ROPES & GRAY

ALERT

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New York Seeks New Regulatory Review of Health Care Transactions with Private Equity Investment

On Wednesday, February 1, 2023, Governor Kathy Hochul released the New York State ("NYS" or the "State") executive budget for State Fiscal Year ("SFY") 2023–24. Embedded within the executive budget at Part L of the Health and Mental Hygiene Article VII draft legislation is a proposal that would significantly reshape the health care investment landscape in New York by giving the State Department of Health ("DOH") new authority to review and approve certain "material transactions" taking place in the State. If enacted, this bill would add a new Article 45-A to the New York Public Health Law subjecting health care transactions involving private equity and investor-backed entities to a largely undefined regulatory review process by DOH that could result in transaction closing delays, unwanted publicity, new structural considerations, and increased costs. Coming on the heels of similar legislative efforts in certain West Coast states, this proposal should be front and center in the minds of all health care investors that are doing business or that may want to do business in New York.

A detailed description of this proposal and what it would mean to health care transactions in New York, especially those involving private equity and venture-capital-funded entities, is provided below.

Purpose of the Material Transaction Review Proposal

In its discussion of legislative intent, the executive gives insight into the reasons for proposing this new review process. Specifically, New York has found that investor-backed entities have assumed characteristics associated with licensed clinics that are subject to the Certificate of Need ("CON") process under Article 28 of the New York Public Health Law. However, these entities, which are largely structured as private professional practice entities, remain otherwise "unregulated by the state outside of licensure of the individual practitioners who practice at these sites and enrollment in Medicaid."

Given this perceived lack of meaningful oversight that would be afforded by the CON process, the State seeks to review transactions that involve a "change of control, by virtue of a sale, merger, or acquisition of these providers" but are not already subject to existing regulatory review and approval processes, such as those under the CON process or state insurance approvals. This new review would then focus on any potential impact of a proposed transaction on "cost, quality, access, equity, and competition" within the New York health care ecosystem.

As context, the transaction review and approval construct proposed by New York in effectuating this review is very similar to laws recently enacted in Washington, Oregon, and California. A comparison of these laws reflects this similarity:

	Washington	Oregon	California	New York
Timing	60 days; Attorney General can request more information within 30 days of initial filing	0–180 days	90 days' prior notice (unclear if pre-signing or closing)	30-day pre-closing
Covered Entities	Health care entities (e.g., hospitals, hospital systems, provider organizations)	Must involve a health care entity	Health care entities (e.g., payor, provider, or fully integrated delivery system)	Health care entities, but the full list of health care entities will be defined in regulation
Covered Transactions	Mergers and acquisitions ("M&A"); contracting affiliations that allow entities to negotiate rates with payors	M&A; managed services organizations ("MSOs") that impact access to essential services	M&A	M&A and most forms of change-in-control transactions but not clinical affiliations
Materiality Thresholds	If one entity is not licensed in WA, they must generate $10M in revenue from WA patients	One entity >= $25 million/year in revenue (all states + OR) One entity >= $10 million/year in revenue (all states + OR)	"Material change" to ownership, operations, or governance structure	To be defined in regulation

Review Process

Definition of Material Transactions. As currently written, the bill would grant DOH broad authority to *review and approve* material transactions. The review process would include assessment of the transaction's impact on cost, quality of care, access to care, health equity, and competition in health care service markets. NYS's new law defines "material transactions" as follows:

1. A merger with a health care entity;

2. An acquisition of one or more health care 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;

3. An affiliation or contract formed between a health care entity and another person; or

4. The formation of a partnership, joint venture, accountable care organization, parent organization, or management services organization for the purpose of administering contracts with health plans, third-party administrators, pharmacy benefit managers, or health care providers.

Exclusions to Review. The bill further states that material transactions shall not include clinical affiliation of health care entities formed with the intent to facilitate collaboration between the entities. Additionally, any transactions already subject to the CON process or an insurance entity approval process under the New York Public Health or Insurance Laws would not be impacted, largely leaving these existing approval processes intact.

Application and Approval. Notably, if adopted, the law would allow DOH to expand or modify the definition of material transactions as part of forthcoming regulations, which does not define a materiality threshold in the form of a dollar amount. Moreover, as part of the review process, a covered health care entity would be required to submit a notice and

application thirty (30) days prior to the closing date of the transaction, which aligns with typical Hart-Scott-Rodino ("HSR") filing timeframes, but includes the following elements (all of which could be made public):

1. Provide copies of definitive agreements;
2. Identify locations impacted by the transaction;
3. Describe plans to reduce or eliminate services or plan participation;
4. Describe the purpose for the transaction;
5. Conduct a market impact analysis on cost, quality, access, equity, and competition; and
6. Discus any commitments made in connection with the transaction on service expansion or on health equity.

Following submission, DOH would operate consistently with a typical "no action" process such that it would need to notify parties of whether it requires more information or else the transaction is approved as soon as the 30-day review period elapses. If DOH requests additional information during the 30-day period, which could be informed by public comment, then DOH would be able to take more formal action on the application, which could include an approval, a rejection, a referral to the New York Attorney General due to competition concerns, or approval with "conditions" or "undertakings" that could require community reinvestments, contributions to the State's health care transformation fund, or other actions. To the extent DOH elects to conduct this more fulsome review, the proposal does not impose a specific timeline in issuing an approval, an approval with conditions, a rejection, or referral.

Consequences of Non-Compliance

To ensure that penalties for non-compliance ensure adherence, the proposed law would grant DOH the power to impose a civil penalty of up to ten thousand dollars ($10,000) for each day that a transaction is out of compliance. This penalty presumably extends in perpetuity until and unless an application is filed. Moreover, the bill would similarly enable DOH to pursue an injunction against the closing of a material transaction if the application process was not followed.

Impact of the Proposal

At the present moment, the bill simply reflects the executive's desire to impose this new approval process on material transactions, but the proposed law has yet to be enacted. This proposal will be debated as part of the three-way budget negotiation process with the New York State Legislature, such that any final adoption will require legislative consent that the proposed transaction review process is needed and in the best interests of the State. Given the inherent uncertainty of the State budget process, the proposal of this review process by the executive does not guarantee its eventual adoption.

That said, if this proposal is enacted into law, New York would join a growing list of states—including Washington, Oregon, and California—that have recently enacted *new* review processes of material health care transactions. Much like these other states, New York's proposal is a reflection that existing state approval processes often do not give regulators appropriate insight into private capital transactions and that the impact of these transactions on the health care delivery systems is far from understood. At a minimum, this law would subject private equity, venture capital, and other health care investors to new levels of transparency and potential scrutiny such that transactions (especially in the clinical practice management space)—both in terms of buyouts and roll-ups of physician, dental, and other clinical practices—may become more complicated, time intensive and expensive to close. Moreover, the 30-day "no action" process contemplated for transactions that are not singled out by DOH for additional review would effectively preclude a simultaneous sign and close, which would be a significant change for any transaction that might trigger the material transaction threshold in New York but not for HSR filing requirements.

Finally, the law would also allow the State to extract new monetary investments and value out of transactions submitted for review. By highlighting the potential for community reinvestment and contributions to the state transformation fund, the State is indicating that it would seek financial contributions to underfunded parts of the delivery system, which would be a direct response to the perceived negative impact from these material transactions.

Implications for Clients

Until the law is enacted, this bill should be something to watch closely during the budget negotiation period. Further, even if the bill is enacted in the final budget, the regulatory rulemaking will become incredibly important, given that the threshold for materiality of transactions that would be subject to review is not expressly defined in the statute. To that end, there is much to be determined in the coming weeks, but investors and venture-backed health care companies should monitor this proposal closely based on its potential to have a significant impact on the current investment landscape in New York.