New York Seeks Review and Approval Authority over Certain Healthcare Transactions

March 7, 2023

Last month, Governor Kathleen Hochul released the proposed New York State Executive Budget for Fiscal Year 2024,[1] which contained, among other things, a proposal ("Article 45-A" or the "bill") that would provide review and approval powers to the State Department of Health ("DOH") over "material transactions" involving certain healthcare entities. While the operative provisions of Article 45-A do not single out private equity in particular, precatory language expresses concern that large investor-backed physician practices, as well as management service organizations ("MSOs") that support physician practices, (a) siphon business away from community hospitals and other safety net providers, weakening their financial sustainability, and (b) are increasingly concentrated, significantly contributing to healthcare cost inflation. The lead-in language also notes that the purported proliferation of investor-backed physician practices constitutes a significant change in healthcare delivery systems for which there is no existing regulatory machinery.

REVIEW AND APPROVAL OF MATERIAL TRANSACTIONS

As written, the bill would vest the DOH with review and approval authority over any "material transaction" closing on or after April 1, 2024, with few exceptions.[2] A "material transaction" is broadly defined to include any of the following:

- A merger with a healthcare entity;
- An acquisition of one or more healthcare entities, including but not limited to the assignment, sale or other conveyance of assets, voting securities, membership or partnership interest or the transfer of control;

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1 The full text of the State Executive Budget is available here.

2 Article 45-A currently excepts (1) clinical affiliation of healthcare entities formed for the purpose of collaborating on clinical trials or graduate medical education programs and (2) any transaction already subject to the Certificate of Need approval process or an insurance entity approval process.

- An affiliation or contract formed between a healthcare entity and another person; or

- The formation of an organization for the purpose of administering contracts with health plans, third-party administrators, pharmacy benefit managers or healthcare providers.

Application seems, at present, to be reasonably circumscribed: the definition of "healthcare entity" is focused on physician practices and MSOs (though the DOH may expand the scope through regulation) and specifically excludes insurers and pharmacy benefit managers. Forthcoming regulations will clarify the scope of what transactions may be subject to review: the DOH may opt to set additional limits to the definition, such as dollar thresholds; alternatively, it may choose to broaden the definition of "healthcare entity" to capture additional entity types.

Certain elements of the bill's proposed approval criteria are to some extent ambiguous. The DOH is instructed to focus on a host of factors when appraising a potential material transaction, including: (a) whether parties can demonstrate that the positive impacts of the transaction will outweigh its negative impacts; [3](b) whether there is a substantial likelihood of anticompetitive effects from the transaction that outweigh the benefits; (c) the financial condition of the parties; (d) the character and competence of the parties and their officers and directors; (e) the source of funds or assets for the transaction; and (f) *the fairness* of any exchange of shares, assets, cash or other consideration for the shares or assets to be received. It is not clear how the DOH would judge the fairness of the consideration paid in a transaction; including that as a factor may, too, be seen as a departure from the bill's stated goals of lowering cost, protecting quality and safeguarding competition.

The proposed bill will impact transaction timing, raises concerns regarding confidentiality and imposes certain additional costs on the transacting parties:

Timing

Parties to a "material transaction" must submit notice and an application for approval to the DOH at least thirty (30) days prior to closing. If the DOH takes no action during the 30-day period, the transaction is deemed approved. The DOH may withhold approval beyond the 30-day deadline in order to obtain additional information from any healthcare entity that is a party to the transaction and complete a more thorough analysis under the criteria listed above. Should the DOH undertake a more fulsome review, the bill does not currently impose limitations on the DOH's timeframe, actions

[3] To assess this first factor, the DOH will look at the following sub-factors: (i) patient costs; (ii) access to services; (iii) health equity; and (iv) health outcomes.

or scope of review. Failure to impose limiting regulations would likely result in transaction delays.

Confidentiality

In their initial application for approval, transacting parties must submit certain information to the DOH for review, some of which may be sensitive: (i) copies of any definitive agreements governing the terms, including pre- and post-closing conditions; (ii) the locations likely to be impacted by the transaction; (iii) any plans to reduce or eliminate services and/or participation in specific plan networks; (iv) the desired closing date and (v) a description of the nature and purpose of the transaction. The DOH is then required to encourage public comment and to make a public post containing a summary of the transaction with a description of the groups and individuals likely to be impacted, as well as information about the services currently provided and any commitments to continue or reduce such services. Because Article 45-A does not presently place any confidentiality constraints on the DOH,[4] the agency could potentially make public any or all of the information submitted by the parties, although unlike analogous statutes in certain other jurisdictions the DOH is not explicitly encouraged or required to make public all information submitted. However, should the DOH exercise its power to request additional information from the transacting healthcare entities, the bill requires parties to comply with such information requests and *explicitly prevents* the healthcare entity from refusing on confidentiality or privilege grounds. Additional rulemaking may be required to adequately protect the confidentiality of information submitted by transacting parties.

Costs

Article 45-A imposes multiple costs on transacting parties. Parties bear the initial cost of production for all documentation related to the approval application and must pay a non-refundable application fee. If outside consultants are utilized to analyze the transaction, transacting parties shall be financially responsible for the consultants' costs, without cap or reasonableness limit. As part of its approval power, the DOH can require the parties to a material transaction to undertake certain community reinvestments to offset the alleged negative effects of the deal, or to make contributions to the State's healthcare transformation fund. Additionally, parties that fail to comply with any requirements set forth under Article 45-A may be subject to penalties of up to $10,000 per day that a transaction is out of compliance.

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[4] The one constraint is that information submitted by the parties is not subject to the state's freedom of information law.

LOOKING AHEAD

New York is the latest in a string of states seeking to establish greater oversight and control over healthcare transactions, often with an explicit or implicit focus on private equity or investor-backed healthcare transactions—including California,[5] Massachusetts, Oregon and Washington. We provide a chart below comparing the major elements of each state's law. Article 45-A implements measures similar to New York's current "Certificate of Need" approval process,[6] and appears to apply to a narrow subset of healthcare entities (physician practices and MSOs), but nonetheless is poised to introduce a level of regulatory complexity and transaction costs that investor entities will need to consider.

Article 45-A requires the DOH to adopt regulations defining the relevant thresholds to determine whether a transaction is a "material transaction" subject to review, including but not limited to changes in revenue. The DOH may also further circumscribe affected healthcare entities, create criteria for the consideration of requests of healthcare entities to consummate a material transaction, and promulgate other rules and regulations as necessary to implement the bill. Given the DOH's limited time and resources, further narrowing the scope of its review would allow regulators to both counteract certain unintended consequences of the bill as well as focus on transactions that are most likely to impact healthcare costs, access to services, health equity and health outcomes. With the April 1, 2023, deadline to approve the State Budget quickly approaching, Article 45-A is sure to receive pushback from industry stakeholders seeking amendments to the bill and appropriate regulations.

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We will continue to monitor the status of this proposal and other similar state legislative developments. Please do not hesitate to contact us with any questions.

	New York	California	Massachusetts	Oregon	Washington
Agency	DOH	Office of Health Care Affordability ("OHCA")	Massachusetts Health Policy Commission ("HPC")	Oregon Health Authority ("OHA")	Attorney General
Authority	Approval	Review	Review	Approval	Review
Effective Date	April 1, 2024	April 1, 2024	November 5, 2012	March 1, 2022	January 1, 2020

[5] We recently discussed the California Health Care Quality and Affordability Act ("SB 184"), which was similarly enacted as part of a California budget bill. For a discussion on the implications of SB 184, see our Debevoise Update here.

[6] Applicable to hospitals, home healthcare and other state-licensed providers.

	New York	California	Massachusetts	Oregon	Washington
Entities Affected	Physician practices, MSOs, and similar entities, excluding insurers or pharmacy benefit managers; scope to be further defined by regulation	Payers, providers, and fully integrated delivery systems; scope to be further defined by regulation	Providers and provider organizations	Healthcare professionals, hospitals, carriers, coordinated care organizations, managed care organizations, etc.; excludes long-term care facilities	Hospitals and provider organizations
Materiality Threshold	To be defined by regulation	To be defined by regulation	$25M+ net Massachusetts patient revenue	One party, $25M+ annual revenue; second party, $10M+ annual revenue (not limited to assets and operations in Oregon)	No threshold if both parties are in state; if one or both parties are out of state, $10M+ net Washington patient revenue
Timing of Notice	30 days before closing	90 days before "entering" a transaction; unclear whether such term refers to signing or closing	60 days before closing	180 days before closing	60 days before closing
Review Period	30 days; however, DOH's request for and review of any additional information is not subject to a set timeframe	60 days; however, OHCA's request for and review of any additional information is not subject to a set timeframe	30 days; if HPC elects to conduct a market impact review, such review is not subject to a set timeframe	30 days; any comprehensive review shall be completed within the 180-day notice period, subject to defined tolling and extension periods	60 days; the Attorney General may request additional information within 30 days
Review / Approval Criteria	Competition concerns; relative weight of positive and negative impacts of the transaction; parties' financial condition; parties' character and competence; source of consideration	Size and market share; relative market position; relative prices; cost; quality; equity; access; benefits to consumers; other factors OHCA determines to be in the public interest	Size and market share; relative prices; cost; quality; benefit to individuals with substance use disorder and mental health conditions; providers' health status-adjusted total medical expense; other	Competition concerns; legality; parties' financial condition; cost; equity; access; benefits to underserved populations; consumer and public interest; health outcomes	Antitrust and competition concerns; consumer harm in healthcare markets

	New York	California	Massachusetts	Oregon	Washington
			factors HPC determines to be in the public interest		
Confidentiality	The transaction summary prepared by DOH shall be made public; no explicit requirement to keep nonpublic information confidential	Nonpublic information may be disclosed if deemed to be in the public interest; parties may request confidential treatment	The notice itself shall be a public record; nonpublic information shall be kept confidential and shall not be disclosed without the parties' express consent	The notice itself shall be a public record; nonpublic information shall be kept confidential	Nonpublic information shall be kept confidential and shall not be disclosed without the parties' express consent, subject to certain exceptions
Costs	All reasonable costs (uncapped); $10,000/day penalty for non-compliance	All reasonable costs (uncapped)	Funded by appropriations	Costs shall be proportionate to the size of the parties; capped at $100,000	$200/day penalty for non-compliance

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