



ADVANCING NATIONAL HEALTH REFORM

*A policy series from the Warren Institute's Health, Economic & Family Security Program
and the UC Berkeley School of Public Health*

POLICY BRIEF
December 2011

Breaking Down Barriers to Creating Safety-Net Accountable Care Organizations: *State Statutory and Regulatory Issues*

Matthew Chayt
Legal Fellow
UC Berkeley School of Law

Ann Marie Marciarille
Visiting Assistant Professor
University of California, Hastings College of the Law
Senior Research Fellow
UC Berkeley School of Law

Noah Metz
Research Assistant

Anita Pandhoh
Research Assistant

David Vernon
Research Assistant

BerkeleyLaw
UNIVERSITY OF CALIFORNIA

Chief Justice Earl Warren
Institute on Law and
Social Policy

This brief was funded by a grant from
Blue Shield of California Foundation

EXECUTIVE SUMMARY

In the state of California, a transformation in health care delivery is about to begin. The implementation of a newly energized delivery and finance model, the accountable care organization (ACO), aims to improve health outcomes while reducing the cost of care. By giving health care providers financial incentives to achieve these two goals, the ACO model has the potential to be a major step forward in making providers accountable for the quality of the care they provide to their patients.

This brief illuminates and recommends action on some of the challenges that will confront policymakers as ACOs begin their imminent rollout. This brief focuses on California not only because it is our state, but also because California's exceptional qualities, such as diversity and size, often prompt the creation of innovative solutions to problems that most states will eventually confront.

Health care in the United States is a three trillion dollar industry. The industry is highly regulated not only by the federal government, but also by state governments, and sometimes by both together. Therefore, the impending transformation in health care will occur simultaneously in at least two directions. The Affordable Care Act is spurring enormous change at the federal level that will move from the top down, while also influencing private sector initiatives.¹

But the change in health care will also come from the bottom up, as local governments and local health providers seize the moment to finally control hemorrhaging costs by adopting a whole-patient approach to their work. This brief discusses ways that states, counties, and local communities may be stymied in accountable care efforts by legal, regulatory and other barriers—and how states can take the lead in addressing these barriers.

This paper makes policy recommendations about the steps that lawmakers should take to prime California's health care system to embrace safety-net ACOs. It concludes with brief examinations of ACO formation strategies that have been implemented successfully in other states.

We offer the following recommendations to policymakers:

- **State regulators should ease capitalization requirements for safety-net providers.** If California's existing capitalization rules are applied to safety-net providers without accounting for these providers' unique roles, it is highly unlikely that any safety-net providers will be able to become ACOs. State policymakers should examine how to balance the need for consumer protection with the real need for innovative health care delivery in the safety net.

¹ The first policy brief in this series outlined how safety net accountable organizations fit into these sweeping changes. See "Breaking Down Barriers to Creating Safety-Net Accountable Care Organizations: Federal Statutory and Regulatory Issues," August 2011, UC Berkeley Law School.

- **State legislators should clarify how California’s existing medical liability rules will apply to ACOs, and particularly to safety-net ACOs.** Because liability for medical malpractice is such a major concern for providers of all sizes, providers need regulatory certainty before experimenting with structuring themselves as ACOs.
- **State legislators and regulators should promote scope of practice rules that acknowledge the crucial role played by independently licensed providers, such as nurse practitioners.** A variety of health professionals have a role to play in ensuring that accountable care works.
- **Repeal the corporate practice of medicine doctrine. If complete repeal is not feasible, safety-net ACOs should be exempted from the doctrine.** In order for ACOs to fulfill their mandate of better coordinating care while simultaneously saving the health care system money, they must have maximum autonomy to structure their relationships with physicians. This is particularly true in the safety net, where workarounds like the medical foundation are not practical.

Some states have already made notable achievements toward new health care paradigms, and we describe them here. As California moves forward with regulation of ACOs, we should consider these efforts, and bear in mind the special needs of safety-net ACOs. Better patient outcomes are indeed compatible with reduced health care costs, but to realize these benefits, states must work proactively in concert with national health care reform—and they must do so promptly. The first ACO agreements in the Medicare Shared Savings Program will begin April 1, 2012.ⁱⁱ

ⁱⁱ *Proposed Rule versus Final Rule for Accountable Care Organizations (ACOs) In the Medicare Shared Savings Program*, Centers for Medicare & Medicaid Services (2011), <http://www.cms.gov/aco/downloads/Appendix-ACO-Table.pdf>.

Breaking Down Barriers to Creating Safety-Net Accountable Care Organizations: State Statutory and Regulatory Issues

INTRODUCTION

The purpose of this brief is to show how outmoded statutory and regulatory frameworks in California and the other 49 states need to be rethought to accommodate new models of health care delivery and finance. Specifically, this paper discusses the benefits—and challenges—for California’s development of accountable care organizations (ACOs) in the health care safety net. For the purpose of this paper, an ACO is defined an organization of health care providers that agrees to become, or is committed to becoming, accountable for the quality, cost and overall care of a group of patients such that the ACO 1) can provide or manage the continuum of care for patients as a real or virtually integrated delivery system, 2) is of sufficient size to support comprehensive performance measurement and expenditure projections, and 3) is capable of designing a provider-payer contract that supports prospective budget planning and internal distribution of shared savings.

The newly released final regulations for the Medicare Shared Savings Program, far from merely embracing a single Medicare program, will have far-reaching effects on all types of ACOs. This is because Medicare experimentation is often the bellwether for Medicaid³ and commercial insurance experimentation.⁴ Indeed, the MSSP proposed regulations specifically contemplated that much of what is eventually promulgated for Medicare ACOs may hold true for Medicaid ACOs as well as ACOs in the commercial insurance arena.⁵ For this reason alone, safety-net providers interested in safety-net ACO participation need to focus on the MSSP program and CMS in turn needs to focus on the implications of the MSSP program for safety-net providers.

The Case of California

California is not only the most populous state, but its residents are highly diverse—recent Census statistics indicate California has the largest proportion of nonwhite residents of any state.⁶ Furthermore, these diverse communities are disproportionately represented in

³ Medi-Cal is California’s version of Medicaid.

⁴ See Frequently Asked Questions, ACO Resource Center, available at <http://thecamdengroup.com/aco-resource-center-faqs.php>.

⁵ Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19,527, 19,592 (proposed Apr. 7, 2011) (to be codified at 42 C.F.R. pt. 425) (“we also anticipate the ACO quality measures will evolve over time in an effort to achieve our quality program alignment goal of developing a single quality measure set that could be used by ACOs operating across a wide variety of payers, including those dealing with Medicaid, the Children’s Health Insurance Program (CHIP), and Special Needs Plans”).

⁶ See *State & County QuickFacts: California*, U.S. CENSUS BUREAU, <http://quickfacts.census.gov/qfd/states/>

low-income brackets: African Americans, Latinos, Native Americans and Alaska Natives in the state are more than two times as likely as whites to have an income below poverty level.⁷ The next generation of Californians will be even more diverse, with roughly 73 percent of California's babies born to nonwhite families.⁸

The state's size and complexity are not the only reasons the rest of America should watch and learn from California's successes and mistakes. California has also been at the forefront of the implementation of the Patient Protection and Affordable Care Act (PPACA, or simply the Affordable Care Act), having become the first state to create a health insurance exchange for its residents to purchase health coverage.⁹ As the state moves forward with health reform implementation, policymakers can apply California's solutions to their own states while also observing how California manages (successfully or otherwise) the challenges created by structural health system reform.

The Health Care Safety Net: A Brief Snapshot

The health care safety net has no standardized definition, a legacy of its lack of formal structure.¹⁰ We prefer a broad definition that embraces all the ways that underserved Americans receive care. "Generally, though, the safety net includes public hospitals and health systems, health care districts, community health centers and clinics, and for-profit and nonprofit health care organizations that provide free or discounted care."¹¹ The safety net traditionally serves low-income populations. However, the population served by the safety net is increasingly middle-class; about 1 in 3, or 32 percent, of middle-income adults aged 18-64 years went without health insurance during some part of 2009.¹² Thus, the safety net is greatly needed, but its patchwork of providers is fragile. Nationally, the shortage of readily available health care resources, especially in rural states, is so severe that in 2007, 60 percent of federally designated medical shortage areas in the Midwest, 40 percent in the South, 37 percent in the Northeast, and 31 percent in the West did not have a health center.¹³

In California, as of 2007, 27 percent of the population was in or apparently eligible for the safety net as determined by earning below 300 percent of the federal poverty level (as

06000.html (last updated June 3, 2011) (indicating that only 40.1 percent of California's residents are "White persons not Hispanic").

⁷ See Kaiser Family Found., *California: Poverty Rate by Race/Ethnicity*, STATEHEALTHFACTS.ORG, <http://www.statehealthfacts.org/profileind.jsp?rgn=6&ind=14&cat=1> (last visited September 30, 2011) (noting that 12 percent of whites, 29 percent of African American, and 32 percent of Hispanics in California live in poverty).

⁸ Lucile Packard Found. for Children's Health, *Births, By Race/Ethnicity: 2007*, KIDSDATA.ORG, <http://www.kidsdata.org/data/topic/table/births-race.aspx> (last visited September 30, 2011).

⁹ Anna Wilde Mathews, *Health Insurance Market Moves Ahead in California*, WALL ST. J., Aug. 26, 2010, <http://online.wsj.com/article/SB10001424052748704540904575452020633405364.html>.

¹⁰ Elizabeth C. Saviano, *California's Safety-Net Clinics: A Primer*, CAL. HEALTHCARE FOUND., 2 (Mar. 2009), <http://www.chcf.org/resources/download.aspx?id=%7bA321B9E0-763B-4F33-A81E-64D8BF6E86E9%7d>.

¹¹ *Id.*

¹² *Health Care: See Why Being Insured Matters*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/features/vitalsigns/HealthcareAccess/> (last updated Nov. 8, 2010).

¹³ Irwin Redlener & Roy Grant, *America's Safety Net and Health Care Reform—What Lies Ahead?*, 361 NEW ENG. J. MED. 2201, 2202 (2009), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp0910597>.

of 2011, \$67,050 for a family of four) and being uninsured or enrolled in Medi-Cal, or another program, such as Healthy Families.¹⁴ Of this subset of Californians, one in five is uninsured.¹⁵ Latina/os make up the largest proportion of the safety-net population at 46 percent, while whites are next at 20 percent.¹⁶

Government-funded insurance plays a crucial role in caring for safety net populations, and new research demonstrates that the state-run, federally-funded Medicaid program is effective at improving outcomes for its enrollees.¹⁷ In California, city and county hospitals receive 70 percent of their net patient revenue from Medi-Cal and county indigent programs, with the bulk of this revenue coming from Medi-Cal.¹⁸

Nevertheless, the safety net is more than government funded insurance programs. For instance, numerous small private providers accept sliding scale reimbursement from the uninsured or under-insured and accept Medicare or (significantly lower) Medicaid reimbursement for others. And throughout the country, providers frequently supply care that is wholly uncompensated or discharged as bad debt.¹⁹ Thus, practitioners and policymakers should consider the safety net from a patient-centric perspective and examine the numerous avenues to health care that exist in America. Due to the unique characteristics of both its providers and patients, **the safety net presents a significant opportunity and challenge to reaping ACO-generated savings and improved health outcomes.**

California Regulation of ACOs

This section briefly describes the state regulatory environment awaiting newly formed ACOs in California. In its Proposed Rule for the Medicare Shared Savings Program (MSSP), CMS noted they did not intend for the MSSP to render states responsible for bearing any costs resulting from its operation. But they acknowledged that “some States may regulate risk bearing entities.”²⁰ Indeed, traditionally, the states have been the regulators of health insurance.²¹ And many states, including California, do regulate risk-bearing entities.

¹⁴ Trisha McMahon & Matthew Newman, *California’s Health Care Safety Net: Facts and Figures*, CAL. HEALTHCARE FOUND., 9 (Oct. 2010), <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/C/PDF%20CAHealthCareSafetyNetFactsFigures.pdf>. In California, Healthy Families is the name the state uses to refer to its State Children’s Health Insurance Program, which covers children who otherwise do not qualify for Medi-Cal coverage. In 2014, Medicaid will expand to offer access to all adults with incomes up to 133 percent of the federal poverty line.

¹⁵ *Id.* at 10.

¹⁶ *Id.* at 14.

¹⁷ Amy Finkelstein et al., *The Oregon Health Insurance Experiment: Evidence from the First Year*, NAT’L BUREAU OF ECON. RESEARCH (Jul. 2011), <http://www.nber.org/papers/w17190.pdf>.

¹⁸ McMahon & Newman, *supra* note 14, at 20.

¹⁹ Jonathan Gruber & David Rodriguez, *How Much Uncompensated Care Do Doctors Provide?* 1 (Nat’l Bureau of Econ. Research, Working Paper No. 13585, 2007), available at <http://www.nber.org/papers/w13585.pdf>.

²⁰ Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center, 76 Fed Reg. at 19,624.

²¹ Mila Kofman & Karen Pollitz, *Health Insurance Regulation by States and the Federal Government: A Review of Current Approaches and Proposals for Change*, GEORGETOWN UNIV. HEALTH POLICY INST., 1 (Apr. 2006), <http://www.allhealth.org/briefingmaterials/HealthInsuranceReportKofmanandPollitz-95.pdf>.

A risk-bearing entity is an organization that takes on financial responsibility for providing a set list of benefits and in exchange receives prepayment for a portion or all of the cost of care. Any organization may be a risk-bearing entity, such as a payor, a plan, or an employer that self-insures. Health providers and provider organizations (such as IPAs) could also be risk-bearing entities if they receive global payments.²²

In California, the State’s Department of Managed Health Care (DMHC) will be the primary agency overseeing the implementation of ACOs. The agency’s primary oversight goals for ACOs are to provide an incentive to organize a fragmented delivery system to provide better access, quality and affordability, create a regulatory framework for ACO financial solvency, and protect consumers and collaborating providers against ACO insolvencies.²³

The regulation of risk-bearing organizations in California can be traced to the requirements of S.B. 260—put into place to establish standards that would identify and prevent provider group insolvency in California. S.B. 260 requirements are a collection of bills from 1999²⁴, 2000²⁵ and 2009.²⁶ These requirements define a “risk-bearing organization” (RBO) in contrast to a “health care provider” and a “health care service plan.” S.B. 260 imposes significant disclosure requirements on health plans and RBOs and requires that if the entity fails to meet certain criteria, the organization must submit a corrective action plan (CAP) to rectify the situation. An RBO must receive capitation or fixed periodic payments.

By contrast, a “health plan” is “any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, 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.”²⁷

An RBO, which does not trigger the licensing requirements of the Knox-Keene Act, receives compensation on a capitated basis, assumes financial risk and payment of claims for physician services (outpatient care), and other delegated functions. RBOs are, however, subject to S.B. 260 financial solvency requirements. They are monitored by the Financial Solvency Standards Board (FSSB), which scrutinizes RBOs as to maintenance of positive working capital, tangible net equity, incurred but not reported (IBNR) claims, and the

²² A “global payment” for health care is determined by the number of persons covered for defined services over a set period of time, rather than the amount or cost of services actually provided.

²³ Bill Barcellona, Vice President, Cal. Ass’n of Physician Grps., State Oversight of ACOs at California Department of Managed Health Care Financial Solvency Standards Board Meeting 2 (May 19, 2011), *address outline available at* <http://www.hmohelp.ca.gov/library/reports/news/fssbcapg.pdf>.

²⁴ Act of Sep. 27, 1999, ch. 529, 1999 Cal. Stat. 3669 (codified as amended at CAL. HEALTH & SAFETY CODE §§ 1347.15, 1349.3, 1375.4-6 (2006)).

²⁵ Act of Sep. 30, 2000, ch. 1067, 2000 Cal. Stat. 8189 (codified as amended in scattered sections of CAL. CIV. CODE, CAL. HEALTH & SAFETY CODE, CAL. INS. CODE, and CAL. WELF. & INST. CODE).

²⁶ Act of Oct. 11, 2009, ch. 298, 2009 Cal. Stat. 1548 (codified in scattered sections of CAL. GOV’T CODE, CAL. HEALTH & SAFETY CODE, and CAL. WELF. & INST. CODE).

²⁷ CAL. HEALTH & SAFETY CODE § 1345(f) (West, Westlaw through ch. 312 of 2011-12 Reg. Sess. and ch. 11 of 2011-12 1st Extraordinary Sess.).

promptness with which RBOs resolve claims.²⁸ Importantly, key to S.B. 260's definition of an RBO is that no entity can be both an RBO and a health plan – but the ACO model blurs this distinction.

How Will California's Classification of ACOs Impact Their Success?

In a recent report on ACO implementation, the DMHC considered the issue of whether ACOs are considered health plans or RBOs, both of which are subject to DMHC jurisdiction and administration.²⁹ The classification matters because only “health plans” trigger the licensing requirements of the Knox-Keene Act. The DMHC concluded that the MSSP, built upon the Medicare fee-for-service (FFS) payment system, does not trigger the Knox-Keene Act.

Compensation to providers in the Medicare Shared Savings Program is based on the original Medicare fee-for-service schedule, and not on capitation or another form of prepaid or periodic payment. The California DMHC has taken the position that ACOs under the MSSP are “health plans” not subject to their licensure requirements due to the fact providers are still paid on an FFS basis.³⁰ ACO payment systems may yet evolve, however, as may the California DMHC's thinking and analysis. For example, as a result of a future move from fee-for-service to capitation, ACOs could arguably shift from plan to RBO status. This fluidity is probably not what was intended by S.B. 260. Recognizing this, the DMHC is currently offering ACOs a six-month “fast-track” restricted health plan license, acknowledging that ACOs, as currently configured, are not truly health plans. While this stop-gap solution may be sufficient for the expected initial trickle of ACOs, when ACOs proliferate, the fast track may be overwhelmed.

RECOMMENDATIONS FOR RESPONDING TO POTENTIAL CHALLENGES

Recommendation 1

Re-Examine Capitalization Requirements with Implications for ACOs

S.B. 260 requires disclosures by health plans to the other parties to their risk arrangements, and to the California Department of Managed Health Care (DMHC) themselves. In the event the information disclosed reveals a problem, the disclosing organization must formulate a CAP with the counterparties and the DMHC to rectify the situation. Both the DMHC and all counterparties must vet the CAP.³¹ All RBOs, regardless of size, must prepare an equally thorough—and publicly available—annual report for the DMHC with financial data on solvency, and percentage of claims timely reimbursed, contested or denied (if that number is below 95 percent, an explanation is required as to how the problem will be corrected).

²⁸ See 28 CAL. CODE REGS. tit. 28, § 1300.75.1 (West, Westlaw through Sept. 26, 2011).

²⁹ See CAL. DEP'T OF MANAGED HEALTH CARE, ACCOUNTABLE CARE ORGANIZATIONS: OVERSIGHT IMPLEMENTATION 8 (2010), available at <http://www.hmohelp.ca.gov/library/reports/news/fssbacooi.pdf>.

³⁰ See *id.*

³¹ See 28 CAL. CODE REGS. tit. 28, § 1300.75.4.8 (West, Westlaw through Sept. 26, 2011).

But equally or more important for safety-net ACOs, S.B. 260 also has capitalization and related requirements for entities under its purview. RBOs must keep a minimum amount of cash on hand (cash-to-claims ratio of 0.75) and maintain sufficient tangible net equity (TNE). Health plans must make an insolvency deposit equal to 120 percent of all claims not yet processed, denied or approved but not yet paid within 45 days.³² Additionally, health plans must maintain TNE in excess of \$1 million, depending on the annualized premium revenues.³³

If a health plan becomes insolvent, patients could be denied access to health services, and/or providers could have nowhere to turn for payment for services rendered. Safety-net providers and safety-net patients are not entirely immune from these concerns. The profit structure of health care finance in the safety net is modest, however, and state policymakers should be able to strike a balance between consumer protection and addressing the need for improved health care delivery in the safety net. These capitalization requirements could be modified to recognize the particular contribution of safety net providers or a government sponsored loan program could be structured to help free the flow of capital for safety-net providers with low capitalization.

California Regulatory Landscape: Policy Solutions

In the future, it may be necessary to revise the law as to what defines an RBO and what defines a health plan, as ACOs may blur that line. Further, while it is necessary to protect beneficiaries and providers from organizations that take on unnecessary risk for themselves or their counterparties, the exact protections envisioned in 1999 when S.B. 260 was written may need rethinking.³⁴ While ACOs have similarities to the HMOs that S.B. 260 is meant to regulate, they bring important differences that cannot be ignored indefinitely.

The potential harm from regulating ACOs like HMOs is multi-faceted. But the key problem is that ACOs are a delivery system innovation with the potential to increase health care quality while reducing costs. If regulated in the same manner as a previously existing model (HMOs) that has faced serious backlash and has not ultimately delivered hoped-for savings, there is a danger that providers, patients and payors will opt for the status quo. If onerous capitalization requirements are not carefully set to allow safety-net ACOs to flourish, it may not be possible to test the ACO premise in the safety net.

California should move quickly to clarify the regulatory landscape for ACOs—particularly for safety-net providers for whom capitalization requirements will be a challenge or complete obstacle to ACO formation. But more than clarifying regulations, states should consider whether a “one size fits all” approach is appropriate given the uphill battle that safety-net ACOs face. In other words, safety-net ACOs may need dedicated regulations of their own that incentivize coordinated care in the safety net while still protecting patients and payors. Sacramento should study the issue and promulgate new regulations.

³² HEALTH & SAFETY § 1377.

³³ REGS. § 1300.76...

³⁴ S.B. 260 was revised as recently as 2009, which may indicate the Legislature, eager to encourage health care innovation, may jump on the opportunity to adapt an old framework to a new idea.

Recommendation 2

Tailor Medical Liability Rules to the Specific Needs of ACOs

Because the final ACO regulations do not insist on a uniform organizational structure for ACOs, many different forms of health care organizations might seek to participate in ACO formation. Physicians in group practices, independent practice associations, preferred provider organizations, clinics without walls and group and staff model HMOs may all participate. Further along the integration continuum, physician-hospital organizations, and foundation-model systems may also participate.³⁵ Safety-net entities such as Federally Qualified Health Centers, FQHC lookalikes, Rural Health Centers, and other community clinics may participate as well. And each of these entities might choose to collaborate with myriad different types of others in ACO formation. This is particularly true in safety-net ACO formation where capitalization concerns may challenge the capacity of safety-net entities to integrate care across venues without partnering with both nonprofit and commercial entities.

The permutations of possible safety-net ACO collaboration are many. This makes it challenging to discuss the liability implications of new organizational forms of integrated care systems, but a general discussion of California law on tort liability for integrated delivery systems illuminates some of the provider concerns with participating in new safety-net integrated care systems. In particular, the complexity of the questions surrounding tort liability and integrated care militate in favor of clearly defined provider relationships. It is these relationships on which liability often hinges.

The question of whether safety net-ACO participation alters existing liability standards for participating providers is an important one for three reasons. First, provider relationships are the linchpin of medical malpractice liability insurance. Second, theories of tort liability may have to adapt to the realities of ACO-driven standardization of care. Finally, the drive to cost containment, better outcomes, and improved patient experience as mutually consistent goals may require re-thinking theories of tort liability.

Provider Relationships Matter

Whatever form of business organization a safety-net ACO takes, it will be required to take a leadership role in collecting and analyzing health care quality data relevant to its provider staff across the four domains and 33 quality measures that are the hallmark of ACOs.³⁶ This kind of close supervision of provider utilization and outcome data will be new to some in the fee-for-service Medicare world. It may also be new to classic safety net entities such as FQHCs that only recently have begun to assemble some of the data required

³⁵ See Thomas L. Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust*, 79 CORNELL L. REV. 1507, 1517-19 (1994) (discussing this taxonomy of integrated health care systems).

³⁶ *Proposed Rule versus Final Rule for Accountable Care Organizations (ACOs) In the Medicare Shared Savings Program*, Centers for Medicare & Medicaid Services (2011), <http://www.cms.gov/aco/downloads/Appendix-ACO-Table.pdf>.

by the proposed regulations for the MSSP.³⁷ The MSSP proposed regulations contemplate that the utilization and effectiveness data collected will be population based but provider specific. Reviewers will be able to monitor the compliance of individual providers with the standardized treatment guidelines and protocols required to be internally generated at the safety net ACO.³⁸ Thus, tort liability issues are necessarily implicated when, as with ACOs, providers join each other in new forms of shared accountability relationships.

The MSSP is placed firmly within fee-for-service Medicare. Participating providers who are employees of safety-net clinics will likely continue to routinely receive their medical liability insurance through the clinic. Providers who are not or do not become employees of the safety-net ACO – community-based practitioners, for example – will remain independent providers while newly subject to an unprecedented metric of practice scrutiny for fee-for-service Medicare. Whether the allocation of liability for medical negligence may be altered by this level of practice scrutiny is an interesting question. The answer depends, in part, on whether accountable care will be treated as managed care under California law, for allocation of liability purposes.

Managed care provider liability in California is framed by ERISA, the federal Employee Retirement Income Security Act of 1974, and California’s Managed Care Liability Act (CMCLA).³⁹ ERISA preempts many types of enrollees lawsuits against managed care entities. CMCLA reclaims liability for managed care entities that fail to use care in arranging for provision of medically necessary services, resulting in denial, delay, or modification of recommended services. This statute also limits managed care medical negligence liability in certain ways, requiring a degree of severity of damage to the patient and requiring external review.⁴⁰ The California statute, in short, narrows individual medical negligence liability in comparison to general California tort law⁴¹ but weakens the preemptive sweep of ERISA. How this already complex interaction will affect accountable care organizations remains to be seen. Whether accountable care’s deliberate distancing from the managed care label extends to the application of CMCLA deserves clarification.⁴²

³⁷ Letter from Ann Marie Marciarille and Matt Chayt, UC Berkeley Warren Institute, to CMS and other Federal Agencies (May 26, 2011), *available at* http://www.law.berkeley.edu/files/chefs/MedicareMedicaidServices_ACO_Project_letter05.26.11.pdf.

³⁸ *See* Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. at 19,554 (“[O]ur data could be combined with provider level data compiled within the ACO. Combining aggregate and beneficiary identifiable data as well as provider level and other internally generated data would provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO . . .”).

³⁹ *See* CAL. CIV. CODE § 3428 (West, Westlaw through ch. 312 of 2011-12 Reg. Sess. and ch. 11 of 2011-12 1st Extraordinary Sess.).

⁴⁰ *Id.* § 3428(k)(1) (“A person may not maintain a cause of action pursuant to this section against any entity required to comply with any independent medical review system or independent review system required by law unless the person or his or her representative has exhausted the procedures provided by the applicable independent review system.”).

⁴¹ CMCLA is a product of an attempt to offer California’s citizens some managed care liability scope in light of ERISA preemption .

⁴² Underwriters themselves are confused. *See, e.g., Healthcare Market Update*, LOCKTON, INC., 2 (May 2011), www.locktonmarketupdate.com/Docs/Healthcare.pdf (questioning whether “ACOs will take on managed care-like exposures”).

As a practical matter, California’s managed care practitioners have many of the claims against them resolved through arbitration. Cases arguing that physician’s treatment decision have been inappropriately influenced by the physician payment plan have also achieved little success.⁴³ How ACO provider liability will dovetail with existing medical negligence liability law, as a result, depends on whether ACO providers will be considered managed care providers under the law. Legislative and regulatory clarification is essential.

Policy Solutions

Patients, providers, and nascent safety-net ACOs require clarity on provider liability constraints that may or may not accompany ACO participation. The State of California would serve all of these populations well by clarifying the applicability, if any, of California’s Managed Care Liability Act (MCLA) to safety-net ACO provider participants. If it is indeed applicable, then safety net ACOs will need assistance to understand changing standards of care.

Recommendation 3 **Promote Transparency in Physician Credentialing**

Physician Credentialing in a Safety Net ACO

Economic credentialing is the use of economic criteria unrelated to the quality of care delivered in determining a physician’s eligibility for hospital privileges.⁴⁴ Put simply, economic credentialing might entail a hospital conditioning staff privileges on a doctor providing a certain volume of services or referring a particular number of patients to the hospital. Incorporating a prediction of a physician’s likelihood to contribute to the financial health of a practice or health care entity is arguably a reductive way of assessing quality of practice, and has been controversial.⁴⁵

If safety-net ACOs, like other ACOs, thread the needle of achieving both better quality health care and cost savings, economic credentialing will not be implicated. If safety-net ACOs, however, focus exclusively on cost savings as the *sine qua non* of successful operation, safety-net providers may turn to economic credentialing. The scarcity of safety-net providers may have insulated those physicians willing to accept Medicare and, particularly, Medi-Cal reimbursement from some of the economic credentialing requirements that exist among those who serve the commercially insured. Increased

⁴³ See, e.g., *Pulvers v. Kaiser Found. Health Plan*, 160 Cal. Rptr. 392, 394 (Ct. App. 1979) (holding that HMO incentive plans are not contrary to public policy).

⁴⁴ Ann Bittinger, Remarks at the American Health Lawyers Association Annual Meeting and In-House Counsel Program: Quality Measures Continue to Matter for Physicians in the Accountable Care Organization Era 4 (June 28, 2011), available at <http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM11/bittinger.pdf>.

⁴⁵ See, e.g., *Medical Staff Topics: Economic Credentialing – Issues and Answers*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/medical-staff-topics/economic-credentialing.page> (last visited Oct. 3, 2011) (“The AMA opposes the use of economic criteria unrelated to patient care to grant privileges.”).

competition for patients in the safety net and for California's residually uninsured⁴⁶ may inject economic credentialing requirements into the professional lives of safety net providers. Safety-net providers and the health care consuming public would benefit from increased transparency in physician credentialing, beginning with physician credentialing in safety-net accountable care organizations.

Recommendation 4
Promote Scope of Practice Laws That Empower Independently Licensed Providers

Scope of practice (SOP) legislation, which determines the extent to which physicians and independently licensed providers, such as nurse practitioners, can practice medicine, is often described as the third rail of politics. Most importantly for ACOs, scope of practice issue sees the dovetailing of state-specific concerns, namely licensing of providers, with federal control over federally-funded health insurance via billing rules.

Overall trends, reinforced by the Patient Protection and Affordable Care Act of 2010 (PPACA) and the political messages surrounding it, are toward enhancing the role independently licensed providers play in care delivery. Notably, PPACA prohibits insurers from discriminating against providers acting within their scope of practice.⁴⁷

ACOs may strengthen the push for an enhanced role for NPs, physician assistants (PAs), pharmacists and potentially other health professionals. An enhanced focus on patient self-management will put NPs/PAs at the forefront of care in many ways. New models that focus on group visits, e-visits, telemedicine and enhanced remote monitoring may put nurses at the vanguard of care. Increased care coordination and efficiency will bring increased responsibility.

States are the ultimate gatekeepers of professional licensing. Nationwide, SOP laws vary greatly. The federal government makes important SOP determinations through revision of Medicare and Medicaid laws, and influences scope of practice by giving states opt-in and opt-out choices as to those rules. For example, although an NP can bill Medicare directly,⁴⁸ they must still operate within the state's SOP guidelines.⁴⁹ As such, the SOP guidelines in a given state are determinative of the kinds of independently licensed providers that may exist there.

⁴⁶ *See generally*, Abby Kahn, Competing for California's Residually Uninsured: Health Care Safety Net Providers After Health Reform, May 2011.

⁴⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2706, 124 Stat. 119, 160 (2010).

⁴⁸ CTRS. FOR MEDICARE & MEDICAID SVCS., U.S. DEP'T OF HEALTH & HUMAN SVCS., PUB. NO. 100-04, MEDICARE CLAIMS PROCESSING MANUAL: CHAPTER 12 – PHYSICIANS/NONPHYSICIAN PRACTITIONERS § 120 (2011), *available at* <http://www.cms.gov/manuals/downloads/clm104c12.pdf>.

⁴⁹ *Id.* § 30.6.12(D) (allowing nonphysician practitioners to provide critical care services, but requiring that “[t]he provision of critical care services must be within the scope of practice and licensure requirements for the State in which the qualified NPP practices and provides the service(s).”).

Scope of Practice: Policy Solutions

Independently licensed providers are crucial in the safety net. SOP changes, which broadly tend to reduce some pressure on primary care providers, are only one part of the legislative approach of providing more comprehensive primary care for less money. Other approaches may have the same effect, but by more directly increasing the supply of primary care doctors.

Additionally, giving primary care doctors more power, status or compensation might be an effective way to grow their ranks. Currently, primary care physicians are often the “gatekeepers” of specialty referrals. But once they make a referral, they lose much of their leverage and power. ACOs may help change this equation by putting primary care physicians at the center of the care model and governing structure. But ACOs and their proponents must also accept that all healthcare professionals have a role to play in safeguarding patients’ health—and in doing so efficiently.

Recommendation 5

Repeal the Corporate Practice of Medicine Doctrine

There are some California state laws with potential effects on ACOs, but which are not anticipated to pose significant problems. For instance, Business & Professions Code § 650, the Physician Ownership and Referral Act of 1993, California’s anti-kickback statute, arguably contravenes the essence of how an ACO is supposed to work (i.e. providers reaping the rewards of collaborating to improve care).⁵⁰ But the federal government, in its own fraud and abuse waivers, has set a clear example for states to follow in addressing the problem.

By contrast, with the Corporate Practice of Medicine Doctrine (CPM), there was no equivalent federal statute to be waived, nor has the doctrine been pre-empted by the Medicare Shared Savings Program regulations. Policymakers and providers alike should consider repealing it outright.

Originally, the CPM was conceived as a means to prevent commercial exploitation of physicians.⁵¹ It further served to solidify and protect the guild through licensing requirements in an effort to set physicians apart from untrained individuals who provided “medical services.”⁵² But many academics now argue the doctrine is outdated in light of the rise of modern health insurance and medical practice.

⁵⁰ See Cal. Health & Safety Code § 445 and Cal. Bus. & Prof. Code § 650. See also Philip J. Goldberg, *What is Fraud and Abuse?*, San Francisco Medical Society, available at http://www.sfms.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/HTMLDisplay.cfm&SECTION=Article_Archives&CONTENTID=1483.

⁵¹ See Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 243 (2004) (noting that the corporate practice of medicine doctrine was created “to prevent quackery and commercial exploitation of physicians”).

⁵² *Id.* (“Simply stated, the corporate practice of medicine doctrine prevents persons or entities that are not licensed by the state in which they are located from providing physician or other medical services . . .”).

While there are many exemptions and workarounds that seem available to potential safety-net ACOs, the CMS Medicare Shared Savings Program (MSSP) ACO regulations⁵³ do not incorporate federal preemption of the CPM. Therefore, safety-net providers must not ignore the CPM when approaching safety-net ACO creation.

While the doctrine remains law in 48 states, there are drastic differences in the enforcement of the doctrine across the country. Decisional law and attorneys general opinions have had a major impact on the CPM's status in many states, including California.

Indeed, California's CPM doctrine—as written and as interpreted—is robust. In California, the CPM is a “prohibition on non-licensed persons, lesser-licensed persons, or corporations . . . from employing physicians to practice medicine, restricting the delivery of medical services to those entities owned and controlled only by licensed professionals, and prohibiting the division or splitting of professional fees between licensed medical doctors and non-licensed . . . individuals or entities.”⁵⁴ The doctrine is an amalgam of state law, case law, and California Attorney General Opinion exegesis that notes that “[c]orporations and other artificial entities shall have no professional rights, privileges, or powers.”⁵⁵ In recent years, the doctrine has even been strengthened as the ban has been applied to physicians as independent contractors⁵⁶ and to nonprofit corporations.⁵⁷

The accountable care concept is incompatible with the corporate practice of medicine doctrine. The ACO model depends on all ACO components pursuing common objectives, frequently communicating with and directing each other—perhaps especially hospitals and physicians. Yet the CPM makes this impossible. Even in a very common workaround for the doctrine, the medical foundation, it has long been understood that physicians offering medical services must be independent contractors, not employees. As a result, a medical foundation “lacks the vehicle to influence the manner or means used by individual physicians to accomplish the results desired. . . .”⁵⁸ Thus, even workarounds to the doctrine, by their nature, obstruct the ability to coordinate care and achieve significant savings.

California's CPM places some serious constraints on the kinds of provider relationships that may be built into a safety-net ACO. Federal preemption is unlikely, thus modification and exemption are serious options to consider on a legislative level. However, even modification and additional exemptions are difficult.

⁵³ See Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, Final Rule, RIN 0938-AQ22 (released Oct. 20, 2011) (to be codified at 42 C.F.R. pt. 425).

⁵⁴ Michael F. Schaff & Glenn P. Prives, *The Corporate Practice of Medicine Doctrine: Is it Applicable to Your Client?*, BUS. L. & GOVERNANCE, (Am. Health Lawyers Ass'n, Washington, D.C.), May 2010, at 2.

⁵⁵ CAL. BUS. & PROF. CODE § 2400 (West, Westlaw through ch. 312 of 2011 Reg. Sess. and ch. 11 of 2011-2012 1st Extraordinary Sess.).

⁵⁶ See 65 Op. Cal. Att'y Gen. 223 (1982).

⁵⁷ See, e.g., 83 Op. Cal. Att'y Gen. 170 (2000); *Cal. Physicians' Serv. v. Aoki Diabetes Research Inst.*, 78 Cal. Rptr. 3d 646, 654 (2008) (“Nor are we persuaded . . . that the ban on the corporate practice of medicine is inapplicable to nonprofit corporations.”).

⁵⁸ Anrew J. Demetriou, *Medical Foundations and the Corporate Practice Doctrine: Toward a Rational Approach*, CALIFORNIA HEALTH LAW NEWS (1993) at 33.

The CPM does have a number of exceptions that make it less of a bar on the direct employment of physicians by hospitals. The first of these is due to federal preemption since the enactment of the Federal Health Maintenance Organization Act of 1973.⁵⁹ If ACOs can be fit into the definition of HMOs,⁶⁰ then they will not be impacted by the CPM. But because ACOs will likely come in many shapes and sizes, it is difficult to predict whether some will fit within the definition. Second, framing ACOs as a type of HMO may result in “skepticism, if not overt opposition.”⁶¹

Next, there are California-specific exemptions to the CPM. First, the Moscone-Knox Professional Corporation Act in California’s Corporations Code allows the formation of professional medical corporations.⁶² A second set of exceptions is linked to § 2401 of the Medical Practice Act, which stipulates that specific entities may employ physicians directly. Crucially for the safety net, one of the entities exempted from the CPM under § 2401 is non-profit community clinics (also covered are teaching hospitals⁶³ and narcotic treatment programs⁶⁴). A third group exempt from the CPM because they are exempt from licensure are medical foundations and outpatient departments.⁶⁵

There are numerous ways in which the CPM may pose a barrier to safety-net ACO formation. First, the most common workaround/exemption that organizations plan to fit into – medical foundations⁶⁶ – is expensive to create and maintain, as well as vehemently opposed by the California Medical Association when the purpose of the medical foundation is to avoid the CPM.⁶⁷ Even before Congress passed PPACA, scholars criticized prevalent

⁵⁹ See 58 Op. Cal. Att’y Gen. 571 (1975) (determining that HMOs are exempt from the corporate practice of medicine because the Federal HMO Act supersedes the California Medical Practice Act).

⁶⁰ The Federal Health Maintenance Organization Act of 1973 defines an HMO as, in short, a risk-assuming organization offering health care services from a closed group of professionals in exchange for a fixed payment unrelated to the frequency, kind or extent of services provided. 42 U.S.C. § 300e (2006).

⁶¹ *What are Accountable Care Organizations?*, HEALTHCARE ECONOMIST (Jan. 26, 2010), <http://healthcare-economist.com/2010/01/26/what-are-accountable-care-organizations/>.

⁶² Allegra Kim, *The Corporate Practice of Medicine Doctrine*, CAL. RESEARCH BUREAU, 6 (Oct. 2007), <http://www.library.ca.gov/crb/07/07-011.pdf>.

⁶³ See Cal. Med. Ass’n v. Regents of the Univ. of Cal., 79 Cal. App. 4th 542, 547 (2000).

⁶⁴ See CAL. BUS. & PROF. CODE § 2401 (West, Westlaw through ch. 312 of 2011-12 Reg. Sess. and ch. 11 of 2011-12 1st Extraordinary Sess.).

⁶⁵ See Debra A. Draper & Elizabeth A. November, *A Tighter Bond: California Hospitals Seek Stronger Ties with Physicians*, CAL. HEALTHCARE FOUND., 3 (Dec. 2009), www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/T/PDF%20TighterBondCAHospitalsSeekTiesWithDocs.pdf.

⁶⁶ See CAL. HEALTH & SAFETY CODE § 1206(l) (West, Westlaw through ch. 312 of 2011-12 Reg. Sess. and ch. 11 of 2011-12 1st Extraordinary Sess.).

⁶⁷ CAL. MED. ASS’N, ACO/MEDICAL FOUNDATION PRINCIPLES: PHYSICIAN-HOSPITAL ALIGNMENT TAC REPORT [page] n.31 (2011) (“[T]he Legislature did not intend to provide a pathway for tax-exempt hospitals to organize and control a large group of physicians in the outpatient setting and, in doing so, circumvent the corporate practice of medicine prohibition. Indeed, existing CMA policy provides that it will ‘take all appropriate steps to ensure that the corporate practice of medicine bar is enforced and that no exceptions be made for foundations that do not meet the statutory requirements of Health & Safety Code § 1206(l)”).

hospital CPM workarounds as potentially “unworkable for smaller, financially weaker, and rural hospitals.”⁶⁸

Second, while certain safety-net organizations are sure to fit within exemptions to the Medical Practice Act (i.e, non-profit community clinics⁶⁹), “safety net” should be defined broadly to encompass a larger cross-section of providers serving needy patients. Given this, it seems unlikely that all will fit into the statutory exemptions and it is not clear that they will be able to contract around them without legal hurdles.

The Rural Problem: CPM Doctrine and Rural Health Care Integration

Thirdly and worthy of special emphasis is that rural safety-net ACOs will most likely struggle more with the CPM than their urban/suburban counterparts, because of the cost of medical foundation creation.⁷⁰ First, medical foundations may be prohibitively expensive and difficult to create for smaller, financially weaker, and rural hospitals.⁷¹ In rural settings, for example, collecting the appropriate number of physicians and surgeons may itself prevent medical foundation formation.⁷²

Second, some safety-net ACOs will be able to fit within the non-profit community clinics exemption from Cal. Bus. & Prof. Code § 2401, provided they are “licensed, serve a defined population (such as low-income), be operated as a non-profit corporation, and charge based on ability to pay, if at all.”⁷³ This seems to indicate that many safety-net ACOs could fit into this exemption, however, as the safety-net ACOs are yet to be constructed it is unclear that they will all fit into these exemptions or be able to contract themselves into this exemption. As different models are developed for safety-net ACOs (for example, for-profit physician practice group linking with a nonprofit clinic and non-for-profit hospital) it is possible that non-for-profit status will no longer be a foregone conclusion for the new ACO legal entity, because a linkup with a for-profit could imperil the nonprofits’ tax status. As a result, this may create issues concerning the CPM and tax law.⁷⁴ Increased use of medical

⁶⁸ See Debra A. Draper & Elizabeth A. November, *A Tighter Bond: California Hospitals Seek Stronger Ties with Physicians*, CAL. HEALTHCARE FOUND., 3 (Dec. 2009), www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/

⁶⁹ CAL. BUS. & PROF. CODE § 2401 (West, Westlaw through ch. 312 of 2011-12 Reg. Sess. and ch. 11 of 2011-12 1st Extraordinary Sess.).

⁷⁰ See Jim Hester, Julie Lewis, & Aaron McKethan, *The Vermont Accountable Care Organization Pilot: A Community Health System to Control Total Medical Costs and Improve Population Health*, THE COMMONWEALTH FUND, 19 (May 2010), [http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/May/](http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/May/1403_Hester_Vermont_accountable_care_org_pilot.pdf)

1403_Hester_Vermont_accountable_care_org_pilot.pdf.

⁷¹ See Draper & November, *supra* note 69, at 1.

⁷² *Id.* at 4.

⁷³ Kim, *supra* note 66, at 7.

⁷⁴ See I.R.S. Notice 2011-20, 2011 I.R.B. 16, at 655 (requesting comments concerning “whether and under what circumstances a tax-exempt organization’s participation in non-MSSP activities through an ACO will be consistent with an organization’s tax-exemption under §501(c)(3) or not result in [unrelated business income tax]”).

foundations, and especially master medical foundations, may increase consolidation among entities, raising substantial fair competition concerns. The medical foundation CPM fix may thus have its own undesirable side effects.

Third, as previously mentioned, rural ACOs will most likely struggle with the CPM more than their urban and suburban counterparts because of the high cost and possible impracticability of medical foundation formation,⁷⁵ legislative solutions to assist rural areas have expired and renewal plans are struggling to get passed,⁷⁶ and high cost⁷⁷ of Health Information Technology (HIT) which is most likely needed for ACO effectiveness.⁷⁸ These three issues raise serious concerns about how easy it will be for rural safety-net organizations to create a legal entity robust enough to be an ACO while avoiding the CPM bar. Funding for HIT might require partnerships that make the legal entity fall outside an exemption, for example, and the issues of physician recruitment alone suggest that having the additional barrier of being forbidden from direct employment will further hinder rural safety-net ACO formation.

Corporate Practice of Medicine: Policy Solutions

The corporate practice of medicine doctrine is not merely an obstacle in and of itself, but also correlates with other legal obstacles. There are substantial fair competition concerns that exist as a result of the application of the CPM exemptions. States still enforcing some version of the corporate practice of medicine doctrine should consider an exception for ACOs or, in any event, for safety-net ACOs who may otherwise be priced out of the expensive well-established workarounds.

⁷⁵ See Draper & November, *supra* note 69, at 1.

⁷⁶ See CAL. BUS. & PROF. CODE § 2401.1, *repealed by* Act of Sept. 16, 2003, ch. 411, 2003 Cal. Stat. 1 (creating a pilot program to allow certain hospitals to employ physicians and surgeons directly, but automatically sunseting the pilot on January 1, 2011); S.B. 726, 2009-10 Reg. Sess. (Cal. 2009) (extending a pilot project allowing qualified hospitals to employ physicians and surgeons); A.B. 926, 2011-12 Reg. Sess. (Cal. 2011) (would re-enact expired pilot demonstration project allowing qualified hospitals to employ physicians and surgeons directly); A.B. 1360, 2011-12 Reg. Sess. (Cal. 2011) (would allow certain health-care districts as well as clinics owned and operated by such districts to employ physicians and surgeons directly).

⁷⁷ AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, PUB. NO. 06-E006, COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 45-46 (2006), *available at* <http://www.ahrq.gov/downloads/pub/evidence/pdf/hitsyscosts/hitsys.pdf> (observing that the cost of implementing an electronic health record system in Swedish primary health care setting with 50 staff was \$240,000 in first year (in 1995 U.S. dollars) while a large HMO with 13 outpatient care locations in Ohio's ambulatory EHR was estimated to have had a system development cost of \$10 million (in 1996 dollars) and additional annual expenses of \$630,000 (in 1996 dollars)).

⁷⁸ Donald M. Berwick, *Launching Accountable Care Organizations — The Proposed Rule for the Medicare Shared Savings Program*, NEW ENG. J. MED. (Mar. 31, 2011), <http://www.nejm.org/doi/full/10.1056/NEJMp1103602#t=article>.

For example, states should consider whether there are problems that are created as a result of the HMO exemption to the CPM where ACOs do not have a specific carve-out. While there are sure to be other legal barriers that are of greater concern for safety-net ACOs, the CPM, and more specifically the reaction to it, leads to the confrontation of other legal and regulatory barriers. This discussion can only offer a broad sketch of the tangled web of law that has arisen in connection with the CPM. California lawmakers, and those in other states, should consider whether, beyond exemption, the corporate practice of medicine doctrine should be repealed as out of step with how health care is and should be delivered today.

SAFETY NET ACCOUNTABLE CARE PROGRESS IN OTHER STATES

California and several other states have made substantial inroads toward coordinated care. Notably, in South Central Los Angeles, a large group of organizations is working to develop an expressly safety-net ACO.

In implementing coordinated care, some have not even used the term “accountable care organization,” but have nevertheless achieved impressive results, and many states have moved considerably ahead of California. This section will address developments in state legislation that could impact safety-net ACOs.

Throughout the country, states are taking initial steps toward accountable care in a myriad of ways. There is ACO-related legislation pending in Connecticut, Florida, Illinois, Indiana, Iowa, Massachusetts, New York, Vermont, Washington and elsewhere. The Governor of Massachusetts has called on the state legislature to quickly pass his blueprint for health care cost containment, which would establish ACOs as a key part of the state’s health care system.⁷⁹ Earlier this year, Montana passed a bill that waives the HMO requirements for ACOs on a three-year renewal cycle that considers the financial condition of the ACO, consumer complaints against the ACO, and the length of time the ACO has been in business.⁸⁰ New York has passed a law defining and establishing a certification process for ACOs and directing the creation of a Medicaid ACO.⁸¹ Other states have passed laws requiring agencies to evaluate or establish ACOs in concert with federal health reform.⁸² A bill now pending in Indiana would exempt ACOs from corporate practice of medicine limitations.⁸³ A pending bill in New York would provide immunity from state and federal antitrust laws with respect to planning, implementing and operating ACOs.⁸⁴

⁷⁹ Matt Murphy, *Demanding Action, Deval Patrick Presses for January Vote on Health Care Cost Bill*, BOS. HERALD, Oct. 21, 2011, <http://news.bostonherald.com/news/politics/view.bg?articleid=1375041&format=&page=2&listingType=M A2004#articleFull>.

⁸⁰ S.B. 221, 62nd Leg., Reg. Sess. (Mont. 2011).

⁸¹ S. 2809, 2011 Legis. Sess. (N.Y. 2011).

⁸² *See, e.g.*, An Act Relating to Creating Flexibility in the Medicaid Program, S.B. 5596, 62nd Leg., 2011 1st Spec. Sess. (Wash. 2011); S.F. 50, 61st Leg., 2011 Gen. Sess. (Wyo. 2011).

⁸³ S.B. 174, 2011 Leg., 1st Reg. Sess. (Ind. 2011).

⁸⁴ A. 6261, 2011 Legis. Session (N.Y. 2011).

ACOs and Medicaid: New Jersey

With the basic framework for federally recognized ACOs having been set by the proposed rule for the Medicare Shared Savings Program, the stage is set for Medicaid ACOs to form as well. In some states, efforts are already underway that offer insight into Medicaid ACOs and best practices for such organizations.

A broad coalition of stakeholders of businesses, hospitals, healthcare providers, and consumers (known as the Camden Coalition) joined together to propose the creation of Medicaid Accountable Care Organizations (ACOs) in New Jersey. As a result, legislation was passed on June 29, 2011, that will initiate a three-year Medicaid ACO demonstration project whereby community-based, non-profit coalitions can apply for recognition by the State of New Jersey as Medicaid ACOs.⁸⁵ The Department of Human Services (DHS) will work with the Department of Health and Senior Services (DHSS) to certify these Medicaid ACOs, and no more than one shall be certified for each designated area.

If, after three years, officials determine that the demonstration project was successful in reducing costs and improving health outcomes and the quality of care for Medicaid recipients, the commissioners will recommend expansion of the project to include additional communities and become a permanent program.⁸⁶

Lessons from the New Jersey Legislative Process

The New Jersey legislation required numerous changes to be passed, including amendments to tighten the requirements for ACO acceptance into the demonstration project, increase the administrative responsibilities of DHS and DHSS, insure against potential fraud and abuse, increase coordination among the administering entities, and prevent the emergence of preemption issues.

Importantly, the Legislature declared its intent to, via the state action immunity doctrine, exempt activities undertaken pursuant to the Medicaid ACO demonstration project that might otherwise be constrained by state antitrust laws.⁸⁷ The Legislature clarified that it

⁸⁵ S. 2443, 214th Leg., 2010-11 Legis. Sess. (N.J. 2011), www.njleg.state.nj.us/2010/Bills/PL11/114_.PDF.

⁸⁶ *Id.* § 14.

⁸⁷ *Id.* § 1(g).

did not intend to allow or authorize any person or entity to engage in activities or to conspire to engage in activities that would constitute per se violations of state or federal antitrust laws.⁸⁸ Thus the Legislature had to address a host of legal barriers in order to ensure the effectiveness of their ACO, among them **fair competition** (antitrust), **state regulation of insurance**, and **oversight authority**.

Colorado's Accountable Care Collaborative

The desire to improve health care access and quality of care led Colorado to propose initiatives that subsequently turned into pioneering legislation creating an Accountable Care Collaborative (ACC) that is now in the initial phase of enrollment. Colorado created the ACC in response to the impending increase in Medicaid beneficiaries⁸⁹ and after careful evaluation by a commission created for this purpose. The ACC is an effort to control costs by reducing avoidable and inappropriate use of health care resources, while improving health outcomes through a client-centered system.

The ACC combines the Primary Care Case Management System with the Accountable Care Organization model.⁹⁰ Medicaid clients enrolled in the ACC receive services using the fee-for-service model, and also belong to a Regional Care Collaborative Organization (RCCO) that provides care-coordination among providers and other community and government services.⁹¹ The program incorporates a drive toward improved IT capacity.⁹²

Primary care medical providers (PCMPs) are affiliated with a RCCO and act as “medical homes” for patients.⁹³ These medical homes are outcome-focused and will coordinate and manage a client’s health needs across specialties and along the continuum of

⁸⁸ *Id.*

⁸⁹ See John Holahan & Irene Headen, *Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL*, KAISER COMM’N ON MEDICAID AND THE UNINSURED, 10 tbl.1 (May 2010), www.kff.org/healthreform/upload/Medicaid-Coverage-and-Spending-in-Health-Reform-National-and-State-By-State-Results-for-Adults-at-or-Below-133-FPL.pdf (reporting that Colorado will experience an increase of over 245,000 Medicaid enrollees by 2019 as a result of health-care reform’s Medicaid enrollment expansion).

⁹⁰ See Sarah Roberts, Colo. Dep’t of Health Care Policy & Fin., Presentation at the Accountable Care Collaborative Women’s Health and Family Planning Conference: Understanding the ACC Program, 3 (Jun. 9, 2011), www.cdph.state.co.us/pp/womens/pdf/Understanding%20the%20ACC%20Program4%20SARAH%20ROBERTS.pdf.

⁹¹ *Accountable Care Collaborative*, COLO. DEP’T OF HEALTH CARE POLICY & FIN., <http://www.colorado.gov/cs/Satellite/HCPF/HCPF/1233759745246> (last visited Oct. 5, 2011).

⁹² COLO. DEP’T OF HEALTH CARE POLICY & FIN., RFP NO. HCPFKQ1102RCCO, REQUEST FOR PROPOSALS: REGIONAL CARE COLLABORATIVE ORGANIZATIONS FOR THE ACCOUNTABLE CARE COLLABORATIVE PROGRAM 9 (2010), *available at* http://www.colorado.gov/cs/Satellite?c=Document_C&childpagename=HCPF%2FDocument_C%2FHCPFAddLink&cid=1251590262362&pagename=HCPFWrapper [hereinafter COLORADO RFP].

⁹³ *Id.* at 12.

care.⁹⁴ The Colorado DHCPF is working with stakeholders to support communities and individual health care providers interested in participating in the Colorado Regional Health Information Organization (CORHIO) health information exchange in order to help providers become better equipped to facilitate the exchange of health information.

California's Medicaid Waiver

Some accountable care progress has been made in our own state of California, despite the need for regulatory clarity and proactive legislative work to clear the way for ACOs to thrive. California's newest Medicaid waiver (the agreement with the federal government under which California will administer Medi-Cal) is a far-reaching \$10 billion program that uses an integrated care concept, the medical home, as a "central component."⁹⁵ A medical home could be understood as a mini-ACO, deploying as it does the concept of primary care physician-led care, but on a smaller scale than an ACO.⁹⁶

But more than medical homes, the waiver also will lead to a Delivery System Reform Investment Pool (DSRIP) established by the waiver offering funding to public hospital systems who improve coordinated systems of care for vulnerable populations. Specifically, applicants for DSRIP funds must target one or more of the following: strengthening coordinated systems of care, enhanced access to care, and improved quality of patient care.⁹⁷ These focus areas encompass such aspects of ACOs such as preventing admissions for ambulatory sensitive conditions and readmission rates generally, as well as investments in information technology.

The waiver even provides for testing of a provider-based ACO for children with special health care needs. In October 2011, the California Department of Health Care Services announced it would join with regional health care organizations in January 2012 to create several demonstration projects benefiting children with special health care needs. Two of the pilot projects, one in Orange County and one in San Diego County, are accountable care organizations. For each of the two pilot ACOs, the county will determine if a given California Children's Services-eligible child meets a set of criteria. If the child is enrolled, the existing Medi-Cal Managed Care Carve-Out will be eliminated for that patient.

⁹⁴ *Information for Primary Care Medical Providers (PCMP)*, COLO. DEP'T OF HEALTH CARE POLICY & FIN., http://www.colorado.gov/cs/Satellite?c=Content_C&childpagename=HCPF%2FContent_C%2FHCPFDetail&cid=1251594448104&pagename=HCPFWrapper (last visited Oct. 5, 2011).

⁹⁵ CAL. DEP'T OF HEALTH CARE SERVS., CALIFORNIA SECTION 1115 COMPREHENSIVE DEMONSTRATION PROJECT WAIVER: A BRIDGE TO REFORM: A SECTION 1115 WAIVER PROPOSAL 12 (2010), *available at* www.dhcs.ca.gov/provgovpart/Documents/A%20Bridge%20to%20Reform%206-10-2010.pdf.

⁹⁶ Rittenhouse DR, Shortell SM, and Fisher ES. "Primary Care and Accountable Care – Two Essential Elements of Delivery System Reform" *New England Journal of Medicine*, December 10, 2009, 361(24):2301-2303.

⁹⁷ *Id.* at 28.

Instead, the contractor will be responsible for managing all of the child or youth's health care needs for enhanced continuity of care, align incentives and optimize health outcomes. While the pilot ACO in San Diego has projected a relatively modest enrollment of 625 members, the Orange County pilot expects over 5,000. The Department of Health Care Services will evaluate the pilots based on types of services and expenditures thereof, improvement in the coordination, quality, and value of care provided, and the satisfaction of both providers and parents.⁹⁸

⁹⁸ CAL. DEP'T OF HEALTH CARE SERVS., CALIFORNIA CHILDREN'S SERVICES DEMONSTRATION PROJECTS (2011), *available at* <http://www.dhcs.ca.gov/provgovpart/Documents/CCSPilots.pdf>

CONCLUSION

Policymakers and advocates should place the safety net at the forefront of their health care reform efforts. Not only are safety-net patients the most in need of health care reform's benefits, but safety-net populations also present an opportunity to control the ballooning cost of health care in America by coordinating care to, for example, reduce hospital readmissions.

California has been a leader in health care innovation, but policymakers should move quickly to clarify where ACOs fit into current regulatory and legislative schemes. Successes both within California and in other states like New Jersey and Colorado strongly suggest that accountable care in the safety net requires attention from policymakers. On issues from the corporate practice of medicine doctrine and medical liability to fair competition laws, states must be proactive if the potential of health care reform is to be realized. States can improve care while reducing costs, but it will take decisive action that puts aside politics in favor of more cost-effective patient outcomes.

University of California, Berkeley
School of Law
2850 Telegraph Avenue, Suite 500
Berkeley, CA 94705-7220
510.642.8527
www.law.berkeley.edu/ewi.htm

BerkeleyLaw
UNIVERSITY OF CALIFORNIA

Chief Justice Earl Warren
Institute on Law and
Social Policy

Warren Institute's Health, Economic & Family Security Program

The Chief Justice Earl Warren Institute on Law and Social Policy is a multidisciplinary, collaborative venture to produce research, research-based policy prescriptions, and curricular innovation on the most challenging civil rights, education, criminal justice, immigration, family and economic security, and healthcare issues facing California and the Nation.

Acknowledgments

The research culminating in this brief was funded by Blue Shield of California Foundation. We thank them for their support. We thank Steve Shortell of the UC Berkeley School of Public Health for his vision. We also thank Richard Thomason of Blue Shield of California Foundation, Professor Timothy Jost of the Washington & Lee School of Law, Dr. Ben Rich of the UC Davis School of Medicine, and Marjorie Swartz of the California Assembly Health Committee for providing essential comments on earlier drafts. Additionally, we thank Ann O'Leary, who served as Director of the Warren Institute's Health, Economic and Family Security Program during the creation of this brief, for her contributions. Finally, renewed thanks to Phyliss Martinez for her sharp editorial eye and unflagging patience with multiple drafts.



Matthew Chayt

Legal Fellow
UC Berkeley School of Law

Ann Marie Marciarille was a Senior Research Fellow at the Warren Institute's Health, Economic & Family Security Program at the UC Berkeley School of Law, and now is a visiting Assistant Professor at the University of California, Hastings College of the Law.

Noah Metz

Research Assistant

Anita Pandhoh

Research Assistant

David Vernon

Research Assistant