JONES DAY

COMMENTARY

NOVEMBER 2018

IN SHORT

The Situation: On October 8, 2018, California's Office of Administrative Law ("OAL") rejected a regulation that the Department of Managed Health Care ("DMHC") proposed. The regulation would require accountable care organizations ("ACOs") and other entities that assume financial risk for both professional and institutional services to obtain licensure as a health care service plan.

The Result: The DMHC's efforts to further regulate risk arrangements have been derailed—at least temporarily. The DMHC is widely expected to attempt to remedy the deficiencies that the OAL identified, and a modified form of the regulation should be forthcoming (perhaps as early as January 1, 2019). If so, there will be a brief additional comment period for the public to weigh in on the revised regulation.

Looking Ahead: While the DMHC is expected to clarify the regulation's description of the exemption process, we do not anticipate that it will revisit the regulation's sweeping scope. Accordingly, ACOs and other entities that currently consider themselves outside the reach of the Knox-Keene Act may be required to submit to DMHC jurisdiction or to abandon or restructure their risk-based arrangements.

On August 24, 2018, the DMHC submitted to the OAL a proposed regulation that defines "global risk" (financial risk for both institutional and professional risk) and requires entities that assume global risk either to obtain a "restricted" Knox-Keene license or seek the DMHC's exemption from the licensure requirement. By very broadly defining "global risk," the proposed regulation appears to require licensure for participation in many emerging shared-risk and other value-based payment arrangements, such as bundled payment, direct-to-employer, and other arrangements involving "downside" risk (*see* "California Closing in on Licensure Requirements for ACOs and Other Risk-Bearing Entities").

Moreover, because entities licensed under the regulation are able to take global risk from fully licensed health care service plans only, the proposed regulation potentially precludes health care providers from engaging in even limited shared-risk arrangements with self-funded plans. Further, the regulation may pose barriers to participation as an ACO under the Medicare Shared Savings Program. Although the proposed regulation contemplates an exemption process, the regulation's critics argued that the regulation provides no clear guidelines for determining the circumstances under which an exemption might be granted.

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The OAL agreed. In addition to determining that the DMHC did not obtain requisite sign-off from the California Department of Finance, the OAL rejected the DMHC's licensing regulation on the grounds that the regulation's "exemption" process language violated the California Administrative Procedure Act's "clarity" requirement.

Specifically, the OAL found that regulated entities would not know from the text of the regulation how to apply for an exemption from the new licensure requirement. However, the DMHC had signaled in its notice of rulemaking that it might afford relief to entities that assume only a "small portion" of global risk, possess a "minor market share," or operate in "well served areas." The OAL did not comment on or object to the regulation's broad definition of "global risk."

The DMHC now has 120 days to resubmit a revised version of the regulation to the OAL without a need for another full comment period. Assuming the DMHC will attempt to cure its deficiencies (as it has publically stated it will), there will be an additional, short (15-day) comment period for

the public to once again weigh in on the proposed regulation. The OAL's ruling provides another opportunity for interested parties to voice concerns and provides a brief reprieve for existing arrangements.

THREE KEY TAKEAWAYS

1. The original regulation's sweeping definition of "global risk" (as financial risk for both institutional and professional risk) is likely to be retained in the new version of the DMHC's regulation.
2. Depending on how the DMHC addresses the exemption process, Medicare Shared Savings Program participation, bundled payments, direct-to-employer, and similar arrangements that do not involve a licensed plan—but involve risk for professional and institutional services, no matter how limited—will effectively be prohibited by the proposed regulation.
3. Organizations that engage in risk-based and other value-based contracting arrangements should consider reviewing the terms of such arrangements in order to determine the extent to which they may be affected by the new regulation.


David T. Morris
San Francisco


Catherine A. Ehrgott
Los Angeles


Daniel A. Cody
San Francisco

Taylor A. Goodspeed, an associate in the San Francisco Office, assisted in the preparation of this Commentary.

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