To License or Not To License:
Can healthcare innovation survive an antiquated regulatory regime?

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Talk to any venture capitalist or read any blog these days; healthcare and healthcare innovation are the hottest topics. Running the gamut from hospital mergers to Accountable Care Organizations, physician consolidation to direct primary care, concierge care, telemedicine and e-health, the sector is on fire with change. These are not merely changes in ownership or consolidations. Instead, the industry is undergoing a version of creative destruction, as innovators seek to reconfigure healthcare from delivery systems to payment models. It's an exciting time, full of the promise of a sea change, but also poised to slam into a wall of regulatory incoherence, incapable of accommodating new models into a legal architecture built for a different age.

Seeing the future requires understanding the past. American healthcare is largely defined by its nature as a third-party payor system. Simply put, unlike most other areas of the economy, the patient is not the customer, i.e., not the party actually paying for the service. Current healthcare debates about the purported evils of fee-for-service and managed care payment models and population health all take place on the plains of the third-party payor system. Many of the most promising innovative concepts in healthcare involve attempts to reverse the perceived misalignment of incentives.

Many hospitals and health systems have begun the shift to "global care," or models that permit the hospital to reap the profits of healthy, as opposed to sick, patients. Direct primary care and concierge care typically involve a full or partial shift from third-party to first-party payment for care.[1] Many of the most innovative e-health and telemedicine models are first-party payment models.[2] Although now far less common in medical care, dental discount cards are still widely prevalent and are based on a first-party payer model: the patient pays the provider directly and the discount card program merely allows the patient to access preferred pricing. DentalPlans.com, for example, allows its members to select from established insurer networks such as CIGNA and Aetna.[3]

More common is the consolidation in the provider sector to models that seek to provide many benefits for one price. Some physicians, particularly in the urgent care center sector, have begun offering comprehensive services for a monthly fee. Often these memberships involve prescription drug and/or diagnostic coverage. Many hospitals are exploring substantively similar global care models. These global care models seek to incorporate non-hospital/non-institutional services, such as physician services. The often-mislabeled Accountable Care Organization model frequently seeks to have a physician group providing hospital, drug, or other non-physician coverage. Regardless of the potential economic merits of any of these models, each one faces numerous regulatory hurdles in California. That is particularly true of membership or non-fee-for-service payment models.

California's Knox-Keene Act: What Is or Is Not a Health Plan?

California regulates health plans, often called Health Maintenance Organizations (HMOs), differently from other forms of insurance.[4] The Knox-Keene Health Care Service Plan Act of 1975 is administered and enforced by the Department of Managed Health Care, the nation's only stand-alone HMO regulator.[5] More specifically, the Act applies to "health care service plans" or "specialized health care service plans" defined as:

> (f) "Health care service plan" or "specialized health care service plan" means either of the following:
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> (1) 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.
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> (2) Any person, whether located within or outside of this state, who solicits or contracts with a subscriber or enrollee in this state to pay for or reimburse any part of the cost of, or who undertakes to arrange or arranges for, the provision of health care services that are to be provided wholly or in part in a foreign country in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.[6]

The risk posed to many of the innovative models discussed above lies in two areas: (i) the provision of comprehensive or global services, and (ii) compensation/reimbursement based on monthly or other periodic fees. In addressing non-HMO models the DMHC has interpreted the Knox-Keene Act broadly, typically centering its analysis on the "periodic payment" as synonymous with health plan.[7] The remainder of this article discusses the DMHC analysis and suggests an alternative analysis, which would not unnecessarily stifle emerging and innovative healthcare models.

The *Care Entrée* Decision as a Guidepost

The perplexing policy pickle of "What is a Health Plan?" has continued to plague the Knox-Keene Act since its inception in 1975. Through interpretative opinions, exemption requests and enforcement actions, the DMHC and its predecessor agency have expressly opined on everything from consumer benefits associations, retail giant Costco's pharmacy, fake union plans[8] and air transport services, to the nascent discount card industry. The aggressiveness with which the DMHC pursued the discount card industry provides an illuminating example of what a DMHC analysis might look like.

Beginning in 2004, the DMHC doggedly pursued the discount card industry through an enforcement action against a major discount card issuer, *Care Entrée*. The matter proceeded to an administrative hearing and was eventually adopted by DMHC as a precedential decision.[9] Care Entrée was a discount card issuer: it charged members a monthly fee to access a network of providers who had allegedly agreed to provide discounts for cash-paying customers who were Care Entrée members. Care Entree contended it was not a health plan because even though it charged a monthly fee, it did not arrange for any health care services, but instead merely provided a list of providers. The ensuing decision agreed with DMHC, and is illustrative of a straightforward but mechanistic analysis.

In concluding Care Entrée was a health plan subject to the Knox-Keene Act, the decision focused on several key facts as constituting the arranging for health care services:

> Capella not only enters into service contracts with health care providers and maintains those contracts, Capella enrolls members, provides referrals to network providers, assists members with obtaining appointments, assists providers in verifying member eligibility for discounts, requires members to deposit funds in PMAs, controls the large sums of money aggregated into the PMA trust fund, verifies the ability of the member to pay through the PMA, reprices bills, reviews, reprices and pays claims, and provides medical information through the nurse help line. This panoply of activity constitutes 'arranging for the provision of medical services' within the meaning of sections 1345 and 1349. The nurse help line constitutes direct provision of medical services.[10]

The decision, thus, focused heavily on a "if it quacks like a duck" analysis, unanchored to the statutory scheme as a whole. It bears noting that the discount card industry as a whole at the time was plagued with consumer complaints and many of the purported discounts were illusory or non-existent. Consumer protection statutes, such as the Knox-Keene Act, typically and appropriately receive a broad construction.[11] However, to paraphrase Abraham Lincoln, calling a cow's tail a leg does not mean a cow has 5 legs. The Knox-Keene Act should be construed as a whole, leaving the innovators room to create, without undue regulatory burden.

COMPREHENSIVE STATUTORY CONSTRUCTION YIELDS A VERY DIFFERENT RESULT

The "periodic payment" language in Health and Safety Code Section 1345's definition of a health plan is not the endpoint of the analysis. That is because the definition actually refers to the periodic *pre-payment for services*. One of the singular defining concepts of a managed care health plan is that, unlike a preferred provider organization, catastrophic or indemnity plan, a managed care health plan is not a form of cost-sharing.

An HMO member assumes little risk for her care and pays only the monthly premium, a known deductible amount and, possibly, a co-pay. The HMO plan assumes full financial risk for her care on a prospective basis.[12] Other than the monthly premium, annual deductible and the occasional co-pay, HMO plan enrollees pay nothing more for their care, whether they cost the plan $1.00 or $1million per year. The model is low margin, high volume and relies on contained networks of care, with the primary care physician as a gatekeeper and care coordinator, as the means to control costs.[13]

The Knox-Keene Act doesn't merely focus on the periodic pre-payment, but specifies what the pre-payment must pay for. At the core, an HMO member is entitled to all basic healthcare services, as well as a panoply of specific mandates.[14] Consistent with its essential nature as a prepaid form of health coverage, the services required to be provided to an enrollee are broad, specifically including inpatient hospital care, emergency care, and specialist care.[15] Thus, an HMO is not an entity that provides partial care for a periodic pre-payment, but rather an entity that provides *all of the services mandated by the Knox-Keene Act*, in exchange for the periodic pre-payment.

Many of the cases regarding licensure determinations and jurisdictional reach also involve hospital care. The issue typically arises in the context of California's "delegated" managed care model, whereby physician groups and risk-bearing organizations accept specific financial risks in exchange for capitation payments. The jurisdictional issue often arises in the context of a medical group taking full financial risk. Full financial risk, in this context, would mean accepting responsibility for providing all the services required to be provided under the Knox-Keene Act, including hospital care.[16] Before addressing the legal consequences from such arrangements, it is important to examine what delegated risk really is.

Delegated risk arrangements involve a medical group agreeing with a payor to provide a set suite of services, typically in exchange for capitated payments. Fundamentally, delegated risk arrangements are contracts to provide physician services, often coupled with hospital and other ancillary services, in exchange for payment. Although delegated risk arrangements may provide for payment on a capitated basis, *the purpose of the contract is simply to accept the financial risk of the cost of those services*. The delegated risk arrangement is simply a contract under which the medical group agrees to provide services to the HMO member. If the physician provider is unable to provide the physician services directly, e.g., in an emergency room visit, the medical group will pay for those services anyway, because the medical group has accepted the risk and responsibility to pay for those services.

In California, only physicians can provide physician services.[17] Similarly, a hospital license is required to render hospital services.[18] No person may contract for a purpose prohibited by law. Ergo, the only party who may contract to provide physician services is a licensed physician or physician corporation.[19] Equally then, only a licensed hospital may contract to provide hospital services.

For more than a decade the DMHC has taken the position that a medical group may not contract to provide hospital services or accept hospital risk without a Knox-Keene license or hospital license.[20] Necessarily, any innovative healthcare models, from telemedicine, to concierge physicians, to drug store retail clinics that purport to cover institutional or hospital care, will likely implicate this analysis. This analysis is historically consistent with positions taken by the DMHC's predecessor agency, the Department of Corporations.[21] Such a construction is in accord with the DMHC's precedential decision in *Care Entrée*, because the discount card industry often purported to provide discounts on services they were not licensed to provide. However, to the extent emerging delivery models cover only one category of healthcare service, such as physician care, performed by a person licensed to provide physician services in California, no additional licensing requirements would be triggered.[22]

Attorneys who advise providers with innovative healthcare models should be careful to note that all applicable licensure laws are being followed. For example, a telemedicine app that involves the treatment or diagnosis of a Californian's condition might require each provider who renders physician services to have a valid California physician's license. From a regulatory perspective, a telemedicine app that involves periodic payments, coupled with healthcare performed by a provider in a foreign jurisdiction who is not licensed in California, would likely raise consumer protection concerns and heighten a client's risk of scrutiny and regulatory activity by the DMHC.

CONCLUSION

Any California healthcare delivery model in which (i) an entity contracts directly with the consumer and (ii) under which the entity's consideration is dependent upon the monthly payment of fees or dues, runs a regulatory risk of being classified as a health care service plan under the Knox-Keene Act. This is particularly true where the monthly fee is an advance payment for services. DMHC's precedential decisions notwithstanding, a proper legal analysis of the Knox-Keene Act should examine any innovative healthcare payment model against that act's framework. The author proposes that the DMHC should modify its regulatory stance to promote innovative healthcare delivery systems and suggests that any business model involving payment for healthcare services, which model does not promise services beyond the scope of the healthcare provider's license, should be excluded from DMHC jurisdiction.

ABOUT THE AUTHOR

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END NOTES

1 Direct primary care is the payment of a monthly fee for services without any third-party payer. Concierge care in contrast, is historically a hybrid model coupling a membership payment for access to the physician, but still billing a third-party payor under the fee-for-service model.

2 See e.g., Web MD's Live MD app charges patients under a fee-for-service model, billed direct to a credit card. See https://www.mdlive.com/consumer/faq.html.

3 http://www.dentalplans.com.

4 Health & Saf. Code §1341 et seq.

5 Id.

6 Health & Saf. Code §1345(f)(1).

7 See *In re the Capella Group, Inc., dba Care Entrée*, DMHC Case No. 04-312 at http://www.dmhc.ca.gov/Portals/0/AboutDMHC/2006ccgi.pdf.

8 See *In re Contractors and Merchants Ass'n et al.*, DMHC Matter No. 07-159 at http://www.dmhc.ca.gov/Portals/0/AboutDMHC/2006ccgi.pdf.

9 See *In re the Capella Group, Inc. dba Care Entrée*, supra.

10 Id.

11 See e.g., *People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294, 314.

12 Health & Saf. Code §1375.1(a)(2).

13 *Van de Kamp v. Gumbiner* (1990) 221 Cal. App. 3d 1260.

14 Health and Safety Code §§1367 (i), 1345(b).

15 Health & Saf. Code §1345(b)(1), (2), (6).

16 See generally, Health and Safety Code §§1367 (i), 1345(b).

17 Bus. & Prof. Code § 2000 et seq.; §2052(a).

18 e.g., Cal. Code Regs., tit. 22, §§70005, 70103.

19 The Moscone-Knox Act "prohibits persons other than those answerable to the licensing authority of the particular profession from becoming shareholders … of a corporation engaged in rendering the services of that profession." (*Marik v. Superior Court*, 191 Cal. App. 3d 1136 (Cal. App. 2d Dist. 1987) The Moscone-Knox Act expressly restricts the ownership of medical and professional corporations to individuals licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render the same professional services as are or will be rendered by the professional corporation of which he intends to become a shareholder. (*Corporations Code* § 13401).

20 See "*Overview of Risk-sharing Arrangements*," Financial Standards Solvency Board, Jan. 29, 2002.

21 Commissioner's Opinion 78/3H (1978) 1978 Cal. Sec. LEXIS 27 (addressing a consumer association that provided insurance coverage through membership).

22 The author notes, however, what ought to occur is often different from what does occur. Regulatory actions often depend on the particular timing and organizational philosophies of particular agencies as well as the availability of government resources.