

DEPARTMENT OF MANAGED HEALTH CARE
General Licensure Requirements for
Health Care Service Plans (2017-5220)
Responses to Comments for
Comment Period #3, May 17, 2018 – June 1, 2018

#	FROM	COMMENT	DEPARTMENT RESPONSE
1-1	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>These comments have been prepared jointly, but submitted separately, by The Boeing Company and MemorialCare Medical Foundation (together, “the Commentators”), to the above-referenced proposal. Commentators are participants in an “accountable care” services agreement relationship that was rigorously examined by the Department of Managed Health Care (the “Department” or “DMHC”) in September 2016. The relationship exclusively entails self-funded direct-to-one-employer care for its employees on a fee-for-service basis. It does not operate in the marketplace. There is no “ACO” entity and there is no assumption of risk for the provision of health care services. There is no prepayment or periodic payment for services. There is a contract provision for sharing savings/losses in consideration of the provision of administrative services.</p> <p>The Commentators submit the below Observations not because their accountable care relationship is covered by the terms of the proposed regulation, but rather to share with the Department and perhaps with the Office of Administrative Law (“OAL”) certain dispositive considerations about the current proposed rule and supporting Statements. We believe the text will trigger the OAL’s scrutiny under its statutory evaluative screens of “authority,” “clarity” and “necessity.”</p>	<p>NO CHANGE REQUESTED. Thank you for the comment.</p>
1-2	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>1. The current proposed rule has little relationship to the content and reasoning of the “Informative Digest/Policy Statement Overview” found in the “Notice of Rulemaking Action” dated October 27, 2017, and even less connectivity with the Notice’s companion “Initial Statement of Reasons.”</p> <p>This disconnect between the current proposed rule and the supporting “Initial Statement of Reasons” will mislead persons trying to analyze and comply with the regulations, now and in the future. A rule-promulgating State entity must provide clear explanation and direction to both present and future parties affected by the rule. The</p>	<p>NO SPECIFIC CHANGE REQUESTED. This comment expresses the commenters’ general concerns and opinions with the proposed rule including the supporting documents and does not request a specific change.</p> <p>The “Addendum to the Initial Statement of Reasons” is sufficiently related to the originally noticed material. See Government Code § 11346.8(c). The “Addendum to the Initial Statement of Reasons” addresses the Department’s cost to regulate ACOs and PHSs and <u>does not</u> alter the intended purpose of the regulation which is</p>

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		<p>present disconnect between rule and justification muddies rather than clarifies the legislative record and history, compromising the integrity of the regulation-adoption process and the efficacy of the critical collaborative compact between regulator and regulated on which effective regulation must ultimately rest.</p> <p>The May 17th “Addendum to Initial Statement of Reasons” (see below) exacerbates the disconnects and further confuses the “Reasons” for the proposed regulation.</p> <p>What would a conscientious inquirer in the future conclude from relating the text of Section 1300.49 with the 2017-2018 explanatory materials they would locate in their research? Rule-making agencies of government must make clear for future users and affected persons what their rules mean and the thinking behind them to enlist the regulated in the partnership of compliance.</p> <p>If the Department fails to provide such clarity and conjunctive relevance, between the rule and the explanations, the Office of Administrative Law in its review should take critical note of same in enforcing its requirements of clarity, authority and necessity, key screens it applies to proposed regulations.</p>	<p>to regulate entities meeting the definitions of the proposed regulatory text and associated statute. The information in the Addendum does not create a new issue as referenced in Government Code § 11346.8(e). The Department utilized the study at issue in its effort to determine the number of potential ACOs and PHSs in California impacted by the regulation and is used as an estimate only. The purpose and intent of the proposed regulation is to clarify which entities meet the definition of a health care service plan. This was made clear in the Department’s Initial Statement of Reasons and Notice for this regulation. Therefore, if ACOs, PHS, or other entities, meet the risk and payment arrangements of a health care service plan as defined in statute and the proposed regulations, they must seek licensure or an exemption. It is important to note the Department did receive comments during the second comment period recognizing and identifying the potential impact of the regulation to ACOs.</p> <p>A stated in the Authority section of the Department’s ISOR, California Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate “health care service plans.” Health and Safety Code section 1345, subdivision (f)(1), defines a “health care service plan” (health plan) as “any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost of those services in return for a prepaid or periodic charge paid by or on behalf of subscribers or enrollees.”</p> <p>The Department further stated in its ISOR:</p> <p>Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume “full financial risk” for the provision of covered health care benefits</p>
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			<p>to enrollees or subscribers. However, “full financial risk” is not defined. As a result, provider groups that contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services (professional and institutional risk together is considered “global risk”). These provider groups otherwise meet the definition of a health plan pursuant to Health and Safety Code section 1345, subdivision (f), by arranging for health care services for health plan enrollees and accepting at least a portion of global risk. Without a clear definition of what types and levels of risk may be assumed, entities that meet the definition of a health plan may be operating without a license. This is a violation of Health and Safety Code section 1349, which makes it unlawful to receive advance or periodic consideration in connection with a health plan without first securing a license or an exemption. The regulation would state clearly that a person that accepts global risk receives “advance or periodic consideration” requiring licensure for purposes of Health and Safety Code section 1349.</p> <p>In 2015 the California Court of Appeal, Second District, held that “the level of financial risk under a capitation agreement that causes a ‘risk bearing organization’ ... to become a ‘health care service plan’ ... is precisely the type of regulatory determination involving complex economic policy that should be made by the DMHC...” <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149.</p> <p>In both the Notice of Rulemaking as well as the ISOR, the Department was very clear on its intent to further clarify licensure requirements for health plans as it pertained to entities accepting global risk for providing health care services to enrollees. As additionally noted</p>
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			<p>in the Notice of Rulemaking:</p> <p><u>Purpose of the Regulation:</u></p> <p>The purpose of this rulemaking action is to clarify licensure requirements for health plans. Specifically, the proposed regulation states that a person who accepts global risk (both institutional and professional risk) for services to subscribers or enrollees receives “advance or periodic consideration” from or on behalf of subscribers or enrollees, and shall seek a health plan license. The proposed regulation will also set out requirements for a restricted license for entities that do not market directly to consumers or employers but otherwise meet the statutory definition of a health plan. In addition, the regulation states specific criteria the Department may apply in considering a request for exemption from licensure requirements. Key terms defined by the regulation include global, professional, and institutional risk, as well as “risk.”</p> <p>Based upon the information contained in the ISOR and Notice of Rulemaking, including, but not limited to the information reiterated above, there is no incongruence between the reasoning provided by the Department and the Department’s proposed regulation, including the amendments in the 2nd comment period.</p>
1-3	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>2. The “Addendum to Initial Statement of Reasons” in the Department’s May 17th “Update” suddenly introduces a new objective of the proposed regulation: licensure of “Accountable Care Organizations” and Public Health Systems.</p> <p>Regulation of ACO’s is an objective not identified by the Department until seven months after the initial release for comment. The cited 2015 study by the UC Berkeley School of Public Health (the “Study”) states that there are 67 ACOs in California with risk-bearing</p>	<p>NO SPECIFIC CHANGE REQUESTED.</p> <p>Thank you for the comment. The “Addendum to the Initial Statement of Reasons” addresses the Department’s potential fiscal costs in regulating ACOs and PHSs. It is important to note, the information in the Addendum does not alter the original intended purpose of the regulation which is to regulate entities meeting the definitions of the proposed regulatory text and associated statute. The</p>

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		<p>contracts, although no in-depth research supports this large number, nor what the nature of the “risk -bearing” is (“global”? partial?), nor what it implies. Nor does the Study even define what an ACO is nor how the 67 ACOs fit the profile (a number of these likely are little more than “narrow network” constructs). Nor does the Study explain how the construct implicates public licensure.</p> <p>Despite all these fundamental unknowns, the Department’s Addendum factors for closure and consolidation of some ACOs and the arrival of new ACOs and then finds that there would be <u>still</u> 67 ACOs “that will fall within the terms of the regulation.” The reasoning behind this assumption is not revealed – nor how the Department arrives at the estimate that “one-quarter” of these ACOs will be granted an exemption from the rule, or why that number of exemptions is likely to be granted. The Addendum then cautions that “Because one of the purposes of the regulation is to increase oversight in order to protect consumers, the Department will likely not grant many exemptions to ACOs.”</p> <p>None of this is clear nor an encouraging foundation for a late-breaking campaign of licensure of ACOs and PHSs. It certainly colors the many ambiguities and disconnects from statutory provisions that are rife in the current text.</p>	<p>Department utilized the study at issue in its effort to determine the number of potential ACOs and PHSs that may fall under the proposed criteria. The numbers used in the study are for fiscal estimations only. The Department inadvertently omitted these entities from its originally submitted fiscal estimates and subsequently included the information in the “Addendum to the Initial Statements of Reasons.”</p> <p>The purpose and intent of the proposed regulation is to clarify which entities meet the definition of a health care service plan. Therefore, if ACOs or other entities, meet the risk and payment arrangements of a health care service plan, as defined in statute and the proposed regulations, they must seek licensure or an exemption. The Department did receive comments from other entities during the second comment period recognizing and identifying the potential impact of the regulation to ACOs.</p>
1-4	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>3. Despite the lack of applicable explanation in the Statement of Reasons noted initially above in Section One, the present text appears in its second version, issued March 20, 2018, to have been narrowed to attempt to declare standards for securing licensure as a “restricted health care service plan.”</p> <p><u>Subsection (a)(4) of the proposed text has application with vast licensure implications that takes it far beyond the scope of setting standards for “restricted” licensure.</u> In light of the May 17th “Addendum” identified above in Section Two, this tangential application appears to have been strategically intended but only now revealed, in the third iteration of the proposed regulation. It reads:</p> <p><i>(a)(4) “Prepaid or periodic charge” for the purposes of this section means any amount of compensation, either at the start or end of a</i></p>	<p>NO SPECIFIC CHANGE REQUESTED.</p> <p>The regulation was intended to clarify licensure requirements for all entities, not just restricted health care service plans. Also note that “periodic” charge does not require that the charge be made prior to the start of a set period. Restricting the definition of “prepaid or periodic charge”, or even “advance or periodic”, to payments made only at the start of a period of time is not necessary, as a charge may be “periodic” even if it is not “prepaid” or “advance.” Also, a “periodic” charge may include a payment that is based on a set percentage of savings or losses, as the underlying statute does not require that the charge be a fixed dollar amount.</p>

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		<p><i>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.</i></p> <p>Health and Safety Code section 1345, subdivision (f)(1)), defines a “health care service plan” as “any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost of those services in return for a prepaid or periodic charge paid by or on behalf of subscribers or enrollees.”</p> <p>In the companion Health and Safety Code section 1349 this definitional trigger is framed as “....to receive advance or periodic consideration....”</p> <p>The formulation in proposed section (a)(4) dramatically alters these foundational statutory licensure triggers of “prepaid or periodic charge”/ “advance periodic consideration” to encompass savings or losses realized in health care services risk-sharing constructs – “any amount,” per the Statement of Reasons. Ignoring these 43-year-old Knox-Keene statutory pillars of prepayment/periodicity, it would assert to find such a charge in “any amount of compensation” in such risk-sharing arrangements where there is a sharing of savings or losses. Such arrangements are widespread and very common in today’s health care delivery environment.</p>	
1-5	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>There are two fundamental flaws in such attribution of compensation to creating periodic payment. First, the sharing of savings or losses is simply not “compensation” for services rendered or for arranging same. Risk-sharing arrangements are typically based on fee-for-service compensation, with no periodicity present. The services have been compensated, at rates contractually agreed upon. Any “savings or losses” that may emerge in time are not compensation (positive or negative) but rather the actualization of incentivization mechanisms the parties had agreed upon. They are not compensation, but rather the outcome of disciplines to which</p>	<p>NO CHANGE REQUESTED. Restricting the definition of “prepaid or periodic charge” to only fixed amounts is not necessary. The Knox-Keene Act and supporting regulations do not limit charges to those that are a fixed amount of compensation. Accordingly, a “prepaid or periodic” payment may include a payment that is based on a set amount of savings or losses.</p> <p>See response 1-4.</p>

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		the parties (and basic behavioral economics) had committed themselves as productive to the provision of care.	
1-6	Jeffrey J. White The Boeing Company Mark Schafer, MD MemorialCare Medical Foundation	Second, subsection (a)(4)'s standard of "any amount of compensation" is contrary to another core licensure provision of the Knox-Keene Act. An intrinsic element of the qualifications for requiring licensure (Health and Safety Code section 1375.1, subdivision (a)(2)), requires a health plan to demonstrate that it is fiscally sound and has "assumed full financial risk on a prospective basis for the provision of covered health care services..." This second fundamental flaw is mirrored and reinforced by the standard asserted in the still-standing (see above) "Initial Statement of Reasons" that "full financial risk" really means "some degree" or "at least a portion" of risk", and without benefit of any clarification of these "standards." "Full" is interpreted to mean "at least a portion," thus untethering the proposed regulation from its statutory mooring.	NO CHANGE REQUESTED. 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.
1-7	Jeffrey J. White The Boeing Company Mark Schafer, MD MemorialCare Medical Foundation	The "prepaid or periodic charge" formulation in proposed subsection (a)(4) is thus not grounded in but rather is contrary to the foundational statutory provisions of the Knox-Keene Act. It could sweep into licensure service-providing entities in extant arrangements in ACO's (see above), PPO's, hospital risk-sharing constructs, perhaps some employer self-insured mechanisms and so forth. This would be not only a legally unwarranted result, but also highly disruptive of the present health care delivery marketplace.	NO CHANGE REQUESTED. The proposed regulation may sweep in Accountable Care Organizations or other arrangements that, considering the proposed regulation, meet the definition of a health care service plan. However, licensing such entities will not be disruptive to the health care marketplace and instead will help provide important consumer protections, including financial solvency review. Such entities may always seek an exemption from licensure under subdivision (b)(2) of the proposed regulation.
1-8	Jeffrey J. White The Boeing Company Mark Schafer, MD MemorialCare Medical Foundation	There is in the present proposed rule a progression of reductionism wherein "global risk" is predicated on "a prepaid or periodic charge" (subsection (a)(1)), which prepayment /periodicity is then found in the end phase sharing of savings or losses (subsection (a)(4)). Thus "global risk" would be found in a truing up of savings or losses (no matter how small, see above). If an entity is assuming "global risk," as defined through the reductionism of subsection (a)(1), and, per official DMHC interpretive gloss, not even full financial risk but rather a portion of the risk, down to a saving/loss payment, then that entity would need to secure a license as a health care service plan.	DECLINED. Restricting the definition of "prepaid or periodic charge" to only fixed amounts is not necessary. The Knox-Keene Act and supporting regulations do not limit charges to those that are a fixed amount of compensation. Accordingly, a "prepaid or periodic" payment may include a payment that is based on a set amount of savings or losses.

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		<p>It is for these reasons that the amendment of subsection (a)(4) urged by the California Association of Health Plans should be taken by the Department:</p> <p>“Prepaid or periodic charge” for the purposes of this section means fixed any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares. Shared savings or losses shall not constitute fixed compensation for the purpose of this definition.</p> <p>This is the only formulation that retains a semblance of fidelity to the Knox Keene Act, H&S subsection 1345(f)(1).</p>	
1-9	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>4. The current proposal’s subsection (b)(2) would give the Director of the Department of Managed Health Care the power to “grant an exemption from this section” but provides no criteria for doing so.</p> <p>It would require that an applicant for an exemption submit certain enumerated documentation, all keyed to elements of the licensure regimen for health care service plans, but it fails to state the criteria or standards the Director would use in granting an exemption. This not only deprives would-be applicants of guidance concerning their own compliance, but also creates fertile grounds for “underground regulation.”</p> <p>Moreover, this exemption subsection relates to the articulation of requirements for “restricted licensure,” but lacks clear guidance to this “restricted licensure” cohort of market actors. But it is completely unrelated to the realities of entities which the proposed regulation would now (May 17th) intend to cover in subsection (a)(4). What would an ACO, a PPO, a hospital or other provider entities working in risk-sharing constructs, a self-insured employer use for guidance in seeking an exemption</p>	<p>ACCEPTED IN PART. The Department appreciates the comment, and notes that it has clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act.</p> <p>DECLINED IN PART. However, to the extent you would ask the Department to provide percentiles or numbers indicating how exemption factors are weighed, this is impossible. The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity’s circumstances and region in which it operates.</p> <p>For example, the Department cannot say with certainty that an entity with only “X” percentage of market share will be granted an exemption because not only does the</p>

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		<p>“from this section”?</p>	<p>percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p> <p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department’s ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p>
1-10	<p>Jeffrey J. White The Boeing Company</p> <p>Mark Schafer, MD MemorialCare Medical Foundation</p>	<p>5. The proposed regulation’s flaws are now suddenly compounded and highlighted by the “Addendum” of May 17th, rendering the text even less ready for the scrutiny of the Office of Administrative Law, through the lenses of its statutory screening criteria of “authority,” “clarity,” and “necessity.” Legislation may be required.</p> <p>The Commentators would urge the Department to convene a broadly representative working group of affected parties and stakeholders for the purpose of conducting a professional, collegial discussion and assessment of the objectives the Department believes it has for its proposed regulation and the path to achieving them. Perhaps from such a dialogue could emerge a text grounded in statute, realistically workable in projected practice, and based on what the Department envisions for its proposed regulation. It might also drive home</p>	<p>NO SPECIFIC CHANGE REQUESTED. Thank you for your comment. The Department has complied with the public comment requirements of the Administrative Procedure Act. The Department held a 45-day comment period when the proposed regulation was initially noticed to the public. In addition, the Department has held two 15-day comment periods after making sufficiently related changes to the proposed regulation and supporting material. Moreover, the Department met with interested stakeholders before the regulation was formally noticed to the public as required under Health and Safety Code section 11346.45. The Department provided ample opportunities for the public to be heard on the regulatory matter before and after the formal regulatory process. Therefore, the Department has met the requirements for public comment in Government Code § 11346.6 and</p>

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		to the Department that legislation is required to do what it seeks to do through this proposed regulation.	Government Code §11346.8.
2-11	William E. Kramer Pacific Business Group on Health	<p>We write to express our concerns and offer recommendations regarding the Third Comment version of the proposed DMHC regulation (General 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 for providers, which reward them 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. 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 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 burden on providers. Risk-sharing arrangements are typically based on fee-for-service compensation, with no prepayment or periodicity. Furthermore, these arrangements do not require providers to accept the same level of financial risk as prepaid global payment models.</p>	<p>DECLINED. Restricting the definition of “prepaid or periodic charge” to only fixed amounts is not necessary. The Knox-Keene Act and supporting regulations do not limit charges to those that are a fixed amount of compensation. Accordingly, a “prepaid or periodic” payment may include a payment that is based on a set amount of savings or losses.</p> <p>See responses 1-9 and 1-10.</p>

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		<p>We recommend that subsection (a)(4) be amended as follows:</p> <p>“Prepaid or periodic charge” for the purposes of this section means fixed any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares. Shared savings or losses shall not constitute fixed compensation for the purpose of this definition.</p>	
2-12	<p>William E. Kramer Pacific Business Group on Health</p>	<p>We are also concerned about the lack of explicit criteria in subsection (b)(2) for granting exceptions to the rule. This would create confusion among potential applicants and stifle the development of new value-based payment arrangements.</p>	<p>ACCEPTED IN PART. The Department appreciates the comment, and notes that it has clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act.</p> <p>DECLINED IN PART. However, to the extent you would ask the Department to provide percentiles or numbers indicating how exemption factors are weighed, this is impossible. The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity's circumstances and region in which it operates.</p> <p>For example, the Department cannot say with certainty that an entity with only “X” percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption</p>

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2-13	<p>William E. Kramer</p> <p>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 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>	NO CHANGE REQUESTED.
3-14	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>America's Physician Groups submits the following comments on the 3rd version of the draft rule.</p> <p>The Department has Violated the Provisions of Government Code Section 11346.8(a) and (c) Through Inadequate Notice of Public Comment for the Third Version of the Proposed Rule:</p>	<p>NO SPECIFIC CHANGE REQUESTED.</p> <p>The proposed regulation was intended to clarify licensure requirements for all entities, including ACOs, if the entities meet the enumerated requirements of the</p>

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		<p>As we discuss in a later section of this comment letter, the Department has expressed a previously undisclosed intent to expand its jurisdiction over health care providers that do not accept global capitation in their Accountable Care Organization (ACO) arrangements, including any such plans or products that involve other types of retrospective fee-for-service payments. The Department has done this through its citation to the 2015 Berkeley Forum ACO report¹ which somewhat incorrectly describes a list of 67 ACOs that accept “risk-based” payments. None of the cited ACOs in the report were at any time contracted to accept global risk payments. Many of the ACO arrangements cited in the report didn’t even rise to the level of separate legal entities because several are merely three-way contract agreements, and thus it is unclear why the Department has stated: “... <i>once the regulation is effective, there will be 67 ACOs that will fall within the terms of the regulation.</i>”</p> <p>This expression of increased regulatory jurisdiction beyond traditional restricted licensee applicants to ACOs is a substantive change to the scope of the regulation that has only been expressed at the end of the public comment process and in the form of a cost-impact assessment. Such a change requires a minimum 45-day notice for public comment, as stated in Government Code Section 11346.8(c):</p> <p><i>(c) No state agency may adopt, amend, or repeal a regulation which has been changed from that which was originally made available to the public pursuant to Section 11346.5, unless the change is (1) nonsubstantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. If a sufficiently related change is made, the full text of the resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made available to the public for at least 15 days before the agency adopts, amends, or repeals the resulting regulation. Any written comments received regarding the change must be responded to in the final statement of reasons required by Section 11346.9.</i></p>	<p>proposed regulation and associated statute. The Department inadvertently left out ACOs and PHSs from its original fiscal estimate. The Department’s inclusion of the study to estimate fiscal costs is sufficiently related to the original text. The Addendum addresses the Department’s omission by revising the Addendum to include these entities in its fiscal estimation. The use of the Addendum at issue did not change the intent of the regulation since ACOs and PHSs meeting the regulation’s requirements would need a license or an exemption, which has always been the intent of the proposed regulation. Therefore, the Department properly followed the requirements of Government Code §11346.8(c). The Department provided a 15-day comment period for the 3rd version of the proposed regulation which ran from May 17, 2018 to June 1, 2018.</p> <p>See also response 1-2.</p>
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		<p>A thorough search of the text of the first and second versions of the proposed rule, as well as the Initial Statement of Reasons will reveal that the term “Accountable Care Organization” or “ACO” does not occur in the any of these documents. The change in scope is only expressed in the economic impact assessment of the Addendum to the Statement of Reasons by the Department. No changes to the text of the regulation or the attached filing form are included in the third version. Such changes would be necessary, since under Medicare, MSSP ACOs contract directly with the Centers for Medicare and Medicaid Services (CMS) and not with a Knox Keene Health Care Service Plan, as specified in the filing form for version 3 of the proposed rule. The text and the filing form anticipate that the applicant is a separate and distinct legal entity. In fact, many of the ACOs cited in the 2015 Berkeley Forum report by the Department are not separately incorporated. For example, the Blue Shield “ACO” program, which is cited in the Report, is merely a three-way contractual agreement between a health plan, a hospital and a capitated physician group.</p> <p style="text-align: center;">_____</p> <p>¹<i>Accountable Care Organizations In California: Promise and Performance. University of California Berkeley, School of Public Health, February 2015. Accessed on June 1, 2018 at: http://berkeleyhealthcareforum.berkeley.edu/wp-content/uploads/BerkeleyForumACOEExpBrief3_feb16.pdf.</i></p>	
3-15	<p>William Barcellona, JD, MHA</p> <p>America’s Physician Groups</p>	<p>Government Code Section 11346.8(a) Requires the Availability of a Public Hearing Process:</p> <p><i>In addition, a public hearing shall be held if, no later than 15 days prior to the close of the written comment period, an interested person or his or her duly authorized representative submits in writing to the state agency, a request to hold a public hearing.</i></p> <p>APG would have requested a public hearing to seek clarification of the Department’s newly-expressed intent.</p>	<p>DECLINED. Thank you for the comment. A 45-day comment period is not applicable since the information presented in the “Addendum to the Initial Statement of Reasons” is sufficiently related to the originally noticed material. See Government Code § 11346.8(c). The “Addendum to the Initial Statement of Reasons” addresses the Department’s cost to regulate ACOs and PHSs and does not alter the intended purpose of the regulation which is to regulate entities meeting the definitions of the proposed regulatory text and associated statute. The information in the Addendum does not</p>

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		<p>Sufficient time is not afforded under the 15-day comment period. APG accordingly requests a public hearing of the proposed rule under a 45-day comment period. A public hearing is necessary because of the uncertainty of DMHC's analysis of the 67 ACOs cited in the Addendum to the Statement of Reasons. APG would like to present more detailed evidence of the payment arrangements for these cited ACOs and be permitted to argue that none of them fall under the ambit of the Knox Keene Act jurisdictional requirements. Government Code Section 11346.8(e) states:</p> <p><i>If a comment made at a public hearing raises a new issue concerning a proposed regulation and a member of the public requests additional time to respond to the new issue before the state agency takes final action, it is the intent of the Legislature that rulemaking agencies consider granting the request for additional time if, under the circumstances, granting the request is practical and does not unduly delay action on the regulation.</i></p>	<p>create a new issue as referenced in Government Code § 11346.8(e). The Department utilized the study at issue in its effort to determine the number of potential ACOs and PHSs in California impacted by the regulation and is used as an estimate only. The purpose and intent of the proposed regulation is to clarify which entities meet the definition of a health care service plan. Therefore, if ACOs, PHS, or other entities, meet the risk and payment arrangements of a health care service plan as defined in statute and the proposed regulations, they must seek licensure or an exemption. It is important to note the Department did receive comments during the second comment period recognizing and identifying the potential impact of the regulation to ACOs.</p> <p>See response 1-2.</p>
3-16	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>The Department's Definition of "Global Risk" is Even More Ambiguous considering its Application to 67 California "ACOs" and Violates "Clarity" and "Consistency" Standards:</p> <p>The draft regulation requires an entity that accepts "global risk" from a fully-licensed Knox Keene Health Care Service Plan to file for a Restricted License. "Global risk" has historically been treated by the Department and its 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's newly-stated intent in this third version of the proposed rule is set forth in a troubling section of the Addendum to the Statement of Reasons, as follows:</p> <p><u><i>Costs for New Entities Requiring Licensure:</i></u> <i>In addition to implementing the licensure process for restricted health care service plans, the regulation may also require</i></p>	<p>NO SPECIFIC CHANGE REQUESTED.</p> <p>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. Moreover, 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 potential economic impact. <u>The numbers used are for fiscal estimation purposes only.</u></p>

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<p><i>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. Of those 67, we assume the Department will grant an exemption to one-quarter of the ACOs. Because one of the 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.²</i></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. It has further reinforced that ambiguity in the 3rd version of the draft regulation through new statements made in the Addendum to the Statement of Reasons concerning a conclusion that <i>“once the regulation is effective, there will be 67 ACOs that will fall within the terms of the regulation.”</i> To the best of APG’s knowledge, no ACO in</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 Services. The Department has always deferred to both entities for products licensed by them. Therefore, the Department does not anticipate any conflicts or consistency issues with CMS or CDI regulated products or laws governing these entities.</p> <p>See response 1-2.</p>
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		<p>California has ever received a globally-capitated payment.</p> <p>The text of the regulation has not been amended in this 3rd version to include the definition of an Accountable Care Organization (“ACO”). Many of the operating ACOs in California do not contract with Knox Keene licensed health plans. The current text of the regulation only anticipates arrangements between KKA plans and providers that accept global risk payments. Federally-authorized Medicare ACOs only operate under direct contracts with the Centers for Medicare and Medicare Services (the CMS). Other so-called “ACO’s” operate under agreements with PPO plans licensed and regulated by the California Department of Insurance.³ There is no reference in the text of the 3rd version nor in its modified filing form that anticipates and explains how entities under these two payer models should file and what they should file.</p> <p>These deficiencies in the text of the 3rd version of the proposed rule in relation to the expressed intention of the Department under its Addendum raise an issue over non-compliance with the clarity requirements of the Government Code, Section 11349.1.</p> <p>Because the 3rd version does not define the term “ACO” we must conclude that some relationships between certain fully-insured plans, such as Blue Shield, and existing capitated physician groups may be commercially referred to as an “ACO” and that the Department is referring to such arrangements. In fact, these “ACOs” are essentially operating as a narrow-network HMO product. The Department has previously reviewed the Blue Shield “ACO” program and has not required any provider entity to file for a restricted license, because global capitation is not paid under this arrangement. Similarly, no current federally-authorized ACO arrangement pays capitation in any form, let alone on a global basis.⁴ No PPO-sponsored ACO in California pays capitation to its “ACO.” By process of elimination, it is difficult to understand how <u>any</u> of</p>	
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		<p>the 67 ACOs discussed in the Berkeley Forum Report would require restricted licensure by the DMHC.</p> <p>It is also unclear in each of the three releases of this regulation whether the DMHC intends to regulate <i>non-capitated plan-to-plan agreements</i>, such as so-called “ACO” arrangements that are based on fee-for-service payments with upside/downside “back end” risk provisions. Such payment arrangements are sometimes referred to as “gain-sharing” agreements between payers and providers but are not “prepaid” and arguably don’t fall within the jurisdiction of the Department (unless the Department is now expressing an expansion of jurisdiction). This would be a radical departure from the historic exercise of jurisdiction by the Department, and its silence on this issue during the release of the three comment periods is confounding.</p> <p>The Department should have explained how and why the 67 ACOs cited in the Berkeley Forum report triggered jurisdiction under the proposed rule. The ambiguity concerning the application of jurisdiction over non-capitated entities violates the consistency requirement of the Government Code, Section 11349.1.</p> <p>² <i>Accountable Care Organizations In California: Promise and Performance. University of California Berkeley, School of Public Health, February 2015. Accessed on June 1, 2018 at: http://berkeleyhealthcareforum.berkeley.edu/wp-content/uploads/BerkeleyForumACOExpBrief3_feb16.pdf.</i></p> <p>³ <i>Indeed, no explanation is made concerning how the Department intends to resolve conflicts over licensure requirements of the California Department of Insurance for PPO plans that operate “ACO” programs, and APG asserts that this is violation of Government Code section 11349.1(4), which requires that the submitting agency determine whether there is any conflict with existing state regulation: “The proposed regulation conflicts with an existing state regulation and the</i></p>	
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		<p>agency has not identified the manner in which the conflict may be resolved.”</p> <p>“See the FSSB meeting minutes and presentations on Pioneer and MSSP ACO models by Jennifer Jackman for the November 8, 2012 meeting, accessed on June 1, 2018 at: http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/acou.pdf.</p> <p>The May 9, 2013 FSSB Meeting minutes and presentation by DMHC Deputy Director Dennis Balmer on Pioneer ACOs accessed on June 1, 2018 at: http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/pacoou.pdf.</p> <p>The August 21, 2013 FSSB Meeting minutes and presentation by Deputy Director Dennis Balmer on Pioneer ACOs accessed on June 1, 2018 at: http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/pacoou.pdf.</p> <p>The November 18, 2013 FSSB Meeting minutes and “Risk Assessment” presentation by FSSB Board member Ed Cymerys FSA MAA, accessed on June 1, 2018 at http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/raoepa.pdf.</p>	
3-17	<p>William Barcellona, JD, MHA</p> <p>America’s Physician Groups</p>	<p>Further Amendment of the Proposed Rule is Necessary to Clarify the Department’s Intent to Regulate Risk Arrangements:</p> <p>In the 2002 FSSB Memorandum “Overview of Risk Sharing Arrangements” considered by the Financial Solvency Standards Board during its January 29, 2002 meeting, the historical treatment of the exemption for capitated providers is set forth, reasoning:</p> <p><i>“Although it is unlawful for any person to engage in the business of a health plan or to undertake to arrange for the provision of health care services in return for prepaid or periodic consideration without first securing a Knox-Keene license, Health & Safety Code §1349, health care providers operating within the scope of their license are impliedly exempt from this requirement. Based on this implied exemption, health plans contract with a variety of health care providers on a prepaid or periodic basis who then become responsible for furnishing actual health care services to health plan enrollees.”</i>⁵</p>	<p>NO SPECIFIC CHANGE REQUESTED.</p> <p>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>Moreover, 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 Addendum addresses the Department’s cost to regulate ACOs and PHSs and does not alter the intended purpose of the regulation which is to clarify that entities accepting a prepaid or periodic charge, as defined in the regulation, in return for the assumption of global risk, require licensure or exemption. This is not</p>

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		<p>This memorandum was given judicial notice by the Court in the matter of <i>Hambrick v. Healthcare Partners</i>, cited by the Department as an authority relied upon for this proposed rule.</p> <p>The Knox Keene Act was created to regulate prepaid health plan arrangements. The Legislature determined and intended that such arrangements differed from traditional indemnity health insurance contracts regulated by the Department of Insurance. Thus, the prepaid nature of the arrangement has always been the key differentiation between DOC/DMHC and CDI jurisdiction. The Legislature has never acted subsequently to modify that intent.</p> <p>The Department’s statement that “once the regulation is effective, there will be 67 ACOs that will fall within the terms of the regulation” raises collateral issues:</p> <ul style="list-style-type: none"> • The regulation does not define the term “ACO.” • The regulation does not specify the precise characteristics of an ACO that would render it susceptible to jurisdiction as a health care service plan. • The Addendum to the Statement of Reasons states an assumption that all 67 ACOs in the Berkeley Forum report were receiving “risk based” payments. Over 200 medical groups currently receive “risk based” payments as RBOs – are they also now required to file for exemptions under the regulation? • None of the 67 ACOs referred to in the Berkeley Forum Report of 2015 were accepting prepaid “global risk” at the time of publication nor are they currently doing so. • The regulation does not address how the DMHC has jurisdiction over ACOs operated by CDI-licensed PPO plans that do not pay capitation to their contracted providers. • The regulation text, nor the filing form do not specify how an ACO that is directly contracted to the Centers for Medicare and Medicaid (CMS) would file for a restricted license, because the regulation and form only reference sub-contracted relationships between a fully-licensed Knox Keene Health Care Service Plan and an entity accepting “global risk” which is presumably a 	<p>limited to ACOs. The Department utilized the study at issue in its effort to determine the number of potential ACOs and PHSs in California impacted by the regulation and is used as an estimate only. The purpose and intent of the proposed regulation is to clarify which entities meet the definition of a health care service plan. Therefore, if ACOs, PHS, or other entities, meet the risk and payment arrangements of a health care service plan, they must seek licensure or an exemption. It is important to note the Department did receive comments during the second comment period recognizing and identifying the potential impact of the regulation to ACOs.</p> <p>See response 1-2. It should also 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 healthcare entities, such as ACOs.</p>
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		<p>professionally capitated medical group.</p> <p>_____</p> <p>⁵ Accessed on June 1, 2018 at: http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/Meetings/a020129_info.pdf.</p>	
3-18	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>Unresolved Conflict Over Regulation of ACOs with the Ban on the Corporate Practice of Medicine:</p> <p>There is a further issue raised by the Department's stated intention to regulate previously unregulated Accountable Care Organizations that concerns the interaction of the Medical Practice Act, commonly referred to as the "ban on the corporate practice of medicine." An ACO cannot accept professional or institutional risk under California Law, the Medical Practice Act, because it is not a licensed medical group or hospital. Rather, an ACO must be comprised of at least a medical group that can accept professional capitation and can then apply for a Restricted License to accept the additional institutional risk. An entity that is not a medical group cannot skirt the provisions of the Medical Practice Act by seeking a restricted license to accept professional capitation. This issue was first raised in the California Healthcare Foundation Report, <i>Accountable Care Organizations in California: Programmatic and Legal Considerations</i>⁶ stating: "Because of the ban, ACOs, unless licensed as providers, will likely be unable to employ physicians and other health care professionals directly."</p> <p><i>The DMHC is on constructive notice of this issue by its examination of recent, previous restricted license applications that it has discussed verbally with APG's staff. Because the Department has not defined an ACO in this proposed rule, it has created uncertainty over who can apply for a restricted license, and this in turn creates unresolved conflicts with other regulatory provisions within California law, in violation of Government Code Section 11349.1(4), which requires that the submitting agency determine whether there is any conflict with</i></p>	<p>NO CHANGE REQUESTED. The policy expressed in Business and Professions Code section 2400 against the corporate practice of medicine is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. It is not clear how the commenter believes the proposed regulation will impact the prohibition against the corporate practice of medicine and it is clearly not the Department's intent to do so. Further, it should be noted that Health and Safety Code section 1367(g) requires that medical decisions are rendered by qualified providers, unhindered by fiscal and administrative management.</p>

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		<p><u>existing state regulation and resolve it prior to the finalization of the proposed rule.</u></p> <p>⁶ <i>Accountable Care Organizations in California: Programmatic and Legal Considerations</i>. CHCF July 2011, at page 17-18. Accessed on June 1, 2018 at: https://www.chcf.org/wp-content/uploads/2017/12/PDF-ACOProgrammaticLegalConsiderations.pdf.</p>	
3-19	<p>William Barcellona, JD, MHA</p> <p>America's Physician Groups</p>	<p>Unresolved Collateral Issues Over the Scope of the Regulation and it's Application to the Spectrum of Risk-Sharing Arrangements:</p> <p>There are substantial collateral and unresolved issues created by the Department's newly-expressed position taken in the Addendum to the Statement of Reasons. How does the Department intend to deal with shared-risk arrangements between hospitals and capitated medical groups? The Department is on constructive notice of this collateral issue by its citation to the <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i> (2015) 238 Cal.App.4th 124. There is extensive discussion and judicial notice of 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." 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" referred to in the Berkeley Forum Report cited by the Department. In a more recent discussion by the Financial Solvency Standards Board on November 18, 2013, 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</p>	<p>NO CHANGE REQUESTED.</p> <p>See responses 1-2, 3-14, 3-16 and 3-17.</p>

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		<p>in the Berkeley Forum report.⁷</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? Is the Department going to ban such arrangements in favor of the issuance of restricted licenses?</p> <p>It seems logical that the Department would do so if it has concluded that it is necessary for the public safety to regulate non-capitated ACOs that it deems to have accepted “global risk.”</p> <hr style="width: 20%; margin-left: 0;"/> <p>⁷ <i>The November 18, 2013 FSSB “Risk Assessment” presentation by FSSB Board member Ed Cymerys FSA MAA, accessed on June 1, 2018 at http://dmhc.ca.gov/Portals/0/AbouttheDMHC/FSSB/raoepa.pdf.</i></p>	
3-20	<p>William Barcellona, JD, MHA</p> <p>America’s Physician Groups</p>	<p>Conclusion</p> <p>It is commendable that the Department has undertaken to issue a regulation that has the potential 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 rule limited to that objective, California could rapidly further the expansion of this successful, collaborative model between payers and providers.</p> <p>APG has always asserted that should CMS undertake a program to pay global capitation to Medicare ACOs that the use of the restricted license would be an appropriate vehicle to ensure the financial solvency of the globally-capitated risk-</p>	<p>NO CHANGE REQUESTED. Thank you for your comments.</p>

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		<p>bearing entity. But CMS does not currently operate such a program. None of our previous or current comments should be construed to conflict with our previously-stated policy position.</p> <p>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 cited the elements for exemption by an entity in the regulation, the entire process lacks the clarity and consistency required by the Government Code.</p> <p>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.</p> <p>While the Department has cited the need to protect consumers, we wish to note that to date, no “ACO” 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.</p> <p>APG has stated in previous comment letters on this proposed rule that the purpose of the regulation should be narrowly construed to provide a clear and unambiguous filing procedure for restricted license applicants. Those applicants have</p>	
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		traditionally involved capitated RBOs that sought to enter into globally-capitated plan-to-plan arrangements with fully-licensed Knox Keene Health Care Service Plans. However, APG does not support an expansion of the Knox Keene Act to cover non-capitated ACO arrangements and to force them into a restricted license filing model. The result would be a cumbersome filing and review process that would most likely result in exemptions granted to all currently operating ACOs.	
4-21	Wendy Soe California Association of Health Plans	The California Association of Health Plans (CAHP) represents 48 public and private health care service plans that collectively provide coverage to over 25 million Californians. We write today to submit our comments to the revised proposed rule published May 17th relating to General Licensure Requirements under the Knox Keene Act. CAHP has submitted comments on behalf of our member health plans to the prior two comment periods on this rulemaking effort. We encourage the Department to consider the prior feedback and hope to see the Department address those comments in the Final Statement of Reasons for the rulemaking file. Some of our concerns that remain are reiterated below and our prior two comment letters are attached here for ease of reference.	NO CHANGE REQUESTED. Thank you for your comments.
4-22	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> • <i>(a)(1) “Global risk” means acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk.</i> <p>The definition of “global risk” should include language regarding “arranging for the provision of health care services to subscribers or enrollees” to closely mirror the definition of “health care service plan” under HSC Section 1345 (f). Otherwise, it may have Corporate Practice of Medicine implications. Further, it offers insufficient protection of situations where one party does all of the arranging for the provision of health care services, and by contract gets another entity to assume the risk.</p>	DECLINED. Thank you for your comment. We do not believe that there are corporate practice of medicine implications in the definition and so a change is not necessary. Additionally, the definition of “global risk” refers to “professional and institutional risk” and both of those definitions contain language referring to the definition of a health care service plan in 1345. For example, both definitions refer to “provision of “services” “in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.” Accordingly, because professional and institutional risk contain direct references to the 1345 definition of a health care service plan, it is not necessary for global risk to also have those same references.
4-23	Wendy Soe California Association	<ul style="list-style-type: none"> • <i>(a)(2) “Institutional risk” means the assumption of the cost for the provision of hospital inpatient, hospital outpatient, or hospital ancillary services to subscribers or enrollees</i> 	DECLINED. Hospital inpatient and ambulatory care services (outpatient hospital services) are defined in subdivisions (b) and (c) of title 28 section 1300.67, so

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	of Health Plans	<p><i>undertaken by a person, other than services performed pursuant to the person’s own license under section 1253 of the Health and Safety Code in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.</i></p> <p>CAHP proposed amendments to this definition in our attached comment letter dated April 5, 2018.</p>	<p>adding additional information to the definition of “institutional risk” is not necessary. Additionally, the definition of “institutional risk” is intended to only refer to facility licensure rather than professional licensure, as the financial risk considered with “institutional risk” is based on the facility and not the licensure of the individual performing the service.</p>
4-24	<p>Wendy Soe</p> <p>California Association of Health Plans</p>	<p>• <i>(b)(2) Pursuant to section 1343 of the Health and Safety Code, the Director may grant an exemption from this section to any person upon review and consideration of information the Director deems relevant, including, but not limited to, the following:</i></p> <p><i>(A) The filing of Exhibit GG, Financial Viability, and Exhibit HH, Projected Financial Viability, of the application for licensure, pursuant to rule 1300.51 of this title. The Exhibits shall include current financial statements and projected changes that have or are expected to occur upon the assumption of global risk. A person that currently files audited financial statements with the Department may request an exemption from filing Exhibit GG;</i></p> <p><i>(B) The total percentage of annualized income of institutional risk the person will assume and how it will be assumed;</i></p> <p><i>(C) The contract(s) for the assumption of global risk;</i></p> <p><i>(D) The estimated number of subscribers and enrollees for whom the person will provide health care services;</i></p> <p><i>(E) The geographic service area(s) under the global risk arrangement(s) in which the person intends to operate; and</i></p> <p><i>(F) Information on how the public interest or protection of the public, subscribers, enrollees or persons subject to this chapter will be impacted if the person takes on global risk.</i></p> <p>The current proposal’s subsection (b)(2) would give the Director of the DMHC the power to “grant an exemption from</p>	<p>ACCEPTED IN PART. The Department appreciates the comment, and notes that it has clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act.</p> <p>DECLINED IN PART. However, to the extent you would ask the Department to provide percentiles or numbers indicating how exemption factors are weighed, this is impossible. The Department must be able to consider the particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity’s circumstances and region in which it operates.</p> <p>For example, the Department cannot say with certainty that an entity with only “X” percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only</p>

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		<p>this section.” However, the subsection fails to state the thresholds or standards the Director would use in granting an exemption.</p> <p>The recently released Addendum to the Initial Statement of Reasons demonstrates the widespread reach of these proposed regulatory changes and highlights the need for refined definitions and standards for exemption requests.</p> <p>We appreciate the opportunity for comment and are available to you should you need any additional information.</p>	<p>granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p> <p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department’s ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p> <p>See response 1-9.</p>
4-25	<p>Wendy Soe</p> <p>California Association of Health Plans</p> <p>(4/5/18 comment letter – Comments 4-25 through 4-36 are duplicative of Comments 7-43 through 7-54 of the 2nd comment period comment chart)</p>	<p>The California Association of Health Plans (CAHP) represents 48 public and private health care service plans that collectively provide coverage to over 25 million Californians. We write today to submit our comments to the revised proposed rule published March 20th relating to General Licensure Requirements under the Knox Keene Act.</p> <ul style="list-style-type: none"> ● <i>Incongruence between reasoning provided and proposed regulations</i> <p>As revised, the regulatory text bears little relationship to the content and reasoning of the “Informative Digest/Policy Statement Overview” found in the “Notice of Rulemaking Action” dated October 27, 2017, and the Notice’s companion “Initial Statement of Reasons.” This disconnect between the new draft text and both pieces is misleading and a disservice not only to (1) persons attempting in present time to interpret what the Department is trying to do and say with this proposal but also to (2) persons in the future researching the “regulatory history” of whatever may come to be promulgated. A rule-promulgating State entity must provide clear explanation and direction to both present and future parties affected by the rule. The Department should carefully review its October Statements and revise them to correlate with precise</p>	<p>NO SPECIFIC CHANGE REQUESTED. Thank you for your comment.</p> <p>It should be noted that as stated in the Authority section of the Department’s Initial Statement of Reasons, California Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate “health care service plans.” Health and Safety Code section 1345, subdivision (f)(1), defines a “health care service plan” (health plan) as “any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost of those services in return for a prepaid or periodic charge paid by or on behalf of subscribers or enrollees.”</p> <p>The Department further stated in its ISOR:</p> <p>Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume “full financial risk” for the provision of covered health care benefits to enrollees or subscribers. However, “full financial risk” is not defined. As a result, provider groups that</p>

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		<p>consistency to its substantially revised proposed regulation text of March.</p>	<p>contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services (professional and institutional risk together is considered “global risk”). These provider groups otherwise meet the definition of a health plan pursuant to Health and Safety Code section 1345, subdivision (f), by arranging for health care services for health plan enrollees and accepting at least a portion of global risk. Without a clear definition of what types and levels of risk may be assumed, entities that meet the definition of a health plan may be operating without a license. This is a violation of Health and Safety Code section 1349, which makes it unlawful to receive advance or periodic consideration in connection with a health plan without first securing a license or an exemption. The regulation would state clearly that a person that accepts global risk receives “advance or periodic consideration” requiring licensure for purposes of Health and Safety Code section 1349.</p> <p>In 2015 the California Court of Appeal, Second District, held that “the level of financial risk under a capitation agreement that causes a ‘risk bearing organization’ ... to become a ‘health care service plan’ ... is precisely the type of regulatory determination involving complex economic policy that should be made by the DMHC...” <i>Hambrick v. Healthcare Partners Medical Group, Inc.</i>, (2015) 238 Cal.App.4th 124, 149.</p> <p>Additionally, although the term “risk” is used in the Knox-Keene Act, it is not defined. Rule 1300.49 will clarify and implement the licensing requirements laid out in the Knox-Keene Act. In consideration of the overarching duty of the Department to safeguard the health care delivery system, the Department has determined that, unless otherwise provided, any</p>
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			assumption of global risk, as defined in Rule 1300.49, requires licensure.
4-26	Wendy Soe California Association of Health Plans	We provide two examples of disconnect. First, the “Initial Statement of Reasons” and the “Informative Digest/Policy Statement Overview” equate the assumption of “global risk” with “advance or periodic consideration,” yet new subsection “(b)(1)” strikes that definitional nexus. Second, the “Initial Statement of Reasons” states that licensure as a health care service plan would be triggered if there were the acceptance of “at least a portion of global risk” or the “taking on” of “any portion of institutional risk”. However, the text of the proposed regulations provides no objective standards or guidelines as to what would constitute “a portion” of risk that would trigger licensure. Current statutory requirements are already clear that health plans assume “full financial risk” (Health and Safety Code (HSC) section 1375.1, subdivision (a)(2).)	NO CHANGE REQUESTED. See response 4-25.
4-27	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> • <i>(a)(1) “Global risk” means acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk.</i> <p>The definition of “global risk” should include language regarding “arranging for the provision of health care services to subscribers or enrollees” to closely mirror the definition of “health care service plan” under HSC Section 1345 (f). Otherwise, it may have Corporate Practice of Medicine implications. Further, it offers insufficient protection of situations where one party does all of the arranging for the provision of health care services, and by contract gets another entity to assume the risk.</p>	DECLINED. The use of “prepaid or periodic charge” language in the proposed definition of “global risk” ties the term to the “health care service plan” definition and so additional language mirroring that definition is not necessary.
4-28	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> • <i>(a)(2) “Institutional risk” means the assumption of the cost for the provision of hospital inpatient, hospital outpatient, or hospital ancillary services to subscribers or enrollees undertaken by a person, other than services performed pursuant to the person’s own license under section 1253 of the</i> 	DECLINED. Hospital inpatient and ambulatory care services (outpatient hospital services) are defined in subdivisions (b) and (c) of title 28 section 1300.67, so adding additional information to the definition of “institutional risk” is not necessary. Additionally, the

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		<p><i>Health and Safety Code in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.</i></p> <p>CAHP proposes the following edit to the definition:</p> <p>“Institutional risk” means the assumption of the cost for the provision of hospital inpatient, hospital outpatient, or hospital ancillary services to subscribers or enrollees undertaken by a person, other than services performed <i>in a hospital</i> pursuant to the person’s own license under section 1253 of the Health and Safety Code <u>or Division 2 of the Business and Professions Code</u>, in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee.</p> <p>The proposed definition of “institutional risk” has some ambiguity regarding what is meant by the various categories of “hospital” services, all of which could include a professional component (for example, hospitalist services, radiology, anesthesiology, etc.). Although the “institutional risk” definition as currently written carves out services performed pursuant to a license under Section 1253 that section only applies to facility licensure, not professional licensure.</p>	<p>definition of “institutional risk” is intended to only refer to facility licensure rather than professional licensure, as the financial risk considered with “institutional risk” is based on the facility and not the licensure of the individual performing the service.</p>
4-29	Wendy Soe California Association of Health Plans	<p>CAHP’s proposed edits above “Institutional risk” are consistent with the DMHC’s historical position, which is that the DMHC does not object to providers receiving prepaid or periodic payments (such as capitation) for any professional services that the providers themselves are licensed to provide, regardless of the setting where the services are provided. The proposed edit narrows the overly-broad categories of hospital services that are incorporated into the “institutional risk” definition. Because of the possibility that certain professional services could be inappropriately considered “hospital” services for the purpose of the “institutional risk” definition, we recommend that the definition retain the existing reference to Section 1253, but also include the additional references to the appropriate professional licensure statutes so that professional services that are provided in the hospital setting are clearly carved out of the definition.</p>	<p>DECLINED. Hospital inpatient and ambulatory care services (outpatient hospital services) are defined in subdivisions (b) and (c) of title 28 section 1300.67, so adding additional information to the definition of “institutional risk” is not necessary. Additionally, the definition of “institutional risk” is intended to only refer to facility licensure rather than professional licensure, as the financial risk considered with “institutional risk” is based on the facility and not the licensure of the individual performing the service. Because the language in the proposed rule already accomplishes what the commenter is suggesting, no change to the regulation is necessary.</p>

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4-30	Wendy Soe California Association of Health Plans	<p>• (a)(4) <i>“Prepaid or periodic charge” for the purposes of this section means any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of the contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares.</i></p> <p>CAHP proposes the following edit to the definition:</p> <p>“Prepaid or periodic charge” for the purposes of this section means fixed any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares. <u>Shared savings or losses shall not constitute fixed compensation for the purpose of this definition.</u></p> <p>The Department’s Statement of Reasons does not identify any need for the term, “prepaid or periodic charge” to be defined beyond its plain meaning. The term has been commonly understood as, a “charge” (i.e. specific amount of compensation) that is either “prepaid” (i.e. paid beforehand) or “periodic” (i.e. paid on a regular basis). The proposed definition is overly broad and could encompass compensation that is neither “prepaid” nor “periodic.”</p>	DECLINED. Restricting the definition of “prepaid or periodic charge” to only fixed amounts is not necessary. The Knox-Keene Act and supporting regulations do not limit charges to those that are a fixed amount of compensation. Accordingly, a “prepaid or periodic” payment may include a payment that is based on a set amount of savings or losses.
4-31	Wendy Soe California Association of Health Plans	For example, shared savings/loss arrangements typically distribute payment to providers after the end of a defined reporting period, with the one-time payment depending on the amount of saving or loss. Shared savings or losses are not “compensation” for services rendered to or arranged for enrollees. Rather, savings or losses are actualization of incentive mechanisms that the parties had agreed upon. Although such shared savings arrangements would not fit a plain meaning of “prepaid or periodic charge,” they would be	NO CHANGE REQUESTED. The Department notes that shared saving and loss arrangements, although not traditional capitation, are provided to compensate for services rendered as well as to incentivize quality care. We agree that such arrangements will fall within the proposed definition of “prepaid or periodic charge”, as they are considered charges even if they are not a fixed amount. A charge may considered “periodic” even if it is provided at the end of a set period of time.

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		fall under the proposed definition in (a)(4) which references neither prepayment nor periodicity. It is important to further note that the Department has separate existing authority over risk sharing arrangements between plans and non-licensed risk bearing organizations which can be found in California Code of Regulations, Title 28, subsection 1300.75.4(d)(1), 1300.75.4.2(a)(5) & (6).	While the Department does have authority over risk bearing organizations, the purpose of this regulation is to clarify licensure requirements for health care service plans.
4-32	Wendy Soe California Association of Health Plans	Proposed subsection (a)(4)'s standard of "any amount of compensation" is contrary to another core licensure provision of the KKA. As a qualification for licensure, HSC section 1375.1(a)(2) requires a health plan to demonstrate that it is fiscally sound and has "assumed full financial risk on a prospective basis for the provision of covered health care services..." There is a concern that (a)(4) as currently stated could sweep into licensure service-providing entities in Accountable Care Organizations (ACOs), hospital risk-sharing constructs, or other such arrangements. This would be legally unwarranted and highly disruptive to the present health care delivery marketplace.	NO CHANGE REQUESTED. Section 1375.1(a)(2), which refers to the requirement to assume "full financial risk" is a regulatory requirement applied to health care service plans. The proposed regulation, however, will clarify which entities meet the definition of a health care service plan and therefore must seek licensure. Whether those entities must be licensed, and, if they are licensed, whether they meet the "full financial risk" regulatory requirement, are distinct issues. The proposed regulation may sweep in Accountable Care Organizations or other arrangements that, considering the proposed regulation, meet the definition of a health care service plan. However, licensing such entities will not be disruptive to the health care marketplace and instead will help provide important consumer protections, including financial solvency review. Such entities may always seek and exemption from licensure.
4-33	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> • <i>(b)(2) Pursuant to section 1343 of the Health and Safety Code, the Director may grant an exemption from this section to any person upon review and consideration of information the Director deems relevant, including, but not limited to, the following:</i> <ul style="list-style-type: none"> <i>(A) The filing of Exhibit GG, Financial Viability, and Exhibit HH, Projected Financial Viability, of the application for licensure, pursuant to rule 1300.51 of this title. The Exhibits shall include current financial statements and projected changes that have or are expected to occur upon the assumption of global risk. A person that currently files</i> 	ACCEPTED IN PART. The Department appreciates the comment, and notes that it has clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act. DECLINED IN PART. However, to the extent you would ask the Department to provide percentiles or numbers indicating how exemption factors are weighed, this is impossible. The Department must be able to consider the

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		<p><i>audited financial statements with the Department may request an exemption from filing Exhibit GG;</i></p> <p><i>(B) The total percentage of annualized income of institutional risk the person will assume and how it will be assumed;</i></p> <p><i>(C) The contract(s) for the assumption of global risk;</i></p> <p><i>(D) The estimated number of subscribers and enrollees for whom the person will provide health care services;</i></p> <p><i>(E) The geographic service area(s) under the global risk arrangement(s) in which the person intends to operate; and</i></p> <p><i>(F) Information on how the public interest or protection of the public, subscribers, enrollees or persons subject to this chapter will be impacted if the person takes on global risk.</i></p> <p>The current proposal's subsection (b)(2) would give the Director of the DMHC the power to "grant an exemption from this section." However, the subsection fails to state the thresholds or standards the Director would use in granting an exemption. This deprives applicants of pertinent guidance and could create a breeding ground for underground regulating.</p>	<p>particular circumstances and information provided by the entity as part of the exemption request and give each factor individual weight depending on the entity's circumstances and region in which it operates.</p> <p>For example, the Department cannot say with certainty that an entity with only "X" percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p> <p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department's ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p> <p>See response 1-9.</p>
4-34	Wendy Soe California Association of Health Plans	<p>Additionally, this subsection relates to requirements for "restricted licensure" but lacks guidance as to the entities that would be eligible for an exemption. We are concerned that under the sweep of subsection (a)(4), ACOs, hospitals, or other provider entities participating in risk-sharing constructs could be included in licensure and/or exemption requirements.</p>	<p>NO CHANGE REQUESTED. Any entity that meets the definition of a health care service plan, taking into account the proposed regulation, must apply for either licensure or an exemption.</p>

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4-35	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> • <i>Technical edit to the Restricted Health Care Service Plan Responsibility Form Instructions.</i> <p>On page 1 of the form, a reference to the former name of the form (“DMHC Division of Financial Responsibility Form”) appears to have been inadvertently left in. See middle of the first page of the form, in the instruction that begins “Please review the instructions below...” That reference should be changed to reflect the new name of the form.</p>	ACCEPTED. Thank you for pointing out this error, the suggested change was made.
4-36	Wendy Soe California Association of Health Plans	<p>On page 2 of the form, in the heading for the second column of the form, we would recommend inserting “<u>Contracting Full Service or Specialized</u>” before “Health Plan.”</p> <p>We appreciate the opportunity for comment and are available to you should you need any additional information.</p>	ACCEPTED. Thank you for pointing out this error, the suggested change was made.
4-37	Wendy Soe California Association of Health Plans (12/11/17 comment letter – Comments 4-37 through 4-49 are duplicative of Comments 7-64 through 7-76 of the 1st comment period comment chart)	<p>The California Association of Health Plans (CAHP) represents 49 public and private health care service plans that collectively provide coverage to over 25 million Californians. We write today to submit our comments to the proposed rule published October 27th relating to General Licensure Requirements under the Knox Keene Act.</p> <p>Existing law</p> <p>Current law defines a “health care service plan” as “any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost of those services <i>in return for a prepaid or periodic charge</i> (emphasis added) paid by or on behalf of subscribers or enrollees.” (Health and Safety Code section 1345, subdivision (f)(1)). In a companion section (HSC section 1349) this definitional trigger is framed as “....to receive <i>advance or periodic consideration....</i>” (emphasis added).</p> <p>HSC section 1375.1, subdivision (a)(2) requires a health plan to demonstrate that it is fiscally sound and has “assumed full financial risk on a prospective basis for the provision of covered</p>	NO CHANGE REQUESTED. The Department appreciates the comments.

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		health care services....” As the DMHC’s Statement of Reasons for the proposed regulation notes, “full financial risk” is not defined in the statute, but that reinsurance is acceptable.	
4-38	Wendy Soe California Association of Health Plans	Ambiguities in the proposed regulations First, Section 1300.49(b)(1) of the proposed regulations indicates that any “person” who accepts what is calls “global risk” will be deemed to have received “advance or periodic consideration,” thereby triggering the need for licensure. This is an interpretive leap, inconsistent with the definition of a health plan, equating assumption of risk with advance or periodic payment without their being a “prepaid or periodic charge.” The definition of risk in 1300.49(a)(6) should be revised to include “prepaid or periodic charge” language as required in the definition. An entity that does not receive a “prepaid or periodic charge” would not be required to obtain a health care service plan license under the terms of the Knox-Keene Act.	ACCEPTED. Revised subsection 1300.49(a)(1) now defines global risk to mean the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk. The narrower definition applies to the subsection 1300.49(b)(1) licensure provision.
4-39	Wendy Soe California Association of Health Plans	If the Department’s intent is to regulate as health care service plans providers that participate in risk-sharing arrangements but do not receive a prepaid or periodic charge, this would be inconsistent with the terms of the Act and historical treatment by the Department. Risk-sharing arrangements between plans and providers are already subject to extensive regulation under Title 28 CCR Section 1300.75.4, et. seq.	ACCEPTED. The revised definition of global risk applies to entities that receive a prepaid or periodic charge (subsection 1300.49(a)(1)).
4-40	Wendy Soe California Association of Health Plans	The jurisdictional provision that triggers the Department’s authority is HSC Section 1345(f)(1).“Any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse <i>any part of the cost for those services, in return for a prepaid or periodic charge</i> paid by or on behalf of the subscribers or enrollees.” If there is an agreement to pay for any part of the services in exchange for a prepaid or periodic charge, the arrangement falls within the definition of a health care service plan. Assumption of risk is irrelevant to this determination. Stated differently, in the case where a provider agrees to assume risk for hospital services, the important fact is they are agreeing to pay for hospital services for a plan’s enrollees in exchange for capitation or a periodic payment because that	DECLINED. The revised regulation’s definition of global risk is the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk (proposed subsection 1300.49(a)(1)). This is consistent with the statutory definition in Health and Safety Code section 1345(f)(1). Assumption of risk is relevant in that the Knox-Keene Act also requires that “every plan” shall have assumed full financial risk on a prospective basis for the provision of covered health care services (Health and Safety Code section 1375.1(a)(2)).

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		falls squarely within the definition of HSC 1345(f). Including risk in the determination of whether a person is operating as a health plan expands the scope of HSC 1345 and would be impermissible under the necessity and authority standards of the APA. HSC 1345 f does not include risk. When the Legislature uses a term or phrase in one place but excludes it from another, the court must assume the Legislature intended the exclusion and it should not be implied where the Legislature excluded it. (<i>People v. Gardeley</i> (1997) 14 Cal.4th 605,621 [59 Cal.Rptr.2d 356, 366].)	
4-41	Wendy Soe California Association of Health Plans	Second, whereas current statute refers to the assumption of “full financial risk” and although the statutory requirement “full” is not altered in the text of the proposed regulation, in two places in the official “Initial Statement of Reasons”, it is stated that the requirement for licensure as a health plan would be triggered if there were the acceptance of “at least a portion of global risk”, or the “taking on” of “any portion of institutional risk.” This also seems to be an interpretive leap, and one that it is not included in the actual text of the proposed regulations but rather only in the companion Statement of Reasons. Assuming this interpretation stands, for discussion sake, the proposed text provides no objective standards or guidelines as to what would constitute “a portion.” Is it a “mere scintilla” of financial risk? A “material” amount or degree of financial risk?	DECLINED. The amount of global risk is relevant to exemption from licensing, but does not alter the applicability of the licensure requirement. The requirement to assume “full financial risk”, on the other hand, is a regulatory requirement that must be met once an entity is determined to fall within the scope of the licensure requirement.
4-42	Wendy Soe California Association of Health Plans	Proposed subsection 1300.49(b)(2) would make available an exemption from Section 1300.49 on the basis of the Department’s review of certain variables (projected financial impact, percentage of income from assumed institutional risk, number of subscribers or enrollees, service area). The Statement of Reasons, again, indicates these are intended to mean “a small portion” of financial risk, “minor market share”, and/or operate in “well-served areas”. But the proposed text gives no guidance on what would constitute triggers or threshold amounts for these variables. An entity assuming global risk would not be able to determine if it were crossing a triggering line for a “portion” of financial risk that would require seeking licensure or an exemption.	ACCEPTED IN PART. The Department appreciates the comment, and notes that it has clarified the exemption criteria in the revised proposed regulation, in subsection (b)(2). DECLINED IN PART. As stated in the proposed regulation, the Department will consider whether the exemption is in the public interest and not detrimental to the protection of subscribers, enrollees, or persons regulated under the Act. However, the Department cannot provide percentiles or numbers indicating how exemption factors are weighed. The Department must be able to consider the particular circumstances and information provided by the entity as part of the

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			<p>exemption request and give each factor individual weight depending on the entity's circumstances and region in which it operates.</p> <p>For example, the Department cannot say with certainty that an entity with only "X" percentage of market share will be granted an exemption because not only does the percentage of market share matter, but so too do the financial reserves of the entity, the number of other entities operating in the region, the financial state of the other entities in the region, and many other factors.</p> <p>Additionally, setting the percentile at which an exemption would be granted may incentivize entities to craft a business model which allows them to fall just below that limit. This would frustrate the intent of the exemption provision, which is to ensure that exemptions are only granted if they would not harm the public interest or be detrimental to subscribers or enrollees.</p> <p>Thus, the Department must be able to provide a case-by-case review of requests in order to ensure that the Department looks at the whole of a situation, and not just a number. To remove this would be to take away the Department's ability to perform a meaningful review of the entity. This would prevent the Department from fulfilling its legislative mandate of ensuring a stable health care marketplace and protecting the rights of enrollees to access medically necessary care.</p> <p>See response 1-9.</p>
4-43	Wendy Soe California Association of Health Plans	Third, the purpose of section (b) generally is not entirely clear. Section (b)(1) inappropriately equates "global risk" with receiving "advance or periodic consideration" and requires such person obtain a license. The requirement under Health and Safety Code §1349 is that a person that receives "advance or periodic consideration" on behalf of persons in this state needs to obtain a license. If a person doesn't receive "advance	ACCEPTED. The risk definitions in the revised proposed regulation now refer to a prepaid or periodic charge (subsection 1300.49(a)(1), (a)(2), and (a)(5)). See also response 4-25.

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		or periodic consideration”, which is the term used by California’s legislature and governor in enacting §1349, “advance or periodic consideration” can’t be redefined as something else and then used to require a person obtain a license. The Department’s Statement of Reasons does not include any evidence that the term “advance or periodic consideration” needs further clarity. This concern would be addressed with the above referenced revision to the definition of risk in section 1300.49(a)(6) to include “prepaid or periodic charge.”	
4-44	Wendy Soe California Association of Health Plans	We read section (b)(2) as allowing persons that accept such global risk to request an exemption from the requirement to obtain a license. While the proposed rule specifies the information persons are to provide to the Department to request an exemption, it offers no standards for the review of such information. The proposed rule should articulate the standards that the Department will use to evaluate the exemption.	ACCEPTED IN PART. The revised subsection 1300.49(b)(2) clarifies that Health and Safety Code section 1343 standards apply in reviewing an exemption request. See 4-42.
4-45	Wendy Soe California Association of Health Plans	Fourth, section (c) sets forth the requirements related to a restricted license. Included in this section is a Division of Financial Responsibility form. “Division of Financial Responsibility” is a term of art in the health plan industry and relates to a document that identifies the party that is at risk for various health care services. The proposed form does not do this and instead relates to which entity is responsible for providing services by provider type. We suggest that a different term be used for the Department’s form to avoid confusion, such as the “Division of Network Responsibility.”	ACCEPTED. The form is changed in the revised proposed regulation to the “Restricted Health Care Service Plan Responsibility Statement” (section 1300.49(c)(2)(C)).
4-46	Wendy Soe California Association of Health Plans	Full licensees typically remain responsible for network adequacy when contracting with a restricted licensee. In such instances, the form should not be required and the restricted licensee’s network would be reviewed as part of the full licensee’s network, which puts the restricted licensee in the same position as limited licensees and other providers that contract with a full licensee. This is also consistent with the requirements of Health and Safety Code section 1373.3 that allows an enrollee to select any primary care physician as long the primary care physician is within the full licensee’s service	DECLINED. The references to network adequacy requirements in subsection 1300.49(c)(3) may help ensure adequate access to services for which a restricted health care service plan is responsible. The Department agrees the network adequacy requirements only apply to those services for which the restricted health care service plan maintains responsibility, however it is important to highlight the network adequacy provisions of the Knox-Keene Act.

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		area where the enrollee lives or works. The references to the statutory and regulatory network requirements in subsection (c)(3) are unnecessary, and would only be applicable if the network responsibility is delegated to the restricted licensee and even then would not need to be specified in the proposed regulation, which does not reference specific Knox-Keene Act requirements for other services delegated to the restricted licensee.	
4-47	Wendy Soe California Association of Health Plans	Lastly, we offer some input on key terms defined in section (a). <ul style="list-style-type: none"> ● The term “person” is already defined in the Knox-Keene Act and do not need to be defined in these regulations. 	ACCEPTED. The revised proposed regulation does not include the “person” definition.
4-48	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> ● The term “restricted license” should be additionally defined to be clearly distinct from a full Knox Keene license. 	ACCEPTED. The revised proposed regulation includes a definition of “restricted health care service plan” (subsection 1300.49(a)(6)).
4-49	Wendy Soe California Association of Health Plans	<ul style="list-style-type: none"> ● The definition of “institutional risk” and “professional risk” should be defined as an assumption of “risk” and not assumption of the “cost of providing services”. The services specified in both proposed definitions should also be simplified and more accurately stated as “Medicare Part A services” (for Institutional) and “Medicare Part B services” (for Professional). The listed services in the proposed definition do not reflect current industry usage of the terms institutional services and professional services. <p>We appreciate the opportunity for comment and are available to you should you need any additional information.</p>	ACCEPTED. The revised proposed regulation clarifies the definitions of “institutional risk” and “professional risk” (subsections 1300.49(a)(2) and (a)(5)).