New York Proposes Regulatory Overhaul for HealthCare Transactions with a Focus on Investor-Backed Healthcare Transactions

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Proposed legislation from the New York State Executive Budget for 2024 includes significant changes to the state's regulatory approach and authority over healthcare transactions. New York is following a trend on the state level regarding concern over the consolidation of the healthcare marketplace and investor-backed practices and how such transactions should be reviewed. Such proposal follows states like California, Oregon, and Washington. The proposal creates a new statutory article to review "material transactions" and has made changes to the certificate of need process for new and existing entities.

Review of "Material Transactions"

New York is proposing to introduce a new Article 45-A to its Public Health Law to provide review and oversight of "material transactions" (the Bill). The Legislature and Governor recognize that there are new models of health care delivery and have reviewed shifts in the delivery of care by ambulatory care centers and physician practices, noting that physician practices generally "are subject to far less regulation and oversight than hospitals...home care agencies...hospice providers...or providers of behavioral health services..."[1] As such, the intent of the Bill is to address the "proliferation of large physician practices being managed by entities that are investor-backed," noting that the State currently does not have oversight of the "sale, merger or acquisition of these providers, [and they] are not subject to any state change of ownership or control review, such that the state is not able to track or monitor the impact of these transactions on cost, quality, access, equity and competition."[2] New York State is now expressing a desire to review these transactions, like many other states, over what is perceived to be a potential for the "negative impact on patient care, health care costs, and ultimately access to services"[3] and to ensure that there are competitive health care markets focused on quality of care to patients.

The proposed Bill applies to "Health Care Entities," which it defines as including "a physician practice or management service organization or similar entity providing all or substantially all administrative or management services under contract with one or physician practice, provider-

sponsored organization, health insurance plan, or any other kind of health care facility, organization or plan providing health care services in this state; provided, however, that [it] shall not include an insurer...or a pharmacy benefit manager..."[4] The Bill proposes that Health Care Entities will be subject to review if they are engaged in the following defined "material transactions":

- a merger with a health entity;
- an acquisition of one or more health care entities;
- an affiliation or contract formed between a health care entity and another person; or
- the formation of a partnership, joint venture, accountable care organization, parent organization, or management services organization for the purposed of administering contracts with health plans, third-party administrators, pharmacy benefit managers, or health care providers as prescribed by the commissioner by regulation.

Material transactions specifically excludes that transactions already subject to review under Public Health Law Article 28, 30, 36, 40, 46, 46-A, or 46-B.

The proposed Bill directs the Department of Health (DOH) to adopt criteria for consideration of approval that should include factors including "the potential positive impacts...outweigh the potential negative impacts related to factors such as (i) patient costs; (ii) access to services; (iii) health equity; and (iv) health outcomes."[5] Additional factors would also focus on the "substantial likelihood of anticompetitive effects," the financial characteristics of the parties and the fairness of the transaction.[6]

If passed, parties engaging in a material transaction would have to obtain approval from DOH prior to closing the transaction and DOH would have to be notified at least 30 days prior to the proposed closing date. Notably, if DOH does not approve the transaction, discretion is given to DOH to refer "the transaction to the Attorney General, who may investigate as to whether there has been "unfair competition or anticompetitive behavior."[7]

Certificate of Need Changes

The Executive Budget also proposes a few changes to the certificate of need process including:

- Decreasing the review period for affiliations from ten to seven years;[8]
- Clarifying the types of affiliations that must be disclosed;[9]
- Clarifying the types of ownership transfers and changes that may proceed without full CON review;[10]
- Increasing application fees for construction projects;
- Clarifying that home health agencies do not need to submit the name and information for the "stockholders or members of third level or higher entities that will exercise no control of the agency functions."[11]

Going Forward

The Bill seeks to address what New York perceives as a gap in oversight in the otherwise heavily-regulated healthcare industry. While the Bill on material transactions does not cite to any data regarding the perceived risks, given New York's historic strong stance on the corporate practice of medicine and other regulatory oversight, we will continue to closely monitor the Bill and update our clients and readers in the event of additional oversight in New York for various healthcare transactions.

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[1] FY 2024 New York State Executive Budget, Health and Mental Hygiene Article VII Legislation, p.276-77, available at https://www.budget.ny.gov/pubs/archive/fy24/ex/artvii/hmh-bill.pdf.

[2] *Id*.

[3] *Id*.

[4] Id. at p. 278.

[5] Id. at p. 281.

[6] *Id.* at p. 281-82.

[7] Id. at p. 284.

[8] Id. at p. 262-63, amending N.Y. Pub. Health Law § 2801-a(3).

[9] *Id*.

[10] Id. at p. 263-68, amending N.Y. Pub. Health Law §§ 2801-a(4)(b)-(c), 3611-a(1)-(2), 4004(3)(b).

[11] Ia. at p. 287, amending N.Y. Pub. Health Law § 3611(2).

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