

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #1, October 27, 2017 – December 11, 2017

#	FROM	COMMENT	DEPARTMENT RESPONSE
1-1	Victoria Bermudez	<p>Thank you for proposing the above referenced regulations clarifying licensure requirements for any person that accepts global risk, as defined, for services to subscribers or enrollees in exchange for advance or periodic consideration.</p> <p>The absence of regulations defining the level of assumption of financial risk that triggers a requirement to obtain licensure by the DMHC may have been a contributing factor that allowed defendant Healthcare Partners Medical Group, Inc. (HPMG) in Hambrick v. Healthcare Partners Medical Group, Inc., 238 Cal. App. 4th 124 (Cal. App. 2d Dist. 2015) to fly under the radar of the DMHC and to avoid complying with the Knox-Keene requirements set for health care service plans in California. I am pleased to see that the DMHC is remedying this deficiency through rulemaking.</p> <p>According to the California Health Care Foundation (CHCF), "Accountable care organizations are growing in number and importance on the national stage."¹ Accountable care organizations who assume global risk and qualify as health care service plans must be licensed as such, must comply with Knox-Keene requirements and must fall under the authority of the DMHC. It is interesting to note that defendant HPMG was designated as a Pioneer ACO in California and it looked and acted like a health service plan for its subscribers and enrollees. Nonetheless it operated without a license by DMHC. These regulations must assure subscribers and enrollees of all other ACO in California that are operating as Health Care Service Plans that the protections afforded consumers under Knox-Keene will be enforced by the DMHC.</p> <p>¹ http://www.chcf.org/publications/2012/08/aco-map</p>	NO CHANGE REQUESTED. The Department appreciates the comment.
1-2	Victoria Bermudez	I am puzzled by the separation of proposed Section 1300.49 General Licensure Requirements, (a) Definitions from the existing definitions under Section 1300.45. It would seem that all definitions that relate to health care service plans should be	NO CHANGE REQUESTED. The Department appreciates the comment.

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		<p>under the same section. However, I can also understand that keeping the definitions being used in subsection (b) close together allows for easier reference to the newly defined terms. At this time, I have no other comment to contribute, other than support for adoption of these regulations</p> <p>I would like to receive notice of any modified text that is proposed by DMHC as well as the Final Statement of Reasons that will be submitted to the Office of Administrative Law for review of compliance with all requirements of the Administrative Procedure Act.</p>	
2-3	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>The Local Health Plans of California (LHPC) represents all 16 of the community-based and not-for-profit health plans that collectively cover 70% of California’s 10.7 million Medi-Cal managed care beneficiaries. Local health plans were created to be mission-driven health plans closely connected to the communities that established them, with nearly all local health plans being public entities.</p> <p>Local health plans support policies that advance transparency, accountability and quality in our health care delivery system. We believe the Department of Managed Health Care’s (Department) proposed regulations amending the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene) adding Section 1300.49 to title 28 of the California Code of Regulations establishing licensing requirements for “restricted” licensees (Proposed Regulation) may advance these important objectives.</p> <p>However, concepts central to the Proposed Regulation – such as what entities are subject to licensure or exemptions and what prime plans’ ongoing obligations are – remain unclear. Our comments are intended to clarify and strengthen the provisions of the Proposed Regulation so that the new licensing framework firmly establishes - for the benefit of all stakeholders - the roles, responsibilities, and accountability requirements for the delegated model.</p> <p>Thank you for considering our specific comments, which are as</p>	<p>NO CHANGE REQUESTED. The Department appreciates the comment. Note that the Department has considered the request and clarified the exemption criteria in the revised proposed regulation, in subsections (b)(2) and (b)(3).</p>

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		follows:	
2-4	Brianna Lierman Local Health Plans of California (LHPC)	A. §1300.49(a) - Definitions The Proposed Regulation defines “limited license” but does not define “restricted license”. The Proposed Regulation should be revised to define “restricted license” as appropriate, taking into consideration the additional clarifications requested.	ACCEPTED. The Department has added a definition of “restricted health care service plan” to the proposed regulation.
2-5	Brianna Lierman Local Health Plans of California (LHPC)	B. §1300.49(b)(1)-(2) – Entities & Arrangements Subject to Restricted Licensure and Eligible for Exemption 1. Lack of Standards for Exemptions The Proposed Regulation defines the entities which must obtain a restricted Knox-Keene license and lists the filings the Department will review in considering licensure exemption. Section (b)(1) provides that “any person who accepts global risk... shall obtain a license to operate a health care service plan.” Global risk, the intended trigger for a restricted license, is defined as “the assumption of both professional and institutional risk.” (1300.49(a)). Professional risk is “the <i>assumption of the cost</i> for provision of physician, ancillary, or pharmacy services...” while “institutional risk” is defined as the <i>assumption of cost</i> for hospital inpatient, outpatient or ancillary services, except those performed pursuant to the entity’s own license. (1300.49(a),(d)) (emphasis added). The Initial Statement of Reasons (ISOR) states that, in establishing the restricted license framework, the Department’s intent is to exempt from restricted licensure entities with “only a small portion of global risk”, that “have only a minor market share” and/or “operate in well served areas.” However, the Proposed Regulation fails to define what constitutes “small portion”, a “minor market share” or “well served”. Instead, (b)(2) only sets forth the types of filing exhibits an applicant must submit to be considered for exemption, which is left to the Department’s complete discretion without reference to any standards or criteria. Would a combination of two factors be sufficient to allow an exemption? Or, must all three be present? Is “small portion” of risk a specific dollar amount? Will it be measured relative to how well capitalized the applicant is? If an applicant has professional risk and some risk for hospital services, but not all, is licensure still required? Is “minor market share” less than half the market? Less than a quarter? Dependent on other factors? The requirements for licensure	ACCEPTED IN PART. The Department has considered the request and clarified the exemption criteria in the revised proposed regulation, in subsections (b)(2) and (b)(3). DECLINED IN PART. As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act. However, the Department cannot provide percentiles or numbers indicating how exemption factors are weighed. The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity’s circumstances and region in which it operates. For example, the Department cannot say with certainty that an entity with only “X” percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors. Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.

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		<p>and standards for exemptions are threshold issues for a licensing framework. Clarification on this is critical so that health plans can assess their current or prospective delegated arrangements for compliance with the Proposed Regulation.</p>	<p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department's ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p>
<p>2-6</p>	<p>Brianna Lierman Local Health Plans of California (LHPC)</p>	<p>2. Distinguishing “risk” from “prepaid or periodic charge”?</p> <p>The Proposed Regulation’s definitional trigger for licensure seems to use terminology that is inconsistent with statute, which creates confusion as to whether the Department is intending to draw distinctions of regulatory consequence. By statute, an entity that functions a health care service plan (“health plan”) must obtain a Knox-Keene license. A health plan is “any person who undertakes to arrange for the provision of health care services... or to pay for or to reimburse any part of the cost of those services <i>in return for a prepaid or periodic charge.</i>” (Health & Safety Code §1345(f)(1)). Once licensed, a health plan must demonstrate that it is fiscally sound and accepts “full financial risk.” (§1375.1(a)(2)). Statutory licensure requirements make no reference to “risk” or assumption of cost. Rather, the reference is to acceptance of prepaid or periodic charges.</p> <p>By contrast, the Proposed Regulation states that an entity that accepts “global risk” is “deemed to” have received the advanced or periodic consideration that triggers the statutory requirement to get licensed as a health plan. As noted above, it defines this trigger for licensure - “global risk” - in terms of assumption of certain costs, rather than the statutory acceptance of prepaid or periodic charges. With that, does the Department now view “risk” and “advanced or periodic consideration” as synonymous? Or distinct?</p>	<p>DECLINED IN PART, ACCEPTED IN PART. The Department has considered the request and clarified that global risk is the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk and has removed the reference to advanced or periodic consideration (proposed subsection 1300.49(a)(1)) . This is consistent with Health and Safety Code sections 1345(f)(1) and 1349.</p> <p>Subsection 1300(c)(1)(A) of the revised proposed regulation provides that a restricted health care service plan may contract only with and accept global risk only from a licensed health care service plan or licensed specialized health care service plan to provide or arrange services for that entity’s subscribers or enrollees. The regulation also clarifies and modifies the requirements for an applicant seeking licensure as a restricted health care service plan.</p>

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		<p>Section (c)(1), which sets forth the limitations on restricted licensees, creates more ambiguity on how the Department distinguishes risk from prepaid payments. It provides that a restricted licensee may: (a) “accept prepaid and periodic payments for both professional and institutional risk” from a health plan <i>and</i> (b) “accept global risk”, suggesting that there is a distinction between the terms. Moreover, insofar as (b) permits a restricted license to accept “global risk” generally - as opposed to only from a health plan as provided in (a) - it conflicts with other provisions of the Proposed Regulation and should be deleted.</p> <p>If the Department views risk and advance or periodic payment as distinct concepts - both triggering licensure - the Proposed Regulation should clarify the basis and consequence of the distinction. Alternatively, if they are the same, the Department should revise the regulation to track the language in the Health & Safety Code.</p>	
2-7	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>3. Transparency in Licensure Exemptions</p> <p>Finally, it is particularly important that health plans know which entities have applied for and been granted exemptions from restricted licensure. Rather than require stakeholders to obtain this information through public records’ requests, local health plans recommend that the Proposed Regulations be revised to require the Department to disclose on its website the entities which have requested and been granted or denied exemption as well as the bases for these determinations. Sharing the rationale behind exemptions will help stakeholders understand how standards are being applied.</p>	<p>DECLINED. Public information is available from the Department through the California Public Records Act as required by law. The rationale behind exemptions will be stated on the exemption itself. The Department has no plans at the current time to make this information available on its public website.</p>
2-8	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>C. §1300.49(c) - Granting of Restricted Licenses</p> <p>The Proposed Regulation clarifies the Department’s authority to grant a restricted license to a person that accepts global risk and contracts only with a full service or specialized “health care service plan”. However, not all Medi-Cal plans are a “health care service plan”, as defined. If consistent with the Department’s intent, this subdivision should be revised (and other conforming changes made) to permit a restricted licensee</p>	<p>DECLINED. The Department has considered the request and notes that the proposed regulation does not affect existing licensure requirements or exemptions for Medi-Cal entities.</p> <p>The amended proposed regulation clarifies licensure requirements by defining a restricted health care service plan licensee as an entity that is licensed to provide or arrange payment or reimbursement to subscribers under</p>

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		<p>to also contract for global risk with these types of Medi-Cal plans.</p> <p>Second, while it has historically been the Department’s practice to issue licenses only where there are contracts in place for the business being licensed, local plans request that subdivision (c) clearly state that a restricted license cannot be <i>obtained or maintained</i> by a person who does not have an executed contract for operations subject to licensure. This clarification is important to maintain Medi-Cal network stability.</p>	<p>a contract or other arrangement whereby the person assumes both professional and institutional risk (subsection 1300.49(a)(6)).</p>
2-9	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>D. §1300.49(c)(1) - Limitations for Restricted Licenses</p> <p>Subdivision (c)(1) outlines the limitations for restricted licenses, which may (a) accept prepaid or periodic payments for both professional and institutional services from a licensed health plan and (b) may accept “global risk”. As noted above, local health plans believe this subdivision needs further clarification and revision generally.</p> <p>Additionally, local health plans recommend that this subdivision be further refined to specify that a restricted licensee, which is generally a provider, may not hold itself out as a health plan. In today’s delegated environment, restricted entities are identified by consumers, plans, and other stakeholders as “providers”. This is an important distinction between payor and provider, reflecting the reality that the licensed health plan bears ultimate responsibility for that entity’s performance and the consumer’s care. If that same provider entity must now get a restricted license, is it then referred to as a “health plan”? Will restricted licensees be subject to all laws and requirements impacting health plans? Will referring to restricted licensees as health plans relieve or cause more confusion in the market? Local plans believe it will cause confusion and therefore recommend careful consideration and limitation on whether these entities are referred to as “health plans”, particularly without reference to their restricted status.</p>	<p>DECLINED. As noted above, revised subsection 1300.49(c)(1) now clarifies that a restricted health care service plan may contract with and accept global risk from only a licensed health care service plan or specialized health care service plan to provide or arrange services for that plan’s enrollees or subscribers.</p> <p>A restricted health care service plan, as now defined in revised subsection 1300.49(a)(6), must contract with a health care service plan or specialized health care service plan, and may not directly market, solicit, or sell health care service plan contracts. Parties to these contracts who are licensed from the Department will be required to comply with the Knox-Keene Act.</p>
2-10	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>E. §1300.49(c)(2)-(3) - Restricted License Application Filings</p> <p>Proposed Regulation subdivision (c) requires an entity to file an application for licensure, which must include several exhibits, including contracts and a division of financial responsibility (DOFR).</p>	<p>DECLINED IN PART, ACCEPTED IN PART. The Department has considered the comment and has revised the proposed regulation to state that an applicant for a restricted health care service plan license shall maintain its own contract provider network that ensures</p>

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		<p>Additionally, (c) requires the entity to maintain and substantiate its network adequacy as required by relevant provisions of the Health & Safety Code. Local health plans have the following suggestions and recommendations for incorporation into the license application process:</p> <p>1. Require Documentation of Suitability to Delegation</p> <p>As a first recommendation under license application requirements, local health plans suggest that a restricted license applicant be required to submit to the Department supplemental documentation that specifically substantiates its suitability to delegation. Currently, for health plans, the pre-delegation audit is an important tool in ascertaining and confirming whether an entity is qualified to take on the care management and fiscal responsibilities inherent under a global risk arrangement. The additional documents to be required by the Department could be a pre-delegation audit report or appropriate accreditation by a recognized accrediting agency. Incorporating this additional element is critical to promoting both quality and accountability in delegated arrangements.</p>	<p>adequate access to all health care services for which it maintains responsibility pursuant to the Health Care Service Plan Responsibility Statement (subsection 1300.49(c)(3)). During the application process, all information will be thoroughly reviewed by the Department to ensure that the license applicant has sufficient contracts in place and to comply with the requirements of the Knox-Keene Act, including the ability to delegate. The Department already has the ability to audit a health plan under provisions of the Knox-Keene Act.</p>
2-11	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>2. Clarify Requirements for Parallel Filings</p> <p>Second, for plan-plan arrangements or plan-RBO arrangements, the full-service plan typically submits a parallel filing to the Department. However, subdivision (c) makes no reference to the prime plan's filing requirements in relation to the restricted entity's. Does the prime plan have to submit a parallel filing, which the Department will review for consistency as part of the restricted license application? Local plans suggest that the application process requirements clarify the obligations of the restricted applicant's partner plan.</p>	<p>ACCEPTED IN PART, DECLINED IN PART. The Department has revised the proposed regulation to clarify that the restricted health care service plan's responsibility statement shall disclose which Knox-Keene Act requirements are the responsibility of the full service plan, and which are the responsibility of the restricted licensee. Both entities would sign the statement (subsection 1300.49(c)(2)(C)). Further, existing Health and Safety Code section 1351 and title 28, rule 1300.51, require the applicant to disclose information related to its application that will include information substantiating its arrangement with the licensed health care service plan or specialized health care service plan.</p>
2-12	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>3. Clarify Prime Plans' Responsibilities and Department's Expectations in Instances of Delegates' Non-Compliance</p> <p>The Department's reference to the DOFR as establishing who retains "sole responsibility" raises questions as to how the Department envisions the new licensing framework interacting</p>	<p>ACCEPTED IN PART. Subsection 1300.49(c)(2)(C) of the revised proposed regulation renames the DOFR the Restricted Health Care Service Plan Responsibility Statement (Statement). The Statement discloses which requirements remain the sole responsibility of the full service or specialized health care service plan, and</p>

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		<p>with the existing obligations between delegating parties. It appears that the Department intends to use the DOFR to create a dividing line in what each entity is regulated and accountable for; however, this is not the appropriate application of a DOFR or consistent with the nature of delegation.</p> <p>In a plan-plan agreement or a plan-IPA agreement, though certain functions are delegated, the prime plan still retains ultimate responsibility for the delegate's performance, compliance and non-compliance. The retention of this responsibility with the prime plan is reinforced by the terms of plans' contracts with the Department of Health Care Services. How does the Department envision its licensing framework impacting - either altering, complementing, or minimizing - the prime plan's existing responsibility over and accountability for its delegate? Will prime plans be held responsible for restricted licensee's non-compliance with regulatory requirements?</p> <p>If the Department expects no change to existing delegation oversight and accountability, local plans recommend the Proposed Regulations be revised to clarify that, and also to reinforce that the licensing requirement does not relieve a restricted licensee of the obligation to comply with their partner plans' oversight requirements.</p>	<p>which services are the responsibility of the applicant restricted health care serve plan. Both the plan and the applicant would be required to sign the Statement attesting to its veracity.</p> <p>Subsection 1300.49(c)(3) of the proposed regulation now specifically requires the restricted health care service plan to comply with network adequacy requirements as to services for which the plan maintains responsibility.</p> <p>DECLINED IN PART. The renaming of the form and the disclosures that must be made by the licensee clarify which functions are the responsibilities of the parties. All parties must maintain compliance with the Knox-Keene Act requirements.</p>
2-13	<p>Brianna Lierman</p> <p>Local Health Plans of California (LHPC)</p>	<p>4. Require All Contracts to be Executed, Received Before Application Review</p> <p>Currently, subdivision (b)(2) [(c)(2)?] specifies that an application must include all necessary contractual agreements, among other things. However, this would not necessarily preclude the Department from beginning to review an application on the assurance that the final, executed contract will be provided later. To avoid this scenario, which can cause substantial market and network disruption at the local level, local health plans recommend that the subdivision be revised to further specify that an application cannot be <i>accepted, considered or reviewed</i> by the Department until it includes the relevant, executed contracts or letters of agreement.</p> <p>Thank you for considering local health plans' comments on the</p>	<p>ACCEPTED IN PART. Subsection 1300.49(c)(2)(A) of the revised proposed regulation requires an applicant for a restricted health care service plan license to file all contractual agreements between the applicant and the full service plan. Review of the agreements would be carried out under existing licensure provisions.</p> <p>DECLINED IN PART. The proposed regulation as well as existing Health and Safety Code section 1351 and title 28, rule 1300.51, already require the applicant to submit contracts demonstrating its compliance with relevant Knox-Keene Act provisions. It is not necessary to restate this existing requirement in the proposed regulation.</p>

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		Proposed Regulation. With the clarifications requested, we believe the Proposed Regulation can bring additional transparency, oversight, accountability and quality into delegated arrangements.	
3-14	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	The California Association of Public Hospitals and Health Systems (CAPH) appreciates the opportunity to submit comments on the proposed rule published by the Department of Managed Health Care (DMHC) around general licensure requirements for health care service plans. We appreciate the need to clarify the scope of risk that health care providers may assume before a Knox-Keene license is required, and we support the DMHC’s effort to codify a rational approach to making licensing decisions based on assumption of financial risk.	NO CHANGE IS REQUESTED. The Department appreciates the comment.
3-15	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	<p>CAPH represents California’s 21 public health care systems that are owned or operated by counties, special county hospital authorities, and the University of California medical centers (PHS) who deliver primary, specialty, emergency, and inpatient care through their hospitals, clinics, and physician networks to all who need it, regardless of ability to pay or circumstance. As core safety net providers to California’s low-income population, public health care systems serve 2.85 million Californians and provide over 10 million outpatient care visits each year. They operate half of the state’s top-level trauma and burn centers, and train more than half of the state’s new physicians. These hospital systems are typically referred to as “designated public hospitals” in the California Welfare and Institutions code, but are referred to here as public health care systems or PHS.</p> <p>Before the regulation is finalized, we would like to bring to your attention unique circumstances that apply to California’s PHS, which should be addressed in the final rule to ensure that DMHC’s clarifications do not mistakenly disrupt the state’s health care safety net.</p> <p>A. PHS are integrated providers that personally furnish both professional and institutional services, and have not previously been required to obtain a Knox-Keene license. The final regulation should preserve this historical treatment, and clearly exempt PHS from Knox-Keene</p>	NO CHANGE IS REQUESTED. The Department appreciates the comment.

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		licensing requirements.	
3-16	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	Under California law, PHS are permitted to act as integrated health systems that personally furnish professional services, through contract, employment or otherwise, in addition to institutional services (PHS also may provide services through public clinics that are exempt from state licensure). PHS routinely bill payors for both professional and institutional services in both fee-for-service and managed care settings. When PHS take on risk for services performed through their own systems, they are not fundamentally changing the scope of services for which they may be reimbursed—they continue to bill such services as health care providers, not as health care service plans. We urge DMHC to confirm, by adopting one of our recommendations below, that consistent with longstanding policy and practice, the proposed new regulatory focus on “global risk” will not require PHS to hold a Knox-Keene license simply because they personally furnish both institutional and professional services.	DECLINED. The Department has considered the comments and has determined in situations when the proposed regulation would require licensure for taking on global risk, public health systems may be able to obtain exemptions under the statutory criteria set out in Health and Safety Code section 1343. The public health system applicant will be required to demonstrate to the Director that the application for an exemption would meet the criteria under Health and Safety Code section 1343(b).
3-17	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	As DMHC acknowledges, the longstanding policy in California is that providers furnishing services under the scope of their own professional license do not need Knox-Keene licensure unless they undertake to arrange for services they are not personally licensed to furnish. As reflected in DMHC’s initial statement of reasons, while all providers who contract with health plans assume some degree of risk for the cost of services they provide, the Knox-Keene Act does not typically require such licensed health care providers to become a licensed health plan. DMHC’s longstanding policy strikes an appropriate balance by regulating only those providers that take on additional roles and responsibilities beyond what they can provide pursuant to their provider license. In this way, DMHC minimizes unnecessary burdens on California’s health care providers, while serving the genuine policy goals of the statutory scheme: safeguarding health plan enrollees and protecting the stability of the health care marketplace. Under the proposed rule, an entity that accepts global risk is deemed to have received “advance or periodic consideration”	NO CHANGE REQUESTED. We appreciate your comment and agree that a provider furnishing services under the scope of his or her professional license does not fall within the definition of a health care service plan and does not accept global risk and therefore does not require licensure as a health care service plan. The policy expressed in Business and Professions Code section 2400 against the corporate practice of medicine is intended to prevent unlicensed persons from interfering with or influencing the physician’s professional judgment. It is not clear how the commenter believes the proposed regulation will impact the prohibition against the corporate practice of medicine and it is clearly not the Department’s intent to do so. Further, it should be noted that Health and Safety Code section 1367(g) requires that medical decisions are rendered by qualified providers, unhindered by fiscal and administrative management.

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		on behalf of subscribers or enrollees, and required to obtain a Knox-Keene license. In most circumstances, DMHC’s proposal to rely on the concept of “global risk” as the indicator of whether licensure is required for a provider is both sensible and consistent with longstanding practice. Licensed health care providers are usually able to furnish and bill for only professional or institutional services, but not both. This is especially true in California because the doctrine prohibiting the corporate practice of medicine forecloses most institutional providers from employing physicians or otherwise personally furnishing (or contracting for the provision of) professional services. Thus, for example, a medical group that takes on institutional risk would effectively be contracting for services it cannot perform itself. Similarly, a private hospital that assumes risk for professional services would receive payment for, and be responsible for reimbursing, professional services in a way not permitted under its facility license. Providers taking on such “global risk” implicate the Knox-Keene Act because they would be “undertaking to arrange” for health care services furnished by other providers, thereby raising potential solvency concerns and modifying their relationship with enrollees.	
3-18	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	Because PHS personally furnish both professional and institutional services, they are in a uniquely different position from other health care providers. In short, because PHS may contract with a plan on an at-risk basis to provide a global scope of services (i.e., both professional and institutional services) as health care providers, they should not be subject to further regulation as health care service plans, consistent with longstanding policy. For the reasons stated below, DMHC should ensure that the final regulation does not mistakenly apply the concept of “global risk” to prevent PHS from entering into capitated contracts for the full scope of services a PHS may provide under California law—which includes both institutional services, as well as professional services through employed or contracted physicians.	DECLINED. See response to 3-16. It should be noted that the proposed regulation will not prevent a PHS from entering into capitated contracts for the full scope of services a PHS may provide. The proposed rule requires licensure only when risk is assumed for institutional services provided by another entity.
3-19	Erica Murray California Association of Public	1. PHS Are Subject to Extensive Public Oversight. Consistent with the proposed exemption consideration in section 1300.49(b)(2)(A), PHS are subject to extensive reporting and oversight. For example, detailed financial reports	NO CHANGE REQUESTED.

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	Hospitals and Health Systems (CAPH)	about counties are filed with the State Controller every year pursuant to section 12463 of the Government Code. Even if not identical to Exhibit GG and Exhibit HH, these statements make significant financial information available. Thus, PHS are much less at risk of sudden financial distress or insolvency, and their capacity to take care of patients can effectively be monitored from a fiscal standpoint. Unlike typical health care service plans, PHS are also subject to oversight from licensing agencies; their hospitals are regulated by the Department of Public Health, and their employees are overseen by licensing organizations like the California Medical Board.	
3-20	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	2. The Government Entities that Own or Operate PHS Take On Extremely Limited Institutional Risk as A Proportion of Annual Income. PHS are owned or operated by units of government—counties, county hospital authorities, and the Board of Regents of the University of California—which have taxation authority or access to tax revenues. Moreover, counties have diversified revenue streams beyond health care income. With the involvement of the affiliated governmental entity, PHS are more financially resilient than other providers. And as integrated systems, the majority of the services provided under their contract with a health care service plan would be provided directly through the PHS’ own licenses or its employed or contracted professionals. As a result, consistent with the proposed exemption consideration in section 1300.49(b)(2)(B), the institutional risk the PHS might assume would be extremely small as a fraction of their public entity owner’s total operating budget.	DECLINED. See response to 3-16.
3-21	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	3. PHS Are Inherently Local. Consistent with the proposed exemption consideration in section 1300.49(b)(2)(C) and (D), PHS serve their own community members, which usually means enrollees in the same county. As local providers, they cover clearly defined geographic service areas; this also limits the number of enrollees for whom they provide services.	NO CHANGED REQUESTED.
3-22	Erica Murray California Association of Public Hospitals and Health	4. PHS Do Not Directly Enroll or Market to Subscribers. PHS maintain their professional relationship with health plan members. Rather than enrolling members directly, or marketing to them, they contract with licensed health plans to be providers.	NO CHANGE REQUESTED.

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	Systems (CAPH)		
3-23	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	5. Interpreting the Knox-Keene Act to Restrict PHS Would Conflict with Other Statutory and Policy Directives. California agencies like the Department of Health Care Services have encouraged PHS to become integrated systems, which research shows deliver the best health outcomes to patients. In particular, the standards and timelines set forth in current law (Welf. & Inst. Code § 14184.50(g)) and the Medi-Cal 2020 demonstration require PHS to expand their use of alternative payment arrangements that include the assumption of risk for institutional and professional services. These existing requirements do not contemplate and are not consistent with DMHC’s proposed licensure requirements.	NO CHANGED REQUESTED. See also the response to 3-16.
3-24	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	We believe aspects of the proposed regulation are sensitive to these concerns—the definition of “institutional risk” and the exemption criteria discussed in subdivision (b) make clear that legal and structural differences between providers matter. However, because the regulation does not specifically address PHS, there is a risk that it will be improperly or inconsistently applied to them. <i>To avoid that outcome, we seek an exemption from the proposed regulation that ensures PHS may continue to furnish both institutional and professional services, without the added requirement to seek a Knox-Keene license.</i>	DECLINED. The Department has considered the comment and has determined that a specific exemption for public health systems in the regulation is not required, because they may be able to obtain exemptions under Health and Safety Code section 1343, based on the factors cited in the comments. Further, the ability to request an exemption is detailed in the proposed regulation, subdivisions (b)(2) and (b)(3).
3-25	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	B. Some PHS may also take on limited responsibility for services furnished by other providers; these arrangements should not be deemed to create “global risk” requiring licensure. As you are aware, some PHS have historically contracted with health plans to take responsibility for the health care needs of identified members in exchange for capitation payments. These arrangements encourage efficient delivery of care by rewarding the PHS for coordinated, quality care that improves long-term patient health without driving up costs. These contracts are intended to predominantly be for services furnished directly by the PHS through its own network of integrated, publicly-operated facilities and professional practices. However, the PHS and the health care service plans they contract with have developed financial arrangements to account for the treatment of the occasional needed services	DECLINED. The Department has considered the comment and has determined that a specific exemption for public health systems is not required, because they may seek exemption under Health and Safety Code section 1343. Further, the ability to request an exemption is detailed in the proposed regulation, in subdivision (b)(2). These arrangements will be reviewed by the Department during a request for exemption by the Director.

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		<p>outside of the PHS, primarily in the case of emergency services rendered by other providers.</p> <p>A common arrangement is for health care service plans that contract with PHS on a capitated basis for certain assigned members to continue to take responsibility for limited services provided by other providers to the assigned members, such as emergency services, and to deduct expenses they have incurred for such services from capitation payments to the PHS. This kind of arrangement aligns the interests of the health plan and the PHS to promote the use of the integrated system, while ensuring that emergency and other necessary services outside that system are paid consistent with the requirements of the Knox-Keene Act. In most cases, the PHS does not “undertake to arrange” for these services from other providers, and the health plan retains responsibility for processing and paying the claims. Also, the services provided by other providers represent a small fraction of the PHS’ total operating budget and total assumed financial risk. Moreover, PHS do not directly enroll subscribers, but rather they contract with licensed health plans to be providers of services. However, for PHS that are capitated, the PHS may hold indirect financial risk for payments the health care service plan makes to other providers.</p> <p>We seek confirmation that these limited arrangements will not force DMHC into the conclusion that a public health care system is assuming “global risk” outside the scope of its license or other authority to provide services. In the circumstances described above, the PHS should not be deemed to have taken on “institutional risk” outside the scope of its own license if its only responsibility is indirect financial liability for out-of-network services. As a result, the stability of the health care system is unlikely to be materially impacted. Additionally, these arrangements allow PHS to focus on their core role as providers of service—the PHS do not hold themselves out, or interact with other providers, as health care service plans.</p>	
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		<p>These out-of-network financial arrangements are a necessary consequence of capitation-based contracts—which align incentives to provide high quality, cost effective care—that include emergency services. The recognition of some out-of-network claims in the calculation of payments to a PHS does not fundamentally change the predominant character of the PHS as a provider of services, and should not render the system liable to licensure under Knox-Keene.</p> <p>Without confirmation of this conclusion, integrated providers like PHS may be faced with a stark choice under the proposed regulation: to either revert entirely to a fee-for-service model, thereby undermining key financial incentives to effectively manage patient care, or take on all responsibilities attendant to operating as a health care service plan. We do not believe either of these alternatives would further the interests of the state or of health plan enrollees.</p>	
3-26	<p>Erica Murray</p> <p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>Recommendations</p> <p>To fully address the concerns discussed above, we request the following amendment be included in the final (new text is underlined):</p> <p>(b)(1) <u>Except as provided in paragraph (3) below</u>, any person who accepts global risk receives “advance or periodic consideration” from or on behalf of subscribers or enrollees and shall obtain a license to operate a health care service plan pursuant to section 1349 of the Health and Safety Code.</p> <p>(b)(3) <u>The provisions of paragraph (1) shall not apply with respect to any person who operates a designated public hospital, as the term is defined in section 14184.10(f) of the Welfare and Institutions Code, insofar as it would otherwise preclude such person from accepting global risk without obtaining a license to operate a health care service plan, as long as the majority of services for which the person is at risk are performed pursuant to the person’s own license or other authority to furnish health care services.</u></p> <p>We believe this amendment would appropriately support and protect the public safety net by maintaining the traditional role of the PHS without compromising the policy objectives of the</p>	<p>DECLINED. The Department has considered the comment and has determined that a specific exemption for public health systems is not required, because they may be able to obtain exemptions under Health and Safety Code section 1343, based on the factors cited in the comments. Further, the ability to request an exemption is detailed in the proposed regulation, subdivision (b)(2). These arrangements will be revised by the Department during a request for exemption by the Director.</p>

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		Knox Keene Act.	
3-27	Erica Murray California Association of Public Hospitals and Health Systems (CAPH)	<p>If the above recommendation cannot be implemented, we request, in the alternative, the following modification to subdivision (b)(2):</p> <p>(b)(2) An exemption from this section may be granted by the Director to any person upon review and consideration including the following:</p> <p>(A) The filing of Exhibit GG, Financial Viability, and Exhibit HH, Projected Financial Viability, the application for licensure, pursuant to rule 1300.51 of title 28. The Exhibits shall include current and projected changes that have or are expected to occur upon the assumption of global risk. A person that currently files audited financial statements with the Department or the State Controller may request an exemption from filing Exhibit GG;</p> <p>...</p> <p><u>(E) The person operates an integrated health system that includes a designated public hospital, as the term is defined in section 14184.10(f) of the Welfare and Institutions Code.</u></p> <p>Thank you for the opportunity to address the unique circumstances of PHS. We appreciate the chance to work with you to improve the regulatory guidance in this important area.</p>	DECLINED. The Department has reviewed the suggestion and has determined that separate exemption provisions for public health systems are not necessary because these types of entities may request an exemption under the proposed regulation as well as existing Health and Safety Code section 1343(b).
4-28	Dietmar A. Grellmann California Hospital Association (CHA)	<p>The California Hospital Association (CHA), representing over 400 hospitals and health systems, is concerned that the proposed regulation will have the unintended consequence of requiring providers to obtain licensure, or at least pursue an exemption from licensure, for common financial arrangements that are not subject to the Knox-Keene Act. We understand the Department never intended to extend licensure to these arrangements. However, the ambiguous nature of some elements of the regulation could lead to this interpretation. Accordingly, CHA requests that the regulation be revised to more specifically state which arrangements trigger a licensure requirement and to exempt those arrangements that do not trigger Department jurisdiction pursuant to Health & Safety Code Section 1341(a) and Section 1345(f)(1).</p>	ACCEPTED. The Department revised the proposed regulation clarifying the definitions of global, institutional, and professional risk, and also clarified how to obtain an exemption under Health and Safety Code section 1343.

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4-29	Dietmar A. Grellmann California Hospital Association (CHA)	Section 1341(a) authorizes the Department to regulate “health care service plans” defined in Section 1345(f)(1) as: “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.” We believe the definition of “global risk” in Section 1300.49(a)(1) and the related definitions of the proposed regulation may implicate the following types of financial arrangements that do not involve a provider accepting a prepaid charge from or on behalf of an enrollee for arranging health care services as defined in Health & Safety Code Section 1345(f)(1):	NO CHANGED REQUESTED. See also response 4-28, above.
4-30	Dietmar A. Grellmann California Hospital Association (CHA)	1. <u>Bundled Payment Arrangements</u> Parties to these arrangements are incentivized to work together under a common budget or target cost. This coordination of effort improves the quality of care because hospitals, physicians and post-acute care providers are working as a team. These arrangements are also more efficient and thus reduce the cost of care.	ACCEPTED IN PART. The revised proposed regulation now includes clarified definitions of global, institutional, and professional risk. DENIED IN PART. The Department will review each applicant who requests an exemption from the proposed regulation as stated under subdivision (b)(2) of the proposed regulation. An applicant with the type of arrangement noted by the commenter may request an exemption from the Director under Health and Safety Code section 1343.
4-31	Dietmar A. Grellmann California Hospital Association (CHA)	2. <u>Institutional Risk Pool Arrangements</u> Parties to these arrangements allocate a surplus/deficit to an agreed target for health care services that are provided by hospitals. Various mechanisms are used to ensure participating physicians and other providers are not incurring a significant amount of risk, but are encouraged to participate in a meaningful way in the coordinated delivery of health care services.	ACCEPTED IN PART. The revised proposed regulation now includes clarified definitions of global, institutional, and professional risk. DENIED IN PART. The Department will review each applicant who requests an exemption from the proposed regulation as stated under subdivision (b)(2) of the proposed regulation. An applicant with the type of arrangement noted by the commenter may request an exemption from the Director under Health and Safety Code section 1343.

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4-32	Dietmar A. Grellmann California Hospital Association (CHA)	<p style="text-align: center;">3. Integrated Care Arrangements</p> <p>In these arrangements hospitals and physicians form an integrated system to coordinate health care services for enrollees. Reimbursement is often a combination of fee-for-service and a limited amount of shared savings.</p>	<p>ACCEPTED IN PART. The revised proposed regulation now includes clarified definitions of global, institutional, and professional risk.</p> <p>DENIED IN PART. The Department will review each applicant who requests an exemption from the proposed regulation as stated under subdivision (b)(2) of the proposed regulation. An applicant with the type of arrangement noted by the commenter may request an exemption from the Director under Health and Safety Code section 1343.</p>
4-33	Dietmar A. Grellmann California Hospital Association (CHA)	<p>Not only do these arrangements not trigger DMHC jurisdiction or implicate licensure requirements under the Knox-Keene Act, they also meet the “spirit” of the Knox-Keene Act which was intended to ensure health plans are able to deliver on their promise to arrange health care services after accepting a pre-paid charge from enrollees. The arrangements listed above, and similar types of arrangements, are low-risk to the stability of the health care system, are intended to improve efficiencies in the delivery of health care, and most importantly allocate resources among participants in the health care delivery system and do not include the assumption of risk that occurs by accepting prepaid charges from or on behalf of enrollees.</p>	<p>ACCEPTED IN PART. The revised proposed regulation now includes clarified definitions of global, institutional, and professional risk.</p> <p>DENIED IN PART. The Department will review each applicant who requests an exemption from the proposed regulation as stated under subdivision (b)(2) of the proposed regulation. An applicant with the type of arrangement noted by the commenter may request an exemption from the Director under Health and Safety Code section 1343.</p> <p>It should also be noted that the commenter has not supplied any information that these types of arrangement would fall outside of the jurisdiction of the Knox-Keene Act if they met the criteria within the proposed regulation.</p>
4-34	Dietmar A. Grellmann California Hospital Association (CHA)	<p>It appears the Department attempted to address these concerns by establishing an exemption process in Section 1300.49(b)(2). This section, however, does not establish any criteria upon which the parties can determine if an exemption is necessary. Section 1300.49(b)(2) merely states the documents and information needed for the Director’s “review and consideration.” This ambiguity may result in the Department</p>	<p>DECLINED. The revised proposed regulation clarifies the exemption provision, but the criteria for exemptions remain the statutory criteria set out in Health and Safety Code section 1343. As required under the statute, the Director will review each request for exemption to ensure that it meets the criteria listed in subdivision (b) of the statute.</p>

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		being inundated with requests for exemption by parties that have developed arrangements that were never intended to be subject to the regulation. In addition, this lack of certainty will increase compliance costs for providers and slow the development of efforts to coordinate the delivery of cost-effective high quality health care services.	
4-35	Dietmar A. Grellmann California Hospital Association (CHA)	We encourage the Department to provide more detail in the definitions of the proposed regulation to exclude the many successful arrangements that do not implicate Health & Safety Code Section 1345(f)(1). An appropriate option may be to convene stakeholders to obtain a better understanding of the innovation that is occurring in the provision of coordinated health care services before engaging in a regulatory process that may have serious unintended consequences. Thank you for the opportunity to provide comments.	DECLINED. See responses 4-30 and 4-34.
5-36	Andy Coe Stanford Health Care	On behalf of <i>Stanford Health Care</i> , we appreciate the opportunity to submit comments on the Department's proposed regulations defining both global risk and the requirements for licensure of entities that take global risk. In this area in particular, the Knox-Keene Act and its regulations are less than clear and, in some cases, subject to unwritten interpretation (take, for example, the unwritten rule that permits licensed physicians/medical groups to accept capitation/assume financial risk for the provision of professional services). We thank the Department for its efforts to bring clarity to the rules governing organizations and arrangements that will be subject to the Department's jurisdiction.	NO CHANGE SUGGESTED. The Department appreciates the comment.
5-37	Andy Coe Stanford Health Care	As threshold matter, we understand the importance of ensuring uninterrupted access to health care services through licensure and oversight of entities that assume significant financial risk. However, we believe that access to care not only means establishing the availability of financially solvent providers in a service area; it also means ensuring that patients can financially afford to seek professional services in the first place. Health care costs have continued to rise across California. As a consequence, providers and payers are increasingly seeking to enter into new and innovative relationships in an effort to	NO CHANGE REQUESTED. The Department appreciates the comment.

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		lower costs and improve quality for patients. To the extent the proposed regulations impact these efforts, we ask that you carefully consider and balance multiple considerations that affect patients and their ability to access care.	
5-38	Andy Coe Stanford Health Care	<p>1. Defining "global risk."</p> <p>While we agree that it may be beneficial to establish a new rule in order to clearly "set the level of financial risk that triggers a requirement to obtain licensure by the [D]epartment,"¹ we believe the proposed regulations do not clearly do so, and may actually capture arrangements that do not meet the statutory definition of a "health care service plan." Though the language of the proposed regulation itself is not clear on this point (the proposed regulation does not clearly define risk as the assumption of all or only a portion of the cost for health care services), the Department's Initial Statement of Reasons suggests that the assumption of any "cost" for the provision of both professional and institutional risk, no matter how small, constitutes "global risk."² By broadly defining "global risk", the proposed regulations implicate arrangements that we believe are not equivalent to assuming "global risk" and certainly not as accepting a "prepaid or periodic charge by or on behalf of. . . subscribers or enrollees."³ For example:</p> <hr/> <p>¹ See Initial Statement of Reasons, Section II.</p> <hr/> <p>² See Initial Statement of Reasons, Section III, in which the Department states that "entities that take on <i>any portion</i> of institutional risk [in addition to professional risk]... need to be licensed" (emphasis added).</p> <p>³ California Health & Safety Code Section 1345(f)(l) (defining " health care service plan").</p>	See response 4-30.
5-39	Andy Coe Stanford Health Care	<p>A. Bundled payment arrangements, in which an entity (typically a hospital or other institutional provider) assumes limited financial risk for the provision of health care services (both professional and institutional) related to a specific procedure or diagnostic condition (<i>e.g.</i>, knee or hip revisions). By establishing a budget or target cost for the provision of services related to the specified procedure or diagnostic condition, the parties to such arrangements aim to incentivize providers across the</p>	See response 4-30.

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		continuum of care to coordinate their efforts and provide high quality, cost-efficient services. Bundled payment have been embraced by Medicare (e.g., the Bundled Payment for Care Improvement (or "BPCI") and Comprehensive Care for Joint Replacement (or "CCJR") programs), and, to a lesser extent, by commercial payers in California (ironically, because of uncertainty regarding the applicability of the Knox Keene Act to such arrangements and the cost benefit analysis of obtaining a restricted license).	
5-40	Andy Coe Stanford Health Care	B. Institutional risk pool arrangements, in which payers and capitated professional provider (medical groups or IPAs) agree to share some portion of the financial upside/downside of the cost, relative to an agreed upon budget, of health care services furnished by institutional providers. Typically, these arrangements are structured such that the provider's share of any "downside risk" (or risk pool deficit) for any given period is limited to fifty percent (50%) or less of the total deficit and is not immediately payable by the provider. Instead the provider's share of the risk pool deficit is carried forward and used to offset the provider's share of any surplus in the risk pool (upside gains) in future periods. Institutional risk pool arrangements have been structured this way in large part due to an understanding that the Department does not view such an arrangement as creating "global risk" or the acceptance by the provider of a "prepaid or periodic charge." However, a literal reading of the proposed regulations suggest that such arrangements might, in fact, constitute the acceptance "global risk", as the provider is ultimately responsible for a portion of the cost of providing institutional services.	See response 4-30. To the extent that these types of risk arrangements meet the definitions contained in the proposed regulation, these entities would be required to either obtain a license or an exemption from licensure under the Knox-Keene Act.
5-41	Andy Coe Stanford Health Care	C. Institutional risk pool arrangements such as those described above in which the professional provider's share of the risk pool deficit (again, typically no greater than fifty percent (50%) of the risk pool deficit) is [immediately payable, but] limited to an agreed upon aggregate dollar amount or cap. In such arrangements, the provider's assumption of the cost of institutional	See response 4-30. To the extent that these types of risk arrangements meet the definitions contained in the proposed regulation, these entities would be required to either obtain a license or an exemption from licensure under the Knox-Keene Act.

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		services (risk) is clearly limited, typically well within what the organization is able to absorb, and not typically viewed or interpreted as the acceptance of a "pre-paid or periodic charge."	
5-42	Andy Coe Stanford Health Care	D. Arrangements in which a health system consisting of both professional and institutional providers, a "clinically integrated network," an institutional provider, or a medical group or IPA agrees to manage and coordinate the delivery of health care services for a defined population of enrollees, receives fee-for-service reimbursement for health care services provided to such enrollees, and shares a limited portion (typically less than twenty percent (20%)) of the amount by which the total cost of providing health care services to such enrollees (both professional and institutional) is greater or less than an agreed upon annual budget for the provision of such care	See response 4-30. To the extent that these types of risk arrangements meet the definitions contained in the proposed regulation, these entities would be required to either obtain a license or an exemption from licensure under the Knox-Keene Act.
5-43	Andy Coe Stanford Health Care	In all of these scenarios, providers are assuming only a portion or small part of the risk of providing health care services as part of a coordinated effort to improve efficiencies and control or lower the total cost of providing such services. Under none of these scenarios do we believe a provider is accepting a "prepaid or periodic charge" in exchange for providing or arranging for the provision of health care services. Accordingly, we ask the Department to consider modifying the definition of "global risk" to expressly exclude such types of arrangements. Given the limited risk, we believe these types of arrangements pose little threat to the financial solvency of the provider (particularly when the provider is a health system or other institutional provider) and therefore no threat to enrollees' uninterrupted access to health care services. Moreover, to the extent that it requires a provider to seek and obtain licensure or an exemption, we believe the regulations as proposed could chill efforts in the industry to encourage cooperation and innovation intended to control costs and improve quality.	See response 4-30. To the extent that these types of risk arrangements meet the definitions contained in the proposed regulation, these entities would be required to either obtain a license or an exemption from licensure under the Knox-Keene Act.
5-44	Andy Coe Stanford Health Care	2. Clarifying the requirements for exemption. As proposed, the regulations would give the Department discretion to grant an exemption in situations in which the Director	ACCEPTED IN PART. The Department has considered the request and clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2).

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		<p>determines that an entity is assuming only a "small portion of global risk, [has] only a minor market share, and/or operate[s] in well served areas and [is], therefore less likely to disrupt the market and access to health care services in the event of failure."⁴ We appreciate the Department's efforts to recognize "global risk" arrangements that pose little or no risk of insolvency to a provider or disruption of enrollee care by creating a mechanism by which the Director may grant exemptions to the restricted license requirement. However, because the proposed regulation does not define what constitutes a "small portion of global risk", a "minor market share", or a "well served area" or otherwise indicate what weight the Director will give to these various factors, industry participants have no way of knowing whether an arrangement will require a license or not.</p> <hr/> <p>⁴ See Initial Statement of Reasons Section III.</p>	<p>DECLINED IN PART. As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act. However, the Department cannot provide percentiles or numbers indicating how exemption factors are weighed.</p> <p>The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity's circumstances and region in which it operates. For example, the Department cannot say with certainty that an entity with only "X" percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p> <p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department's ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p>
5-45	Andy Coe	Further, we are concerned that in the absence of clear guidelines	See response 5-44.

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	Stanford Health Care	distinguishing arrangements that will be granted an exemption from those that will not, providers seeking to enter into risk arrangements may not be treated equally or fairly. For example, a provider in an underserved market (typically a market that could most benefit from decreased costs and increased quality) may have less of a chance of obtaining an exemption than a provider in a well-served market, even though each bears the same relative amount of risk. As a consequence, efforts to innovate may be stifled in certain markets, as the time and expense to a provider of applying for a restricted license and modifying its operations to conform to a new and unfamiliar regulatory scheme may outweigh the anticipated return on investment and cause the provider to forego the opportunity to engage with the payer in the arrangement. To the extent this chills innovation or imposes barriers on the ability of payers and providers to align interests, it's the consumer that may ultimately have the most to lose.	
5-46	Andy Coe Stanford Health Care	In the interests of clarity, transparency and predictability, we believe that the specific grounds upon which exemption may be granted should expressly be made part of any new regulation. The Department already has a framework for determining whether an entity (at least certain types of entities) is sufficiently financially sound. The RBO financial solvency provisions added to the Knox-Keene Act by Senate Bill (SB) 260 and set forth in Health and Safety Code §1375.4 and its accompanying regulations provide a clear and well-known set of guidelines for determining an entity's capacity for assuming financial risk. Such guidelines could be used as a starting point for developing fair and transparent criteria for granting exemption under the new regulation. Utilizing a similar framework would satisfy the Department's needs, and would also provide a much needed level of clarity to provider organizations as they work with payers to address the affordability issue.	See response 5-44.
5-47	Andy Coe Stanford Health Care	Alternatively, the Department should consider codifying specific types of "low risk" arrangements (such as those described above) that will be deemed to be exempt from the licensure requirement. In addition to providing clarity and predictability to industry participants (critically important in today's uncertain and shifting marketplace) such an approach would have the benefit of relieving the Department of a significant portion of the administrative burden associated with reviewing and passing on	ACCEPTED IN PART, DECLINED IN PART. The revised proposed regulation clarifies the exemption provision, however the statutory exemption criteria set out in Health and Safety Code section 1343 will apply to exemption requests.

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		each and every request for exemption.	
5-48	Andy Coe Stanford Health Care	<p>3. Adopting effective date of regulation or grace period.</p> <p>As suggested above, we believe that the proposed regulations may, intentionally or not, cast a net over a number of types of arrangements historically thought to be outside the scope of the Knox- Keene Act's licensure requirements. Industry participants that have entered into arrangements that, under current law, do not violate or otherwise require license under Knox-Keene Act will require time to seek an exemption, apply for a restricted license, or terminate or renegotiate restructure these arrangements. In some cases, it is possible that compliance with the proposed regulations will significantly alter the anticipated cost/benefit analysis of the arrangement, essentially depriving both patties of the benefit of the agreed upon bargain. Accordingly, we ask that the Department consider grandfathering, for a year or some other reasonable period of time, existing arrangements. Alternatively, the Department should contemplate adopting an effective date that affords entities participating in "global risk" arrangements time to bring such arrangements into compliance with the new regulations.</p> <p>Thank you for your consideration of our comments. We support the Department's efforts to bring clarity to these matters.</p>	<p>ACCEPTED IN PART. The revised proposed regulation would become operative on the projected effective date of January 1, 2019, and apply to contracts issued, amended, or renewed on or after that day.</p> <p>DECLINED IN PART. To the extent that these types of risk arrangements described by the commenter meet the definitions contained in the proposed regulation, these entities would be required to either obtain a license or an exemption from licensure under the Knox-Keene Act.</p>
6-49	William Barcellona California Association of Physician Groups (CAPG)	<p>Thank you for the opportunity to comment on the proposed rule. We appreciate the Department's willingness to codify the long-standing application process for globally- capitated entities. We believe that the issuance of a regulation can and should result in clearer guidelines about the type of entity that can enter subcontracted relationships with full-service health plans to accept globally-capitated risk, and how to apply for this licensure.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the comment.</p>
6-50	William Barcellona California Association of Physician Groups (CAPG)	<p>Although our letter is lengthy and proposes major changes to the structure and content of the Department's proposed regulation, we do not wish to lose sight of the fact that by issuing this regulation the Department is demonstrating an intent to facilitate the movement from antiquated fee-for-service contracting to advance risk-based, value- based models. We</p>	<p>NO CHANGE REQUESTED. The Department appreciates the comment.</p>

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		believe that such a transition benefits payers and enrollees, as well as providers.	
6-51	William Barcellona California Association of Physician Groups (CAPG)	<p>With that said, we offer comments concerning this proposed draft in the areas of clarity, ambiguity and unintended consequences. Again, we believe the principal objective behind the issuance of this proposed rule is to codify a long-standing application process by providers who are capitated for professional risk and wish to enter into subcontracts with fully-licensed Knox Keene Health Plans to accept institutional capitated payment (hence, a global risk arrangement).</p> <p>The following proposal provides an alternative section under Title 28 for the regulation, basing it in the licensure application section, which focuses on the following elements:</p> <ul style="list-style-type: none"> ● Provide a narrower definition of “global risk” to incorporate only capitated “prepaid” subcontracted arrangements; ● Eliminate the need for the subsection (b) exemption process altogether; ● Specify which kind of entity can apply for restricted licensure and how to do it in an amended subsection; ● Address the Department’s interest in expanded network adequacy requirements in an alternative manner, and ● Grandfather existing licensees 	<p>ACCEPTED IN PART, DECLINED IN PART.</p> <ul style="list-style-type: none"> ● The Department has revised the definition of global risk, adding that it means acceptance of a prepaid or periodic charge in return for the assumption of both professional and institutional risk (subsection 1300.49(a)(1)). ● The Department has revised subsection 1300.49(b) exemption process statement, and has clarified that Health and Safety Code section 1343 standards apply. ● The Department has revised the restricted licensure provisions (subsection 1300.49(c)). ● The Department revised the network adequacy provisions to clarify that a restricted health care service plan must maintain a network that ensures adequate access to services for which it maintains responsibility pursuant to the plan’s Restricted Health Care Service Plan Responsibility Statement (subsection 1300.49(c)(3)). ● The revised proposed regulation applies only to contracts issued, amended, or renewed after the regulation’s effective date (subsection 1300.49(e)).
6-52	William Barcellona California Association of Physician Groups (CAPG)	<p>At the outset the Department’s proposed rule muddies the waters concerning this intention, because it defines the assumption of “global risk” as triggering a full-licensure requirement under Section 1349 of the Act without regard to the investiture of that assumption of risk within a prepaid coverage model. The proposed rule states:</p> <p><i>(a)(1) "Global risk" means the assumption of both professional and institutional risk</i></p>	See response to 6-55.
6-53	William Barcellona California Association of	The Knox Keene Act was predicated upon the distinction between health insurers that provide retrospective indemnification against the risk of payment for health care services and full-service health plans that assume global risk	See response to 6-55.

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	Physician Groups (CAPG)	through a prepaid coverage model in which they provide or arrange for all covered, medically necessary health care services. The existence of this distinction is why California has bifurcated health insurance regulation between the Department of Insurance and the Department of Managed Health Care.	
6-54	William Barcellona California Association of Physician Groups (CAPG)	The overly-broad definition of “global risk” under subsection (a) of the proposed rule is not limited to prepaid, capitated arrangements, and thus sweeps in all kinds of unrelated entities within the orbit of Knox Keene licensure requirements where the proposed rule states further at subsection (b): <i>(b)(1) Any person who accepts global risk receives "advance or periodic consideration" from or on behalf of subscribers or enrollees and shall obtain a license to operate a health care service plan pursuant to section 1349 of the Health and Safety Code.</i>	See response to 6-55. It should also be noted that the Department purposefully did not limit its proposed regulation to the types of capitated arrangements detailed by the commenter. Health and Safety Code section 1349 states in part that “it is unlawful for any person to engage in business as a plan in this state <u>or to receive advance or periodic consideration</u> in connection with a plan. . . unless such person has first secured from the director a license. . . “(Emphasis added.) To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.
6-55	William Barcellona California Association of Physician Groups (CAPG)	Subsection (b)(1) states that any assumption of global risk is treated as “advance or periodic consideration” which is another trigger for jurisdiction. The Department does not have jurisdiction under Section 1349 to regulate non-capitated, non-prepaid global risk arrangements merely because they may be “periodic.” If it did, then every health insurer operating in California would be subject to Knox Keene licensure, because they all deal in the assumption of global risk, although not in a prepaid coverage model, but certainly through “periodic” payments. Logically, there would be no need to regulate insurers under the Insurance Code. All entities would be regulated by the DMHC. The Department cannot, through regulation, expand the jurisdiction that it is not afforded under statute.	ACCEPTED IN PART, DECLINED IN PART. The Department has the revised the definition of global risk to read: “the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk” (subsection 1300.49(a)(1)). It should also be noted that the Department purposefully did not limit its proposed regulation to the types of capitated arrangements detailed by the commenter. Health and Safety Code section 1349 states in part that “it is unlawful for any person to engage in business as a plan in this state <u>or to receive advance or periodic consideration</u> in connection with a plan. . . unless such person has first secured from the director a license. . . “(Emphasis added.) The statute is quite clear that the requirement of a license is not limited to only capitation arrangement by its use of the phrasing “or period

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			<p>consideration.” Therefore, the commenter’s statement is disingenuous to the statute’s intent and the current law under the Knox-Keene Act. Restricting the definition of “prepaid or periodic charge” to only capitation is not necessary, as the underlying statute does not restrict charges to only capitation. A “prepaid or periodic” charge may include a payment that is based on a set amount of savings or losses, as the underlying statute does not require that the charge be a fixed dollar amount. Additionally, a charge does not have to occur at the start of the period of time, as a charge may still be “periodic” if it occurs at the end of a set period of time.</p> <p>To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.</p> <p>Further, Health and Safety Code section 1343(e)(1), provides an exception to the application of the chapter to an entity that has a certificate from the Department of Insurance.</p>
6-56	William Barcellona California Association of Physician Groups (CAPG)	The Department can, however, clarify its jurisdiction and issue regulations to further the application for licensure by the Department. Since the Department has issued Limited and Restricted Licenses for over 25 years, it has established a track record of who should be licensed and how they should be licensed as a globally-capitated entity. That is why CAPG suggests that this regulation is more clearly vested under section 1351 of the Act, which sets forth the licensure application standards, as well as Title 28, Rule 1300.51 which provides the application process for licensure, than under section 1349.	<p>DECLINED. Subsection 1300.49(c)(2)(A) of the proposed regulation references application of the section 1351 and rule 1300.51 licensure standards to restricted health care service plan applicants.</p> <p>See response 6-56.</p>
6-57	William Barcellona	The currently proposed rule states further at subsection (b) that:	ACCEPTED IN PART, DECLINED IN PART. The Department has revised the exemption provisions of the

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	<p>California Association of Physician Groups (CAPG)</p>	<p><i>(2) An exemption from this section may be granted by the Director to any person upon review and consideration including the following:</i></p> <p><i>(A) The filing of Exhibit GG, Financial Viability, and Exhibit HH. Projected Financial Viability, of the application for licensure, pursuant to rule 1300.51 of title 28. The Exhibits shall include current and projected changes that have or are expected to occur upon the assumption of global risk. A person that currently files audited financial statements with the Department may request an exemption from filing Exhibit GG;</i></p> <p><i>(8) The total percentage of annualized income of institutional risk that will be assumed and how it will be assumed. A contract for the assumption of global risk shall be submitted to the Department;</i></p> <p><i>(C) The estimated number of subscribers and enrollees for whom the person will provide health care services; and</i></p> <p><i>(D) The service area(s) in which the person intends to operate.</i></p> <p>Removing the ambiguity inherent in the current definition of “global risk” in proposed subsection (a)(1) and at (b)(2) removes the need for exemption under subsection (b). Keeping the current structure of the overly-broad definition of global risk under subsection (a), which creates the need for exemption through subsection (b) will require filings from hundreds of entities that function under the equivalent of retrospectively-paid global risk arrangements (See for example, the arguments contained in the California Hospital Association comment letter on this proposed rule). The Department’s Initial Statement of Reasons does not reveal an intention to broaden the scope of its jurisdiction over previously unregulated entities, nor does it assume that the number of filings will increase beyond the historic rate of five applications per year. We can only assume that this likely result is an unintended consequence.</p>	<p>proposed regulation. Subsection 1300.49(b)(2) of the revised regulation clarifies that existing statutory standards for exemption under Health and Safety Code section 1343 will apply. As noted, the revised regulation has also clarified the global risk definition to apply to acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk (subsection 1300.49(a)(1)).</p> <p>It should also be noted that the Department purposefully did not limit its proposed regulation to the types of capitated arrangements detailed by the commenter. To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343. The Department’s Initial Statement of Reasons was very clear that the addition of Rule 1300.49 is necessary to provide clarity to the definition of a health plan by making specific the definition of risk and related terms. Current law allows providers that assume only professional risk to register as a risk-bearing organization (RBO) pursuant to Health and Safety Code section 1375.4. RBO registration and financial solvency provisions were added by Senate Bill (SB) 260 (Stats. 1999, c. 529) to address the problem of provider groups that contracted to assume financial risk for health care services of subscribers and enrollees but became insolvent, threatening to disrupt delivery of health care to consumers. Rule 1300.49 does not change the RBO financial solvency rules, but it clarifies that entities that take on any portion of institutional risk, risk associated with covered hospital inpatient, hospital outpatient, and hospital ancillary services, need to be licensed.</p> <p>Additionally, although the term “risk” is used in the</p>
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			<p>Knox-Keene Act, it is not defined. Rule 1300.49 will clarify and implement the licensing requirements laid out in the Knox-Keene Act. As the court stated in <i>Hambrick</i>, the Department is uniquely situated to determine the level of risk requiring licensure. <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149. In consideration of the overarching duty of the Department to safeguard the health care delivery system, the Department has determined that, unless otherwise provided, any assumption of global risk, as defined in Rule 1300.49, requires licensure.</p>
6-58	<p>William Barcellona</p> <p>California Association of Physician Groups (CAPG)</p>	<p>By alternatively vesting this regulation within the Section 1351 and Rule 1300.51 licensure application sections, it further eliminates the need for the cumbersome, ambiguous subsection (b) of the proposed rule that attempts to set parameters for how entities that assume global risk, but are not sub-contracted providers to fully-insured health plans, could be exempted from the full-service plan licensure requirement. We propose the entire elimination of this subsection from the proposed rule.</p>	<p>DECLINED. Under revised subsection 1300.49(b)(3) exemption criteria of Health and Safety Code section 1343 will apply.</p>
6-59	<p>William Barcellona</p> <p>California Association of Physician Groups (CAPG)</p>	<p>We suggest that the Department alternatively codify the current restricted license application process through a regulation under Title 28, Rule 1300.51.4 titled “Restricted Licenses.” We have attached a draft form of this regulation, which clarifies the definitions of “global risk,” “institutional risk” and “professional risk.” Essentially, the structure of the attached alternative draft regulation would include the following elements:</p> <ul style="list-style-type: none"> • Definitions • Application provisions • Grandfather clause for existing Limited and Restricted licensees <p>We propose a narrower definition of global risk that also references the link to capitated payment:</p>	<p>DECLINED. The Department’s revised proposed regulation addresses some of these concerns:</p> <ul style="list-style-type: none"> • Narrower definition of global risk (subsection 1300.49(a)(1)). • Application provisions tied to existing provisions—section 1351 and rule 1300.51 (subsection 1300.49(c)(2)(A)). • Revised regulation would apply prospectively (subsection 1300.49(e)). <p>However, the proposed narrower definition of global risk does not fully encompass the requirements proposed by the Department nor the intentions laid out in the Department’s Initial Statement of Reasons. To the extent that other entities and their contractual arrangement fall</p>

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		<u>"Global risk" means the agreement to pay for both professional and institutional risk under a subcontract agreement for a prepaid or periodic, capitated payment between a licensed full service Knox Keene Health Care Service Plan, or a licensed specialized Knox Keene Health Care Service Plan, and a Risk Bearing Organization.</u>	under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343. The proposed definition given by the commenter does not accurately describe the types of arrangement contemplated by the Department in its rulemaking package.
6-60	William Barcellona California Association of Physician Groups (CAPG)	We also acknowledge the Department's interest in specifying the need for demonstration of network adequacy by the applicant. However, the full licensee always retains the non-delegable duty to ensure that all covered, medically necessary services are provided in a timely and geographically-accessible manner. All restricted licensee applicants will offer a more limited network than does the full licensee plan with whom it subcontracts. The essential demonstration that must be made by the applicant is that it is currently licensed to provide and arrange for professional services and that it is assuming the additional requirement to provide and/or arrange for institutional services under a globally-capitated subcontract. Entities that do not possess the current professional services licensure and who do not intend to directly provide or arrange for institutional services pursuant to a subcontract with a full licensee should be denied the restricted license. It is not the intended purpose of a restricted license, for example, to facilitate an exception to the ban on the Corporate Practice of Medicine.	ACCEPTED IN PART, DECLINED IN PART. Subsection 1300.49(c)(3) of the revised proposed regulation requires a restricted health care service plan applicant to maintain its own contracted provider network that ensures adequate access to all health care services for which it maintains responsibility pursuant to the Restrict Health Care Service Plan Responsibility Statement. The subsection references existing network adequacy requirements. The information submitted by the applicant will be reviewed to ensure that network adequacy requirements are met under the Knox-Keene Act. The policy expressed in Business and Professions Code section 2400 against the corporate practice of medicine is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. It is not clear how the commenter believes the proposed regulation will impact the prohibition against the corporate practice of medicine and it is clearly not the Department's intent to do so. Further, it should be noted that Health and Safety Code section 1367(g) requires that medical decisions are rendered by qualified providers, unhindered by fiscal and administrative management.
6-61	William Barcellona California Association of Physician Groups (CAPG)	If the regulation provided a clearer, more specific description of the entity that is eligible to apply for a restricted license, then the need for the proposed Division of Financial Responsibility (DOFR) form is eliminated. We agree with the observation by the California Association of Health Plans that "DOFR" is a term of art within the health plan industry and relates to the identification of which party assumes financial risk for services or drugs. The proposed form instead relates to which entity will	ACCEPTED IN PART. The revised regulation incorporates by reference a Restricted Health Care Service Plan Responsibility Statement, and deletes references to the Division of Financial Responsibility Form (subsection 1300.49(c)(2)(C)). The Department appreciates the provision of a proposed amended subsection (c). The Department has renamed the form incorporated by reference to prevent any confusion.

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		provide the services. We therefore, provide an amended version of the Department's proposed subsection (c) that contains a clear statement of eligibility and application procedure.	However, proposed form submitted by the commenter does not adequately address the issues the Department is addressing in its renamed form, therefore, the Department declines to adopt the commenter's proposal.
6-62	William Barcellona California Association of Physician Groups (CAPG)	<p>Finally, we want to emphasize that limited and restricted licenses have historically been used for the singular purpose of enabling a capitated RBO to assume the financial risk of paying for the enrollee's covered and medically-necessary institutional (hospital) services through a globally-capitated subcontract. A restricted license is only good so long as the underlying subcontract(s) between the capitated entity and the full-licensee(s) is in force. Restricted licensees are not mini-health plans. They do not sell health insurance coverage products to the public at large. They exist to facilitate a transition away from fragmented, fee-for-service provider payment models to more advanced risk-based models. In the 25-year history of the operation of both Limited and Restricted licensees, such entities have generated superior value for the coverage dollar. We trust that with the Department's help in issuing this regulation, that legacy will be perpetuated and expanded throughout California. For that reason the final subsection of our proposed alternative regulatory language contains a grandfather clause for the existing Limited and Restricted licensees.</p> <p>Thank you for the opportunity to comment.</p>	<p>ACCEPTED IN PART, DECLINED IN PART. The Department's revised proposed regulation provides:</p> <ul style="list-style-type: none"> • Restricted health care service plans licensed as of the effective date of the regulation may continue to engage in business as restricted health care service plans (subsection 1300.49(c)(4)). • Limited health care service plans may continue to engage in business (subsection 1300.49(d)). • The regulation will apply only to contracts issued, amended, or renewed on or after the regulation's effective date (subsection 1300.49(e)). <p>It should also be noted that the Department purposefully did not limit its proposed regulation to the types of capitated arrangements detailed by the commenter. To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.</p> <p>The proposed regulation also addresses existing restricted and limited licensees continuing to operate under their existing licenses pursuant to subdivisions (c)(4) and (d).</p>
6-63	William Barcellona California Association of Physician Groups (CAPG)	<p style="text-align: center;"><u>CAPG Proposed Alternative Draft</u> <u>Section 1300.51.4 Restricted Licenses</u> <u>(a) Definitions</u></p> <p><u>As used in this section:</u></p> <p>(1) <u>"Global risk" means the agreement to pay for both professional and institutional risk under a subcontract agreement for a prepaid or periodic, capitated payment</u></p>	<p>DECLINED. As discussed, the Department's revised proposed regulation makes several of the changes included in the alternative draft. The Department has considered and appreciates the suggestions in the alternative draft; however, the proposal from the commenter does not accurately address the intention of the Department.</p> <p>It should also be noted that the Department purposefully</p>

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		<p><u>between a licensed full service Knox Keene Health Care Service Plan, or a licensed specialized Knox Keene Health Care Service Plan, and a Risk Bearing Organization.</u></p> <p>(2) <u>"Institutional risk" means the assumption of the cost for the provision of hospital inpatient, hospital outpatient, or hospital ancillary services to subscribers or enrollees undertaken by a Risk Bearing Organization, other than services performed pursuant to the person's own license under section 1253 of the Health and Safety Code, pursuant to a subcontract with a licensed full-service Knox Keene Health Care Service Plan for prepaid, capitated payment.</u></p> <p>(3) <u>"Limited license" means a license with waivers issued by the Department or its predecessor prior to January 1, 2000, to a health care service provider or its affiliate for the provision of, or the arranging, payment, or reimbursement for the provision of health care services to subscribers or enrollees of another health care service plan under a contract or other arrangement whereby the person assumes financial risk for the provision of both professional and institutional services to the other health care service plan's subscribers or enrollees.</u></p> <p>(4) <u>"Person," for purposes of this section, shall have the same meaning as Health and Safety Code section 1345, subdivision (i).</u></p> <p>(5) <u>"Professional risk" means the assumption of the cost for the provision of physician, ancillary, or pharmacy services undertaken by physicians or other licensed or certified providers to subscribers or enrollees as a Risk Bearing Organization pursuant to a subcontract with a licensed full-service Knox Keene Health Care Service Plan, or a licensed specialized Knox Keene Health Care Service Plan, for prepaid, capitated payment.</u></p> <p>(6) <u>"Risk" means the assumption of the cost for the provision of covered health care services to subscribers or enrollees through a prepaid, capitated agreement.</u></p>	<p>did not limit its proposed regulation to the types of capitated arrangements detailed and proposed by the commenter. To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.</p>
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(7) “Risk Bearing Organization” has the same meaning as set forth under Health and Safety Code Section 1375.4(g).

(b) A restricted license may be granted to a Risk Bearing Organization that accepts global risk pursuant to subdivision (a)(1) and subcontracts only with a licensed full service or specialized health care service plan to provide or arrange health care services for that plan's subscribers or enrollees through a prepaid, capitated agreement.

(1) A restricted licensee may not market, solicit, or sell plan contracts to individual members of the public, employers, or any other person or group.

(2) An applicant seeking licensure as a restricted licensee shall complete and file an application for licensure as a health care service plan or specialized health care service plan in accordance with section 1351 of the Health and Safety Code and section 1300.51 of title 28. The application for licensure shall include all exhibit types and shall specify which functions remain the sole responsibility of the licensed full service or licensed specialized health care service plan and which functions will be delegated to and for which the applicant restricted licensee will assume financial risk and delegated authority under a subcontract for capitated payment. The application for licensure shall include all contractual agreements between the licensed full service or licensed specialized health care service plan and the applicant restricted licensee.

(3) The restricted licensee shall demonstrate its own administrative capacity and contracted provider network that ensures adequate access to all health care services delegated to the restricted licensee by the licensed full service or licensed specialized health care service plan. The restricted licensee shall demonstrate compliance under that delegated agreement pursuant to the network adequacy requirements of the Knox-Keene Act and this chapter, including those set forth in

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		<p>sections 1367, 1367.03, and 1375.9 of the Health and Safety Code. as well as sections 1300.51. 1300.67.2. 1300.67.2.1. and 1300.67.2.2 of title 28.</p> <p><u>(c) (1) Restricted licensees that were previously licensed by the Department, and, as of the effective date of this regulation, continue to be licensed by the Department. may continue as restricted licensees under this section.</u></p> <p><u>(2) Limited license health care service plans, with exemptions and waivers that are licensed by the Department as of the effective date of this regulation, may continue to engage in business as limited licensees.</u></p> <p><u>NOTE: Authority Cited: Section 1351, Health and Safety Code. Reference: Sections 1345. 1349, 1375.1 and 1375.4, Health and Safety Code.</u></p>	
7-64	Wendy Soe California Association of Health Plans (CAHP)	<p>The California Association of Health Plans (CAHP) represents 49 public and private health care service plans that collectively provide coverage to over 25 million Californians. We write today to submit our comments to the proposed rule published October 27th relating to General Licensure Requirements under the Knox Keene Act.</p> <p>Existing law</p> <p>Current law defines a “health care service plan” as “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 of those services <i>in return for a prepaid or periodic charge</i> (emphasis added) paid by or on behalf of subscribers or enrollees.” (Health and Safety Code section 1345, subdivision (f)(1)). In a companion section (HSC section 1349) this definitional trigger is framed as “...to receive <i>advance or periodic consideration...</i>” (emphasis added).</p> <p>HSC section 1375.1, subdivision (a)(2) requires a health plan to demonstrate that it is fiscally sound and has “assumed full financial risk on a prospective basis for the provision of</p>	NO CHANGE REQUESTED. The Department appreciates the comments.

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		covered health care services..." As the DMHC's Statement of Reasons for the proposed regulation notes, "full financial risk" is not defined in the statute, but that reinsurance is acceptable.	
7-65	Wendy Soe California Association of Health Plans (CAHP)	Ambiguities in the proposed regulations First, Section 1300.49(b)(1) of the proposed regulations indicates that any "person" who accepts what is calls "global risk" will be deemed to have received "advance or periodic consideration," thereby triggering the need for licensure. This is an interpretive leap, inconsistent with the definition of a health plan, equating assumption of risk with advance or periodic payment without their being a "prepaid or periodic charge." The definition of risk in 1300.49(a)(6) should be revised to include "prepaid or periodic charge" language as required in the definition. An entity that does not receive a "prepaid or periodic charge" would not be required to obtain a health care service plan license under the terms of the Knox-Keene Act.	ACCEPTED. Revised subsection 1300.49(a)(1) now defines global risk to mean the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk. The narrower definition applies to the subsection 1300.49(b)(1) licensure provision. To the extent that other entities and their contractual arrangement fall under the scope of the revised definition within the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.
7-66	Wendy Soe California Association of Health Plans (CAHP)	If the Department's intent is to regulate as health care service plans providers that participate in risk-sharing arrangements but do not receive a prepaid or periodic charge, this would be inconsistent with the terms of the Act and historical treatment by the Department. Risk-sharing arrangements between plans and providers are already subject to extensive regulation under Title 28 CCR Section 1300.75.4, et. seq.	ACCEPTED. The revised definition of global risk applies to entities that receive a prepaid or periodic charge (subsection 1300.49(a)(1)). To the extent that other entities and their contractual arrangement fall under the scope of the revised definition within the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.
7-67	Wendy Soe California Association of Health Plans (CAHP)	The jurisdictional provision that triggers the Department's authority is HSC Section 1345(f)(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 <i>any part of the cost for those services, in return for a prepaid or periodic charge</i> paid by or on behalf of the subscribers or enrollees." If there is an agreement to pay for any part of the services in exchange for a prepaid or periodic charge, the arrangement falls within the definition of a health care service plan. Assumption of risk is irrelevant to this determination. Stated differently, in the case where a provider agrees to assume risk for hospital services, the important fact is they are agreeing to pay for hospital services for a plan's enrollees in	DECLINED. The revised regulation's definition of global risk is the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk (proposed subsection 1300.49(a)(1)). This is consistent with the statutory definition in Health and Safety Code section 1345(f)(1). Assumption of risk is relevant in that the Knox-Keene Act also requires that "every plan" shall have assumed full financial risk on a prospective basis for the provision of covered health care services (Health and Safety Code section 1375.1(a)(2)). This is done to ensure that

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		<p>exchange for capitation or a periodic payment because that falls squarely within the definition of HSC 1345(f). Including risk in the determination of whether a person is operating as a health plan expands the scope of HSC 1345 and would be impermissible under the necessity and authority standards of the APA. HSC 1345 f does not include risk. When the Legislature uses a term or phrase in one place but excludes it from another, the court must assume the Legislature intended the exclusion and it should not be implied where the Legislature excluded it. (<i>People v. Gardeley</i> (1997) 14 Cal.4th 605,621 [59 Cal.Rptr.2d 356, 366].)</p>	<p>enrollees receive necessary health care services and to ensure the stability of the health care marketplace.</p> <p>To the extent that other entities and their contractual arrangement fall under the scope of the revised definition within the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.</p> <p>Additionally, although the term “risk” is used in the Knox-Keene Act, it is not defined. Rule 1300.49 will clarify and implement the licensing requirements laid out in the Knox-Keene Act. As the court stated in <i>Hambrick</i>, the Department is uniquely situated to determine the level of risk requiring licensure. <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149. In consideration of the overarching duty of the Department to safeguard the health care delivery system, the Department has determined that, unless otherwise provided, any assumption of global risk, as defined in Rule 1300.49, requires licensure.</p>
7-68	<p>Wendy Soe</p> <p>California Association of Health Plans (CAHP)</p>	<p>Second, whereas current statute refers to the assumption of “full financial risk” and although the statutory requirement “full” is not altered in the text of the proposed regulation, in two places in the official “Initial Statement of Reasons”, it is stated that the requirement for licensure as a health plan would be triggered if there were the acceptance of “at least a portion of global risk”, or the “taking on” of “any portion of institutional risk.” This also seems to be an interpretive leap, and one that it is not included in the actual text of the proposed regulations but rather only in the companion Statement of Reasons. Assuming this interpretation stands, for discussion sake, the proposed text provides no objective standards or guidelines as to what would constitute “a portion.” Is it a “mere scintilla” of financial risk? A “material” amount or degree of financial risk?</p>	<p>DECLINED. The amount of global risk is relevant to exemption from licensing, but does not alter the applicability of the licensure requirement. To the extent that other entities and their contractual arrangement fall under the scope of the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343.</p> <p>Additionally, although the term “risk” is used in the Knox-Keene Act, it is not defined. Rule 1300.49 will clarify and implement the licensing requirements laid out in the Knox-Keene Act. As the court stated in <i>Hambrick</i>, the Department is uniquely situated to</p>

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			determine the level of risk requiring licensure. <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i> , (2015) 238 Cal.App.4th 124, 149. In consideration of the overarching duty of the Department to safeguard the health care delivery system, the Department has determined that, unless otherwise provided, any assumption of global risk, as defined in Rule 1300.49, requires licensure.
7-69	Wendy Soe California Association of Health Plans (CAHP)	Proposed subsection 1300.49(b)(2) would make available an exemption from Section 1300.49 on the basis of the Department’s review of certain variables (projected financial impact, percentage of income from assumed institutional risk, number of subscribers or enrollees, service area). The Statement of Reasons, again, indicates these are intended to mean “a small portion” of financial risk, “minor market share”, and/or operate in “well-served areas”. But the proposed text gives no guidance on what would constitute triggers or threshold amounts for these variables. An entity assuming global risk would not be able to determine if it were crossing a triggering line for a “portion” of financial risk that would require seeking licensure or an exemption.	ACCEPTED IN PART, DECLINED IN PART. The revised proposed regulation makes clear that Health and Safety Code section 1343 applies to exemptions. Health and Safety Code section 1343 requires the Director to consider an exemption request when the Director finds the action to be in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Knox-Keene Act. Each entity requesting an exemption will be required to submit information demonstrating this criteria has been met.
7-70	Wendy Soe California Association of Health Plans (CAHP)	Third, the purpose of section (b) generally is not entirely clear. Section (b)(1) inappropriately equates “global risk” with receiving “advance or periodic consideration” and requires such person obtain a license. The requirement under Health and Safety Code §1349 is that a person that receives “advance or periodic consideration” on behalf of persons in this state needs to obtain a license. If a person doesn’t receive “advance or periodic consideration”, which is the term used by California’s legislature and governor in enacting §1349, “advance or periodic consideration” can’t be redefined as something else and then used to require a person obtain a license. The Department’s Statement of Reasons does not include any evidence that the term “advance or periodic consideration” needs further clarity. This concern would be addressed with the above referenced revision to the definition of risk in section 1300.49(a)(6) to include “prepaid or periodic	ACCEPTED. The risk definitions in the revised proposed regulation now refer to a prepaid or periodic charge (subsection 1300.49(a)(1), (a)(2), and (a)(5)) as referenced in the Department’s Initial Statement of Reasons (ISOR). A stated in the Authority section of the Department’s Initial Statement of Reasons, California Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate “health care service plans.” Health and Safety Code section 1345, subdivision (f)(1), defines a “health care service plan” (health plan) as “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 of those services in return for a

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		<p>charge.”</p>	<p>prepaid or periodic charge paid by or on behalf of subscribers or enrollees.”</p> <p>The Department further stated in its ISOR:</p> <p>Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume “full financial risk” for the provision of covered health care benefits to enrollees or subscribers. However, “full financial risk” is not defined. As a result, provider groups that contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services (professional and institutional risk together is considered “global risk”). These provider groups otherwise meet the definition of a health plan pursuant to Health and Safety Code section 1345, subdivision (f), by arranging for health care services for health plan enrollees and accepting at least a portion of global risk. Without a clear definition of what types and levels of risk may be assumed, entities that meet the definition of a health plan may be operating without a license. This is a violation of Health and Safety Code section 1349, which makes it unlawful to receive advance or periodic consideration in connection with a health plan without first securing a license or an exemption. The regulation would state clearly that a person that accepts global risk receives “advance or periodic consideration” requiring licensure for purposes of Health and Safety Code section 1349.</p> <p>In 2015 the California Court of Appeal, Second District, held that “the level of financial risk under a capitation agreement that causes a ‘risk bearing organization’ ... to become a ‘health care service plan’ ... is precisely the type of regulatory determination involving complex economic policy that should be made by the DMHC...”</p>
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			<p><i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149.</p> <p>By defining the term “prepaid or periodic charge” the Department is clarifying the statute and addressing the licensure requirement for entities that accept global risk.</p>
7-71	Wendy Soe California Association of Health Plans (CAHP)	We read section (b)(2) as allowing persons that accept such global risk to request an exemption from the requirement to obtain a license. While the proposed rule specifies the information persons are to provide to the Department to request an exemption, it offers no standards for the review of such information. The proposed rule should articulate the standards that the Department will use to evaluate the exemption.	ACCEPTED IN PART, DECLINED IN PART. The revised subsection 1300.49(b)(2) clarifies that Health and Safety Code section 1343 standards apply in reviewing an exemption request. Health and Safety Code section 1343 requires the Director to consider an exemption request when the Director finds the action to be in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Knox-Keene Act. Each entity requesting an exemption will be required to submit information demonstrating this criteria has been met.
7-72	Wendy Soe California Association of Health Plans (CAHP)	Fourth, section (c) sets forth the requirements related to a restricted license. Included in this section is a Division of Financial Responsibility form. “Division of Financial Responsibility” is a term of art in the health plan industry and relates to a document that identifies the party that is at risk for various health care services. The proposed form does not do this and instead relates to which entity is responsible for providing services by provider type. We suggest that a different term be used for the Department’s form to avoid confusion, such as the “Division of Network Responsibility.”	ACCEPTED. The form is changed in the revised proposed regulation to the “Restricted Health Care Service Plan Responsibility Statement” (section 1300.49(c)(2)(C)).
7-73	Wendy Soe California Association of Health Plans (CAHP)	Full licensees typically remain responsible for network adequacy when contracting with a restricted licensee. In such instances, the form should not be required and the restricted licensee’s network would be reviewed as part of the full licensee’s network, which puts the restricted licensee in the same position as limited licensees and other providers that contract with a full licensee. This is also consistent with the requirements of Health and Safety Code section 1373.3 that allows an enrollee to select any primary care physician as long	DECLINED. The references to network adequacy requirements in subsection 1300.49(c)(3) may help ensure adequate access to services for which a restricted health care service plan is responsible.

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		the primary care physician is within the full licensee’s service area where the enrollee lives or works. The references to the statutory and regulatory network requirements in subsection (c)(3) are unnecessary, and would only be applicable if the network responsibility is delegated to the restricted licensee and even then would not need to be specified in the proposed regulation, which does not reference specific Knox-Keene Act requirements for other services delegated to the restricted licensee.	
7-74	Wendy Soe California Association of Health Plans (CAHP)	Lastly, we offer some input on key terms defined in section (a). ● The term “person” is already defined in the Knox-Keene Act and do not need to be defined in these regulations.	ACCEPTED. The revised proposed regulation does not include a “person” definition.
7-75	Wendy Soe California Association of Health Plans (CAHP)	● The term “restricted license” should be additionally defined to be clearly distinct from a full Knox Keene license.	ACCEPTED. The revised proposed regulation includes a definition of “restricted health care service plan” (subsection 1300.49(a)(6)).
7-76	Wendy Soe California Association of Health Plans (CAHP)	● The definition of “institutional risk” and “professional risk” should be defined as an assumption of “risk” and not assumption of the “cost of providing services”. The services specified in both proposed definitions should also be simplified and more accurately stated as “Medicare Part A services” (for Institutional) and “Medicare Part B services” (for Professional). The listed services in the proposed definition do not reflect current industry usage of the terms institutional services and professional services. We appreciate the opportunity for comment and are available to you should you need any additional information.	ACCEPTED. The revised proposed regulation clarifies the definitions of “institutional risk” and “professional risk” (subsections 1300.49(a)(2) and (a)(5)).
8-77	Edward A. Morrissey County of Los Angeles (CoLA)	The County of Los Angeles (CoLA) hereby submits comments to the above-referenced proposed regulation. It is noted by CoLA that comments were submitted by the California Association of Public Hospitals (CAPH). With four public hospitals and the principal safety net provider in Los	DECLINED. We acknowledge the unique position of public health systems. The regulation provides a process for requesting exemption from licensure under the statutory criteria in Health and Safety Code section 1343, based on the factors listed in the statute. Health and Safety Code section 1343 requires the Director to

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		<p>Angeles County, CoLA is a member of, and agrees with the comments submitted by CAPH.</p> <p>CAPH indicates that counties inherently have diverse revenue streams such that they are subject to very limited institutional risk in proportion to their incomes. CoLA agrees. With an annual revenue in Fiscal Year 2015-16, CoLA revenues were approximately \$22.5 billion. Revenue from capitated managed care contracts comprised a small fraction, approximately 3.5% of that revenue.</p> <p>CAPH further indicates that counties are unique in that financial and public scrutiny is already an everyday fact of life. For example, as a public entity, the CoLA budgeting process and meetings are transparent and open to the public, and most documents are available for public inspection under the California Public Records Act.</p> <p>CoLA also files a Comprehensive Annual Financial Report (CAFR) as required by California Government Code section 25253. The CAFR details all sources of revenues and liabilities, and can be found online on the website of LA County's Auditor-Controller (see http://auditor.lacounty.gov/la-county-cafr/).</p> <p>For the foregoing and other reasons articulated by CAPH, CoLA believes that designated public hospitals (DPHs)/healthcare systems operated by a public entity should be exempt from Knox-Keene licensure. As such, the proposed regulations should include a clear exemption to that effect.</p>	<p>consider an exemption request when the Director finds the action to be in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Knox-Keene Act. Each entity requesting an exemption will be required to submit information demonstrating this criteria has been met.</p>
8-78	Edward A. Morrissey County of Los Angeles (CoLA)	<p>In the alternative, the proposed regulations should be revised so that the current financial relationships of DPHs/healthcare systems operated by a public entity are reflected and not included in the licensure requirement contemplated by the proposed regulation.</p>	<p>DECLINED. To the extent that licensure requirements apply, public health systems may seek exemptions under Health and Safety Code section 1343, consistent with the regulation in subsection (b)(2). Health and Safety Code section 1343 requires the Director to consider an exemption request when the Director finds the action to be in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated</p>

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			under the Knox-Keene Act. Each entity requesting an exemption will be required to submit information demonstrating this criteria has been met.
8-79	Edward A. Morrissey County of Los Angeles (CoLA)	<p>Specifically, it is noted that the proposed definition of "institutional risk", which is a component of "global risk", does not include assumption of the cost for services performed pursuant to an acute care hospital license. In reality, DPHs/healthcare systems operated by a public entity often assume some financial obligation for "out of network" services, such as emergency services, intermittently needed care when hospital capacity has been reached, and some specialty/unique services, such as pain management and transplant services that are provided by other institutions.</p> <p>As such, to avoid any unintended consequences by way of this proposed regulation in the manner of significant disruption to health care safety net services, the definition of "institutional risk" should not include an assumption of the cost for any services that could be performed under an acute care license, and for other specialty care services as long as the majority of services for which a DPH/healthcare system operated by a public entity are provided by that entity.</p> <p>Feel free contact me if you have any questions or comments.</p>	DECLINED. The definition of institutional risk excepts "services performed pursuant to the person's own license under section 1253 of the Health and Safety Code" (subsection 1300.49(a)(2)). A public health system may seek an exemption under Health and Safety Code section 1343 as stated in the proposed regulation, subdivision (b)(2).
9-80	Lynsey A. Mitchel Sheppard, Mullin, Richter & Hampton LLP	<p>Sheppard, Mullin, Richter & Hampton LLP is a law firm that represents a number of entities in connection with efforts to obtain and maintain a license with restrictions from the Department of Managed Health Care (the "Department") to operate as a Knox-Keene Health Care Service Plan for the purpose of managing risk under plan-to-plan contracts will fully-licensed health care service plans.</p> <p>We appreciate this opportunity to submit our comments on the proposed regulations regarding general licensure requirements (the "Proposed Regulations"). We respectfully request that the Department clarify the meaning and scope of certain features of the Proposed Regulations as set forth below.</p>	ACCEPTED. The revised regulation clarifies that, for purposes of licensing, global, professional, or institutional risk is assumed in return for a prepaid or periodic charge (subsection 1300.49(a)(1), (a)(2), and (a)(5)).

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		<p><u>Import of Advance or Periodic Consideration: Impact on Shared Savings Arrangements</u></p> <p>We request clarification of the ongoing import and meaning of advance or periodic consideration under the Proposed Regulations. Section 1300.49(a)(6) defines risk as the “assumption of the cost for the provision of covered health care services to subscribers or enrollees” and, pursuant to subsection (b)(1), “any person who accepts global risk receives advance or periodic consideration from or on behalf of subscribers or enrollees and shall obtain a license to operate a health care service plan pursuant to section 1349 of the Health and Safety Code.” Does this mean that, in the absence of an exemption, any assumption of the cost for the provision of professional and institutional (i.e., global) covered health care services to subscribers or enrollees—<u>whether or not such assumption involves a fixed advance or fixed periodic consideration</u>—would require licensure?</p>	
9-81	Lynsey A. Mitchel Sheppard, Mullin, Richter & Hampton LLP	In connection with the foregoing inquiry, we respectfully request that the Department clarify the impact of the Proposed Regulations on shared savings arrangements, both (a) upside-only arrangements, and (b) two-sided arrangements. Do the Proposed Regulations extend past global capitation to require licensure of a provider entity that is a party to a shared savings arrangement with a licensed health care service plan?	<p>DECLINED. However, The revised proposed regulation clarifies the definition of a restricted health care service plan to include a person with a license for the provision of, or arranging, payment, or reimbursement for the provision of, services to subscribers or enrollees of another plan under a contract whereby the person assumes both professional and institutional risk, but does not directly market plan contracts (subsection 1300.49(a)(6)).</p> <p>To the extent that other entities and their contractual arrangement fall under the scope of the revised definition within the proposed regulation, the entity will be required to either obtain a license under the proposed regulation or seek an exemption pursuant to Health and Safety Code section 1343, as stated in the proposed regulation in subsection (b)(2). Health and Safety Code section 1343 requires the Director to consider an exemption request when the Director finds the action to be in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the</p>

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			Knox-Keene Act. Each entity requesting an exemption will be required to submit information demonstrating this criteria has been met.
9-82	Lynsey A. Mitchel Sheppard, Mullin, Richter & Hampton LLP	<p>Scope of the Exemption As currently drafted, subsection (b)(2) sets forth four (4) factors that the Department would take into account when considering whether to grant an exemption from the license requirement. Noticeably absent from the Proposed Regulations is any articulated standard or threshold governing the Department’s determination, as well as any articulated process governing the Department’s review, including a requirement for the Department to respond to a request for an exemption in a certain period of time.</p>	<p>ACCEPTED IN PART. The Department has considered the request and clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2).</p> <p>DECLINED IN PART. As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act. This is the standard by which the exemption request will be considered. Note that the Department has clarified the criteria by which the exemption request will be considered. However, the Department cannot provide threshold, such as percentiles or numbers, indicating how exemption factors are weighed.</p> <p>The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity’s circumstances and region in which it operates. For example, the Department cannot say with certainty that an entity with only “X” percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p>

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			Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department's ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.
9-83	Lynsey A. Mitchel Sheppard, Mullin, Richter & Hampton LLP	We respectfully express concerns relating to business uncertainty, and Department accountability and transparency, arising from this subsection (b)(2) as currently drafted. Should any final version of the Proposed Regulations include such exemption, we request that such final version of the Proposed Regulations clarify the standards on which the Department will rely and to which the Department will be held in granting exemptions from the license requirement. We appreciate your consideration of these issues.	ACCEPTED IN PART/DECLINED IN PART, see response to 9-82.