

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

#	FROM	COMMENT	DEPARTMENT RESPONSE
1-1	<p>Mark Schafer, M.D.</p> <p>MemorialCare Medical Foundation</p>	<p>These comments are provided in response to the above-referenced proposed revisions to the Knox Keene General Licensure Requirements by the Department of Managed Healthcare (Department). We remain concerned that the proposed regulation would subject a number of providers to licensure based on the adoption of innovative, yet low-risk payment models that were not the intended subject of regulation under the Knox-Keene Act, such as bundled payment arrangements, institutional risk pools, and accountable care organizations.</p> <p>On behalf of MemorialCare, a nonprofit, fully-integrated health care delivery system located in Southern California, that includes four hospitals with 11,000 employees and 2,550 medical staff physicians, that advocates innovative value-based care to help bend the cost curve for multiple populations of patients, we appreciate the opportunity to submit comments on the Department's efforts to clarify when an exemption from the licensure requirement may be granted.</p>	<p>NO CHANGE REQUESTED. Thank you for the comment.134</p>
1-2	<p>Mark Schafer, M.D.</p> <p>MemorialCare Medical Foundation</p>	<p><b>The Department's Fourth Revision Does Not Directly Respond to or Resolve the Comments in the Office Of Administrative Law's October 15, 2018 Decision of Disapproval of Administrative Action.</b></p> <p>On October 15, 2018, the California Office of Administrative Law (OAL) notified the Department of OAL's disapproval of the final proposed regulations for (1) failure to comply with the "clarity" standard of Government Code Section 11349.1 and (2) failure to follow all required procedures of the California Administrative Procedures Act. Specifically, OAL stated that the public would have difficulty utilizing the exemptions in subsection (b)(2) because of (1) an absence of procedures to request an exemption, and (2) exemption criteria that are subject to more than one interpretation. Specifically, the OAL noted that the Department did not define relevant terms like "minor market share," "small portion of global risk," and "well-served areas;" definitions important to the public to understand how to comply with the regulations, or for the public to determine the need to incur the substantial legal and consulting costs in seeking an exemption.</p> <p>The Department's Fourth Revision is not responsive to the OAL's comments. It proposes additional vague and undefined terms in the form of standards for the Director to consider in granting exemptions, but neither defines the terms nor states threshold standards that the Director will use – all elements critical to the "clarity" necessary to ensure that the public can reasonably and logically interpret the regulation.</p> <p>For instance, in (3)(A), what portion of global risk (as now defined by the Department) compared to overall risk is critical? In (3)(B), which "portion of market share" the provider assumes compared to other market players is important? In 3(C), the level of "financial capacity" is not defined; in (3)(D) "financial impact" is not defined; in (3)(E), standards for "negative impact" on the public interest are not defined.</p>	<p>DECLINED. The Department declines to make further changes to the regulatory text for policy and logistical reasons. The Department has responded to the comments in the OAL's disapproval decision. The Department, in response to previous comments, clarified the process and the standards by which an entity's request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible to create. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities conducting business in the geographic region. Additionally,</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity was unable to maintain financial solvency, and how an exemption would impact the public interest. These clarifications addressed OAL's concerns expressed in the Decision of Disapproval.</p>
<p>1-3</p>	<p>Mark Schafer, M.D.</p> <p>MemorialCare Medical Foundation</p>	<p>Instead of bright line standards, application of the criteria for exemption is left to the complete discretion of the Director, a situation rife with opportunity for underground regulation and that will likely result in all arrangements potentially affected by the statute being required to apply for an exemption – a considerable burden to the industry and to the Department, when as noted in previous comments, there is no public interest cited by the Department in the Statement of Reasons justifying this substantial increase in the Department's jurisdiction.</p>	<p><b>NO CHANGE REQUESTED.</b></p> <p>The Department notes that the regulation does provide standards by which the Director will consider an exemption request.</p> <p>The Department, in response to previous comments, already clarified the process by which and the standards by which an entity's request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the vast differences between regions within California, a bright-line standard is impossible to create. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. It should be noted that the Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption. This is stated in Health and Safety Code section 1343.5. These clarifications addressed OAL's concerns.
1-4	Mark Schafer, M.D.  MemorialCare Medical Foundation	Additionally, there should clearly be an exemption for payment arrangements that operate pursuant to State or Federal statutes or regulations. Given the significant impact of these proposed regulations and the significant increase in the jurisdiction of the Department, appeal rights for denial of an exemption should be considered.	DECLINED. Thank you for your comment, but the Department does not think it is necessary to provide a specific exemption for payment arrangements that operate pursuant to State or Federal statutes or regulations. Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. This regulation will not affect products licensed by the California Department of Insurance (CDI) or the Centers for Medicare and Medicaid Services (CMS). Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
1-5	Mark Schafer, M.D.  MemorialCare Medical Foundation	Likewise, the Department should respond to a request for exemption within thirty days; a request for exemption should be deemed granted if the Department does not act within thirty days, or the licensure requirement should not apply while an appeal is pending. The applicant should have a period to unwind the arrangement if an exemption is denied.	DECLINED. The Director will respond within 30 days of receipt of the request, and so providing a mechanism whereby the exemption will be automatically granted if not decided upon is not necessary. Adding such a provision is also against the public interest because consumer access to care and the healthcare market place could be jeopardized if a thorough analysis of

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			the request is not completed.
1-6	Mark Schafer, M.D.  MemorialCare Medical Foundation	As you consider specific criteria for granting exemptions for providers, please consider our recommendation that a provider is exempt if "no more than 25% of the provider's cash on hand is at risk across all payors with whom the provider has entered into payment arrangements." We understand that other commenters have proposed quantitative thresholds and standards as additional alternative criteria to the Department's proposed standards for exemption. However, we want to reinforce that if different exemption criteria are considered, that our recommendation is considered as one of many alternative pathways to granting an exemption. These proposed exemption criteria recognize the extensive experience that California providers have working with innovative payment arrangements that encourage quality and cost-savings.	DECLINED. As stated in response to 1-2, the Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Similarly, the Department declines to set a percentage for cash on hand because the individual specifics of the entity's situation must be considered.
1-7	Mark Schafer, M.D.  MemorialCare Medical Foundation	<b>There Remains no Statutory Purpose or Authorization for Regulatory Expansion of the Definition of "prepaid or periodic charges" or the Department's Jurisdiction in the Knox Keene Act.</b>  As stated in our comments of June 1, 2018, we remain concerned that the proposed regulations are a significant departure from the statutorily authorized and historic jurisdiction of the Department, imposing extensive uncertainty and requiring a vast number of arrangements that may have been in place for many years, to seek a license or an exemption at considerable cost, without any indication of the concerns that the Department is seeking to address, at a time when flexibility and innovation are critical to lowering costs and improving efficient delivery of quality healthcare to all Californians.	DECLINED. This comment is irrelevant because it does not address the changes made during the 4 <sup>th</sup> comment period.  The proposed regulation may impact 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 an exemption from licensure as clearly laid out in the regulation.
1-8	Mark Schafer, M.D.  MemorialCare Medical Foundation	Moreover, the Department's oversight should not be necessary where California providers have extensive experience with low-risk arrangements tying performance on quality metrics and cost reductions that encourage coordinated care and quality improvement.	NO CHANGE REQUESTED.
1-9	Mark Schafer, M.D.	Indeed, the changes proposed in the Fourth revision will still likely result in a cumbersome filing and review process for almost all arrangements that are impacted by the regulations.	NO CHANGE REQUESTED. The Department notes that some of the entities affected by the

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	MemorialCare Medical Foundation		regulation either already have licenses with the Department (including full-service and restricted health care service plans) and/or are sophisticated entities which will be able to seek licensure or an exemption using the established procedures in this regulation.
1-10	Mark Schafer, M.D.  MemorialCare Medical Foundation	<p>There is no demonstrated reason to extend the Department's well-defined statutory jurisdiction beyond capitation risk or prepayment, to impact and impede the provision of institutional or hospital professional services arrangements with quality and cost savings incentive mechanisms agreed amongst the parties to an arrangement. These arrangements are widespread and common without any adverse impact on professional health care providers or consumers.</p> <p>Again, we urge the Department to convene a broadly representative working group to assess the objectives the Department believes it has for the proposed regulations and the path to achieving them.</p>	<p>DECLINED. This comment is irrelevant because it does not address the changes made during the 4<sup>th</sup> comment period.</p> <p>The Department appreciates the comment but notes, again, that the regulation is clarifying the definition of a "health care service plan" and which entities must seek licensure or an exemption. A working group is not required because the Department received feedback during informal meetings prior to the commencement of the formal APA rulemaking and has gotten feedback through these four formal comment periods and made changes accordingly.</p>
2-11	Catrina Reyes, Esq.  California Medical Association	On behalf of our more than 43,000 physician and medical student members, the California Medical Association (hereinafter "CMA") would like to thank you for considering comments on the Department of Managed Health Care's (hereinafter "the Department") proposed regulations on General Licensure Requirements. While CMA understands that the intention of these regulations is to clarify which health care entities that assume global risk are required to obtain a Knox-Keene license, CMA has concerns that the proposed regulations as drafted may have certain unintended adverse consequences.	NO CHANGE REQUESTED.
2-12	Catrina Reyes,	While CMA reads the proposed regulations to require only	DECLINED. This comment is irrelevant

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>Esq.  California Medical Association</p>	<p>those entities that assume global risk – that is, those entities standing to incur financial losses as the result of their risk assumption—to obtain a license, CMA is concerned that these regulations may have a chilling effect on delivery system and payment innovations that lead to higher quality care and lower costs. In defining "prepaid or periodic charge," to include a "percentage of savings or losses in which the entity shares," the proposed regulations have the potential to include parties to a host of value-based contracting arrangements. While the proposed regulations contain provisions allowing the Director to grant exemptions to the licensure requirements, CMA is concerned that many practices interested in pursuing value-based contracts geared toward improving healthcare quality and reducing costs will be disincentivized from doing so given this new regulatory burden. Accordingly, we urge the Department to consider narrowing the scope of the proposed regulations in order to balance the need for oversight of risk-based contracts with the need for innovation in healthcare delivery.</p>	<p>because it is not addressing the changes made during the 4<sup>th</sup> comment period.</p> <p>The Department believes the exemption process and/or the ability to seek licensure as a restricted health care service plan, which is a less burdensome and less expensive licensure process, will not be a disincentive to contracting arrangements. Licensing entities of the type of you noted will not be disruptive to the health care marketplace and instead will help provide important consumer protections, including financial solvency review.</p>
<p>2-13</p>	<p>Catrina Reyes, Esq.  California Medical Association</p>	<p>Additionally, CMA is concerned that the proposed regulations, while intended to provide clarity, will result in considerable confusion among physicians, patients, and other healthcare stakeholders. First, while the proposed regulations require that entities assuming global risk obtain a license, it is unclear whether restricted health care service plans have all the same obligations under the Knox-Keene Act as full service health care service plans as the Act itself makes no distinction.</p>	<p>DECLINED. The comment is irrelevant because it does not address the changes made during the 4<sup>th</sup> comment period.</p> <p>The Department notes the regulation states that a restricted health care service plan cannot directly market, solicit, or sell health care service plan contracts and also states that it must specify which functions it will be responsible for and which will be the responsibility of its partner full service or specialized health care service plan. Between</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			the restricted health care service plan and their partner full service or specialized health care service plan partner, the entire requirements of the Knox-Keene Act consumer protections must be covered. The Restricted Health Care Service Plan Responsibility Statement, which is incorporated by reference in the regulation, has clear directions. If the restricted health care service plan will not provide a function mandated by the Knox-Keene Act, the partner health care service plan must provide that function.
2-14	Catrina Reyes, Esq.  California Medical Association	Second, the proposed "Restricted Health Care Service Plan Responsibility Statement" suggests that obligations associated with Knox-Keene compliance may be split between the restricted health care service plan and the full service health care service plan or specialized health care service plan. However, given that only the Department and the parties to the contract will receive the Responsibility Statement, physicians contracted with restricted health care service plans will not be informed as to which Knox-Keene obligations have been assumed by which entity.	DECLINED. The comment is irrelevant because it does not address the changes made during the 4 <sup>th</sup> comment period.  The Department notes that this regulation does not impact existing provider provisions within the Knox-Keene Act concerning provider contracts, such as Health and Safety Code section 1375.7, which requires, in part, provider notice and an opportunity to negotiate and agree to changes to a material term of a contract provision.
2-15	Catrina Reyes, Esq.  California Medical Association	Finally, given the Director's ability to exempt an entity from obtaining a license without any requirement that such exemption decision be made public, downstream contractors, including physicians, will not know whether an entity is licensed or not. Accordingly, CMA urges the Department to provide additional guidance and public information regarding applicability of the Knox-Keene Act to restricted health care service	DECLINED. The comment is irrelevant because it does not address the changes made during the 4 <sup>th</sup> comment period.  The Department notes that this regulation does not impact existing provider provisions within the Knox-Keene Act concerning provider contracts, such as Health and Safety Code section 1375.7, which requires, in part, provider

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>plans.</p> <p>Thank you for your careful consideration of CMA's comments. We look forward to working with the Department and other stakeholders to ensure the goals of improved clarity and ensuring stability of the health care delivery system are achieved without having the unintended adverse consequences CMA has highlighted here.</p>	<p>notice and an opportunity to negotiate and agree to changes to a material term of a contract provision.</p>
3-16	<p>Amber Kemp</p> <p>California Hospital Association</p>	<p>The California Hospital Association (CHA), representing more than 400 hospitals and health systems, is pleased to provide additional comments on the modified proposed general licensure regulations released by the Department of Managed Health Care on November 30, 2018. We appreciate the department's efforts to clarify how and why an entity may be granted an exemption from the licensure requirement, and we have several suggestions for further clarifications. We remain concerned that the proposed regulation would subject a number of providers to licensure based on the adoption of innovative — yet low-risk — payment models that were not the intended subject of regulation under the Knox-Keene Act. These include bundled payment arrangements, institutional risk pools and accountable care organizations (ACOs). We encourage you to revise the regulation to strike a balance between encouraging innovative, low-risk arrangements and engaging in necessary oversight. We hope our comments, detailed below, will assist you in this effort.</p>	<p>DECLINED. The comment is irrelevant because it does not address the changes made during the 4<sup>th</sup> comment period.</p> <p>The proposed regulation may impact 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 an exemption from licensure. The Department believes the regulation, as drafted, strikes a balance between encouraging innovation while still engaging in necessary oversight for consumer and market protection.</p>
3-17	Amber Kemp	<p><b>I. The procedure by which the department evaluates exemption requests should be</b></p>	DECLINED.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	California Hospital Association	<p><b>designed to give providers clarity and finality.</b></p> <p>We appreciate the department including, in the proposed regulation, a process for a provider or other entity to seek an exemption from the licensure requirement. This proposal identifies the information an applicant should provide and the department contact to whom a request should be made. In light of the mismatch between the requirements for a health care service plan under the Knox-Keene Act and the low-risk payment arrangements described in this letter, it is critical that the department provide a clear and efficient process for providers to obtain exemptions and inform providers of the outcome as soon as possible.</p>	<p>The Department appreciates the comment but declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity's request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>The Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption as contained in Health and Safety Code section 1343.5. These clarifications addressed OAL's concerns.</p>
3-18	Amber Kemp	<p><b>We urge the department to provide greater clarity around the procedures for seeking an</b></p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>California Hospital Association</p>	<p><b>exemption.</b> As drafted, the regulation leaves a number of questions unanswered. For example:</p> <ul style="list-style-type: none"> <li>• When is a provider required to seek an exemption?</li> <li>• What are a provider’s rights while its request is pending?</li> <li>• What is the status of a request for an exemption if the department does not respond within 30 days?</li> <li>• Can a provider appeal if it disagrees with the department’s decision?</li> </ul> <p>Without this clarity, providers may be forced to put longstanding business relationships on hold or stop expanding their use of the payment arrangements described above. Therefore, we urge the department to create greater structural protections for providers engaged in the exemption request process. Accordingly, we believe a provider should have a 90-day grace period after a contract is issued, amended or renewed before being required to submit an application for licensure or request an exemption.</p>	<p>to the regulatory text. The Department, in response to previous comments, already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. In response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>A provider seeking licensure as a health care service plan cannot act as a health care service plan unless and until it is licensed by the Department. The Director will provide a response to the exemption request within 30 days. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed. The Director has the regulatory requirement to respond to the exemption request within 30 days, therefore, it is not necessary to address what will happen if this regulatory requirement is not met.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>Existing Knox-Keene Act statutory provisions, sections 1354 and 1397, already states that a decision of the Director is subject to administrative and judicial review, including denials of applications for licensure.</p>
3-19	<p>Amber Kemp  California Hospital Association</p>	<p>We strongly support the proposed requirement that the department respond to requests for exemption within 30 days (28 C.C.R. § 1300.49, paragraph (b)(3) (proposed)). To give providers greater certainty around this time frame, we urge the department to deem requests approved if the department does not act on the request within 30 days. We also urge the department to establish appeal rights for applicants whose request is denied, and note that the licensure requirement does not apply to an applicant while any appeal is pending. Finally, if an exemption request is denied and all appeals are unsuccessful, the applicant should have longer than the end of that calendar year or nine months from the date of the denial to unwind the arrangement. This will give providers whose requests for exemptions have been denied the opportunity to unwind payment arrangements for which a license or exemption is required without disrupting patient care. Finally, we urge the department to clarify that any effective date inserted in the regulation by the Office of Administrative Law shall be calculated pursuant to Government Code section 11343.4.</p>	<p>DECLINED. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed and be given time to address any regulatory requirements.</p> <p>The Department notes that the Director will respond to all exemption requests within 30 days as required under the regulation. Adding such a provision is also against the public interest because consumer access to care and the healthcare market place could be jeopardized if a thorough analysis of the request is not completed.</p> <p>Existing Knox-Keene Act statutory provisions, sections 1354 and 1397, already states that a decision of the Director is subject to administrative and judicial review, including denials of applications for licensure.</p> <p>Further, OAL will place the effective date in the</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>regulation pursuant to the requirements of the Administrative Procedures Act; therefore, it is not necessary to clarify this timing issue within the regulation any more than is already stated in the regulation.</p>
3-20	<p>Amber Kemp  California Hospital Association</p>	<p>Specifically, we encourage the department to make the following additions and revisions to paragraph (b) of the regulation:<sup>1</sup></p> <p>(2) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to any person upon review and a finding that the action is in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.</p> <p>(3) A person requesting an exemption shall submit the following information for consideration by the Director:          ...</p> <p><del>(G) Persons requesting an exemption shall submit the request to the following address:          OPLInquiries@dmhc.ca.gov or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.</del>          ...</p> <p><del>(3)</del>(4) When reviewing the information submitted under subdivision (b)<del>(2)</del>(3) of this regulation, the Director shall consider the following criteria:</p>	<p>DECLINED. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed and be given time to address any regulatory requirements.</p> <p>The Department notes that the Director will respond to all exemption requests within 30 days as required under the regulation. Adding such a provision is also against the public interest because consumer access to care and the healthcare market place could be jeopardized if a thorough analysis of the request is not completed.</p> <p>Existing Knox-Keene Act statutory provisions, sections 1354 and 1397, a decision of the Director is subject to administrative and judicial review, including denials of applications for licensure. Therefore, it is not necessary to repeat these existing statutory provisions in the proposed regulation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>...</p> <p><u>(3)(7)</u></p> <p><u>(A) Persons requesting an exemption shall submit the request to the following address: OPLInquiries@dmhc.ca.gov or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.</u></p> <p><u>(B) The Director shall issue the decision on the request for exemption from licensure under this section within 30 days of receipt of the request by the Department. An applicant for exemption shall be deemed exempt from this section while the Department's decision on its request is pending. If the Department does not issue a decision on a request for exemption from licensure within 30 days of its receipt of the request, the request shall be deemed approved.</u></p> <p><u>(8)</u></p> <p><u>(A) The Department's decision to grant or deny a request for exemption shall be subject to review by the Director pursuant to Health &amp; Safety Code section 1397, paragraph (a). An applicant for exemption shall be deemed exempt from this section while the Director's decision is pending pursuant to this subdivision.</u></p> <p><u>(B) The Director's decision shall be subject to judicial review pursuant to Health &amp; Safety Code section 1397, paragraph (b). An applicant for exemption shall be deemed exempt from this section</u></p>	<p>Likewise, for policy reasons, the Department does not feel that only significantly modified contracts falling under the scope of the regulation be subject to licensure. The Department made a policy decision that the potential risk to consumers and the healthcare market place warrants that entities accepting global risk must have proper regulatory oversight. This regulation balances the need to protect consumers and the healthcare market place with the burden of obtaining licensure by the Department only when contracts are issued, amended or renewed.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

<p><u>while judicial review on the appeal of a denial of an exemption upheld by the Director is pending pursuant to this subdivision.</u></p> <p><u>(9) An applicant whose request for exemption is denied shall not be subject to this section until January 1 of the calendar year following the date the denial becomes final or nine months from the date the denial becomes final, whichever comes later. For the purposes of this subdivision (b)(11), a denial shall not be final until any appeals under subdivision (10)(A) and/or (10)(B) above are exhausted, if applicable.</u></p> <p>...</p> <p><u>(e) This section shall apply only to contracts issued, amended, or renewed or significantly modified on or after [Date to be inserted by OAL pursuant to Gov. Code § 11343.4].</u></p> <hr/> <p><sup>1</sup> For clarity, our recommended insertions are underlined, recommended deletions are stricken, and language that we recommend moving is double-underlined. We have suggested separating the information submission requirement that currently appears in paragraph (b)(2) from the substantive standard that appears in that paragraph. We have also suggested moving additional procedural provisions, including the language that currently appears in paragraph (b)(2)(G), <i>after</i> all substantive bases for exemptions such that it would appear in paragraph (b)(7)(A). Finally, it appears that paragraph (b)(3) erroneously appeared twice, so we have revised the numbering accordingly.</p>	
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

3-21	<p>Amber Kemp</p> <p>California Hospital Association</p>	<p><b>II. The department should provide clear, quantitative standards that allow a provider to determine whether it is entitled to an exemption from the licensure requirement.</b></p> <p>We appreciate the department’s efforts to respond to the Office of Administrative Law’s concern that earlier drafts of the proposed regulation did not provide sufficient clarity as to the standard for obtaining an exemption from the licensure requirement. We support the department’s decision to grant applicants an exemption upon the director’s finding that doing so is “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act” (28 California Code of Regulations (“C.C.R.”) § 1300.49, paragraph (b)(2) (proposed)). This standard, which is drawn from Health &amp; Safety Code Section 1343, ensures that the department focuses on the circumstances where its licensing and oversight activities are necessary to protect the public interest.</p> <p>However, as drafted, the exemption process would still require the department to engage in a subjective decision-making process to determine whether an exemption for a particular person or organization would be “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.” Even with the criteria provided in the new draft regulation, a provider cannot accurately predict whether the department will grant its request</p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text for policy and logistical reasons. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The Department, in response to previous comments, clarified the process and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified the Director will consider the entity’s financial capacity to assume risk, the impact to the healthcare marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact the public interest.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>for an exemption because the proposed criteria are too vague. <b>Therefore, we urge the department to identify circumstances in which a person, provider or other organization is presumptively exempt from the licensure requirement and to identify payment arrangements that are not subject to this regulation.</b> Applications for exemption under these categories should be subject to a streamlined review to confirm that the applicant participates in the types of safe, low-risk payment arrangements that are common in California and that we have emphasized in our comments throughout this rulemaking process.</p>	
3-22	<p>Amber Kemp  California Hospital Association</p>	<p><b>For example, the department should establish that a provider that participates in particularly low-risk payment arrangements that fall below quantitative risk thresholds is presumptively exempt from the licensure requirement.</b> Regulatory frameworks outside of California are instructive in demonstrating how such thresholds might be developed and applied. For example, the Centers for Medicare &amp; Medicaid Services (CMS) and the state of New York have determined that provider risk-bearing arrangements in which less than 25 percent of payments are at risk are sufficiently low-risk that the arrangement does not require the same level of oversight.<sup>2</sup> Below these thresholds, providers can take on risk without closer scrutiny by the regulators. These standards show that other state and federal regulators have limited their oversight activity to arrangements that present more significant levels of risk-taking. California’s providers have decades of experience sharing risk</p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The Department, in response to previous comments, clarified the process and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>with payors to incentivize high-value care, resulting in the most sophisticated health care market in the country. <b>The department’s oversight and regulation is, therefore, unnecessary when providers take on modest amounts of risk, when providers have the wherewithal to manage the risk they have taken on, or when the provider has a proven track record of sharing risk with payors in a financially stable manner.</b></p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>2</sup> CMS allows a Medicare Advantage organization to pass risk on to physicians or physician groups by way of a “physician incentive plan.” See 42 C.F.R. § 422.208. The arrangement is subject to additional regulation if it involves “substantial financial risk.” “Substantial financial risk,” in turn, is defined by reference to a number of quantitative risk-taking thresholds, such as facing withholds or liability greater than 25% of total payments.</p> <p>New York subjects managed care organizations’ agreements with provider groups to reduced scrutiny if less than \$1 million of payments to the provider are at risk under the agreement or, if the total amount of payments at risk exceeds \$1 million, no more than 25% of projected annual payments to the provider are at risk. See Provider Contract Guidelines for Article 44 MCOs, IPAs and ACOs, available at <a href="https://www.health.ny.gov/health_care/managed_care/hmoipa/docs/guidelines.pdf">https://www.health.ny.gov/health_care/managed_care/hmoipa/docs/guidelines.pdf</a>.</p>	<p>other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. In order to know that the entity has a “proven track record of sharing risk with payors in a financially stable manner” as suggested by the commenter, an exemption request must be submitted.</p>
3-23	Amber Kemp  California Hospital Association	<p><b>The department’s regulatory oversight is also unnecessary when a provider participates in certain payment arrangements pursuant to state or federal law, and under careful regulation by the Medicare or Medi-Cal programs.</b> For example, as hospitals that participate in Medicare, many of our members are required to or voluntarily participate in various CMS bundled payment initiatives, like the Comprehensive Care for Joint Replacement (CJR) model or the Medicare Shared Savings Program, both of which are considered “alternative payment models” under federal law. It is unnecessary to require that a provider seek licensure as a health care service plan so that it may accept payment under any of the alternative payment models, each of which is subject to a complex and robust regulatory scheme and oversight. Requiring licensure in these circumstances is redundant, and could undermine federal policy and impose outsized burdens on providers that are not otherwise engaged in any risk-bearing activities.</p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. However, the Department also notes that Government Code section 11349(d) requires a proposed regulation to be “consistent with” and not in “conflict with” other provisions of law. As such, this regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			entities.
3-24	Amber Kemp  California Hospital Association	<p><b>We also urge the department to establish that certain types of payment arrangements — including bundled payment arrangements, institutional risk pools, and ACOs — are presumptively exempt from this regulation unless the department determines that special circumstances warrant licensure.</b> These payment arrangements are common tools to improve the quality and coordination of care while posing minimal to no risk to patients, payors and providers. These arrangements may also be regulated under other schemes, as in the case of a health system that operates an ACO for its own employees under the health system’s self-funded plan that is subject to ERISA. These safe, common arrangements should be presumptively exempt from the licensure requirement.</p> <p>With that in mind, we urge the department to insert the following as a new paragraph (b)(5):</p> <p><u>(5)</u></p> <p><u>(A) A person is presumptively exempt from the licensure requirement if the person is a provider and at least one of the following is true:</u></p> <p><u>(i) No more than 25% of the provider’s maximum potential revenue from health care services from all payors is at risk;</u></p> <p><u>(ii) No more than 25% of the provider’s tangible net equity (TNE) is at risk across all payors with whom the provider has entered into payment arrangements; or</u></p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption.</p> <p>Accordingly, the proposed regulation may impact 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 an exemption from licensure.</p> <p>Additionally, Government Code section 11349(d) requires a proposed regulation to be “consistent with” and not in “conflict with” other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.</p> <p>Based upon these reasons, the Department declines to adopt the proposed language of the</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>(iii) No more than 25% of the provider's cash on hand is at risk across all payors with whom the provider has entered into payment arrangements.</u></p> <p><u>(B) A payment is not considered at risk for the purposes of this subdivision (b)(5) if the payment is:</u></p> <p><u>(i) Received under an alternative payment model, as that term is defined in 42 U.S.C. 1395/(z)(3)(C);</u></p> <p><u>(ii) Received from an entity that contracts directly with the United States government to provide services under the Medicare program or an entity that contracts directly with the State Department of Health Care Services to provide services under the Medi-Cal program;</u></p> <p><u>(iii) A bundled payment for a specified set of services provided within ninety (90) days or less that relate to a single episode of care;</u></p> <p><u>(iv) Received in connection with participation in an institutional risk pool;</u></p> <p><u>(v) Received in connection with participation in an accountable care organization;</u></p> <p><u>(vi) Received pursuant to a payment arrangement that has not been</u></p>	<p>commenter.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p style="text-align: center;"><u>materially modified for three (3) or more years where the provider has not sustained a loss of more than 10% of the provider's maximum potential revenue under that arrangement over the last three (3) years;</u></p> <p><u>(vii) Not subject to downside risk; or</u>  <u>(viii) Received under an arrangement in which the provider is paid a per-member, per-month amount by a licensed health care service plan solely for services that the provider is authorized by law to provide (i.e., the provider takes capitated professional risk only or capitated institutional risk only, but does not take global risk).</u></p> <p><u>(C) The calculation made pursuant to subdivision (b)(5)(A) shall take into account any applicable insurance held by the provider, including reinsurance and/or stop-loss coverage.</u></p>	
3-25	Amber Kemp  California Hospital Association	<p>In order to establish eligibility for a presumptive exemption pursuant to this new paragraph (b)(5), a person, provider or other organization should be required simply to provide materials and information demonstrating its satisfaction of the applicable presumptive exemption category or categories. To that end, we recommend inserting the following as paragraph (b)(6):</p> <p><u>(6)</u></p>	DECLINED. The Department declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to ensure the Department has oversight over arrangements that could subject enrollees to harm if the entity were to become financially insolvent or not provide the level of

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>(A) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to a person described under paragraph (b)(5) unless the Department determines there is a compelling reason to deny the request for exemption.</u></p> <p><u>(B) A person requesting an exemption pursuant to subdivision (b)(5) shall not be subject to the requirements of subdivision (b)(3) and shall instead submit materials and information to the Director demonstrating that it is entitled to exemption under the applicable requirement(s).</u></p>	<p>care promised. Narrowing the payment arrangements to which the regulation applies would be contrary to the purpose of the regulation.</p>
3-26	Amber Kemp  California Hospital Association	<p><b>We also urge the department to clarify that an exemption granted to a person or organization would remain in effect unless and until there is a material change in the type of payment arrangements in which the person or organization is engaged.</b> This would relieve the department of the burden of considering each new payment arrangement into which exempt persons and organizations enter. If a person or organization enters into new payment arrangements that do not materially differ from the payment arrangements in place when the person or organization was granted an exemption, there is no need for the department to revisit its analysis. To that end, we recommend inserting the following as a new paragraph (b)(10):</p> <p><u>(10) An exemption granted under this subdivision (b) shall remain in effect unless and until there is a material change in the nature of payment arrangements in which the exempt person is engaged.</u></p>	<p>DECLINED. The Department does not feel this is necessary as the exemption process is well-established and the regulation adds clarity to the existing exemption process. If a party receives an exemption based upon the criteria stated in the regulation, then the party has this exemption based upon the information the party gave to the Director for review and decision. If the entity enters into a new or different arrangement that falls within the scope of the regulation, then the entity is required under the law to either obtain licensure or an exemption for that different arrangement.</p>
3-27	Amber Kemp  California Hospital	<p>For the purpose of clarity, we also suggest inserting the following definitions under paragraph (a):</p>	<p>DECLINED. The comment is irrelevant because it does not address the changes made during this comment period.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	Association	<p><u>(7) “Accountable care organization” shall refer to an arrangement in which one or more providers, paid pursuant to a fee schedule, are held accountable for a patient population’s care over a predetermined period of time by way of incentive payments that are tied to the providers’ performance on quality metrics and/or the providers’ ability to control costs for that patient population by, among other things, comparing the actual cost of care to a target budget.</u></p> <p><u>(8) “Downside risk” shall refer to an arrangement in which one or more providers are paid using a fee schedule, but may be required to repay an amount to a payor at the end of a predetermined period if total payments for health care services under the arrangement exceed a target budget applicable to that arrangement. An arrangement does not subject a provider to downside risk if a deficit from spending exceeding a target budget accrues only against future surpluses under the arrangement, but does not require repayment to the payor.</u></p> <p><u>(9) “Institutional risk pool” shall refer to a payment arrangement in which fee-for-service payments for hospital services for a particular set of patients are compared to a target and any surplus is disbursed to the physicians caring for those patients after a predetermined period of time, but only to the extent the patients’ costs for institutional services fall below the predetermined target, and any shortfall is accrued against future surpluses and does not create a payment obligation by the physicians.</u></p>	<p>It should be noted that Accountable Care Organization, downside risk, and institutional risk pool are not used in the regulation and so defining them is not required and would be confusing. Additionally, because of the frequency with which new arrangements proliferate, the Department declines to attempt to define each new arrangement that may be subject to licensure. Payor and provider are terms already defined in the Knox-Keene Act.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>(10) “Payor” shall have the meaning set forth in Health &amp; Safety Code section 1395.6.</u></p> <p><u>(11) “Provider” shall have the meaning set forth in Health &amp; Safety Code section 1345.</u></p>	
3-28	Amber Kemp  California Hospital Association	<p><b>III. As drafted, the proposed regulation is inconsistent with the Knox-Keene Act and unworkable, and the department should re-engage with stakeholders prior to finalizing it.</b></p> <p>As we described in our earlier comment letters, we are concerned that certain types of payment arrangements that involve little or no financial risk — but create financial incentives to increase quality, access and efficiency — would be subject to licensure under the proposed regulation. These include bundled payment arrangements where the payment provides for both professional and institutional services; institutional risk pool arrangements; and integrated care arrangements, such as ACOs, including those with zero downside risk. <b>Under payment arrangements like these, many of our members provide high-quality care in a cost-effective manner while accepting minimal or no financial risk.</b></p>	<p>DECLINED. The comment is irrelevant because it does not address the changes made during the comment period.</p> <p>The Department engaged in informal meetings with stakeholders, four comment periods and made changes in response to concerns. The Department has extensively considered stakeholder input during the regulatory process as well as having four public comment periods for this regulation. The Department also notes that entities which accept “no financial risk” would not be subject to the licensure requirement under this regulation.</p>
3-29	Amber Kemp  California Hospital Association	<p>These evolving payment arrangements typically encourage providers to coordinate care, improve quality and stay within a target budget. The arrangement might be limited to a narrowly defined set of services linked to an episode of care, in the case of a bundled payment arrangement, or a population’s care during a defined time period, as in the case of an institutional risk pool arrangement</p>	<p>NO CHANGE REQUESTED.</p> <p>Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to ensure the Department has oversight over arrangements that could subject</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		and many integrated care arrangements. However, these arrangements generally do <b>not</b> require a provider to be responsible for the entirety of a patient’s care in exchange for a capitated payment, nor do they require providers to take on such significant risk that the provider’s financial stability may be threatened. As such, these arrangements pose no threat of harm to consumers. However, under the plain language of the proposed regulation, it appears that these common, safe and valuable payment arrangements would be subject to licensure.	enrollees to harm if the entity were to become financially insolvent or not provide the level of care required under the law.
3-30	Amber Kemp  California Hospital Association	The Knox-Keene Act was intended to ensure health plans are able to deliver on their promise to arrange health care services after accepting a pre-paid charge from enrollees. The payment arrangements described above were not contemplated by the drafters of the Knox-Keene Act; shared savings arrangements, episodic payments and other value-based payments simply do not resemble the capitated arrangements that were the drafters’ focus and do not involve prepaid or periodic payments.	NO CHANGE REQUESTED.  Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to ensure the Department has oversight over arrangements that could subject enrollees to harm if the entity were to become financially insolvent or not provide the level of care required under the law.
3-31	Amber Kemp  California Hospital Association	Furthermore, the department’s Statement of Reasons provides little insight as to why it seeks to sweep in such a broad array of arrangements and disrupt California’s health care marketplace. Moreover, regulating such arrangements as “health care service plans” would be inconsistent with the Knox-Keene Act’s existing regulatory framework. <b>The proposed regulation does not address this inconsistency. Rather, it leaves unanswered a number of questions about whether an entity</b>	NO CHANGE REQUESTED.  Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The proposed regulation may impact Accountable Care Organizations or other arrangements that, considering the proposed regulation, meet the definition of a health care service plan.

DEPARTMENT OF MANAGED HEALTH CARE

General Licensure Requirements for Health Care Service Plans (2017-5220)

Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018

<p><b>that participates in these innovative payment arrangements could obtain a license and satisfy the obligations of licensure on an ongoing basis without transforming its care model into a traditional health maintenance organization.</b></p> <p>Indeed, it is unclear whether the department intends for such arrangements to continue under its oversight, or if the proposed regulation would operate as an indirect prohibition of these payment arrangements. If the department is unwilling to revise the regulation to narrow the scope of arrangements for which licensure will be required, then it should at least adopt the recommendations set forth above to ensure that exemptions from licensure are granted for the many common, low-risk arrangements that might now come within the newly expanded range of payment arrangements requiring a license.</p>	<p>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.</p> <p>As stated in the Department’s Initial Statement of Reasons, “Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume “full financial risk” for the provision of covered health care benefits to enrollees or subscribers. However, “full financial risk” is not defined. As a result, provider groups that contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services (professional and institutional risk together is considered “global risk”). These provider groups otherwise meet the definition of a health plan pursuant to Health and Safety Code section 1345, subdivision (f), by arranging for health care services for health plan enrollees and accepting at least a portion of global risk. Without a clear definition of what types and levels of risk may be assumed, entities that meet the definition of a health plan may be operating without a license. This is a violation of Health and Safety Code section 1349, which</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>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>Further, as detailed in the ISOR, 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>
3-32	Amber Kemp  California Hospital Association	<p><b>We urge the department to elicit stakeholder feedback and to refine this regulation prior to making it final.</b> We strongly encourage the department to engage in a collaborative process with the payor, provider and patient communities to formulate a regulatory framework that strikes the proper balance between protecting the public and encouraging value-based payment systems. The federal negotiated rulemaking process set forth in 5 U.S.C. sections 561 <i>et seq.</i> provides a model for stakeholders representing various interests to come</p>	<p>DECLINED. The Department notes your concern but has engaged in informal meetings with stakeholders, four comment periods and has responded appropriately to stakeholder concerns.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>together to inform an agency’s rulemaking process. If implemented as currently written, the proposed regulation is likely to pose substantial operational challenges. We believe the department would benefit from a formal process for obtaining stakeholder input and improving the regulation.</p> <p>CHA appreciates the opportunity to provide comments on the modified regulation.</p>	
4-33	<p>William Barcellona, JD, MHA</p> <p>America’s Physician Groups</p>	<p>America’s Physician Groups submits the following comments on the fourth version of the draft rule.</p> <p><b>Introductory Comments:</b></p> <p>The Office of Administrative Law previously rejected the Department’s final submission of this proposed rule on a ground of lack of clarity. Accordingly, the Department made substantive changes to the exemption criteria in this fourth version. Unfortunately, as we will show, the Department has not met the standard of clarity in this fourth version. In the absence of clear exemption rules, the industry will not understand whether their arrangements may or may not be subject to the Department’s jurisdiction. The time and cost of such uncertainty, and the lack of clear rules create a potential chilling effect on the transition from fee-for-service payment to value-based and risk-based models across the entire California health care market. Rather than risk a cease-and-desist order from the Department, potential ACO participants will decline to participate in that program. Self-funded employers will cease to seek value-based arrangements and will of necessity advocate for centralized, state-run provider rate regulation. Millions of</p>	<p>NO CHANGE REQUESTED.</p> <p>The proposed regulation may impact 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 an exemption from licensure.</p> <p>The Department, in response to previous comments, clarified the process by which and the standards by which an entity’s request for an exemption will be considered and feels that it has met the standard of clarity. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		California patients will pay higher prices for health care under a persisting fee-for- service market. As we will discuss later in this comment letter, this is all due to the vagueness of the Department’s definition of “global risk” and its confusing expressed intention to regulate provider payment models that do not currently incorporate downside financial risk, capitated payment, or combined payments for institutional and professional risk to a single provider entity.	impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. These clarifications addressed OAL’s concerns.
4-34	William Barcellona, JD, MHA  America’s Physician Groups	Recent data from the Integrated Healthcare Association, a body in which the Director sits, has shown that as the level of risk-based payment increases, quality scores increase, per-capita cost declines and patient out-of-pocket costs are significantly lower than fee-for-service (no risk) payment models. The Department, as an arm of the Health & Human Services Agency, should promulgate regulations that incent the continued transformation of the California health care system from costly fee-for-service payment models to value-based.	NO CHANGE REQUESTED.  The Department believes the exemption process and/or the ability to seek licensure as a restricted health care service plan, which is a less burdensome and less expensive licensure process, will remove any disincentives that could occur.
4-35	William Barcellona, JD, MHA  America’s Physician Groups	<b>The Exemption Criteria are Vague, Expensive, Hard to Prove and Largely Irrelevant to the Determination of Financial Solvency of the Applicant for Exemption and Will Curtail the Use of Value-Based Payment Outside of the Knox Keene Model Across California:</b>  Under the fourth version, an applicant is required to submit specific information under subsection 2 (A) – (F)	DECLINED. The Department, in response to previous comments, clarified the process by which and the standards by which an entity’s request for an exemption will be considered and feels that it has met the standard of clarity. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>as part of an exemption request. That information includes financial projections and income statements, the underlying plan-to-plan contract, the proposed operational area, the number of lives, and any other relevant information that the applicant deems necessary to the submittal.</p> <p>From that submittal, the Department, within 30 days of receipt of the application will decide based on the following provisions under subsection 3 (A) – (E) (emphasis added):</p> <p>(A) the portion of contracted global risk when compared to other business;</p> <p><i>(B) the portion of <u>market share</u> the entity assumes for global risk in the geographic region compared to the market share assumed by others in the region and <u>whether disruption will occur in the marketplace if the entity fails to maintain financial solvency;</u></i></p> <p>(C) financial capacity to assume a portion of global risk without jeopardizing access to basic health care services;</p> <p><i>(D) <u>potential impact on healthcare in the marketplace including impact on contracted institutional and professional providers if the person is unable to maintain financial solvency;</u></i> and</p> <p>(E) the exemption will not negatively impact public interest or protection of the public, subscribers or enrollees or persons subject to the KKA if the entity assumes global risk.</p>	<p>must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact the public interest.</p> <p>The exemption criteria ask for information the entity should have access to and therefore will not be expensive or difficult to obtain. As stated in Health and Safety Code 1343.5, the burden of proving an exemption to a definition under the Knox-Keene Act is on the requestor. This is because the requestor is in the unique circumstance of knowing and having access to the information that would demonstrate why an exemption should be granted by the Director according to the law. Additionally, the information requested in the criteria is directly relevant to financial solvency and how potential insolvency would affect the region and market in which the entity operates. As stated in response to comment 4-34, the ability for an entity to seek an exemption or licensure as a restricted health care service plan will not lead</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			to an increase in disincentives but instead balances the need for innovation in the health care marketplace with the safety of consumers.
4-36	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>Let's break the elements of subsection (B) and (D) down for further discussion:</p> <ul style="list-style-type: none"> <li>• <b>(B) Market Share:</b> Neither the applicant nor the Department would have a reliable source of information to compile a comparative market survey of providers and payers in a geographic region that would provide assurances to the Department that the applicant's failure would not adversely affect patients and other providers. The so-called "market" might include Medicare, private payers, employer-sponsored payers, and Medi-Cal. An applicant would have to research several independent sources of information, many of which would be inaccessible due to the proprietary nature of agreements between payers and providers. This would be time-consuming, costly and all but certain to yield generally useless and confusing results. The DMHC also lacks any ready reference on the "market" from which to compare an applicant's analysis to their own. On the provider side, the Department is well-aware that there is no accurate source of information on the active "market" of providers in a geographic region currently. The Department lacks any database from which to reference the accuracy of an applicant's analysis. Any analysis submitted to the Department would become rapidly irrelevant as the provider "market" continues to change daily. Lastly, an applicant has little access to provide a comparative analysis of the "market share" that other providers may</li> </ul>	<p>DECLINED. The Department, in response to previous comments, clarified the process by which and the standards by which an entity's request for an exemption will be considered and has met the standard of clarity. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>The exemption criteria ask for information the entity should have access to and therefore will not be expensive to obtain. As started in Health and Safety Code 1343.5, the burden of proving an exemption to a definition under the Knox-</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>have in a geographic region, due to the proprietary nature of payer agreements and the multiple sources of payers. This required factor is therefore so vague, unprovable, potentially costly, and irrelevant to the future conditions that may exist that it provides little practical worth as an evaluation tool by the Department. The only mechanism that could address these fatal short-comings in Section (B) would be for the Department to mandate extensive, and likely resisted, data reporting on the part of all regulated entities.</p>	<p>Keene Act is on the requestor. This is because the requestor is in the unique circumstance of knowing and having access to the information that would demonstrate why an exemption should be granted by the Director. Additionally, the information requested in the criteria is directly relevant to financial solvency and how potential insolvency would affect the region and market in which the entity operates. As stated in response to comment 4-34, the ability for an entity to seek an exemption or licensure as a restricted health care service plan will not lead to disincentives but instead balances the need for innovation in the health care marketplace with the safety of consumers.</p>
4-37	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>• <b>(B) Whether Disruption Will Occur:</b> Does the Department require an analysis of potential financial disruption to other providers in the market due to unpaid downstream provider payments? If that is the case, the payer would have to delegate downstream claims payment responsibility to the applicant. The Department has stated that it intends to regulate two-thirds of the existing ACOs in California under this regulation. But current ACO arrangements do not include that delegated function because they do not utilize capitation. Providers are only paid for the services that they provide under their own licenses. Entities that do use such arrangements already disclose them to the Department under current regulatory requirements, and the Department's recently closed pending RBO regulation provides even greater protections against downstream provider financial disruption in the form of greater transparency of reporting</p>	<p>DECLINED. The Department, in response to previous comments, clarified the process by which and the standards by which an entity's request for an exemption will be considered and feels that it has met the standard of clarity. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>and higher capitalization requirements for such risk-bearing entities. It is also difficult for the Department to assess the potential of a provider applicant's financial failure on enrollee access to care. Such an analysis is dependent upon the full-service plan's or payer's remaining provider network at the time of the failure. Only the payer can provide that kind of information to the Department. Any analysis provided by an applicant of this element would be speculative and would become rapidly irrelevant after the date of submittal, due to the changing nature of network composition.</p>	<p>Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>The exemption criteria ask for information the entity should have access to and therefore should not be expensive or difficult to obtain. As started in Health and Safety Code 1343.5, the burden of proving an exemption to a definition under the Knox-Keene Act is on the requestor. This is because the requestor is in the unique circumstance of knowing and having access to the information that would demonstrate why an exemption should be granted by the Director. Additionally, the information requested in the criteria is directly relevant to financial solvency and how potential insolvency would affect the region and market in which the entity operates. As stated in previously in response to comment 4-34, the ability for an entity to seek an exemption or licensure as a restricted health care service plan will not lead to disincentives but instead balances the need for innovation in the health care marketplace with the safety of consumers.</p>
4-38	William Barcellona, JD, MHA	<p>• <b>(D) Potential Impact on Healthcare in the Marketplace:</b> Factor (D) is largely duplicative of factor (B) and therefore all the prior criticisms apply. The</p>	<p>DECLINED. The information is not duplicative.</p> <p>As previously stated, under the regulation, an</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>America's Physician Groups</p>	<p>Department already requires <u>payers</u> (i.e. Health Plans) that provide coverage and networks to enrollees to ensure continuity of care and timely access to their enrollees through several mechanisms under the Knox Keene Act, including but not limited to the Plan's application, its annual network filings under the Timely Access regulation, and the Block Transfer regulation. This factor illustrates the fundamental error in this regulation, that the Department is seeking to increase its jurisdictional authority beyond licensed health plans to other payers such as the CMS in Medicare, and statutorily exempted payers such as self-funded employer plans and union trust funds, through the expansion of requirements on the providers who contract with them.</p>	<p>entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. However, the Department also notes that Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. As such, this regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.</p> <p>The Department is not expanding its jurisdiction but is instead clarifying existing law under the Knox-Keene Act. As stated in the Department's Initial Statement of Reasons, "Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume "full financial risk" for the provision of covered health care benefits to enrollees or subscribers. However, "full financial risk" is not defined. As a result, provider groups that contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>(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>Further, as detailed in the ISOR, 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>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

4-39	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>APG argues that it is burdensome and unduly expensive for an applicant to submit information and analysis relevant to the Department's determination under subsections (3) (B) and (D) and therefore urge the Department to strike these two factors in the final version of this regulation. The information necessary to make determinations under these two subsections is more readily provided by the payer plan than the applicant.</p>	<p>DECLINED. The exemption criteria ask for information the entity should have access to and therefore should not be expensive to or difficult to obtain. As started in Health and Safety Code 1343.5, the burden of proving an exemption to a definition under the Knox-Keene Act is on the requestor. This is because the requestor is in the unique circumstance of knowing and having access to the information that would demonstrate why an exemption should be granted by the Director. Additionally, the information requested in the criteria is directly relevant to financial solvency and how potential insolvency would affect the region and market in which the entity operates. As stated in response to comment 4-34, the ability for an entity to seek an exemption or licensure as a restricted health care service plan will not lead to disincentives but instead balances the need for innovation in the health care marketplace with the safety of consumers.</p>
4-40	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>We also note that the nature of the exemption criteria in this regulation focuses on the <u>degree of risk</u> assumed relative to the provider's total revenue, and <u>not the kind of entity</u> with whom the payer contracts. For the Department has specified that an entity assuming global risk may only contract with a full or specialized Knox Keene plan, set forth at subsection (C)(1)(A):</p> <p><i>A restricted health care service plan may contract only with and accept global risk form only a full-service health care service plan or a specialized health care service</i></p>	<p>NO CHANGE REQUESTED.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<i>plan to provide or arrange health care services for that entity's subscribers or enrollees.</i>	
4-41	William Barcellona, JD, MHA  America's Physician Groups	APG concludes that the inclusion of this provision outside of the exemption criteria under subsection (b) conveys an intent to bar any global risk arrangements and prevent exemptions of arrangements with plans operating under statutory exemptions from the Knox Keene Act, such as ERISA-preempted employer plans, plans listed as exempted under Section 1349 (1) & (2), and other statutorily exempted plans. Depending upon the degree to which the Department applies the definition of "global risk" to various payment arrangements across California, this regulation would require the cessation of several existing ACO arrangements with the CMS in Medicare, with self-funded employer payers, union trust fund payers, and even certain COHS plans that lack Knox Keene licensure for Medi-Cal.	NO CHANGE REQUESTED. Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities. Any entity that otherwise meets this regulation's definition of a health plan must either obtain a license or an exemption.
4-42	William Barcellona, JD, MHA  America's Physician Groups	<b>The Department's Definition of "Global Risk" is Even More Ambiguous considering its Application to 67 California "ACOs" and Violates "Clarity" and "Consistency" Standards:</b>  If the Department had not expanded the definition of global risk beyond historical capitated payments that combined the institutional and professional risk component to a single provider entity, the ambiguity could have been avoided.	NO CHANGE REQUESTED. This comment is irrelevant because it does not address the changes made during the comment period.
4-43	William Barcellona, JD, MHA	This version of the proposed regulation continues to require an entity that accepts "global risk" to file for a Restricted License. "Global risk" has historically been treated by the Department and its	NO CHANGE REQUESTED. This comment is irrelevant because it does not address the changes made during the comment period.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>America's Physician Groups</p>	<p>predecessor, the Department of Corporations, to mean the payment of combined professional and institutional <u>capitation from a health plan to a physician group</u>. The Department stated its broader intent in the third version of the proposed rule, as follows:</p> <p><u><i>Costs for New Entities Requiring Licensure:</i></u></p> <p><i>In addition to implementing the licensure process for restricted health care service plans, the regulation may also require entities that previously did not require licensure to seek either licensure or an exemption from licensure from the Department. Accountable Care Organizations (ACOs) and Public Health Systems (PHS) are two entities that, provided they fall within the regulation's provision, will be required to seek licensure or an exemption. Because these entities have not previously been licensed by the Department, the Department has made assumptions in order to estimate the fiscal impact of the regulation of these entities. For ACOs, according to a University of California-Berkeley study, in 2015 there were 67 ACOs with risk bearing contracts in California, covering 1,355,756 lives. Although there are likely new ACOs in California today, some of the ACOs in existence in 2015 may have consolidated or otherwise stopped doing business and so the Department estimates that, once the regulation is effective, there will be 67 ACOs that will fall within the terms of the regulation. <b>Of those 67, we assume the Department will grant an exemption to one-quarter of the ACOs. Because one of the</b></i></p>	
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><i><b>purposes of the regulation is to increase oversight in order to protect consumers, the Department will likely not grant many exemptions to ACOs. The overall cost as a result of licensing ACOs is estimated to be \$2,866,739. Of that, \$1,250,000 is the one-time cost to license three-quarters of the 67 ACOs (each will pay the \$25,000 application fee). The ongoing costs are \$2,119,239, which accounts for the \$1.59 per enrollee fee and the \$10,000 per licensed ACO fee.<sup>1</sup></b></i></p> <p>_____</p> <p><small><sup>1</sup> Accountable Care Organizations In California: Promise and Performance. University of California Berkeley, School of Public Health, February 2015. Accessed on June 1, 2018 at: <a href="http://berkeleyhealthcareforum.berkeley.edu/wp-content/uploads/BerkeleyForumACOExpBrief3_feb16.pdf">http://berkeleyhealthcareforum.berkeley.edu/wp-content/uploads/BerkeleyForumACOExpBrief3_feb16.pdf</a>.</small></p>	
4-44	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>Government Code Section 11349.1 requires that all regulations submitted comply with standards of "clarity" and "consistency."</p> <p>The Department has created an ambiguity during the pendency of this draft regulation by not clearly stating that its jurisdiction is limited to prepaid arrangements. <b>No ACO in California has ever received a globally-capitated payment. Few, if any, currently have downside risk. None are paying providers outside of the scope of their professional licenses. And many of the current ACOs do not contract with full or specialized Knox Keene health plans.</b></p>	<p>NO CHANGE REQUESTED. This comment is irrelevant because it does not address the changes made during the comment period.</p> <p>The Department notes that only entities which are defined as a health plan under the terms of the regulation will be required to seek either licensure or an exemption from the Director. If the entity does not accept global risk, the entity does not fall within the scope of the definition in the regulation.</p>
4-45	<p>William Barcellona, JD, MHA</p> <p>America's</p>	<p>Consider the situation with CalOptima health plan, which is a COHS plan that provides Medicare Advantage and Medi-Cal services in Orange County. The plan is licensed by the DMHC as a full- service plan for Medicare Advantage business but is</p>	<p>NO CHANGE REQUESTED. This comment is irrelevant because it does not address the changes made during the comment period.</p> <p>Further, the Department is not going to discuss</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	Physician Groups	<p>statutorily exempted from licensure for its Medi-Cal business. CalOptima has global risk arrangements with several providers in Orange County. Some of them have obtained restricted licenses for these arrangements, others have not. Some of the arrangements are not currently considered to be “global risk” but may become characterized as such under the expanded definition proposed by the Department. The Plan has recently concluded that upon implementation of this regulation, some providers may have to seek restricted licensure. However, how can a provider accepting global risk apply for a restricted license to accept Medi-Cal global risk if CalOptima is not licensed as a full-service Knox Keene plan for this line of business? For those providers currently accepting global risk across both Medicare and Medi-Cal, would they be required to cease such arrangements once the regulation becomes effective and their existing contracts are amended or renewed under subsection (e) of this proposed regulation? And how will the cessation of these risk-shifting arrangements benefit the taxpayers of California, or even the enrollees of CalOptima health plan?</p>	<p>the specific facts of a specific entity as it relates to this regulation. An entity may approach the Department through the process outlined in the regulation to obtain information regarding licensure or an exemption.</p> <p>Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed and be given time to address any regulatory requirements.</p>
4-46	<p>William Barcellona, JD, MHA</p> <p>America’s Physician Groups</p>	<p>Moreover, if the Department applies the expanded definition of global risk to Medicare ACOs operating in California, how will the ACOs continue to operate under this regulation since they do not contract with a “full service” health plan, but rather in a direct arrangement with CMS?</p>	<p>DECLINED. This comment is irrelevant because it does not address the changes made during the comment period.</p> <p>Government Code section 11349(d) requires a proposed regulation to be “consistent with” and not in “conflict with” other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
4-47	William Barcellona, JD, MHA  America's Physician Groups	How will Medicare beneficiaries benefit from the cessation of the ACO program in California due to the implementation of this regulation?	DECLINED. This comment is irrelevant because it does not address the changes made during the comment period.  Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
4-48	William Barcellona, JD, MHA  America's Physician Groups	Lastly, as the Department implements the regulation over self-funded employer plan, union trust fund and CDI-regulated PPO plan ACO arrangements, and thus prohibits their continuation due to the lack of a full or specialized plan license, how will that benefit the approximate 8 million Californians receiving coverage in that sector of the health care market?	NO CHANGES REQUESTED.  Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
4-49	William Barcellona, JD,	<b>The Lack of Definition of "ACO" is Vague and Ambiguous:</b>	DECLINED. This comment is irrelevant because it does not address the changes made

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

<p>MHA</p> <p>America's Physician Groups</p>	<p>The text of the regulation has not been amended from the third version to include the definition of an Accountable Care Organization (“ACO”). Many of the so-called “ACOs” cited in the reference material relied upon by the Department and provided to the OAL do not in fact involve a single provider entity. For example, Blue Shield ACO arrangements are based on a typical contracting model where the plan has separate agreements with the hospital and capitated provider group. Would the Department require that the hospital and provider group incorporate into a single entity? Medicare ACOs directly contracted to the CMS do in fact form a single legal entity. However, the CMS directs separate payments to the hospitals and physician providers within the entity. The Department’s definition of global risk does not specify whether a payment need be a single, combined amount that includes the institutional and professional components. If it does not, then several value-based payment models across California, such as bundled payments and other episode-based forms may fall under the definition of global risk.</p>	<p>during the comment period.</p> <p>Note that the term “Accountable Care Organization” is not used in the regulation and so defining it would be confusing. Additionally, because of the frequency with which new arrangements proliferate in the healthcare market place, not limited to Accountable Care Organizations, the Department declines to attempt to define each new arrangement which may be subject to licensure under the terms of the regulation.</p> <p>Further, only entities which meet the definition of a health plan as provided in the regulation must seek either licensure or an exemption. The study cited in the Addendum was used by the Department as an estimate for the potential number of ACOs and PHSs affected by the proposed regulation. The study defined ACOs as medical groups with risk-bearing contracts that meet cost and quality criteria for either Medicare/Medicaid or a commercial plan. The Department took the total number of identified Accountable Care Organizations as a ceiling in order to estimate the potential economic impact. The numbers used are for fiscal estimation purposes only.</p> <p>Finally, Government Code section 11349(d) requires a proposed regulation to be “consistent with” and not in “conflict with” other provisions of law. This regulation will not affect</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
4-50	William Barcellona, JD, MHA  America's Physician Groups	<b>Unresolved Collateral Issues Over the Scope of the Regulation and it's Application to the Spectrum of Risk-Sharing Arrangements:</b>  Entities that assume a lower level of risk are cited as potentially covered by the regulation, but other types of arrangements that involve higher levels of risk are not. This lack of clarity and consistency in application creates confusion.	NO CHANGE REQUESTED.
4-51	William Barcellona, JD, MHA  America's Physician Groups	The 2002 California Financial Solvency Standards Board memorandum ("FSSB memo") that analyzes the distinction between "full risk contracting," "shared risk contracting" and "global risk contracting" provides a spectrum-level analysis of financial risk assumed by providers. In that document, shared-risk arrangements between hospitals and medical groups are viewed as a lesser level of assumed risk than a global risk arrangement, and yet such arrangements constitute a higher level of risk than a current fee-for-service-based downside-risk gain-sharing agreement common among the PPO and HMO sponsored commercial "ACOs."  In a more recent discussion by the Financial Solvency Standards Board on November 18, 2013,	NO CHANGE REQUESTED. The comment is irrelevant because it does not address the changes made during the comment period.  It should be noted that the memorandum cited by the commenter is over 16 years old and the health care marketplace has changed considerably since this time. As an example, the Affordable Care Act (ACA) was not in existence at the time of the cited memorandum, and it is the ACA, in part, that has led to the innovation of health care entities, such as ACOs.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>FSSB Board member Ed Cymeris presented a comprehensive assessment of risk arrangements that included all these relevant models. That analysis ranks shared-risk arrangements as further across the risk-assumption spectrum than the current commercial ACO arrangements cited in the Berkeley Forum report.<sup>2</sup></p> <p>If a non-capitated ACO arrangement falls under the risk regulation, an agreement to share risk between a hospital and a medical group for the upside/downside exposure for a population of assigned HMO enrollees must as well. Would such arrangements fall under the regulation? If so, these arrangements do not involve a single entity that receives a combined payment for institutional and professional risk. Who then, would apply for licensure, or an exemption?</p> <hr style="width: 20%; margin-left: 0;"/> <p><small><sup>2</sup> The November 18, 2013 FSSB "Risk Assessment" presentation by FSSB Board member Ed Cymeris FSA MAA, accessed on June 1, 2018 at <a href="http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/raoepa.pdf">http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/raoepa.pdf</a>.</small></p>	
4-52	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p><b>Conclusion</b></p> <p>It is commendable that the Department has undertaken to issue a regulation that is intended to codify a long-standing process for licensure of globally-capitated physician organizations. As recently noted, the Integrated Healthcare Association has determined that restricted licensees demonstrate higher quality of care delivery while operating under significantly lower cost than other comparable delivery models in the California health care system. Were the current draft of the proposed</p>	NO CHANGE REQUESTED.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		rule limited to that objective, California could rapidly further the expansion of this successful, collaborative model between payers and providers.	
4-53	William Barcellona, JD, MHA  America's Physician Groups	It is unnecessarily costly and burdensome to require ACOs that do not receive globally capitated payments to incur substantial costs to file with the Department to seek an "exemption" in a process that is already an <i>exemption</i> from the general licensure requirements of the Knox Keene Act. While the Department indicates that " <i>(e)ntities that seek an exemption from licensure requirements are not required to pay the application fee</i> " the legal and consulting costs incurred in such encounters typically exceed tens of thousands of dollars. Furthermore, since the Department has not fleshed-out the elements for exemption, the entire process lacks the clarity and consistency required by the Government Code.	NO CHANGE REQUESTED. The Department believes the exemption process and/or the ability to seek licensure as a restricted health care service plan, which is a less burdensome and less expensive licensure process, is not overly burdensome for the sophisticated entities that exist in the health care marketplace in California.
4-54	William Barcellona, JD, MHA  America's Physician Groups	The effect of this regulation is to expand the jurisdiction of the Department beyond capitated provider arrangements without the provision of new legislation to expand those powers. The negative impact of this regulation, if adopted, will induce a chilling effect on the continued operation of Accountable Care Organizations in California, and discourage new formation of such entities in the future. California needs more ACOs and more Restricted Licensees to control costs in the healthcare system.	NO CHANGE REQUESTED. The comment is irrelevant because it does not address the changes made during the comment period.  The Department believes the exemption process and/or the ability to seek licensure as a restricted health care service plan, which is a less burdensome and less expensive licensure process, will not create disincentives. Licensing entities of the type of you note will not be disruptive to the health care marketplace and instead will help provide important consumer protections, including financial solvency review.
4-55	William Barcellona, JD,	While the Department has cited the need to protect consumers, we wish to note that to date, no "ACO"	NO CHANGE REQUESTED. The comment is irrelevant because it does not address the

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	MHA  America's Physician Groups	arrangement in California has generated concerns or complaints over financial solvency or denial of care. Indeed, the Department has not cited any problems with the operations of "ACOs" in its Statement of Reasons.	changes made during the comment period.
5-56	Stephanie Shirkey  California Association of Health Plans	The California Association of Health Plans (CAHP) represents 46 public and private health care service plans that collectively provide coverage to over 28 million Californians. This letter sets forth our comments to the revised proposed regulation published on November 30, 2018, relating to General Licensure Requirements under the Knox Keene Act and adding section 1300.49 to Title 28 of the California Code of Regulations (proposed section 1300.49). CAHP has submitted comments to the prior three comment periods for this rulemaking effort and we reiterate the comments made in our previous letters. In addition, although the Department has made some improvements to the regulation, we believe that the exemption from licensure still lacks needed clarity. We would also point out that the Department's responses to previous comments include a misstatement of and inconsistency with a fundamental Knox-Keene Act requirement for licensure. Lastly, there are a few technical errors in the text of the revised regulation.	NO CHANGE REQUESTED. The Department appreciates your comments and participation in the rulemaking process.
5-57	Stephanie Shirkey  California Association of Health Plans	<b>I. The exemption from licensure still lacks needed clarity.</b>  We appreciate the Department's efforts to address the deficiency in clarity noted by the Office of Administrative Law (OAL) in its Decision of Disapproval. <sup>1</sup> This latest version does provide more	NO CHANGE REQUESTED.  The Department declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity's

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>clarity regarding the manner in which an entity should apply for an exemption and what the Director would consider as part of an exemption determination. The revised language still lacks needed clarity, however, specifically in three areas: (1) which entities are exempt from licensure, (2) what is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Knox-Keene Act, and (3) the language concerning market share and disruption in the market. We discuss each of those areas separately below.</p> <p style="text-align: center;"><small><sup>1</sup> Office of Administrative Law, Decision of Disapproval of Regulatory Action, OAL Matter Number 2018-0824-01, p. 2 (citing 1 Cal. Code Regulations sec. 16.)</small></p>	<p>request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>It should be noted that the Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption. This is stated in Health and Safety Code section 1343.5. These clarifications addressed OAL’s concerns.</p>
5-58	Stephanie Shirkey  California Association of Health Plans	<p><b>A. Exempt entities</b></p> <p>The proposed regulation requires a person who assumes global risk to obtain a license to operate a health care service plan and allows a person to request an exemption from that requirement. Under the Department’s proposed standards governing the</p>	<p>NO CHANGE REQUESTED. The Department notes that it cannot state what entities will be exempted without the entities going through the exemption process. Additionally, the Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>exemption, what an exempted entity looks like is still extremely unclear. The only way for a provider group to know if it is exempted is to seek the exemption. In our view, in its Decision of Disapproval, the OAL intended for the Department to specifically describe what an “exempted” entity would look like. It would seem reasonable that these regulations could provide sufficient details that would make clear the types of groups that need not have a license and perhaps even give some examples. As currently written, all provider groups that have any contracts that assume global risk would be required to take some action. Even the action of requesting an exemption seems to require a substantial amount of work and resources. That seems unreasonable and does not correct the deficiencies outlined in the OAL Decision of Disapproval.</p>	<p>request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. These clarifications addressed OAL’s concerns.</p>
5-59	Stephanie Shirkey  California Association of Health Plans	<p><b>B. What is “in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Knox-Keene Act”?</b></p> <p>As the OAL indicated in its Decision of Disapproval, a regulation is presumed not to comply with the clarity standard of the Administrative Procedure Act if the regulation can be reasonably and logically interpreted to have more than one meaning or the regulation uses terms which do not have meanings generally familiar to those directly affected by the regulation and those terms are neither defined in</p>	<p>DECLINED. In the proposed regulation, (b)(2)(a)-(F) provide examples of information that will help the Department determine whether the exemption would be in the public interest and not detrimental, thus providing the public with the factors the Department will consider when reviewing the exemption request.</p> <p>The Department declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>regulation nor in the governing statute.<sup>2</sup> Applying that rule to the text of the proposed regulation governing the exemption from licensure, OAL specifically noted that “the regulated public would not easily understand what would be in the public interest and not detrimental.”<sup>3</sup></p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>2</sup> Decision of Disapproval, <i>supra</i>, p. 2 (citing 1 Cal. Code Regulations sec. 16.)  <sup>3</sup> <i>Id.</i> at p. 3.</p>	<p>which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. These clarifications addressed OAL’s concerns.</p> <p>Further, the Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption. This is stated in Health and Safety Code section 1343.5.</p>
5-60	Stephanie Shirkey  California Association of Health Plans	<p>The revised regulations do not remedy this deficiency. They require the Department to grant an exemption upon review and a finding that the action is “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.”<sup>4</sup> The regulation also requires the Director to consider</p>	<p>NO CHANGE REQUESTED. To the extent which you would request the Department provide set values which would qualify for an exemption, the Department declines the suggestion. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>certain criteria when reviewing material submitted with an exemption request, including whether the issuance of an exemption will negatively impact public interest or protection of the public, subscribers, enrollees, or persons subject to the Knox-Keene Act, if the person assumes global risk.<sup>5</sup> Those public interest and public protection elements are not defined terms and there is no common understanding of them to which exemption applicants or the Department may refer; instead, those terms are subject to more than one interpretation and ripe for arbitrary, subjective decisions.</p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>4</sup> Proposed § 1300.49(b)(2).  <sup>5</sup> Proposed § 1300.49(b)(3)(E).</p>	<p>each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. These clarifications addressed OAL’s concerns.</p> <p>Further, the Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption. This is stated in Health and Safety Code section 1343.5.</p>
5-61	Stephanie Shirkey  California Association of Health Plans	<p><b>C. Market share and market disruption</b></p> <p>Under the proposed regulations, the Department is required to consider certain criteria when reviewing the information submitted with an exemption request. One such criterion is the “portion of the market share the person assumes for global risk in the geographical region compared to the market share assumed by other persons within the region, and whether disruption will occur in the marketplace if the person fails to maintain financial solvency.”<sup>6</sup> As with other elements set forth in the exemption</p>	<p>DECLINED. To the extent which you would request the Department provide set values which would qualify for an exemption, the Department declines the suggestion. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

<p>language, this element would benefit from additional clarity, specifically as to the relevant market, the acceptable ratio of risk assumed as a percentage of revenue, and what constitutes disruption in the marketplace.</p>	<p>_____ <sup>6</sup> Proposed § 1300.49(b)(3)(B).</p>	<p>global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. The Department declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. These clarifications addressed OAL’s concerns.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			Further, the Legislature explicitly placed the burden of proving an exemption to a definition in the Knox-Keene Act on the person claiming the exemption. This is stated in Health and Safety Code section 1343.5.
5-62	Stephanie Shirkey  California Association of Health Plans	<p><b>II. The Department’s responses to previous comments include a misstatement of and inconsistency with a fundamental Knox-Keene Act requirement for licensure.</b></p> <p>The proposed regulation defines the term “prepaid or periodic charge” to mean “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 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.”<sup>7</sup> Under the regulation, receipt of such a prepaid or periodic charge would trigger the requirement of licensure.<sup>8</sup> Based on this language and the requirement of the Knox-Keene Act that a licensee assume full financial risk on a prospective basis,<sup>9</sup> if “any” “compensation” for the assumption of “global risk” appears, the entity assuming global risk must assume the “full financial risk on a prospective basis” for providing the contracted-for health care services.</p> <p><sup>7</sup> Proposed § 1300.49(a)(4).  <sup>8</sup> Proposed § 1300.49(b)(1), (a)(1), (a)(4).  <sup>9</sup> Health &amp; Safety Code § 1375.1(a)(2).</p>	<p>NO CHANGE REQUESTED. This comment is irrelevant because it does not address the changes made during the comment period.</p> <p>Note that the acceptance of a prepaid or periodic charge alone does not trigger the licensure requirement. Rather, it is assuming global risk, which includes the acceptance of a prepaid or periodic charge, which triggers the licensure requirement under this regulation. That is, if an entity accepts a prepaid or periodic charge for only professional risk and not institutional risk, licensure would not be required under this regulation because the entity has not assumed global risk, which leads to the licensure requirement under this specific regulation.</p> <p>The section of the Knox-Keene Act cited which refers to “full financial risk” (section 1375.1(a)(2)) applies only to regulated entities. That is, “full financial risk” is not considered when determining whether an entity falls within the definition of a health care service plan. Rather, “full financial risk” is required to comply with ongoing standards for licensed entities.</p>
5-63	Stephanie Shirkey	In the Department’s “Responses to Comments” submitted	NO CHANGE REQUESTED. The comment is

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	<p>California Association of Health Plans</p>	<p>to OAL, the Department responded to comments raised with respect this issue as follows:</p> <p style="padding-left: 40px;">“Health and Safety Code section 1375.1(a)(2), which refers to the requirement to assume ‘full financial risk’ applies to already licensed health care service plans and requirements for operations and procedures. The proposed regulation clarifies 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.”<sup>10</sup></p> <p>The Department’s response is inaccurate. An entity cannot become a licensed health care service plan unless it demonstrates to the satisfaction of the Department that it will be capable of and will assume full financial risk for the provision of contracted-for health care services. Thus, contrary to the Department’s assertion in its “Responses to Comments,” this is a strict precondition of licensure and not a consideration that is deferred until an entity has already been licensed. While these may be distinct issues, they are also inextricably linked and trigger substantial consequences for the entity receiving the above described “any compensation.”</p> <p><small><sup>10</sup> DMHC, General Licensure Requirements for Health Care Service Plans (2017-5220), Responses to Comments for Comment Period #3, May 17, 2018 – June 1, 2018, p. 7.</small></p>	<p>irrelevant because it does not address the changes made during the comment period.</p>
<p>5-64</p>	<p>Stephanie Shirkey</p>	<p><b>III. There are a few technical errors in the proposed regulations</b></p>	<p>ACCEPTED IN PART/DECLINED IN PART.  The Department has made the non-substantive</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	California Association of Health Plans	<p>We also take this opportunity to mention a few technical errors in the text of the proposed regulations. there are now two provisions numbered (b)(3). In addition, we recommend revision of the second (b)(3), as follows:</p> <p style="text-align: center;">“The Director shall issue the decision on the request for exemption from licensure under this section within 30 days of receipt of the request <del>by the Department.</del>”</p>	correction to the two subdivision (b)(3)s noted by the commenter. The Department declines to remove the term “by the Department” because it is proper usage and adds clarity.
5-65	Stephanie Shirkey  California Association of Health Plans	<p><b>IV. Conclusion</b></p> <p>We thank you for the opportunity to provide these comments and look forward to working with you to further refine these regulations.</p>	NO CHANGE REQUESTED.
6-66	Michael Tou  Providence St. Joseph Health	<p>Providence St. Joseph Health appreciates the opportunity to submit comments to the California Department of Managed Health Care on the modified regulations released on November 30, 2018. We are concerned that the proposed regulation would subject a number of providers to licensure based on the adoption of innovative, yet low-risk payment models that were not the intended subject of regulation under the Knox-Keene Act, such as bundled payment arrangements, institutional risk pools, and accountable care organizations. PSJH urges the department to revise the regulation to strike a balance between encouraging innovative, low-risk arrangements and engaging in necessary oversight, and we hope our comments will assist you in this effort.</p> <p>Providence St. Joseph Health is a not-for-profit</p>	NO CHANGE REQUESTED. The Department appreciates the comment.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>health system that includes a diverse family of organizations dedicated to providing for the needs of communities across our state, with a special focus on those who are poor and vulnerable. In California, we are: Providence Health &amp; Services, including Facey Medical Foundation; and St. Joseph Health, including St. Joseph Heritage Healthcare and the St. Joseph Hoag Health alliance. Working in 18 award-winning hospitals, 238 medical clinics and an array of other care and services, our 36,900 caregivers (all employees) serve with distinction across California.</p>	
6-67	<p>Michael Tou  Providence St. Joseph Health</p>	<p><b><u>I. The procedure by which the department evaluates exemption requests should be designed to give providers clarity and finality.</u></b></p> <p>PSJH appreciates the department’s including in the proposed regulation a process for a provider or other entity to seek an exemption from the licensure requirement, including identifying the information an applicant should provide and the Department contact to whom a request should be made. In light of the mismatch between the requirements for a health care service plan under the Knox-Keene Act and the low-risk payment arrangements described in this letter, it is critical that the Department provide a clear and efficient process for providers to obtain exemptions from the licensure requirement and for a provider to know as soon as possible whether it will be exempt from the licensure requirement.</p>	<p>DECLINED. The Department declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>exemption would impact public interest. These clarifications addressed OAL's concerns.</p> <p>Further, under Health and Safety Code section 1343.5, the burden of proving an exemption from a definition of the Knox-Keene Act is on the person requesting the exemption.</p>
6-68	<p>Michael Tou</p> <p>Providence St. Joseph Health</p>	<p><b>Providence St. Joseph Health urges the department to provide greater clarity around the procedures for seeking an exemption.</b> As drafted, the regulation leaves a number of questions unanswered. For example:</p> <ul style="list-style-type: none"> <li>• When is a provider required to seek an exemption?</li> <li>• What are a provider's rights while its request is pending?</li> <li>• What is the status of a request for an exemption if the Department does not respond within 30 days?</li> <li>• Can a provider appeal if it disagrees with the Department's decision?</li> </ul>	<p>DECLINED. The Department declines to make further changes to the regulatory text. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity's request for an exemption will be considered. In response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p> <p>The Department notes that a provider seeking licensure as a health care service plan cannot act as a health care service plan unless and until it is licensed by the Department. The Director will provide a response to the exemption request within 30 days. Under the terms of the regulation, the requirement for licensure only applies when a contract is</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed. The Director has the regulator requirement to respond to the exemption request within 30-days; therefore, it is not necessary to address what will happen if this regulatory requirement is not met.</p> <p>Existing Knox-Keene Act statutory provisions, sections 1354 and 1397, already states that a decision of the Director is subject to administrative and judicial review, including denials of applications for licensure.</p>
6-69	Michael Tou  Providence St. Joseph Health	Without this clarity, PSJH may be forced to put longstanding business relationships on hold or stop expanding their use of the payment arrangements described above. Therefore, PSJH urges the department to create greater structural protections for providers engaged in the exemption request process. Accordingly, we believe a provider should have a ninety-day grace period after a new contract is issued, amended or renewed before being required to submit an application for licensure or request an exemption from the Department.	DECLINED. A provider seeking licensure as a health care service plan cannot act as a health care service plan unless and until it is licensed by the Department. The Director will provide a response to the exemption request within 30 days. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed.
6-70	Michael Tou  Providence St.	PSJH strongly supports the proposed requirement that the department respond to requests for exemption within thirty days. (28 C.C.R. § 1300.49,	DECLINED. A provider seeking licensure as a health care service plan cannot act as a health care service plan unless and until it is licensed

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	Joseph Health	<p>paragraph (b)(3) (proposed)). In order to give providers greater certainty around this time frame, we urge the department to deem requests approved if the department does not act on the request within 30 days. We also urge the department to establish appeal rights for applicant whose request is denied, and note that the licensure requirement does not apply to an applicant while any appeal is pending. Finally, if an exemption request is denied and all appeals are unsuccessful, the applicant should have longer than the end of that calendar year or nine months from the date of the denial to unwind the arrangement. This will give providers whose requests for exemptions have been denied the opportunity to unwind payment arrangements for which a license or exemption is required without disrupting patient care. Finally, we urge the department to clarify that any effective date inserted in the regulation by the Office of Administrative Law shall be calculated pursuant to Government Code section 11343.4.</p>	<p>by the Department. The Director will provide a response to the exemption request within 30 days. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed. The Director has the regulator requirement to respond to the exemption request within 30 days, therefore, it is not necessary to address what will happen if this regulatory requirement is not met.</p> <p>OAL will provide the correct effective date within the regulation pursuant to the Administrative Procedure Act requirements. This includes Government Code section 111343.4, as cited by the commenter.</p>
6-71	Michael Tou  Providence St. Joseph Health	<p>Specifically, PSJH encourages the department to make the following additions and revisions to paragraph (b) of the regulation:<sup>1</sup></p> <p style="padding-left: 40px;">(2) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to any person upon review and a finding that the action is in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.</p>	<p>DECLINED. Under the terms of the regulation, the requirement for licensure only applies when a contract is issued, amended or renewed. This provision allows existing entities that believe they may fall under the licensure requirements to apply for either licensure or an exemption before their existing contract is amended or renewed and be given time to address any regulatory requirements.</p> <p>The Department notes that the Director will respond to all exemption requests within 30</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>(3)</u> A person requesting an exemption shall submit the following information for consideration by the Director:</p> <p>...</p> <p><del>(G)</del> Persons requesting an exemption shall submit the request to the following address:  <a href="mailto:OPLInquiries@dmhc.ca.gov">OPLInquiries@dmhc.ca.gov</a> or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.</p> <p>...</p> <p><del>(3)</del><u>(4)</u> When reviewing the information submitted under subdivision (b)(2)<u>(3)</u> of this regulation, the Director shall consider the following criteria:</p> <p><del>(3)</del><u>(7)</u></p> <p>...</p> <p><u>(A)</u> <u>Persons requesting an exemption shall submit the request to the following address:</u>  <a href="mailto:OPLInquiries@dmhc.ca.gov">OPLInquiries@dmhc.ca.gov</a> or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.</p> <p><u>(B)</u> The Director shall issue the decision on the request for exemption from licensure under this section within 30 days of receipt of the request by the Department. <u>An applicant for exemption shall be deemed exempt from this section while the Department's decision on its request is pending. If the Department does not issue a</u></p>	<p>days as required under the regulation.</p> <p>Under existing Knox-Keene Act statutory provisions, sections 1354 and 1397, a decision of the Director is subject to administrative and judicial review, including denials of applications for licensure. Therefore, it is not necessary to repeat these existing statutory provisions in the proposed regulation.</p> <p>The Department is declining the commenter's request that only significantly modified contracts falling under the scope of the regulation be subject to licensure. The Department has made a policy decision that the potential risk to consumers and the healthcare market place warrants that entities accepting global risk must have proper regulatory oversight. This regulation balances the need to protect consumers and the healthcare market place with the burden of obtaining licensure by the Department only when contracts are issued, amended or renewed.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

decision on a request for exemption from licensure within 30 days of its receipt of the request, the request shall be deemed approved.

(8)

(A) The Department's decision to grant or deny a request for exemption shall be subject to review by the Director pursuant to Health & Safety Code section 1397, paragraph (a). An applicant for exemption shall be deemed exempt from this section while the Director's decision is pending pursuant to this subdivision.

(B) The Director's decision shall be subject to judicial review pursuant to Health & Safety Code section 1397, paragraph (b). An applicant for exemption shall be deemed exempt from this section while judicial review on the appeal of a denial of an exemption upheld by the Director is pending pursuant to this subdivision.

(9) An applicant whose request for exemption is denied shall not be subject to this section until January 1 of the calendar year following the date the denial becomes final or nine months from the date the denial becomes final, whichever comes later. For the purposes of this subdivision (b)(11), a denial shall not be final until any appeals under subdivision (10)(A) and/or (10)(B) above are exhausted, if applicable.

...

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>(e) This section shall apply only to contracts issued, <del>amended, or renewed</del> <u>or significantly modified</u> on or after [Date to be inserted by OAL <u>pursuant to Gov. Code § 11343.4</u>].</p> <p><small><sup>1</sup> For clarity, our recommended insertions are underlined, recommended deletions are stricken, and language that we recommend moving is double-underlined. We have suggested separating the information submission requirement that currently appears in paragraph (b)(2) from the substantive standard that appears in that paragraph. We have also suggested moving additional procedural provisions, including the language that currently appears in paragraph (b)(2)(G), <i>after</i> all substantive bases for exemptions such that it would appear in paragraph (b)(7)(A). Finally, it appears that paragraph (b)(3) erroneously appeared twice, so we have revised the numbering accordingly.</small></p>	
6-72	<p>Michael Tou</p> <p>Providence St. Joseph Health</p>	<p><b><u>II. The department should provide clear, quantitative standards to allow a provider to determine whether it is entitled to an exemption from the licensure requirement.</u></b></p> <p>PSJH appreciates the department’s efforts to respond to the Office of Administrative Law’s concern that earlier drafts of the proposed regulation did not provide sufficient clarity as to the standard for obtaining an exemption from the licensure requirement, and we support the department’s decision that an applicant should be granted an exemption upon the Director’s finding that granting an exemption is “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.” (28 California Code of Regulations (“C.C.R.”) § 1300.49, paragraph (b)(2) (proposed).) This standard, which is drawn from Health &amp; Safety Code section 1343, ensures that the department focuses on the circumstances where its licensing and oversight activities are necessary to protect the public interest.</p>	<p>DECLINED. The Department declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The Department, in response to previous comments, already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p>
6-73	<p>Michael Tou  Providence St. Joseph Health</p>	<p>However, as drafted, the exemption process would still require the department to engage in a subjective decision-making process to determine whether an exemption for a particular person or organization would be “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.” Even with the criteria provided in the new draft regulation, a provider cannot accurately predict whether the department will grant its request for an exemption because the criteria the Department has proposed are too vague.  <b>Therefore, PSJH urges the department to identify circumstances in which a person, provider or other organization is presumptively exempt from the licensure requirement and to identify payment arrangements that are not subject to this regulation.</b> Applications for exemption under these categories should be subject to a streamlined review to confirm that the applicant participates in the types of safe, low-risk payment arrangements that are common in California and that we have emphasized in our comments throughout this rulemaking process.</p>	<p>DECLINED. The Department declines to make further changes to the regulatory text regarding exemptions. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot exempt a category of entities in the regulation, as each situation must be considered and reviewed individually because of unique marketplace circumstances.</p> <p>Also, the Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			<p>exemption would impact public interest. These clarifications addressed OAL’s concerns.</p>
<p>6-74</p>	<p>Michael Tou  Providence St. Joseph Health</p>	<p><b>For example, the department should establish that a provider that participates in particularly low-risk payment arrangements that fall below quantitative risk thresholds is presumptively exempt from the licensure requirement.</b> Regulatory frameworks outside of California are instructive in demonstrating how such thresholds might be developed and applied. For example, the Centers for Medicare &amp; Medicaid Services (CMS) and the state of New York have determined that provider risk-bearing arrangements pursuant to which less than 25% of payments are at risk are sufficiently low-risk that the arrangement does not require the same level of oversight.<sup>2</sup> Below these thresholds, providers can take on risk without closer scrutiny by the regulators. These standards show that other state and federal regulators have limited their oversight activity to arrangements presenting more significant levels of risk-taking. California’s providers have decades of experience sharing risk with payors to incentivize high-value care, resulting in the most sophisticated health care market in the country. <b>The department’s oversight and regulation is therefore unnecessary when providers take on modest amounts of risk, when providers have the wherewithal to manage the risk they have taken on, or where the provider has a proven track record of sharing risk with payors in a financially stable manner.</b></p>	<p>DECLINED. The Department declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity’s financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest. In order to know that the entity has a “proven track record of sharing risk with payors in a financially stable manner”, an exemption request must be submitted with</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><sup>2</sup> CMS allows a Medicare Advantage organization to pass risk on to physicians or physician groups by way of a “physician incentive plan.” See 42 C.F.R. § 422.208. The arrangement is subject to additional regulation if it involves “substantial financial risk.” “Substantial financial risk,” in turn, is defined by reference to a number of quantitative risk-taking thresholds, such as facing withholds or liability greater than 25% of total payments. New York subjects managed care organizations’ agreements with provider groups to reduced scrutiny if less than \$1 million of payments to the provider are at risk under the agreement or, if the total amount of payments at risk exceeds \$1 million, no more than 25% of projected annual payments to the provider are at risk. See Provider Contract Guidelines for Article 44 MCOs, IPAs and ACOs, available at <a href="http://www.health.ny.gov/health_care/managed_care/hmoipa/docs/guidelines.pdf">//www.health.ny.gov/health_care/managed_care/hmoipa/docs/guidelines.pdf</a>.</p>	<p>information supporting this fact.</p>
6-75	<p>Michael Tou  Providence St. Joseph Health</p>	<p><b>The department’s regulatory oversight is also unnecessary where a provider participates in certain payment arrangements pursuant to state or federal law, and under careful regulation by the Medicare or Medi-Cal programs.</b> For example, as hospitals that participate in Medicare, we are required to or voluntarily participate in various CMS bundled payment initiatives, like the Comprehensive Care for Joint Replacement (CJR) model, or through the Medicare Shared Savings Program, both of which are considered “alternative payment models” under federal law. It is unnecessary for a provider to be required to seek licensure as a health care service plan in order to accept payment under any of</p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The Department, in response to previous comments, has already clarified the process by which and the standards by which an entity’s request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>the alternative payment models, each of which is subject to a complex and robust regulatory scheme and oversight. Requiring licensure in these circumstances is redundant, and could also undermine federal policy and impose outsized burdens on providers that are not otherwise engaged in any risk-bearing activities.</p>	<p>individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p>
6-76	<p>Michael Tou  Providence St. Joseph Health</p>	<p><b>PSJH also urges the department to establish that certain types of payment arrangements – including bundled payment arrangements, institutional risk pools, and ACOs – are presumptively exempt from this regulation unless the department determines that special circumstances warrant licensure.</b> These payment arrangements are common tools to improve the quality and coordination of care while posing minimal to no risk to patients, payors and providers. <i>These arrangements may also be regulated under other schemes, as in the case of a health system that operates an ACO for its own employees under the health system's self-funded plan that is subject to ERISA.</i> These safe, common arrangements should be presumptively exempt from the licensure requirement.</p>	<p>DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. Accordingly, the proposed regulation may impact 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 an exemption from licensure pursuant to the regulation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

<p>With that in mind, PSJH urges the department to insert the following as a new paragraph (b)(5):</p> <p><u>(5)</u></p> <p><u>(A) A person is presumptively exempt from the licensure requirement if the person is a provider and at least one of the following is true:</u></p> <ul style="list-style-type: none"><li><u>(i) No more than 25% of the provider's maximum potential revenue from health care services from all payors is at risk;</u></li><li><u>(ii) No more than 25% of the provider's tangible net equity (TNE) is at risk across all payors with whom the provider has entered into payment arrangements; or</u></li><li><u>(iii) No more than 25% of the provider's cash on hand is at risk across all payors with whom the provider has entered into payment arrangements.</u></li></ul> <p><u>(B) A payment is not considered at risk for the purposes of this subdivision (b)(5) if the payment is:</u></p> <ul style="list-style-type: none"><li><u>(i) Received under an alternative payment model, as that term is defined in 42 U.S.C. 1395/(z)(3)(C);</u></li><li><u>(ii) Received from an entity that contracts directly with the United States government to provide services under the Medicare program or an entity that contracts directly with the State Department of Health Care Services to provide services under the Medi-Cal program;</u></li><li><u>(iii) A bundled payment for a specified set of services provided within ninety (90) days or less that relate to a single episode of care;</u></li><li><u>(iv) Received in connection with participation</u></li></ul>	
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>in an institutional risk pool;</u>  <u>(v) Received in connection with participation in an accountable care organization;</u>  <u>(vi) Received pursuant to a payment arrangement that has not been materially modified for three (3) or more years where the provider has not sustained a loss of more than 10% of the provider's maximum potential revenue under that arrangement over the last three (3) years;</u>  <u>(vii) Not subject to downside risk; or</u>  <u>(viii) Received under an arrangement in which the provider is paid a per-member, per-month amount by a licensed health care service plan solely for services that the provider is authorized by law to provide (i.e., the provider takes capitated professional risk only or capitated institutional risk only, but does not take global risk).</u></p> <p><u>(C) The calculation made pursuant to subdivision (b)(5)(A) shall take into account any applicable insurance held by the provider, including reinsurance and/or stop-loss coverage.</u></p>	
6-77	Michael Tou  Providence St. Joseph Health	In order to establish eligibility for a presumptive exemption pursuant to this new paragraph (b)(5), a person, provider or other organization should be required simply to provide materials and information demonstrating its satisfaction of the applicable presumptive exemption category or categories. To that end, we recommend inserting the following as paragraph (b)(6):	DECLINED. The Department appreciates the comment but declines to make further changes to the regulatory text for policy and logistical reasons. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>(6)</u></p> <p><u>(A) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to a person described under paragraph (b)(5) unless the Department determines there is a compelling reason to deny the request for exemption.</u></p> <p><u>(B) A person requesting an exemption pursuant to subdivision (b)(5) shall not be subject to the requirements of subdivision (b)(3) and shall instead submit materials and information to the Director demonstrating that it is entitled to exemption under the applicable requirement(s).</u></p>	<p>ensure the Department has oversight over arrangements that could subject enrollees to harm if the entity were to become financially insolvent or not provide the level of care promised. Narrowing the payment arrangements to which the regulation applies would be contrary to the purpose of the regulation.</p>
6-78	Michael Tou  Providence St. Joseph Health	<p><b>We also urge the department to clarify that an exemption granted to a person or organization would remain in effect unless and until there is a material change in the type of payment arrangements in which the person or organization is engaged.</b> This would relieve the department of the burden of considering each new payment arrangement into which exempt persons and organizations enter. If a person or organization enters into new payment arrangements that do not materially differ from the payment arrangements in place when the person or organization was granted an exemption, there is no need for the department to revisit its analysis. To that end, we recommend inserting the following as a new paragraph (b)(10):</p> <p><u>(10) An exemption granted under this subdivision (b) shall remain in effect unless and until there is a</u></p>	<p>DECLINED. The Department believes the exemption process is well-established and the regulation simply adds clarity to the existing exemption process. Health and Safety Code section 1343 was enacted in 1993 and has been used by entities during the past 25 plus years. If a party receives an exemption based upon the criteria stated in the regulation, then the party has this exemption based upon the information the party gave to the Director for review and decision. If the entity enters into a new or different arrangement that falls under the scope of the regulation, then the entity is required under the law to either obtain licensure or an exemption for that new or different arrangement.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>material change in the nature of payment arrangements in which the exempt person is engaged.</u></p>	
6-79	<p>Michael Tou  Providence St. Joseph Health</p>	<p>For the purpose of clarity, we also suggest inserting the following definitions under paragraph (a):</p> <p><u>(7) “Accountable care organization” shall refer to an arrangement in which one or more providers, paid pursuant to a fee schedule, are held accountable for a patient population’s care over a predetermined period of time by way of incentive payments that are tied to the providers’ performance on quality metrics and/or the providers’ ability to control costs for that patient population by, among other things, comparing the actual cost of care to a target budget.</u></p> <p><u>(8) “Downside risk” shall refer to an arrangement in which one or more providers are paid using a fee schedule, but may be required to repay an amount to a payor at the end of a predetermined period if total payments for health care services under the arrangement exceed a target budget applicable to that arrangement. An arrangement does not subject a provider to downside risk if a deficit from spending exceeding a target budget accrues only against future surpluses under the arrangement, but does not require repayment to the payor.</u></p> <p><u>(9) “Institutional risk pool” shall refer to a payment arrangement in which fee-for- service payments for hospital services for a particular set of patients are compared to a target and any surplus is disbursed to the physicians caring for those patients after a</u></p>	<p>DECLINED. Accountable care organization, downside risk, and institutional risk pool are not used in the regulation and so defining them is not necessary. Additionally, because of the frequency with which new arrangements proliferate, the Department declines to attempt to define each new arrangement that may be subject to licensure. Payor and provider need not be defined because they are already defined in existing statute in the Knox-Keene Act.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p><u>predetermined period of time, but only to the extent the patients' costs for institutional services fall below the predetermined target, and any shortfall is accrued against future surpluses and does not create a payment obligation by the physicians.</u></p> <p><u>(10) "Payor" shall have the meaning set forth in Health &amp; Safety Code section 1395.6.</u></p> <p><u>(11) "Provider" shall have the meaning set forth in Health &amp; Safety Code section 1345.</u></p>	
6-80	Michael Tou  Providence St. Joseph Health	<p><b><u>III. As drafted, the proposed regulation is inconsistent with the Knox-Keene Act and unworkable, and the department should re-engage with stakeholders prior to finalizing the rule.</u></b></p> <p>PSJH is concerned that certain types of payment arrangements that involve little or no financial risk, but create financial incentives to increase quality, access and efficiency, would be subject to licensure under the proposed regulation. These include bundled payment arrangements where the payment provides for both professional and institutional services; institutional risk pool arrangements; and integrated care arrangements, such as ACOs, including those with zero downside risk. <b>Under payment arrangements like these, PSJH provides high-quality care in a cost-effective manner while accepting minimal or no financial risk.</b></p>	DECLINED. The Department has engaged in informal stakeholder discussions, four comment periods and made changes in response to concerns, and therefore feels that additional stakeholder input is not needed. The Department also notes that entities which accept "no financial risk" would not be subject to the licensure requirement. Entities which accept "minimal" global risk and meet the definition of a health care service plan would be able to seek an exemption under the regulation.
6-81	Michael Tou	These evolving payment arrangements typically encourage providers to coordinate care, improve	NO CHANGE REQUESTED.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	Providence St. Joseph Health	<p>quality, and stay within a target budget. The arrangement might be limited to a narrowly defined set of services linked to an episode of care, in the case of a bundled payment arrangement, or a population’s care during a defined time period, as in the case of an institutional risk pool arrangement and many integrated care arrangements. But these arrangements generally do <b>not</b> require a provider to be responsible for the entirety of a patient’s care in exchange for a capitated payment, nor do they require providers to take on such significant risk that the provider’s financial stability may be threatened. As such, these arrangements pose no threat of harm to consumers. However, under the plain language of the proposed regulation, it appears that these common, safe and valuable payment arrangements would be subject to licensure.</p>	<p>Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to ensure the Department has oversight over arrangements that could subject enrollees and the healthcare market place to harm if the entity were to become insolvent or not provide the level of care required under the law.</p> <p>The Knox-Keene Act, Health and Safety Code section 1341(a), specifically states that the Department is charged with ensuring health care service plans provide enrollees with access to healthcare services and protect and promote the interests of enrollees. The Director has determined this regulation is necessary to ensure the Department’s oversight of entities accepting global risk therefore meeting the definition of a health plan requiring licensure under the regulation.</p>
6-82	Michael Tou  Providence St. Joseph Health	<p>The Knox-Keene Act was intended to ensure health plans are able to deliver on their promise to arrange health care services after accepting a pre-paid charge from enrollees. The payment arrangements described above were not contemplated by the drafters of the Knox-Keene Act: shared savings arrangements, episodic payments and other value-based payments simply do not resemble the capitated arrangements that were the drafters’ focus and do not involve prepaid or periodic payments. Furthermore, the Statement of Reasons provides</p>	<p>NO CHANGE REQUESTED.</p> <p>Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The purpose of the regulation is to ensure the Department has oversight over arrangements that could subject enrollees and the healthcare market place to harm if the entity were to become insolvent or not provide the level of care required under the</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>little insight as to why the department seeks to sweep in such a broad array of arrangements and to disrupt California’s health care marketplace.</p>	<p>law.</p> <p>The Knox-Keene Act, Health and Safety Code section 1341(a), specifically states that the Department is charged with ensuring health care service plans provide enrollees with access to healthcare services and protect and promote the interests of enrollees. The Director has determined this regulation is necessary to ensure the Department’s oversight of entities operating as health plans and accepting global risk.</p>
6-83	<p>Michael Tou</p> <p>Providence St. Joseph Health</p>	<p>Furthermore, the department’s Statement of Reasons provides little insight as to why it seeks to sweep in such a broad array of arrangements and disrupt California’s health care marketplace. Moreover, regulating such arrangements as “health care service plans” would be inconsistent with the Knox-Keene Act’s existing regulatory framework. <b>The proposed regulation does not address this inconsistency. Rather, it leaves unanswered a number of questions about whether an entity that participates in these innovative payment arrangements could obtain a license and satisfy the obligations of licensure on an ongoing basis without transforming its care model into a traditional health maintenance organization.</b> Indeed, it is unclear whether the department intends for such arrangements to continue under its oversight, or if the proposed regulation would operate as an indirect prohibition of these payment arrangements. If the department is unwilling to revise the regulation to narrow the scope of</p>	<p>NO CHANGE REQUESTED. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption. The proposed regulation may impact 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 an exemption from licensure.</p> <p>As stated in the Department’s Initial Statement of Reasons, “Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume “full financial risk” for</p>

**DEPARTMENT OF MANAGED HEALTH CARE**

**General Licensure Requirements for Health Care Service Plans (2017-5220)**

**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>arrangements for which licensure will be required, then it should at least adopt the recommendations set forth above to ensure that exemptions from licensure are granted for the many common, low-risk arrangements that might now come within the newly expanded range of payment arrangements requiring a license.</p>	<p>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>Further, as detailed in the ISOR, in 2015 the California Court of Appeal, Second District, held that “the level of financial risk under a capitation agreement that causes a ‘risk</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			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.
6-84	Michael Tou  Providence St. Joseph Health	<b>PSJH urges the department to elicit stakeholder feedback and to refine this regulation prior to making it final.</b> We strongly encourage the department to engage in a collaborative process with the payor, provider and patient communities to formulate a regulatory framework that strikes the proper balance between protecting the public and encouraging value-based payment systems. The federal negotiated rulemaking process set forth in 5 U.S.C. sections 561 <i>et seq.</i> provides a model for stakeholders representing various interests to come together to inform an agency's rulemaking process. If implemented as currently written, the proposed regulation is likely to pose substantial operational challenges. We believe the department would benefit from a formal process for obtaining stakeholder input and improving the regulation.  Providence St. Joseph Health appreciates the opportunity to provide comments on the modified regulation.	DECLINED. The Department has engaged in informal stakeholder meetings, four comment periods and feel it has responded appropriately to stakeholder concerns.
7-85	William E. Kramer  Pacific Business	We write to express our concerns and offer recommendations regarding the Fourth Comment version of the proposed DMHC regulation (General	NO CHANGE REQUESTED. The Department appreciates your comments.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

	Group on Health	<p>License Requirements, Adding New Section 1300.49 of Title 28, California Code of Regulations, Control No. 2017-5220). The Pacific Business Group on Health (PBGH) is a not-for-profit organization that represents 65 large public and private employers dedicated to improving quality and affordability throughout the U.S. health system. Though we are a national organization, our roots in California are strong – last year, our members spent more than \$12 billion providing coverage to over three million California employees, retirees, and dependents.</p> <p>Employers are extremely concerned by the high costs and inconsistent quality in our health care system. One solution to these problems is the use of value-based payment models, which reward health care providers for improving quality and managing costs effectively. Increasingly, self-funded employers are contracting directly with health systems and physician groups using value-based payment models.</p> <p>We are concerned that some elements of the proposed regulation will make it more difficult for health systems and physician groups to enter into value-based payment arrangements with self-insured employers.</p>	
7-86	William E. Kramer  Pacific Business Group on Health	<ul style="list-style-type: none"> <li>Specifically, subsection (a)(4) appears to expand the types of payment arrangements that are used to define health care service plans in Health and Safety Code sections 1345 and 1349. The existing codes use the terms “prepaid or periodic charges” and “advance or periodic consideration”. The proposed</li> </ul>	NO CHANGE REQUESTED. The Department notes that the definition of “prepaid or periodic charge”, and indeed the entire regulation, is to add clarity to what qualifies as a health care service plan that must be either licensed and regulated by the Department or exempted from

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		change would add shared savings and losses to the definition of payment models that would trigger the requirement to secure a license as a health care service plan. This is unnecessary and would place an unwarranted administrative burden on providers. Risk-sharing arrangements between large self-insured employers and provide are typically based on fee-for-service compensation, with no prepayment or periodicity.	regulation.
7-87	William E. Kramer  Pacific Business Group on Health	<ul style="list-style-type: none"> <li>• The degree of financial risk in these arrangements is very modest, and it does not threaten the financial viability of these provider organizations. We believe that ERISA protections for employees and dependents are sufficient to provide the necessary consumer protections.</li> </ul>	NO CHANGE REQUESTED. We note that the regulation does not purport to expand the Department’s jurisdiction over ERISA-regulated plans. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption.
7-88	William E. Kramer  Pacific Business Group on Health	<ul style="list-style-type: none"> <li>• More broadly, we are concerned that the regulatory burden would have a chilling effect on the willingness of health systems and provider groups to enter into value-based payment arrangements with self-insured employers. The movement away from traditional fee-for-service toward value-based provider payment arrangements would be stalled, resulting in continued high costs, unnecessary services and inconsistent quality in California’s health care system.</li> </ul>	DECLINED. The comment is irrelevant because it does not address the changes made during the comment period.  The Department believes the exemption process and/or the ability to seek licensure as a restricted health care service plan, which is a less burdensome and less expensive licensure process, will remove any disincentive for parties to enter into value-based payment arrangements.
7-89	William E. Kramer  Pacific Business Group on Health	We recommend that subsection (a)(4) be amended as follows:  “Prepaid or periodic charge” for the purposes of this section means <del>fixed any amount of compensation,</del> either at the start or end of a predetermined period, for	DECLINED. The comment is irrelevant because it does not address the changes made during the comment period.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>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 <del>that may be fixed either in amount or percentage of savings or losses in which the entity shares</del>. <b>Shared savings or losses shall not constitute fixed compensation for the purpose of this definition.</b></p>	
7-90	<p>William E. Kramer  Pacific Business Group on Health</p>	<p>We are also concerned that the criteria in subsection (b)(2) for granting exceptions to the rule are not sufficiently precise to give providers guidance about whether they would qualify for an exemption. This would create confusion among potential applicants and stifle the development of new value-based payment arrangements.</p>	<p>DECLINED. The Department, in response to previous comments, clarified the process by which and the standards by which an entity's request for an exemption will be considered. The Department cannot give an exact number or percentage of market share or risk that will satisfy the exemption criteria, as each situation must be analyzed on an individual basis. Because of the differences between the regions within California, a bright-line standard is impossible. However, in response to concerns, the Department clarified that the portion of global risk and market share will be compared to the overall business and the experience of other entities in the geographic region. Additionally, the Department clarified that the Director will consider the entity's financial capacity to assume risk, the impact to the marketplace if the entity were unable to maintain financial solvency, and how an exemption would impact public interest.</p>
7-91	<p>William E. Kramer  Pacific Business Group on Health</p>	<p>The overall effect of proposed regulation would be to delay the development and implementation of value-based payment and service arrangements between self-funded employers and health systems or other</p>	<p>NO CHANGE REQUESTED.  The Department believes the ability for an entity to seek either an exemption or licensure as a</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		<p>provider groups. While it is important for DMHC to protect consumers by ensuring the financial viability of providers who take on financial risk, we also believe that consumers deserve to be protected from high costs and inconsistent quality. We fear that the proposed regulation would present a significant barrier to entry to high-value health systems and physician groups, and it would lock in the current payment and delivery system, to the detriment of consumers.</p> <p>Thank you for your consideration of our comments and proposed changes to the regulation. Please contact us if you would like us to provide any additional information or clarification.</p>	<p>restricted health care service plan provides the ability for innovation and the continued development of low-cost models of care, while ensuring quality and access to healthcare for enrollees.</p>
8-92	<p>Brianna Lierman, Esq.</p> <p>Local Health Plans of California</p>	<p>The Local Health Plans of California (LHPC) represents all 16 community-based and not-for-profit health plans that collectively cover 70% of California’s 10.7 million Medi-Cal managed care beneficiaries. Local health plans were created to be mission-driven health plans closely connected to the communities that established them, with nearly all local health plans being public entities.</p> <p>We have submitted comments on previous iterations of the Proposed Regulation and appreciate the changes made to provide greater clarity on all aspects, particularly standards for restricted licensure exemptions. We write today for further clarification regarding the Department of Managed Health Care’s (“Department”) response to a question we posed in the first comment period. This additional clarification will help local plans better</p>	<p>NO CHANGE REQUESTED. We appreciate your comment.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

		understand the meaning and application of the Proposed Regulation to their arrangements.	
8-93	Brianna Lierman, Esq.  Local Health Plans of California	Some Medi-Cal managed care plans are a “health care service plan”, as defined under the Knox-Keene Health Care Service Plan Act of 1975 (“Knox-Keene”). However, they are exempt from Knox-Keene licensure for Medi-Cal services. Inasmuch as the Proposed Regulation’s restricted licensure requirements apply to global risk contracts with a “health care service plan”, it is our understanding that entities assuming global risk will be able to seek and be granted a restricted health care service plan license or exemption regardless of whether the full-service health care service plan is licensed or exempt from licensure. Is this understanding correct? In light of the Department’s response (2-7, First Comment Period) that the Proposed Regulation “does not affect existing licensure requirements or exemptions for Medi-Cal entities”, we assume our understanding to be correct. An alternative interpretation would produce more significant market and economic impacts that would need to be disclosed and assessed. Secondly, as a corollary question, are entities that assume global risk from license-exempt plans also covered by the Medi-Cal plan’s statutory exemption? Or, does the Proposed Regulation and its licensure and exemption process apply directly to such entities?	DECLINED. The comments are irrelevant because they do not address the changes made during the comment period. Under the regulation, an entity that accepts global risk as defined meets the definition of a health care service plan and must either obtain a license or seek an exemption.
8-94	Brianna Lierman, Esq.  Local Health Plans of California	Thank you for considering local health plans’ comments on the Proposed Regulation. With the clarifications requested, we believe the Proposed Regulation can bring additional transparency, oversight, accountability and quality into delegated	NO CHANGE REQUESTED.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

9-95	George Choriatis, Esq.  UC Irvine Medical Center	<p>arrangements.</p> <p>UCI Health welcomes the opportunity to submit for consideration comments relating to proposed new Section 1300.49 of Title 28, California Code of Regulations. UCI Health comprises the academic health system of the University of California, Irvine, one of ten campuses of The Regents of the University of California, a public trust created under Article IX, Section 9 of the Constitution of the State of California. UCI Health operates a school of medicine, an academic medical center, and numerous clinics, it employs over 400 faculty physicians, and it provides tertiary and quaternary care, ambulatory and specialty medical care, behavioral health, and rehabilitation services in Orange County, California.</p> <p>UCI Health fully supports the efforts of the Department of Managed Health Care (“DMHC”) to clarify the licensure requirements for health plans. In furtherance of such ends, we urge DMHC to modify proposed Section 1300.49 to further clarify the requirements for licensure with respect to a person’s participation in Medicare alternative payment model programs administered by the Centers for Medicare and Medicaid Services, including participation as an accountable care organization (ACO) in the Medicare Shared Savings Program and participation in Medicare bundled payment programs. Under these Medicare alternative payment model programs, participating health care providers are paid on a fee-for-service basis for healthcare services rendered to their Medicare fee-for-service beneficiaries but also contract with Medicare to participate in incentive payments equal to a percentage of savings or losses in Medicare Part A and Part B expenditures. We believe that DMHC’s responses to public comments made in Comment Period #3, May 17, 2018-June 1, 2018, contain ambiguities with respect to the applicability of Section 1300.49 to Medicare alternative payment model programs, and we urge DMHC to clarify such ambiguities.</p>	DECLINED. The comment is irrelevant because it does not address the changes made during the comment period. It should be noted that the regulation will not affect products licensed by either the California Department of Insurance or the Centers for Medicare and Medicaid Services.
9-96	George Choriatis, Esq.  UC Irvine Medical Center	<p>On the one hand, DMHC has stated that Section 1300.49 is intended to clarify licensure for all entities, including ACOs, and therefore ACOs who accept a prepaid or periodic charge in return for the assumption of global risk must secure a license or an exemption. (See e.g., DMHC, Responses to Comments for Comment Period #3, Item 3-14). Such comments indicate that participation in Medicare ACOs and other Medicare alternative payment model programs may fall within the terms of Section 1300.49, depending on whether the particular payment model provides for the assumption of global risk. On the other hand, DMHC stated that “[Section 1300.49] will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. The Department has always deferred to both entities for products licensed by them.” (DMHC, Responses to Comments for Comment Period #3, Item 3-16). Such comment seems to indicate that participation in Medicare alternative payment model programs does not fall within the terms of Section 1300.49 and would not require licensure or an exemption thereunder because the program is administered by the Centers for Medicare and Medicaid Services and therefore is not affected by Section 1300.49.</p>	<p>NO CHANGE REQUESTED. It is important to note the Department’s jurisdiction is not limited to pre-paid arrangements. Health and Safety Code section 1345(f)(1) uses the terms “prepaid or periodic charge.” The language in Health and Safety Code section 1345(f)(1) provides the term “periodic” as well as “prepaid.” The term “periodic” charge does not require the charge be made prior to the start of a set period.</p> <p>Government Code section 11349(d) requires a proposed regulation to be “consistent with” and not in “conflict with” other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**General Licensure Requirements for Health Care Service Plans (2017-5220)**  
**Responses to Comments for Comment Period #4, November 30, 2018 – December 17, 2018**

			Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.
9-97	George Choriatis, Esq.  UC Irvine Medical Center	Moreover, the option of obtaining a license as a restricted health care service plan under Sections 1300.49(a)(6) and 1300.49(c) is not available with respect to a person's participation in such Medicare alternative payment model programs. A restricted health care service plan license authorizes a person to enter into global risk arrangements only with respect to Knox-Keene licensed full service or specialized health care service plans, not directly with Medicare. Accordingly, if Section 1300.49 is applicable to participation in the Medicare Shared Savings Program and other Medicare alternative payment model programs that involve global risk, then participation in such programs would be prohibited altogether, unless an exemption is secured under Section 1300.49(b)(2).	NO CHANGE REQUESTED. The comment is irrelevant because it does not address the changes made during the comment period. It should be noted that the regulation will not affect products licensed by either the California Department of Insurance or the Centers for Medicare and Medicaid Services.
9-98	George Choriatis, Esq.  UC Irvine Medical Center	Accordingly, we urge DMHC to clarify whether a person's participation in the Medicare Shared Savings Program or other Medicare alternative payment model program involving global risk for both institutional and professional services is subject to Section 1300.49. If DMHC determines that participation in such Medicare programs falls within the terms of Section 1300.49, then we urge DMHC to state that it will grant an exemption under Section 1300.49(b)(2) to persons participating in Medicare alternative payment model programs. Otherwise, the spread of such programs in California would be significantly impeded.  Thank you for your consideration. Should you have any questions about our comments, please do not hesitate to contact George Choriatis, Esq., Health Sciences Counsel.	DECLINED. Government Code section 11349(d) requires a proposed regulation to be "consistent with" and not in "conflict with" other provisions of law. This regulation will not affect products licensed by the California Department of Insurance or the Centers for Medicare and Medicaid Services. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.