

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

#	FROM	COMMENT	DEPARTMENT RESPONSE
1-1	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	<p>CAPH recently commented on a draft DMHC regulation related to health care service plans licensing requirements and we are hoping to speak with someone at DMHC to discuss this with in more detail, as none of our recommendations made it in the revised version that DMHC made available last week. We have some concerns with the draft regulation that are specific to our health care systems and since we don't work with the Agency much, I'm hoping you can direct me to the right person. There are some unique circumstances that apply to California's Designated Public Hospital and health systems ("PHS"), which we would like to address in the final rule to ensure that DMHC's clarifications do not mistakenly disrupt the safety net and these systems' ability to take on provider level risk.</p> <p>Here is some additional background on the issue:</p> <ul style="list-style-type: none"> • California's public health care systems (PHS) are integrated providers that personally furnish both professional and institutional services, and have not previously been required to obtain a Knox-Keene license. We believe the final regulation should preserve this historical treatment, and clearly exempt these systems from Knox-Keene licensing requirements. 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 (and provided predominantly within PHS own system and providers), they should not be subject to further regulation as health care service plans. We would like to 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. 	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.</p> <p>As stated in the proposed regulation in subsection (b)(2), the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act.</p> <p>Public health systems may use this process to request an exemption from licensure.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

1-2	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	<ul style="list-style-type: none"> • Additionally, there are certain inherent differences that make PHS unique. 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. Also, 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. 	NO CHANGE REQUESTED. Please see response 1-1.
1-3	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	<ul style="list-style-type: none"> • In our comment letter (also attached), we requested that DMHC adopt one of two recommendations, 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. Our primary recommendation is that PHS would be excluded from being required to obtain a Knox Keene license altogether. In the alternative, if that was not acceptable to DMHC, we recommended at least set up an exemption process where PHS could be excluded on a case by case basis. <p>I look forward to hearing from you and appreciate any guidance you can offer.</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.</p> <p>As stated in the proposed regulation, the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act. Public health systems may use this process to request an exemption from licensure.</p>
1-4	Sarah (Muller)	The California Association of Public Hospitals and Health	NO CHANGE REQUESTED. The Department

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	Hesketh California Association of Public Hospitals and Health Systems (CAPH)	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.	appreciates the input.
1-5	Sarah (Muller) Hesketh 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 licensing requirements.</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.</p> <p>As stated in the proposed regulation, the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act.</p> <p>Public health systems may use this process to request an exemption from licensure.</p> <p>Also, it should be noted that a PHS does not require licensure when a PHS accepts the risk for services it provides itself. It only requires licensure when services are provided by an outside entity.</p>
1-6	Sarah (Muller) Hesketh	Under California law, PHS are permitted to act as integrated health systems that personally furnish professional services,	DECLINED. We acknowledge the unique position of public health systems. However, public health systems

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	<p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>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.</p>	<p>do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.</p> <p>As stated in the proposed regulation, the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act.</p> <p>Public health systems may use this process to request an exemption from licensure.</p> <p>Also, it should be noted that a PHS does not require licensure when a PHS accepts the risk for services it provides itself. It only requires licensure when services are provided by an outside entity.</p>
<p>1-7</p>	<p>Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>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</p>	<p>NO CHANGE REQUESTED. The Department appreciates the input. Also, note that the definition of “global risk” was modified to refer to “prepaid or periodic charge” after the first comment period rather than “advance or periodic consideration.” Proposed regulation subdivision (a)(1).</p> <p>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</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>protecting the stability of the health care marketplace.</p> <p>Under the proposed rule, an entity that accepts global risk is deemed to have received “advance or periodic consideration” 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.</p>	<p>that medical decisions are rendered by qualified providers, unhindered by fiscal and administrative management</p> <p>Please also see response 1-1.</p>
1-8	<p>Sarah (Muller) Hesketh</p> <p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>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</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.</p> <p>As stated in the proposed regulation, the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		includes both institutional services, as well as professional services through employed or contracted physicians.	that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act. Public health systems may use this process to request an exemption from licensure. Also, it should be noted that a PHS does not require licensure when a PHS accepts the risk for services it provides itself. It only requires licensure when services are provided by an outside entity.
1-9	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	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 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.	NO CHANGE REQUESTED. The Department appreciates the input. Please also see response 1-1.
1-10	Sarah (Muller) Hesketh 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	NO CHANGE REQUESTED. The Department appreciates the input. Please also see response 1-1.

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		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.	
1-11	Sarah (Muller) Hesketh 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 CHANGE REQUESTED. The Department appreciates the input. Please also see response 1-1.
1-12	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	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. The Department appreciates the input.
1-13	Sarah (Muller) Hesketh 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 CHANGE REQUESTED. The Department appreciates the input. Additionally, the Department notes that the requirements of this regulation, requiring licensure of an entity that accepts global risk, do not conflict with existing requirements on public health systems. Please also see response 1-1.
1-14	Sarah (Muller) Hesketh California Association of Public Hospitals and Health	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	DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement.

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	Systems (CAPH)	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>	<p>As stated in the proposed regulation, the Department will consider information supplied by the licensee applicant when making a determination of whether to grant an exemption. As detailed in Health and Safety Code section 1343(b), this information shall include a finding that the action would be in the public interest and not detrimental to the protection of subscribers, enrollees or person regulated under the Knox-Keene Act.</p> <p>Public health systems may use this process to request an exemption from licensure.</p> <p>Also, it should be noted that a PHS does not require licensure when a PHS accepts the risk for services it provides itself. It only requires licensure when services are provided by an outside entity.</p>
1-15	<p>Sarah (Muller) Hesketh</p> <p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>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.</p> <p>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 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</p>	<p>NO CHANGE REQUESTED. The Department appreciates the input, but cannot advise on whether certain arrangements would require licensure. Specific questions may be directed to the Department on a case-by-case basis. However, the Department also notes that, in order to require licensure as a health care service plan, an entity must both accept global risk <i>and</i> otherwise meet the definition of a health care service plan. Even if an entity meets these requirements, pursuant to proposed section (b)(2), an entity may request an exemption from licensure.</p> <p>Please also see response 1-1.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>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> <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>	
--	--	---	--

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		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.	
1-16	Sarah (Muller) Hesketh California Association of Public Hospitals and Health Systems (CAPH)	<p style="text-align: center;"><u>Recommendations</u></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 style="padding-left: 40px;">(b)(1) <u>Except as provided in paragraph (3) below, 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.</u></p> <p style="text-align: center;">. . .</p> <p style="padding-left: 40px;"><u>(b)(3) 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 Knox Keene Act.</p>	DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure. See response 1-1.
1-17	Sarah (Muller) Hesketh	If the above recommendation cannot be implemented, we request, in the alternative, the following modification to subdivision (b)(2):	DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	<p>California Association of Public Hospitals and Health Systems (CAPH)</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 style="text-align: center;">* * * * *</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>	<p>because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure.</p> <p>See response 1-1.</p>
<p>1-18</p>	<p>Sarah (Muller) Hesketh</p> <p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>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.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the input.</p>
<p>1-19</p>	<p>Sarah (Muller) Hesketh</p> <p>California Association of Public Hospitals and Health Systems (CAPH)</p>	<p>Before the regulation is finalized, we would like to bring to your attention unique circumstances that apply to 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"). To that end, we refer you to our comments previously submitted comment (see attached comment letter dated December 11, 2017). We</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>believe that the above referenced comments remain pertinent even with the revised text published by DMHC on March 20, 2018, and hope that these comments will be addressed and reflected in the final regulations.</p> <p>As described in detail in the attached comment letter, 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. As integrated systems, PHS personally furnish both professional and institutional services, and therefore 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 and integrated systems, they should not be subject to further regulation as health care service plans, consistent with DMHC’s longstanding policy. We ask that PHS’ unique role in health care delivery to vulnerable populations 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>licensure.</p> <p>See response 1-1.</p>
2-20	<p>Brad Byars</p> <p>Providence Health Network</p>	<p>Providence Health Network, a California licensed Knox-Keene Health Care Service Plan, operated by Providence Health & Services, submits the following comments on the draft rule.</p> <p>Section 1300.49(6)(c)(1)(B) Marketing Prohibition: PHN is requesting clarification from the Department whether prohibition language is intended to prevent a Restricted Licensee from co-marketing with the contracted full-service plan, once a subcontract relationship has been established under an approved application. PHN believes it is overly-prohibitive to exclude any ability to market the business of the Restricted Licensee within the subcontracted relationship, as allowing commercial speech about the role and function of the entity may be helpful to enrollees of the full-service plan to better understand and navigate the relationship. PHN suggests this alternative language:</p> <p style="padding-left: 40px;">(B) A restricted health care service plan may not market, solicit, or sell <u>its own</u> health care service plan contracts to individual members of the public, employers, or any other person or group.</p>	<p>DECLINED. Historically, restricted health care service plans have not been permitted to co-market with the contracted full-service health care service plan. Because the regulation clarifies restricted health care service plan licensure requirements, the proposed language prohibits marketing generally by restricted health care service plans. See 1300.49, subdivision (c)(1)(B).</p>
2-21	<p>Brad Byars</p> <p>Providence Health Network</p>	<p>Section 1300.49(6)(c)(2)(C) Responsibility Statement: It is unclear whether the responsibility statement can/should be filed with joint signatures from the restricted license applicant and the full-service plan, or whether two separate documents should be signed. PHN requests clarification from the Department about the intended procedure.</p> <p>Thank you for the opportunity to comment on the modified text. If you have any questions, please do not hesitate to contact me at (310) 793-8164 or bradley.byars@providence.org.</p>	<p>NO CHANGE REQUESTED. The Department would refer to the language of the proposed regulation, which states in 1300.49(c)(2)(C) that the Restricted Health Care Responsibility Statement must be signed by both the full service health care service plan or specialized health care service plan and the applicant restricted</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			health care service plan.
2-22	Brad Byars Providence Health Network	<p>Thank you for acknowledging receipt of our comment letter. We would like to add another comment via this email, since the comment deadline has approached. Please see below.</p> <p>Section 1300.49(6)(b)(1) Global Risk: PHN requests clarification from the Department as to the type of license being referred to in this section. We are uncertain if the reference is to a full, limited or restricted licensed plan. Under this section, is the Department proposing not to require a restricted plan to obtain a full license if the plan assumes global risk (e.g. Medicare Advantage products)?</p> <p>Thank you again for the opportunity to add a comment on behalf of Providence Health Network.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the comment. We note that proposed section 1300.49(b)(1) refers to licensure requirements generally and is not limited to a particular type of plan. The section states that any person who assumes global risk shall obtain a license to operate as a “health care service plan pursuant to section 1349 of the Health and Safety Code.” Section 1349 refers to the requirement to obtain a license to operate as a health care service plan or a specialized health care service plan. Because a restricted health care service plan is considered a health care service plan, albeit one with a license subject to certain restrictions, the proposed subsection applies to both full and restricted health care service plan licenses.</p>
3-23	Andy Coe Stanford Health Care	<p>On behalf of Stanford Health Care, we once again thank you for 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. While we appreciate the Department’s efforts to further clarify the scope of the proposed regulations, we continue to believe that the Department has taken an exceedingly broad view of the sorts of arrangements that are subject to the Department’s regulatory authority.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the input.</p>
3-24	Andy Coe Stanford Health Care	<p>1. Prepaid or Periodic Charge.</p> <p>At the outset, we appreciate that the Department has modified the original proposed regulation to distinguish the assumption of financial risk (“global risk”) from the compensation paid for the provision of services (“prepaid or periodic charge”). Though fee for service payments may involve the assumption of some financial risk (<i>i.e.</i>, that the cost of providing the service will exceed the fee for service rate paid for providing that service), that does not make fee for service payments a “prepaid or periodic charge” nor does it render an entity that accepts fee for service a “plan” within the meaning of the Knox-Keene Act. However, it appears that the definitions of “global risk” and “prepaid or periodic charge” now proposed by the Department continue to confuse and blur the lines between arrangements that clearly and historically warrant the issuance of a restricted license (<i>i.e.</i>, global capitation arrangements with fully licensed health plans) and arrangements that may have a gainsharing or other aligned-incentive component but that are fundamentally fee-for-service based.</p> <p>To eliminate this ambiguity we submit that the Department consider further revisions to the proposed regulations. Specifically, we ask that the Department modify the definitions of “global risk” and “prepaid or periodic charge” as follows:</p>	<p>DECLINED.</p> <p>The Department appreciates the input. However, with respect to the suggested change to the definition of “global risk”, the change is not necessary to effectuate the intent of the provision in the proposed regulation.</p> <p>With respect to the proposed change to the definition of “prepaid or periodic charge”, the Department declines to make the suggested changes. First, it is not necessary to reference the payment being made “by or on behalf of a subscriber or enrollee” because that language is already included in the definition of a health care service plan, in Health and Safety Code section 1345(f)(1), and in the proposed definitions of “institutional risk” and “professional risk.” Additionally, limiting the definition of “prepaid or periodic charge” to payments made only at the start of a period of time is incorrect, as a charge may</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>(1) “Global risk” means the acceptance <u>by a person or entity</u> of a prepaid or periodic charge from or on behalf of <u>subscribers or enrollees</u> in return for the assumption <u>by such person or entity</u> of both professional <u>risk</u> and institutional risk.</p> <p>(4) “Prepaid or periodic charge” for purposes of this section means <u>a predetermined, fixed in any amount of compensation (i.e., capitation) paid on behalf of a subscriber or enrollee, either at the start or end of a predetermined period of time, in exchange for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of the contracted-for health care services for to such subscribers or enrollees during such period of time and assuming the professional risk and institutional risk of providing or arranging for the provision of such services, that may be fixed with in amount or percentage of savings or losses in which the entity shares.</u></p>	<p>be “periodic” even if it is not “prepaid.” The Knox-Keene Act and supporting regulations do not require a charge to be made at the start of a period of time. Finally, a “prepaid or periodic charge” may include a payment that is based on a set percentage of savings or losses, as the underlying statute does not require that the charge be a fixed dollar amount.</p> <p>In addition to the reasons stated above, the Department declines to make the suggested change because it would not support the Department’s goal of clarifying which entities meet the definition of a health care service plan, and would exclude payment arrangements the Department intends to regulate through the promulgation of this regulation.</p>
3-25	<p>Andy Coe</p> <p>Stanford Health Care</p>	<p>2. Clarifying the requirements for exemption.</p> <p>In response to the Department’s original proposal, we expressed concerns regarding the mechanism by which the Director may grant exemptions to the restricted license requirement. We remain concerned that in the absence of clear guidelines 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. In the interests of clarity, transparency and predictability, we urge the Department to specify in the new regulation the requirements for obtaining an exemption to the restricted license requirement. Apart from benefitting provider organizations, such an approach will eliminate the burden to the Department of what may very turn out to be a tsunami of requests for exemption (particularly if the Department broadly defines the types of arrangements requiring a restricted license).</p> <p>Thank you for your consideration of our comments.</p>	<p>ACCEPTED. The Department has considered the request and further clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2).</p> <p>However, to the extent your request would have the Department establish set percentiles or numbers indicating how exemption factors are weighed, this request is declined.</p> <p>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. 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.</p> <p>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</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			<p>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>
4-26	Edward A. Morrissey County of Los Angeles (CoLA)	<p>As you may know, the County of Los Angeles previously submitted comments to the above-referenced proposed regulation. For your convenience, a copy of these comments is enclosed. As set forth therein, and in conjunction with the comments submitted by the California Association of Public Hospitals, the County of Los Angeles would like to enumerate several unique aspects that justify an exemption applicable to Designated Public Hospitals/healthcare systems operated by a public entity (DPHs) with respect to any licensure requirement under the Knox-Keene Act pursuant to the proposed regulations:</p> <p>1. As a public entity, professional and institutional services can be directly provided by DPHs. Such status should not trigger Knox-Keene licensure.</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure.</p> <p>See response 1-1.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

4-27	Edward A. Morrissey County of Los Angeles (CoLA)	<p>2. While the regulation under Knox-Keene is intended to address the risk to enrollees arising from potential financial problems of regulated entities, DPHs already maintain many other financial controls and operate with a much broader budget insulating them from the types of problems that may arise with regulated entities such as health plans.</p> <p>For example, the health care revenues for Los Angeles County attributed to health care service plan contracts account for a mere 3.5% of the County's revenue.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the information.</p> <p>See response 1-1.</p>
4-28	Edward A. Morrissey County of Los Angeles (CoLA)	<p>3. As traditional safety net providers, DPHs have designed their health care delivery systems consistent with the rules and incentives applicable to Medicaid. These rules have emphasized the integration of physician and institutional services. DPHs should not be subject to Knox-Keene licensure in their efforts to comply with Medicaid rules and incentives.</p> <p>Feel free to contact me if you have any questions or comments.</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure.</p> <p>See response 1-1.</p>
4-29	Edward A. Morrissey County of Los Angeles (CoLA)	<p>The County of Los Angeles (CoLA) hereby submits comments to the above-referenced proposed regulation.</p> <p>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 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</p>	<p>DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure.</p> <p>See response 1-1.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>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>	
4-30	Edward A. Morrissey County of Los Angeles (CoLA)	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.	DECLINED. We acknowledge the unique position of public health systems. However, public health systems do not require a specific exemption from licensure because proposed section 1300.49(b)(2) provides for a process whereby an entity may request an exemption from the licensure requirement. Public health systems may use this process to request an exemption from licensure. See response 1-1.
4-31	Edward A. Morrissey County of Los Angeles (CoLA)	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.	DECLINED. The Department appreciates the comment but declines to add an exception within the definition of "institutional risk" whereby services that could be provided under an acute care license would not qualify as institutional risk as long as the majority of service for which a DPH/healthcare system operated by a public entity are provided by that entity. Any entity may request an exemption from the licensure requirements pursuant to proposed section (b)(2), consistent with Health and Safety Code section 1343.

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<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>	See response 1-1.
e5-32	<p>Dietmar A. Grellmann, JD, FACHE</p> <p>California Hospital Association (CHA)</p>	<p>The California Hospital Association (CHA), representing over 400 hospitals and health systems, is pleased to provide additional comments on the modified regulations released on March 20, 2018. Thank you for the department's efforts to address the concerns raised in our December 11, 2017, letter during the initial comment period. However, we remain concerned 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 a "prepaid or periodic charge" and thus not subject to the Knox-Keene Act and Health & Safety Code sections 1341(a) and 1345(f)(1).</p>	NO CHANGE REQUESTED. The Department appreciates the input.
5-33	<p>Dietmar A. Grellmann, JD, FACHE</p> <p>California Hospital Association (CHA)</p>	<p>Specific examples of these arrangements —generally, fee-for-service payments with an aligned-incentive such as a gainsharing payment — were included in our April 5 letter. Such arrangements clearly are not within the scope of the Knox-Keene Act. Any ambiguity that results in these arrangements being defined as a "prepaid or periodic charge" subject to Knox-Keene Act requirements will remove an important mechanism that encourages the coordination of effort between hospitals, physicians and post-acute care providers to provide more efficient and higher quality care for patients.</p>	NO CHANGE REQUESTED. The Department appreciates the input.
5-34	<p>Dietmar A. Grellmann, JD, FACHE</p> <p>California Hospital Association (CHA)</p>	<p>To address these concerns, we recommend amending the definitions of "global risk" and "prepaid or periodic charge" as follows:</p> <p>(1) "Global risk" means the acceptance <u>by a person or entity</u> of a prepaid or periodic charge from or on behalf of <u>subscribers or enrollees</u> in return for the</p>	DECLINED. The Department appreciates the input. The proposed changes do not effectuate the intent of the provision nor the intent of the Department to regulate entities accepting global risk.

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		assumption <u>by such person or entity</u> of both professional <u>risk</u> and institutional risk.	
5-35	Dietmar A. Grellmann, JD, FACHE California Hospital Association (CHA)	(4) "Prepaid or periodic charge" for purposes of this section means <u>a predetermined, fixed amount of compensation (i.e., capitation) paid on behalf of a subscriber or enrollee, either at the start or end of a predetermined period of time, in exchange for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of the contracted-for health care services for to such subscribers or enrollees during such period of time and assuming the professional risk and institutional risk of providing or arranging for the provision of such services, that may be fixed either in amount or percentage of savings or losses in which the entity shares</u>	DECLINED. It is not necessary to reference the payment being made "by or on behalf of a subscriber or enrollee" because that language is already included in the definition of a health care service plan, in section 1345(f)(1), as well as in the proposed definitions of "institutional risk" and "professional risk." Additionally, restricting the definition of "prepaid or periodic charge" to only fixed amounts is not necessary, as the Knox-Keene Act and the supporting regulations do not require the charge be a predetermined, fixed amount. Finally, the charge may be paid at the start or the end of a period of time, as a charge may be "periodic" without being "prepaid."
5-36	Dietmar A. Grellmann, JD, FACHE California Hospital Association (CHA)	These amendments will ensure certainty and significantly reduce the need for the exemption process proposed in the regulation, which will be important factors in encouraging innovation and ensuring fairness to all participants. Thank you for the opportunity to provide comments.	NO CHANGE REQUESTED. The Department appreciates the comment.
6-37	Brianna Lierman, Esq. Local Health Plans of California (LHPC)	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. LHPC submitted comments during the initial comment period for this proposed regulation, which establishes licensing requirements for "restricted" health plans (Proposed Regulation). We believe the Department of Managed Health Care's (Department) revisions to the Proposed Regulation are an improvement and address some of our concerns. Below are our comments on the remaining issues we've identified.	NO CHANGE REQUESTED. The Department appreciates the comment.
6-38	Brianna Lierman, Esq.	A. §1300.49(a) – Definitions "Prepaid or periodic charge"	DECLINED. The Department appreciates the concern but is not restricting licensure to only shared risk arrangements in the proposed regulation. However, the

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	Local Health Plans of California (LHPC)	The revised Proposed Regulation includes a new definition for “prepaid or periodic charge”, terminology which is used throughout and central to Knox- Keene. Many types of risk arrangements could fall within a “prepaid or periodic charge”. However, the Proposed Regulation appears to define “prepaid or periodic charge” too narrowly so that restricted health plan licensure would only be required for shared risk arrangements. We suggest the definition be revised to reflect that other types of risk arrangements would trigger licensure. Making this change would, by cross-reference, also improve the definitions of “institutional risk” and “professional risk”, since “prepaid or periodic charge” is a key component of both.	Department believes that the language in the definition of “prepaid or periodic charge” is not overly narrow. It states that the charge “ <i>may be</i> fixed either in amount or percentage of savings or losses in which the entity shares.” (Emphasis added.) Accordingly, the charge is not required to be tied to savings or losses. For example, traditional capitation arrangements would meet the definition of “prepaid or periodic charge” as proposed.
6-39	Brianna Lierman, Esq. Local Health Plans of California (LHPC)	<p>B. §1300.49(b)(1)-(2) – Entities & Arrangements Subject to Restricted Licensure and Eligible for Exemption</p> <p>Lack of Clarity on Standards for Exemption As we conveyed on our initial comment letter, LHPC is concerned at the lack of objective standards to govern determinations of whether an entity’s risk arrangement with a health plan would trigger licensure. The Proposed Regulation would, in short, require licensure for “global risk” arrangements. It would also give the Director discretion to grant license exemptions based on review of specified documents. However, the Proposed Regulation still does not detail the requirements or standards for an exemption.</p>	<p>NO CHANGE REQUESTED. The Department appreciates the input. However, the Department notes that it has further clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2).</p> <p>To the extent that you would like the Department to list percentiles or numbers indicating how exemption factors are weighed, this is not possible. 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</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			<p>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>
6-40	<p>Brianna Lierman, Esq.</p> <p>Local Health Plans of California (LHPC)</p>	<p>In its Initial Statement of Reasons (ISOR) the Department states its intent exempt entities with "only a small portion of global risk", that "have only a minor market share" and/or "operate in well served areas." But, the Proposed Regulation still fails to define or provide any point of reference for what the Department may view as a "small portion", a "minor market share" or "well served". Defining the entities and arrangements subject to and exempt from Department purview are threshold matters for a licensing framework. Without more clarity, health plans cannot assess their current and future delegated arrangements for compliance with these new restricted license requirements.</p>	
6-41	<p>Brianna Lierman, Esq.</p> <p>Local Health Plans of California (LHPC)</p>	<p>B. §1300.49(c)(2)-(3) - Restricted License Application Filings</p> <p>Require Documentation of Suitability to Delegation</p> <p>LHPC reiterates its initial comment that a license applicant should be specifically required to submit to the Department documentation substantiating 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. Thus, such information should be readily available. Incorporating this additional element is critical to promoting quality and accountability in delegated arrangements.</p>	<p>DECLINED. The Department appreciates the input, but believes that a pre-delegation audit is not necessary because the Department will consider the solvency of the health plan at the time it reviews the licensure application of the restricted health care service plan. Because the Department performs routine and non-routine surveys of health plans, an additional, pre-delegation audit is not necessary. The Restricted Health Care Service Plan Responsibility Statement will also provide additional information crucial to the Department's review and determination.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

6-42	Brianna Lierman, Esq. Local Health Plans of California (LHPC)	Thank you for considering local health plans' second comments on the Proposed Regulation. We appreciate and thank the Department for the revisions made thus far. With the additional clarifications requested, we believe the Proposed Regulation can bring additional transparency, oversight, accountability and quality into delegated arrangements.	NO CHANGE REQUESTED. The Department appreciates the input.
7-43	Wendy Soe California Association of Health Plans (CAHP)	<p>The California Association of Health Plans (CAHP) represents 48 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 revised proposed rule published March 20th relating to General Licensure Requirements under the Knox Keene Act.</p> <ul style="list-style-type: none"> • <i>Incongruence between reasoning provided and proposed regulations</i> <p>As revised, the regulatory text bears little relationship to the content and reasoning of the "Informative Digest/Policy Statement Overview" found in the "Notice of Rulemaking Action" dated October 27, 2017, and the Notice's companion "Initial Statement of Reasons." This disconnect between the new draft text and both pieces is misleading and a disservice not only to (1) persons attempting in present time to interpret what the Department is trying to do and say with this proposal but also to (2) persons in the future researching the "regulatory history" of whatever may come to be promulgated. A rule-promulgating State entity must provide clear explanation and direction to both present and future parties affected by the rule. The Department should carefully review its October Statements and revise them to correlate with precise consistency to its substantially revised proposed regulation text of March.</p>	<p>NO CHANGE TO THE REGULATION REQUESTED. As defined under Government Code section 11349(d), consistency means "being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions or other provisions of law."</p> <p>Further, Government Code section 11349(c), defines clarity as meaning "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."</p> <p>CCR, Title 1, section 16, further defines clarity. The Department believes it has met both the statutory and regulatory standards for consistency and clarity and that its supporting documents, in addition to the proposed regulation, are sufficient under the APA.</p> <p>A stated in the Authority section of the Department's ISOR, 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 prepaid or periodic charge paid by or on behalf of subscribers or enrollees."</p> <p>The Department further stated in its ISOR: Existing law defines a health plan pursuant to Health</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			<p>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...” <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149.</p> <p>In both the Notice of Rulemaking as well as the ISOR,</p>
--	--	--	--

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			<p>the Department was very clear on its intent to further clarify licensure requirements for health plans as it pertained to entities accepting global risk for providing health care services to enrollees. As additionally noted in the Notice of Rulemaking:</p> <p><i>Purpose of the Regulation:</i></p> <p>The purpose of this rulemaking action is to clarify licensure requirements for health plans. Specifically, the proposed regulation states that a person who accepts global risk (both institutional and professional risk) for services to subscribers or enrollees receives “advance or periodic consideration” from or on behalf of subscribers or enrollees, and shall seek a health plan license. The proposed regulation will also set out requirements for a restricted license for entities that do not market directly to consumers or employers but otherwise meet the statutory definition of a health plan. In addition, the regulation states specific criteria the Department may apply in considering a request for exemption from licensure requirements. Key terms defined by the regulation include global, professional, and institutional risk, as well as “risk.”</p> <p>Based upon the information contained in the ISOR and Notice of Rulemaking, including, but not limited to the information reiterated above, there is no incongruence between the reasoning provided by the Department and the Department’s proposed regulation, including the amendments in the 2nd comment period.</p>
7-44	Wendy Soe California Association of Health Plans	We provide two examples of disconnect. First, the “Initial Statement of Reasons” and the “Informative Digest/Policy Statement Overview” equate the assumption of “global risk” with “advance or periodic consideration,” yet new subsection “(b)(1)” strikes that definitional	NO CHANGE REQUESTED. The definition of “institutional risk” in the proposed regulation does not include language stating that, to have accepted institutional risk, an entity must assume “all” the institutional risk. Accordingly, there is not an “all-or-

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	(CAHP)	nexus. Second, the “Initial Statement of Reasons” states that licensure as a health care service 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”. However, the text of the proposed regulations provides no objective standards or guidelines as to what would constitute “a portion” of risk that would trigger licensure. Current statutory requirements are already clear that health plans assume “full financial risk” (Health and Safety Code (HSC) section 1375.1, subdivision (a)(2).)	nothing trigger” but rather, any portion of institutional risk accepted qualifies as accepting institutional risk for purposes of the proposed regulation. If an entity believes that the portion of risk should not require licensure, the proposed regulation, subdivision (b)(2), allows for an exemption if certain statutory criteria are met. See responses 6-40 and 7-43.
7-45	Wendy Soe California Association of Health Plans (CAHP)	<ul style="list-style-type: none"> • <i>(a)(1) “Global risk” means acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk.</i> <p>The definition of “global risk” should include language regarding “arranging for the provision of health care services to subscribers or enrollees” to closely mirror the definition of “health care service plan” under HSC Section 1345 (f). Otherwise, it may have Corporate Practice of Medicine implications. Further, it offers insufficient protection of situations where one party does all of the arranging for the provision of health care services, and by contract gets another entity to assume the risk.</p>	DECLINED. The use of “prepaid or periodic charge” language in the proposed definition of “global risk” ties the term to the “health care service plan” definition and so additional language mirroring that definition is not necessary and duplicative. 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
7-46	Wendy Soe California Association of Health Plans (CAHP)	<ul style="list-style-type: none"> • <i>(a)(2) “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 person, other than services performed pursuant to the person’s own license under section 1253 of the Health and Safety Code in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.</i> <p>CAHP proposes the following edit to the definition:</p>	DECLINED. Hospital inpatient and ambulatory care services (outpatient hospital services) are defined in subdivisions (b) and (c) of title 28 section 1300.67, so adding additional information to the definition of “institutional risk” is not necessary. Additionally, the definition of “institutional risk” is intended to only refer to facility licensure rather than professional licensure, as the financial risk considered with “institutional risk” is based on the facility and not the licensure of the

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>“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 person, other than services performed <i>in a hospital</i> pursuant to the person’s own license under section 1253 of the Health and Safety Code <i>or Division 2 of the Business and Professions Code</i>, in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.</p> <p>The proposed definition of “institutional risk” has some ambiguity regarding what is meant by the various categories of “hospital” services, all of which could include a professional component (for example, hospitalist services, radiology, anesthesiology, etc.). Although the “institutional risk” definition as currently written carves out services performed pursuant to a license under Section 1253, that section only applies to facility licensure, not professional licensure.</p>	individual performing the service.
7-47	Wendy Soe California Association of Health Plans (CAHP)	CAHP’s proposed edits above “Institutional risk” are consistent with the DMHC’s historical position, which is that the DMHC does not object to providers receiving prepaid or periodic payments (such as capitation) for any professional services that the providers themselves are licensed to provide, regardless of the setting where the services are provided. The proposed edit narrows the overly-broad categories of hospital services that are incorporated into the “institutional risk” definition. Because of the possibility that certain professional services could be inappropriately considered “hospital” services for the purpose of the “institutional risk” definition, we recommend that the definition retain the existing reference to Section 1253, but also include the additional references to the appropriate professional licensure statutes so that professional services that are provided in the hospital setting are clearly carved out of the definition.	DECLINED. Hospital inpatient and ambulatory care services (outpatient hospital services) are defined in subdivisions (b) and (c) of title 28 section 1300.67, so adding additional information to the definition of “institutional risk” is not necessary. Additionally, the definition of “institutional risk” is intended to only refer to facility licensure rather than professional licensure, as the financial risk considered with “institutional risk” is based on the facility and not the licensure of the individual performing the service.
7-48	Wendy Soe California Association of	<ul style="list-style-type: none"> • (a)(4) <i>“Prepaid or periodic charge” for the purposes of this section means any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume</i> 	DECLINED. Restricting the definition of “prepaid or periodic charge” to only fixed amounts is not necessary. The Knox-Keene Act and supporting regulations do not limit charges to those that are a fixed amount of

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	<p>Health Plans (CAHP)</p>	<p><i>the risk, of delivering or arranging for the delivery of the contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares.</i></p> <p>CAHP proposes the following edit to the definition:</p> <p>“Prepaid or periodic charge” for the purposes of this section means fixed any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares. <u>Shared savings or losses shall not constitute fixed compensation for the purpose of this definition.</u></p> <p>The Department’s Statement of Reasons does not identify any need for the term, “prepaid or periodic charge” to be defined beyond its plain meaning. The term has been commonly understood as, a “charge” (i.e. specific amount of compensation) that is either “prepaid” (i.e. paid beforehand) or “periodic” (i.e. paid on a regular basis). The proposed definition is overly broad and could encompass compensation that is neither “prepaid” nor “periodic.”</p>	<p>compensation. Accordingly, a “prepaid or periodic” payment may include a payment that is based on a set amount of savings or losses.</p>
<p>7-49</p>	<p>Wendy Soe California Association of Health Plans (CAHP)</p>	<p>For example, shared savings/loss arrangements typically distribute payment to providers after the end of a defined reporting period, with the one-time payment depending on the amount of saving or loss. Shared savings or losses are not “compensation” for services rendered to or arranged for enrollees. Rather, savings or losses are actualization of incentive mechanisms that the parties had agreed upon. Although such shared savings arrangements would not fit a plain meaning of “prepaid or periodic charge,” they would be fall under the proposed definition in (a)(4) which references neither prepayment nor periodicity. It is important to further note that the Department has separate existing authority over risk sharing arrangements between plans and non-licensed risk</p>	<p>NO CHANGE REQUESTED. The Department notes that shared saving and loss arrangements, although not traditional capitation, are provided to compensate for services rendered as well as to incentivize quality care. We agree that such arrangements will fall within the proposed definition of “prepaid or periodic charge”, as they are considered charges even if they are not a fixed amount. A charge may considered “periodic” even if it is provided at the end of a set period of time.</p> <p>While the Department does have authority over risk bearing organizations, the purpose of this regulation is to clarify licensure requirements for health care service</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		bearing organizations which can be found in California Code of Regulations, Title 28, subsection 1300.75.4(d)(1), 1300.75.4.2(a)(5) & (6).	plans.
7-50	Wendy Soe California Association of Health Plans (CAHP)	Proposed subsection (a)(4)'s standard of "any amount of compensation" is contrary to another core licensure provision of the KKA. As a qualification for licensure, HSC section 1375.1(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 covered health care services..." There is a concern that (a)(4) as currently stated could sweep into licensure service-providing entities in Accountable Care Organizations (ACOs), hospital risk-sharing constructs, or other such arrangements. This would be legally unwarranted and highly disruptive to the present health care delivery marketplace.	NO CHANGE REQUESTED. Section 1375.1(a)(2), which refers to the requirement to assume "full financial risk" is a regulatory requirement applied to health care service plans. The proposed regulation, however, will clarify which entities meet the definition of a health care service plan and therefore must seek licensure. Whether those entities must be licensed, and, if they are licensed, whether they meet the "full financial risk" regulatory requirement, are distinct issues. The proposed regulation may sweep in Accountable Care Organizations or other arrangements that, considering the proposed regulation, meet the definition of a health care service plan. However, licensing such entities will not be disruptive to the health care marketplace and instead will help provide important consumer protections, including financial solvency review. Such entities may always seek and exemption from licensure.
7-51	Wendy Soe California Association of Health Plans (CAHP)	<ul style="list-style-type: none"> • <i>(b)(2) Pursuant to section 1343 of the Health and Safety Code, the Director may grant an exemption from this section to any person upon review and consideration of information the Director deems relevant, including, but not limited to, the following:</i> <ul style="list-style-type: none"> <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 this title. The Exhibits shall include current financial statements 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> 	ACCEPTED IN PART. The Department has considered the request and clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). DECLINED IN PART. The Department appreciates the comment and notes that it has further clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). 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

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>(B) <i>The total percentage of annualized income of institutional risk the person will assume and how it will be assumed;</i></p> <p>(C) <i>The contract(s) for the assumption of global risk;</i></p> <p>(D) <i>The estimated number of subscribers and enrollees for whom the person will provide health care services;</i></p> <p>(E) <i>The geographic service area(s) under the global risk arrangement(s) in which the person intends to operate; and</i></p> <p>(F) <i>Information on how the public interest or protection of the public, subscribers, enrollees or persons subject to this chapter will be impacted if the person takes on global risk.</i></p> <p>The current proposal's subsection (b)(2) would give the Director of the DMHC the power to "grant an exemption from this section." However, the subsection fails to state the thresholds or standards the Director would use in granting an exemption. This deprives applicants of pertinent guidance and could create a breeding ground for underground regulating.</p>	<p>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>
7-52	Wendy Soe California Association of Health Plans (CAHP)	Additionally, this subsection relates to requirements for "restricted licensure" but lacks guidance as to the entities that would be eligible for an exemption. We are concerned that under the sweep of subsection (a)(4), ACOs, hospitals, or other provider entities participating in risk-sharing constructs could be included in licensure and/or exemption requirements.	NO CHANGE REQUESTED. Any entity that meets the definition of a health care service plan under the proposed regulation and the Knox-Keene Act, must apply for either licensure or an exemption.
7-53	Wendy Soe	<ul style="list-style-type: none"> <i>Technical edit to the Restricted Health Care Service Plan Responsibility Form Instructions.</i> 	ACCEPTED. Thank you for pointing out this inadvertent error, the suggested change was made.

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

	California Association of Health Plans (CAHP)	On page 1 of the form, a reference to the former name of the form (“DMHC Division of Financial Responsibility Form”) appears to have been inadvertently left in. See middle of the first page of the form, in the instruction that begins “Please review the instructions below...” That reference should be changed to reflect the new name of the form.	
7-54	Wendy Soe California Association of Health Plans (CAHP)	On page 2 of the form, in the heading for the second column of the form, we would recommend inserting “ <u>Contracting Full Service or Specialized</u> ” before “Health Plan.” We appreciate the opportunity for comment and are available to you should you need any additional information.	ACCEPTED. Thank you for pointing out this inadvertent error, the suggested change was made.
8-55	William Barcellona, JD, MHA America’s Physician Groups	America’s Physician Groups submits the following comments on the draft rule. General Comments: This version demonstrates significant progress toward refining the proposed rule to clarify the process of obtaining a Restricted License, the limitations of such a license, and the entities eligible to apply for such a license. The license has historically been limited to entities that already had the ability, under law, to accept professional risk. Typically, that is a medical group comprised of physicians with licenses to deliver professional medical services. Expanding the license beyond those entities creates ambiguities and conflicts with the Medical Practice Act’s ban on the corporate practice of medicine. By specifying that eligible entities must possess the legal ability to deliver professional risk the Department could eliminate a significant ambiguity. For this reason, we again urge the Department to vest this proposed Rule under Section 1351 of the Act, since its underlying goal is to clarify and specify who is eligible and how they apply for this license. Accordingly, we urge the Department to readopt the definition of “person” from the first version at (a)(4) that references Health & Safety Code Section 1345(i) to further clarify its usage in subsection (b)(1) of this second version of the rule. We reference our proposed version of rule attached to our December 2017 comment letter on the first proposed version of this rule.	DECLINED. The Department appreciates the comments and support. However, the Department will vest this proposed Rule under Section 1345 of the Knox-Keene Act, which defines a health care service plan. Because the regulation clarifies what entities fall within the definition of a health care service plan, and therefore must seek licensure or an exemption, section 1345 is the more proper statutory section on which to base this regulation. The Department declines to define “person”, as that term is already defined in the Knox-Keene Act and therefore does not need to be defined in the proposed regulation. 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

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

			management
8-56	William Barcellona, JD, MHA America's Physician Groups	<p>Section 1300.49(a)(1) Definition of “Global Risk”: To follow our general comment that the regulation should be vested under HSC Section 1351 rather than 1349, the proposed definition of “global risk” is still ambiguous in that it does not clarify that the nature of the risk accepted is <u>solely</u> prepaid capitation for institutional and professional services. We suggest that the definition is amended further to state:</p> <p>1) "Global risk" means the acceptance of a <u>capitated</u> prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk.</p>	<p>DECLINED. Restricting the definition of global risk to only capitated payments is not consistent with the rest of the proposed regulation, nor is it consistent with the goal of the proposed regulation. Because a “prepaid or periodic charge” may include a charge that is based on a set amount of savings or losses, limiting global risk to capitated payments is inconsistent. Additionally, the suggested change would not support the Department’s goal of clarifying which entities meet the definition of a health care service plan, and would exclude the novel payment arrangements the Department intends to regulate through the promulgation of this regulation.</p> <p>The Department appreciates the comments and support. However, the Department will vest this proposed Rule under Section 1345 of the Knox-Keene Act, which defines a health care service plan. Because the regulation clarifies what entities fall within the definition of a health care service plan, and therefore must seek licensure or an exemption, section 1345 is the more proper statutory section on which to base this regulation.</p>
8-57	William Barcellona, JD, MHA America's Physician Groups	<p>Alternatively, the use of the term “fixed prepaid or period charge” may be appropriate as well. Adopting this simple amendment would clarify that the global risk acceptance is derivative of a fully-licensed health care service plan’s function under Health & Safety Code Section 1345(f) of “arranging for the provision of health care services to subscribers or enrollees” and will alleviate the need for further exemptions from the application of section 1349 and 1345 for globally capitated service providers.</p>	<p>DECLINED. It is not necessary to use the term “fixed prepaid or periodic charge,” as the definition of prepaid or periodic charge already refers to the charge being “fixed,” either in amount or percentage of savings or losses.</p>
8-58	William Barcellona, JD, MHA America's Physician Groups	<p>Section 1300.49(a)(2) Definition of “Institutional Risk”: The 2nd revised proposed rule adds the qualification “<i>in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee</i>” to the prior version’s text. However, it has been a common practice for professionally capitated physician groups to enter into risk-sharing agreements and pools with hospitals that do not involve the complete</p>	<p>NO CHANGE REQUESTED. The definition of “institutional risk” in the proposed regulation does not include language stating that, to have accepted institutional risk, an entity must assume “all” the institutional risk. Accordingly, there is not an “all-or-nothing trigger” but rather, any portion of institutional risk accepted qualifies as accepting institutional risk for</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		<p>assumption of institutional risk. The current definition used in this draft uses an all-or-nothing trigger to require registration as a restricted licensee, especially at subsection (b)(1). That would seem to indirectly ban any further use of risk-sharing and/or hospital risk pool arrangements. It would be useful to the industry to know one way or the other whether that is the Department's intention with the use of this definition.</p>	<p>purposes of the proposed regulation.</p> <p>If an entity believes that the portion of risk should not require licensure, the proposed regulation, subdivision (b)(2), allows for an exemption if certain statutory criteria are met.</p>
<p>8-59</p>	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>Section 1300.49(a)(4) Definition of "Prepaid or Periodic Charge": We offer a similar comment with respect to the amended definition from the 1st and 2nd versions. This version still confuses the structure of global capitation, which is only paid at the beginning of a coverage period, not at the end. Capitation is historically defined as <i>"fixed, pre-arranged monthly payments received by a physician, clinic or hospital per patient enrolled in a health plan."</i> The inclusion of the end of a period raises the inference that the proposed rule would expand jurisdiction over fee-for-service-based gain-sharing arrangements, which are not "global risk" arrangements within the context and jurisdiction of the Knox Keene Act. The DMHC does not possess jurisdiction over these arrangements in the body of the Act because such payments occur after the service has been rendered, and therefore cannot expand jurisdiction through subsequent rule. The Knox Keene Act was created to govern <i>prepaid</i> arrangements for health care services. The Department already has existing regulatory authority over risk-sharing arrangements between plans and risk bearing organizations at Title 28, Sections, 1300.75.4(d)(1), and 1300.75.4.2(a)(5) & (6). The timing and structure of applicable provider payment methodologies must be clarified in the final version to avoid ambiguity over the scope of this rule's application. APG suggests that the definition is amended further to state:</p> <p>4.) "Prepaid or periodic charge" for the purposes of this section means any <u>capitation paid at the beginning of a period compensation, either at the start or end of a predetermined period</u>, for assuming the risk of delivering or arranging for the delivery of the contracted-for health care services for</p>	<p>DECLINED. 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 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>The suggested change would not support the Department's goal of clarifying which entities meet the definition of a health care service plan, and would exclude the novel payment arrangements the Department intends to regulate through the promulgation of this regulation.</p>

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #2, March 20, 2018 – April 5, 2018

		subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares.	
8-60	William Barcellona, JD, MHA America's Physician Groups	<p>Section 1300.49(6)(c)(1)(B) Marketing Prohibition: APG supports the inclusion of a statement prohibiting the sale of coverage contracts to the public by Restricted Licensees. However, our members have asked for clarification whether the Department's prohibition language is intended to prevent them from co-marketing with the contracted full-service plan, once a subcontract relationship has been established under an approved application. It seems overly-prohibitive to exclude any ability to market the business of the Restricted Licensee within the subcontracted relationship, as allowing commercial speech about the role and function of the entity may be helpful to enrollees of the full-service plan to better understand and navigate the relationship. We suggest this alternative language:</p> <p>(B) A restricted health care service plan may not market, solicit, or sell <u>its own</u> health care service plan contracts to individual members of the public, employers, or any other person or group</p>	DECLINED. The language in the proposed regulation will prohibit restricted health care service plans marketing in any way, including co-marketing. The purpose of the regulation is to simplify the Department's review of restricted health care service plan applications and ongoing regulation, in order to efficiently monitor the product while keeping costs low. Allowing restricted health care service plans to market with health care service plans would be contrary to existing practice and could cause potential disruption to the health care marketplace and compromise enrollee access to health care services.
8-61	William Barcellona, JD, MHA America's Physician Groups	<p>Section 1300.49(6)(c)(2)(C) Responsibility Statement: It is unclear whether the responsibility statement can/should be filed with joint signatures from the restricted license applicant and the full-service plan, or whether two separate documents should be signed. Would you please clarify the intended procedure?</p> <p>Thank you for the opportunity to comment. Please direct any questions concerning this comment letter to the undersigned.</p>	The Department would refer to the language of the proposed regulation, which states in 1300.49(c)(2)(C) that the Restricted Health Care Responsibility Statement must be signed by both the full service health care service plan or specialized health care service plan and the applicant restricted health care service plan. The Department requires signatures from both entities, will not require them to be on the same document.