving Medicare up to $430 million over three years. The Pioneer ACO model shares many characteristics with its MSSP counterpart, including its focus on the Medicare FFS program. Pioneer ACOs will be eligible for waivers from the federal Stark and antikickback laws, and gain-sharing provisions and protections afforded by the antitrust rules being developed in concert with the MSSP.

Despite similarities, there are a number of significant differences between Pioneer and MSSP ACOs; these differences will have both policy and regulatory implications. For example, Pioneer ACOs require participants to enter into prepaid population-based reimbursement arrangements. By the third year, Pioneer ACOs are expected to generate a majority of total revenue from outcomes-based payments. Pioneer ACO composition, governance, and assignment methodologies also differ from MSSP ACOs. FQHCs may form Pioneer ACOs and beneficiary assignment is not exclusively PCP-based—selected specialty providers under certain conditions may be assigned ACO beneficiaries. Beneficiaries may be assigned to Pioneer ACOs either prospectively or retrospectively. Finally, Pioneer ACO governance must include both Medicare beneficiaries and consumer advocates. See Table 2 on page 10 for a comparison of many of the core MSSP and Pioneer ACO attributes.

The May 17, 2011 Pioneer announcement included two additional notices. First, CMMI is seeking comment on an Advance Payment ACO Model. This notice was triggered by early feedback suggesting that providers lack ready access to the capital needed to invest in infrastructure and staff for care coordination. Advance payment would enable up-front access to shared savings by MSSP ACOs; funds would be recouped through the ACO’s earned shared savings. CMMI also announced free Accelerated Development Learning Sessions which will provide existing or nascent ACOs the opportunity to learn about essential ACO functions and ways to build capacity for improving care coordination and delivery.
Table 2. MSSP and Pioneer ACO Attributes

<table>
<thead>
<tr>
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<th>MEDICARE SHARED SAVINGS PROGRAM (PROPOSED RULE)</th>
<th>PIONEER ACO MODEL</th>
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<tbody>
<tr>
<td>Minimum Beneficiaries</td>
<td>5,000</td>
<td>15,000 (5,000 in rural areas)</td>
</tr>
<tr>
<td>ACO Legal Status Requirements</td>
<td>ACO must be a legal entity with its own TIN, recognized and authorized under state law.</td>
<td>Identical to MSSP Proposed Rule</td>
</tr>
<tr>
<td>Legal-Regulatory Guidance: FTC-DOJ, IRS</td>
<td>FTC and DOJ propose antitrust approval and enforcement criteria; IRS provides guidance regarding tax exemption.</td>
<td>Consistent with guidance issued by FTC, DOJ, and IRS</td>
</tr>
<tr>
<td>Legal-Regulatory Guidance: OIG-CMS</td>
<td>OIG and CMS issued joint guidance on the application of anti-fraud laws.</td>
<td>OIG and CMS expect to apply consistent principles to fraud and abuse waiver designs for all Medicare ACO programs and models.</td>
</tr>
<tr>
<td>Multipayer Requirement</td>
<td>None</td>
<td>50% of total revenues derived from outcomes-based contracts (by the end of the 2nd performance period)</td>
</tr>
</tbody>
</table>
| Core Payment Arrangement     | Track 1: Shared savings for years 1 and 2, then shared savings and losses in year 3  
|                              | Track 2: Shared savings/losses in all years | One arrangement with escalating shared savings and shared losses. In year 3, transition to population-based payment. Potential for alternative models. |
| Minimum Savings Rate (MSR)   | Track 1: Based on number of assigned beneficiaries  
|                              | Track 2: 2% (flat rate) | 1% (flat rate) |
| Alignment Algorithm          | PCP-based: alignment only to PCPs based on which PCP has the plurality of allowed charges (i.e., evaluation/management codes) | Not PCP-based: prioritizes alignment to PCPs but allows alignment with specialists when PCP services total <10% |
| Beneficiary Attestation       | None at this time                             | Alignment of beneficiaries who attest to ACO as their primary care coordinator and who are newly Medicare-eligible (and others within defined parameters) |

V. The California Context

California’s health care market is incredibly diverse and is represented by large integrated systems such as Kaiser Permanente, integrated delivery networks such as Sutter and Catholic Healthcare West, hospitals and independent physician associations (IPAs), and small and solo group practices (see Table 3). The delivery system also includes an overlapping safety net of 180 community clinic corporations, public hospitals, and private practices.

Table 3. California Insurance Market

<table>
<thead>
<tr>
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<th>Numbers of Members</th>
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<tr>
<td>IPAs and Groups</td>
<td>10 million</td>
</tr>
<tr>
<td>Kaiser Permanente</td>
<td>6.5 million</td>
</tr>
<tr>
<td>Medi-Cal and CHIP</td>
<td>8 million (3.4 million FFS, 4.6 million in managed care)</td>
</tr>
<tr>
<td>PPO and Self-insured</td>
<td>4 million</td>
</tr>
<tr>
<td>Medicare</td>
<td>4.6 million (3 million FFS, 1.6 million in managed care)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>7.3 million</td>
</tr>
</tbody>
</table>


Managed care in California is subject to significant regulation. California’s principal regulators include the Department of Managed Health Care (DMHC) and the California Department of Insurance. DMHC regulates HMOs and their associated “risk-bearing organizations” (RBOs) and certain PPOs. It was formed in 2000 as part of a regulatory health reform effort to oversee capitated plans and groups; it currently regulates 49 health plans representing over 21 million Californians. The California Department of Insurance oversees some FFS and most PPO plans, regulating 285 carriers representing 2.4 million residents.

DMHC was formed in part to regulate the tumultuous managed care market in the late 1990s, exemplified by explosive growth of managed provider networks that ultimately was followed by a precipitous crash. Physician practice management organizations, such as MedPartners and FPA, went first, followed by many IPAs that either failed completely or retrenched into core markets after rapid expansion across California and the nation. A major contributor to financial problems...
was an inability to manage risk, or to accumulate financial reserves and tangible net equity necessary to accommodate that risk. These circumstances contributed to promulgating regulations that would define RBOs, require them to report operational and financial solvency, and submit corrective action plans should they not meet specified requirements. Those unable to meet corrective action plan requirements are at risk for administrative action by DMHC.

Despite past difficulties associated with some risk contracts, in recent years California’s payers and providers have exhibited renewed interest in experimenting with alternative managed care reimbursement arrangements. Because of their goals to reduce cost and increase care coordination, such arrangements resemble federal ACOs. In 2010, CalPERS partnered with Blue Shield of California, Catholic Healthcare West, and Hill Physicians Medical Group to conduct a two-year pilot project focusing on care integration. The pilot includes approximately 41,000 CalPERS beneficiaries in three California counties. According to CalPERS, by October 2010, pilot sites had experienced a 17% reduction in patient readmissions, a 50% reduction in the number of patients hospitalized for 20 or more days, and an almost 14% reduction in the total days patients spent in a facility. CalPERS estimates savings to be as much as $15.5 million. See Table 4.

### Table 4. CalPERS Pilot

<table>
<thead>
<tr>
<th>Counties</th>
<th>Sacramento, El Dorado, Placer</th>
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<tbody>
<tr>
<td>Beneficiaries</td>
<td>41,000</td>
</tr>
<tr>
<td>Savings</td>
<td>$15.5 million</td>
</tr>
<tr>
<td>Total Patient Days</td>
<td>14% decrease</td>
</tr>
<tr>
<td>Patient Readmission</td>
<td>17% decrease</td>
</tr>
</tbody>
</table>


Additional alternatives to traditional capitated managed care arrangements are being prepared for launch. In March 2011, Anthem Blue Cross, Health Care Partners, and Monarch HealthCare announced plans to roll out a commercial ACO pilot for PPO beneficiaries in Southern California. In San Francisco, two commercial ACOs involving Blue Shield of California are underway. The first targets San Francisco City and County employees and includes Catholic Healthcare West, Hill Physicians Medical Group, and the University of California, San Francisco. The second involves Brown & Toland Physicians and Sutter Health. Finally, the Accountable Care Network, a regional safety net initiative in Los Angeles, is planning to launch a commercial ACO-like program in which shared risk pools may be created between hospitals and community clinic participants.

The emergence of commercial ACOs raises an important issue relating to consumer protection. Citing concerns that beneficiaries not be misled about ACOs and services available to them, CMS went to great lengths to articulate ACO marketing guidelines and requirements in the MSSP Proposed Rule. As commercial ACOs emerge, there is significant opportunity for market confusion, especially as commercial programs may have very different requirements from federal ACOs and may serve different populations.
VI. ACOs and the California Legal and Regulatory Environment

Pioneer and MSSP ACOs would not preempt state law; thus, participants must be organized and operated in compliance with California’s existing statutes and regulations. In issuing the MSSP, federal regulators took care to propose simultaneous modifications to existing federal law (i.e., the FTC-DOJ Joint Policy Statement) to remove or lessen the impact of federal laws perceived to create barriers to federal ACO development.

As with the federal landscape, California has a complex framework of laws and regulations that might limit the ability of providers to form and successfully operate ACOs. As the federal implementation proceeds, California lawmakers must assess legal barriers to ACO development—due either to an inconsistency with ACO goals or to conflict with emerging federal rules—that undermine the ability of providers to create a broad, multipayer ACO platform. In some cases, lawmakers may want to consider better alignment of state and federal rules to support more widespread development of ACOs.

Governance

To participate in the MSSP, an ACO must conform with the detailed governance requirements set forth in the MSSP Proposed Rule. In the rule’s preamble, CMS notes that many existing entities will be unable to meet governance requirements in their current form, and therefore many ACOs will need to form new entities to govern the ACO’s activities. CMS affords ACOs broad latitude in choosing their corporate form, noting that the ACO’s legal entity may be established in a variety of ways, including as a corporation, partnership, limited liability company (LLC), foundation, or other entity permitted by state law.

California law allows for a broad array of corporate forms, nearly all of which could be structured to meet MSSP governance requirements—with careful drafting of the formation documents or modification of existing board membership to include beneficiaries and consumer advocates. Some forms, notably the corporation and the LLC, could be easily adapted to meet the governance requirements for an ACO’s legal entity. Other forms, notably the nonprofit public benefit corporation, present significant challenges in this regard. As such, an unintended consequence of the governance requirements in the MSSP Proposed Rule may be that it makes it too difficult for certain types of existing health care organizations to form an ACO.

Among the principal issues that could impede California public benefit corporations from forming ACOs are the prohibition on the gift of charitable funds for private benefit, the statutory prohibition on “distributions” to members, and the limitation on the number of “interested persons” who may serve on the board of directors.

Public benefit corporations hold all their funds and assets in trust for charitable purposes. As such, it is impermissible to use such assets for private benefit. In most instances, this limits payments to private parties to those that are contractually obligated, do not exceed fair market value, and are for property, assets, or services rendered. Payments that do not meet these standards are at substantial risk of constituting a gift of charitable funds.
California law also prohibits the distribution of any gains, profits, or dividends by a public benefit corporation to any member. Members generally include any persons who, pursuant to an article or bylaw provision, have the right to vote to elect members of the governing board of the public benefit corporation. ACOs are intended to receive and distribute cash payments, representing cost savings, to private party participants. In turn, private party recipients may be entitled to elect board members. This represents material risk that payments, to the extent that they do not constitute fair market value payments for services rendered, may constitute prohibited distributions. California law includes board selection mechanisms that may be successful in addressing this issue, assuming CMS would permit such flexibility.

Additionally, California public benefit corporations are subject to a statutory limitation on the number of “interested persons” who may serve on the board of directors. CMS proposes requiring, among many other things, that ACO participants—meaning providers, not investors—control at least 75% of the ACO’s governing body. Under Section 5227 of the California Corporations Code, however, not more than 49% of the board of a nonprofit public benefit corporation may be interested persons. While there are mechanisms to assert governance control through vehicles that do not violate the express terms of Corporations Code Section 5227, these may be subject to regulatory challenge because they are inconsistent with statutory intent. Such mechanisms may also complicate the ability of the public benefit corporation (and its board of directors) to leverage statutory protections of Corporations Code Section 5233 with respect to transactions in which board members have a material financial interest.

While the aforementioned provisions do not prevent the use of the public benefit corporation as an ACO, they are sufficiently complicated to require careful legal review to ensure compliance with applicable California law.

Finally, another form of California nonprofit corporation—the mutual benefit corporation—may better accommodate the MSSP ACO structure and requirements. For mutual benefit corporations that do not hold assets in charitable trust, the concern regarding the gift of charitable assets would not apply. While mutual benefit corporations also are subject to a limitation on distributions to members, that limitation does not apply to distributions upon dissolution. Further, the 49% limitation on interested persons serving on the board of directors does not apply.

In light of the above, California policymakers and providers should consider whether the MSSP’s strict governance requirements will effectively require a significant number of federal ACOs to form special purpose vehicles to participate in the MSSP or Pioneer ACO programs—such would constitute a setback in the effort to redesign our health care delivery system and increase costs associated with federal ACO formation. ACOs are intended to be organized around providers and patients, meaning that a single set of care coordination and quality improvement procedures will guide the care of all patients, regardless of payer. If MSSP and Pioneer ACOs must form special purpose vehicles for each shared savings program into which they enter, then the benefits of uniform policies and procedures will vanish, taking with them the promise of savings from streamlined administration. State and federal policymakers should seek to harmonize governance requirements so that a single governance structure is sufficiently flexible to meet the requirements of Medicare, Medicaid, and commercial payers.
Like many states, California regulates health plans and risk-bearing provider organizations to ensure the financial stability of entities financially responsible for providing care to patients. HMOs and certain provider organizations are regulated through Knox-Keene and its accompanying regulations. Under Knox-Keene, as a practical matter, any entity that assumes global financial risk for the provision of health care must obtain a license from DMHC and comply with specific regulatory requirements. Entities falling under Knox-Keene must, among other things, meet certain financial requirements and disclose to DMHC details pertaining to the entity’s fiscal and administrative activities. Knox-Keene also provides several important beneficiary protections, including specific grievance and appeals procedures.

Knox-Keene’s robust requirements apply only to entities meeting the definition of a “health care service plan.” As outlined in the MSSP, ACOs would likely not meet this definition because they will not receive, provide, or arrange for care “in return for a prepaid or periodic charge,” such as a capitated payment. Recent statements and actions by the DMHC further support this view. For example, in recent meetings of the DMHC Financial Solvency Standards Board, officials have indicated that most, if not all, MSSP ACOs will likely be exempt from licensure since they will not bear financial risk.

Although Knox-Keene will not affect MSSP ACOs, policymakers and providers need to consider how Knox-Keene might affect Pioneer and commercial ACOs as they evolve to bear greater financial responsibility for providing care. Under the Pioneer ACO model, ACOs would enter into population-based prepayment arrangements with CMS through CMMI. These prepayments represent approximately half the expected value of services under the typical FFS arrangements that the ACO will provide to its patients during that year. CMS would then pay half the FFS rate for all claims submitted by ACO participants. At the end of each year, the ACO and CMS engage in a reconciliation process:

1. CMS calculates the full FFS value of all services provided by the ACO to its assigned beneficiaries.
2. CMS calculates the ACO’s shared savings or losses.
3. CMS adds the full FFS value with the total shared savings/losses to determine how much the ACO earned that year.

If the ACO received more in prepayments and partial FFS payments than it earned in full FFS payments plus shared savings/losses, the ACO pays CMS the difference. If it received less than it earned, then CMS pays the ACO the difference. Ultimately, each ACO will receive the equivalent of full FFS payments plus shared savings/losses. Population-based prepayments function, in effect, as a cash advance to the ACO to enable investments in care coordination. Pioneer ACO participants must also commit to entering into outcomes-based contracts with other purchasers such that the majority of their revenue is derived from similar prepayment arrangements.

In many respects, the Pioneer ACO prepayment arrangement resembles a cash advance, rather than an assumption of risk, such as under partial capitation. Therefore, it is unclear whether Knox-Keene would apply to Pioneer ACOs. Knox-Keene is broad enough to include any entity that “arranges for care” for beneficiaries “in return for a prepaid or periodic charge.” As such, population-based payment might be considered a prepaid charge to an entity that arranges care, since the ACO would receive...
the prepayment before providing care. Thus, Knox-Keene may apply.

DMHC will need to clarify whether Knox-Keene applies to Pioneer ACOs, and if so, whether Pioneer ACOs will be subject to the full complement of Knox-Keene requirements. Similar analyses should be undertaken by DMHC as emerging commercial ACOs construct new care delivery and risk-bearing arrangements.

As ACOs evolve to bear increasingly more financial risk for care, lawmakers need to consider the degree to which the state should monitor ACOs. This includes how best to ensure ACOs remain solvent while allowing sufficient flexibility for providers to enter into innovative arrangements to coordinate care and generate savings. DMHC officials have indicated the possibility of a restricted license program for ACOs that engage in global-risk contracting, so that these ACOs may avoid some of the requirements of Knox-Keene. The licensing process may include filing information with DMHC regarding the focus of operations to ensure financial solvency, and describing activities focused on improving quality and reducing health care costs. For now, MSSP ACOs will not trigger any additional oversight under Knox-Keene, and Pioneer ACOs may require some oversight, leaving open the question as to how DMHC will treat emerging commercial ACOs.

State Antikickback Law
California’s antikickback law is unlikely to be a significant barrier to forming federal ACOs in the state; however, providers and policymakers must consider how the antikickback law might affect them.

Under California law, offering or accepting consideration for the purposes of inducing referrals for health care is prohibited. The distribution of shared savings payments could be seen as consideration to induce referrals to federal ACO providers—impermissible kickbacks—or as compensation for services rendered in achieving ACO savings and quality goals—permissible compensation. How each ACO arranges to divide shared savings payments will likely affect whether shared savings payments are considered kickbacks or compensation.

To provide federal ACOs with some certainty, CMS proposes waiving the federal antikickback law with respect to shared savings payments. In other words, shared savings payments would not be considered remuneration for referrals. Because the Proposed Rule does not preempt state law, California’s antikickback provisions would still apply to all ACOs operating in the state. California could adopt a parallel waiver to the proposed federal waiver, thereby providing ACOs with certainty that shared savings payments would not be considered kickbacks. In the absence of a state waiver, ACOs would need to carefully consider how they would divide shared savings payments to ensure that they are considered compensation and not kickbacks.

Physician Ownership and Referral Act (PORA)
In addition to prohibiting kickbacks for referrals, California also prohibits self-referrals by physicians. Like California’s antikickback law, the law prohibiting self-referrals by physicians will likely not be a significant barrier to creating ACOs in California, but lawmakers and providers should consider its implications for ACOs.

California’s law against self-referral, also known as the Physician Ownership and Referral Act (PORA), like the federal Stark law, prohibits a physician from referring patients for certain services and goods to an entity in which the physician or the physician’s immediate family has a direct or indirect financial interest. Because other ACO participants will have...
a stronger incentive to control costs than providers outside the ACO, physicians will likely receive higher shared savings payments if they refer more services to other ACO participants. The combination of such referrals and shared savings payments to ACO physicians may implicate PORA. Importantly, PORA’s exceptions allow for payments to physicians in compensation for services at fair market value. It is unclear, however, whether this exception would apply to shared savings payments among ACO participants.

Intending to encourage ACOs to form, CMS proposes to waive the Stark law with respect to shared savings payments. Again, this narrow waiver applies only to shared savings payments and does not preempt state law. As with the antikickback law, California could adopt a waiver of PORA similar to the federal waiver to the Stark law. If California declines to waive PORA, each federal ACO will need to carefully consider how it structures its distribution of shared savings payments to ensure that it does not run afoul of PORA.

**Corporate Practice of Medicine**

California prohibits the corporate practice of medicine. This ban may influence how ACOs structure care coordination and quality initiatives; lawmakers may want to consider making clear that ACOs are granted broad authority to develop programs that advance care coordination, patient engagement, and quality initiatives.

Under California’s ban on the corporate practice of medicine, in general, entities that are not owned and controlled by health care providers may not direct health care providers in the provision of care. Because of the ban, ACOs, unless licensed as providers, will likely be unable to employ physicians and other health care professionals directly. Instead, ACOs will have to enter into other arrangements with participating providers. Conceivably, the prohibition could prevent some ACOs from hiring physicians to work directly with provider participants in managing and better coordinating the provision of health services.

Under the ban, lay entities may not interfere with a provider’s judgment in caring for a patient. Specifically, corporations may not determine appropriate diagnostic tests for a particular condition, determine the need for referrals, decide among treatment options, or determine how many patients a physician must see. If an ACO’s care coordination or quality guidelines were to be considered “directing” the provision of care, the ban might be implicated.

**Antitrust**

Recognizing that federal antitrust laws could create a substantial barrier to ACO formation, DOJ and FTC issued guidance to accompany the MSSP Proposed Rule. Although California also has an antitrust law, the scope of the California law is more limited than the scope of federal antitrust law. As a result, California antitrust law may prove to be less of an issue for ACO formation than federal antitrust law.

California’s antitrust law, the Cartwright Act, prohibits agreements that restrain competition—similar to Section 1 of the federal Sherman Act. A provision of the Cartwright Act effectively exempts from state antitrust law many internal decisions of provider networks, including in some instances contractual exclusivity with health plans. In other words, many agreements between plans and providers will be exempt from California’s antitrust law.

The DOJ and FTC Joint Policy Statement establishes that federal ACOs that meet CMS standards will be deemed to be clinically integrated for antitrust purposes, allowing them to engage in joint pricing without confronting price-fixing
prohibitions. By establishing this bright-line test, the federal government eliminates much of the uncertainty that might have otherwise discouraged some providers from forming federal ACOs. Because California’s statutory exemption from the Cartwright Act creates a presumption that provider networks create a new product and are therefore inherently integrated, California law effectively creates the same type of presumption that the DOJ/FTC guidance is intended to create at the federal level.

**Data Sharing, Privacy, and Security**

Since sharing real-time health information is critically important to a federal ACO’s success, ACOs must have a clear, legally sanctioned method for sharing data easily among ACO participants and with other providers. California has a number of laws that restrict health information sharing, either by specific types or under specific circumstances. The Confidentiality of Medical Information Act (CMIA) applies to Knox-Keene plans and their contractors and prohibits disclosure of a patient’s medical information except as authorized by a patient or in certain other circumstances. Other state laws restrict sharing other types of personal health information without patient consent — for example, sharing HIV and behavioral health information and information related to sexually transmitted infections. Finally, California’s Constitutional Right to Privacy is sufficiently broad that court interpretations related to health care privacy have been varied and ambiguous.

In meeting CMS requirements to share health information within and outside the ACO, ACOs will need to carefully consider how the CMIA and other California privacy protections interact with the requirements of both the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and CMS data sharing requirements. Given the high degree of coordination and information sharing required under the MSSP Proposed Rule, more transparent guidelines are needed in California to govern how, under what circumstances, and to what end personal health information is exchanged, and how patients will be meaningfully engaged and informed of their choices. ACOs may need to seek guidance from California lawmakers on how to reconcile federal and state privacy law for data sharing within and outside an ACO.
VII. Policy Considerations that May Influence ACO Development in California

While CMS and other federal agencies will determine how ACOs function in the Medicare program, state policymakers will also have an important role to play in the outcome of the ACO experiment. Many health care providers are likely to refrain from forming ACOs if Medicare is the only payer willing to enter into alternative reimbursement arrangements with such entities. Indeed, in the short term, many organizations are looking to test ACOs in the commercial insurance market before participating in the MSSP or Pioneer program. In the long term, providers will hope to spread ACO startup and ongoing costs over their entire patient base, leveraging incentive compensation from Medicare, Medicaid, and commercial insurers to cover such costs. As a result, the success of ACOs in California will likely be linked to the state’s ability to create a market and regulatory environment conducive to ACOs.

As California policymakers consider these important legal and regulatory issues, they will be faced with a number of additional critical issues that may inhibit the formation and growth of ACOs.

ACOs and Medi-Cal

Under federal health reform and the state’s 1115 “Bridge to Reform” waiver, Medi-Cal is projected to grow by 1.8 million members. This would bring total enrollment to 9 million residents, almost a quarter of California’s population. As Medi-Cal expands, further straining California’s tight budget, policymakers are considering using ACO demonstrations to care for some of the more costly populations. The degree to which Medi-Cal embraces the ACO model will likely affect overall ACO growth in California.

Under the state’s $10 billion waiver, Medi-Cal is authorized to test four health care delivery models to provide care to children with special health care needs within the California Children’s Services program— one such proposed model is a provider-based ACO for children. These targeted ACO demonstrations will be critical to controlling Medi-Cal costs, where total spending has nearly doubled in the past decade. Although enrollment increases have accounted for much of the increased spending, adults and children with disabilities account for the highest growth rate increases.31 Medi-Cal will need to consider if an ACO model can be tested under its FFS and managed care arrangements.

Medi-Cal has contracts for managed care with over 20 health plans serving over 3.8 million of its beneficiaries, and plans to move more of its 3.4 million FFS members and newly enrolled beneficiaries into managed care. The managed care arrangements are of three types: County Operated Health Systems, two-plan counties that include both local initiatives and larger national plans, and geographic managed care. Most of the first two types are small, local organizations; only three have over 200,000 Medi-Cal beneficiaries.

Supporting an MSSP or Pioneer ACO on the carrier side requires both administrative and actuarial activities, including regularly sending comprehensive claims data to participants, receiving and publishing quality measures, and calculating baseline costs and incurred savings, among others. Many Medi-Cal managed care plans may find such requirements challenging to meet. If the requirements are overly burdensome, Medi-Cal may
need to consider designing an alternative structure to the one contemplated in the MSSP and Pioneer programs. If the state proposes an alternative, Medi-Cal ACO participants who seek to engage in ACO arrangements beyond Medi-Cal may encounter the complexities of multiple models with divergent, and potentially contrary, requirements. The outcome would be an increased administrative burden, multiple care coordination processes and systems, quality improvement procedures, and reporting requirements. Such duplication is likely to result in a reduction in promised savings. Further, if a special purpose Medi-Cal ACO deviates from the federal ACO definition, then protections (e.g., federal antitrust, Stark, gainsharing, and other waivers) will not apply to these Medi-Cal ACO derivatives, increasing the risk for participants entering into new arrangements.

Medi-Cal may opt to await the outcome of the federal rulemaking process, perhaps even waiting for the development of expected pediatric ACOs, and work closely with its managed care and provider partners, to determine if they will be capable of adopting federal ACO requirements for their own pilots.

**Health IT Infrastructure Supporting ACOs**

How California designs its health IT infrastructure will also affect the growth of ACOs. Federal ACO health IT requirements in many respects exceed those of the federal Meaningful Use Program, requiring extensive use of certified EHRs, care management, patient engagement and decision-support tools, and HIE. Given that federal ACOs are prohibited from restricting where patients choose to get care, the need for information flow within and outside the ACOs to control costs and manage populations will be a critical success factor for ACOs and for the MSSP overall.

California has embarked on an HIE strategy that could support ACO information exchange needs. Cal eConnect, the California HIE Governance Entity, was designed to broker information sharing agreements across California health care institutions and local exchanges, and to provide basic infrastructure to support secure clinical data sharing. While Cal eConnect is still in an early stage of development, significant federal grant dollars have been set aside to support its evolution—an evolution which could enable ACOs to better coordinate care. Cal eConnect and local HIE development will be important enablers to ACOs, both reducing the costs of building the infrastructure necessary to support the flow of information and ensuring that information follows the patient across institutional settings.

Significantly, the MSSP Proposed Rule and Pioneer ACOs recognize the importance of health information exchange while at the same time promoting both access to and the portability of Medicare information to support the provision of high-quality, cost-effective care. In the Proposed Rule, for example, CMS explicitly agrees to share patient-identifiable information with ACOs and proposes to terminate an ACO’s agreement if it finds that the ACO (or its participants, providers, or suppliers) restricts internally compiled beneficiary summary of care or medical records from providers and suppliers either within or outside the ACO. Further, while CMS proposes to share Medicare claims and other data with ACOs, it recognizes that such data may not be as useful for care coordination purposes as real-time information about the clinical care its patients are receiving from other health care providers. According to CMS, real-time information may be more readily available through development and use of interoperable EHRs and participation in HIEs like Cal eConnect.
Health Benefit Exchanges and ACOs

Policies surrounding California’s HBEs could contribute to the success of all ACOs in the state. Over 2.5 million Californians may purchase their health insurance through an HBE, either through their respective employers or as individuals. Under the ACA, only qualified health plans (QHPs) may participate in state HBEs. The ACA defines a QHP as “a health insurance issuer that is licensed in good standing to offer health insurance coverage in each state in which such issuer offers health insurance coverage.” Accordingly, an ACO may not be offered as a coverage option in an HBE. An ACO, however, may contract with a QHP and potentially co-brand a product with it. In addition, the ACA requires the Secretary of Health and Human Services to develop guidelines for the use of payment structures to improve health care outcomes, thereby setting the stage for states to qualify health plans based on their use of innovative payment methodologies and integrated delivery models.

On the one hand, a California HBE could leverage its consumer base to require health plans to adopt payment and delivery reforms and, specifically, to support integrated delivery models, including ACOs. In fact, the ACA encourages states to leverage broader health reform priorities through HBEs. On the other hand, recent experiences in California running private insurance exchanges may result in the state’s HBEs being more conservative than their counterparts in other states. The Health Insurance Plan of California/PacAdvantage was created in 1992 as part of a statewide initiative to make health insurance more affordable to small businesses. It closed in 2006, in large part because adverse risk selection affected the exchange pool, and insurers were losing money. This experience underscores that California policymakers must balance interests in testing complex programs that are designed to reduce cost increases and improve quality with its interests in attracting enough health plans to participate in the exchange and maintain its viability.
VIII. Conclusions

The MSSP and Pioneer ACO programs represent an unprecedented opportunity for providers, purchasers, and the federal government to improve care coordination and patient outcomes while testing new reimbursement models and sharing in savings. The program’s success is implicitly (in the case of the MSSP) and explicitly (in the case of Pioneer) dependent on whether the private market and state Medicaid agencies adopt similar models. The administrative cost associated with establishing federal ACO programs has been described as extensive, leading CMS to consider funding some of those costs up front. Providers will likely refrain from forming ACOs en masse if the costs of creating and operating these entities cannot be allocated across multiple payers. Similarly, if commercial ACOs do not adopt federal ACO requirements, federal regulatory waivers would not necessarily apply, thereby increasing risk.

California will need to consider how to regulate ACOs in their various forms. While MSSP ACOs appear to be non-risk-bearing under state rules and as such likely won’t need to be licensed, Pioneer ACOs will take on prepayments, perhaps triggering Knox-Keene or other regulatory requirements. Commercial ACOs have only recently declared themselves; whether they assume risk and the degree to which those risk arrangements vary from current managed care arrangements will require DMHC to consider how and whether to regulate these entities as new RBOs. And corporate practice of medicine provisions will need to be considered, as ACO care coordination and quality guidelines could be considered directing the provision of care, implicating the ban on corporate practice. Finally, given the proliferation of ACOs in all of their forms, the opportunity for confusion among both providers and beneficiaries, whether intended or otherwise, is genuine, raising the issue of whether consumer protections are needed to ensure that beneficiaries remain well informed of their choices.

Ultimately, for ACOs to be truly successful will require alignment of various related and complementary programs. Robust health information exchange requirements will necessitate that ACO participants consider how they share information using regional, statewide, and private HIE infrastructure, raising policy questions (Is informed consent required?) and financial questions (Who pays for HIE?). The HBE could direct millions of Californians toward innovative ACO networks, as purchasers in the exchange will be pressured to keep costs down, but only if ACOs have relationships with the carriers participating in the exchange. And finally, Medi-Cal will continue to grow, in both its covered lives and its influence in the market. Medi-Cal’s ability to implement an ACO program could drive a significant portion of the market toward shared savings models.

The federal ACO program has the triple aim of improving care for individuals, improving the health status of populations, and reducing costs. For this vision to be realized, federal and state regulation, and a variety of public and private programs, must align to create the necessary environment to support providers as they reorganize and are rewarded for how they deliver care and improve outcomes.
Endnotes


2. Ibid.


11. Both appear to be true for the commercial ACO pilots described above, as their requirements and populations served are very different from those articulated in the MSSP or Pioneer ACO models. The Accountable Care Network intentionally did not call itself an ACO, in order to minimize confusion or imply that it was necessarily participating in the federal ACO programs.


15. “Interested persons” generally includes persons currently being compensated by the corporation for services rendered to it and the relatives of those persons (an exception is made for payments received solely as a director).


17. The Knox-Keene definition of “health care service plan,” which is a touchstone for regulation under Knox-Keene, actually sweeps into its ambit any person who undertakes to arrange for care for enrollees, or pay for or reimburse for care “in return for a prepaid or periodic charge.”


22. The term “California antikickback law” is a misnomer, since there are actually two statutes prohibiting kickbacks for referrals. California Business and Professionals Code § 650 applies to all licensed health care providers, such as physicians. Referrals between entities other than licensed health care professionals would not be subject to this provision. California Health and Safety Code § 445, however, applies more broadly to referrals by any person or entity to a health-related facility and prohibits any referrals for profit: “No person, firm, partnership,
association or corporation, or agent or employee thereof, shall for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition. The imposition of a fee or charge for any such referral or recommendation creates a presumption that the referral or recommendation is for profit.” Additional antikickback statutes apply with respect to referral fees for care covered by insurance, California Insurance Code § 754, and by Medi-Cal, California Welfare and Institutions § 14107.2.


25. A potentially important exception to this rule is that licensed Knox-Keene plans are permitted to hire physicians directly. California Health and Safety Code § 1395(b): “Plans licensed under this chapter shall not be deemed to be engaged in the practice of a profession, and may employ, or contract with, any professional licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code to deliver professional services.”


27. For example, Marin County Board of Realtors, Inc. v. Palsson (1976) 130 California Reporter. 1, 16 Cal.3d 920.


30. California Civil Code §§ 56 et seq.


