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New York Proposes Regulatory Review and Approval of Material Health Care Entity Transactions

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On February 1, 2023, New York Governor Kathy Hochul announced the Fiscal Year 2024 New York State Executive Budget (the Executive Budget). One component of the Executive Budget's Health and Mental Hygiene Article VII Legislation is a proposal to require certain "health care entities" to obtain approval from the New York State Department of Health (DOH) prior to consummating a material transaction, as defined below. If passed, New York will join Connecticut, Delaware, Massachusetts, Nevada, New Jersey, Oregon, Rhode Island, Washington, and most recently California in implementing measures towards health care cost containment and market oversight. While this legislative trend in other states seems to be motivated in part by concerns surrounding private equity investment in health care, New York's proposed legislation specifically identifies these concerns as a primary motivation. The legislative purpose and intent notes that the DOH regulates physician practices far less than other providers, such as hospitals, hospice providers, behavioral health services providers, and managed care organizations. Though these physician practices are managed by "investor-backed entities" that "increasingly take on the characteristics associated with diagnostic and treatment centers," the bill laments that the regulation of these entities stops at their individual practitioners. DOH would utilize the proposed review and approval process to assess the transactions' potential impact on "cost, quality, access, health equity and competition" in the health care system. If enacted, this legislation would add Article 45-A to the New York Public Health Law and impact all material transactions set to close on or after April 1, 2024.

Definition of Health Care Entities & Material Transactions

A full list of entities that would be subject to the new law will be established by regulation, but based on the proposed statutory definition of "health care entity", we know that it would include physician practices and management services organizations (MSOs). The definition also encompasses entities that provide, under contract, "all or substantially all" administrative or management services to physician practices, health insurance plans, or any other kind of health care facilities, plans, or organizations that provide health services in New York. As a result, entities that provide administrative services that have largely avoided pre-transaction scrutiny in the past could have

material transactions blocked by DOH.

A transaction would be considered “material” if any of the below occur, whether in a single transaction or through a series of related transactions, that meet or exceed certain thresholds (that would be specified in DOH regulations):

- a merger with a health care entity;
- 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 (which is presumed if any person directly, or indirectly owns, controls, or holds with the power to vote 10% or more of the voting securities of a health care entity);
- 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 service organization for the purpose of administering contracts with health plans, third-party administrators, pharmacy benefit managers, or health care providers.

A material transaction does not include clinical affiliations of health care entities that are formed for clinical trial collaboration or graduate medical education programs. The definition also explicitly excludes transactions that are required to undergo the Certificate of Need (CON) process or the insurance entity approval process under New York insurance law.

Notification and Approval Process

Under this proposed law, a health care entity would be required to submit to DOH a written notice and application at least thirty days before the desired closing date of the proposed transaction. The written notice must include:

- the names of the parties to the transaction and their current addresses;
- copies of any definitive agreements governing the terms of the material transaction, including pre- and post-closing conditions;
- identification of all locations where each party provides health care services and the revenue generated in the state from such locations;
- any plans to reduce or eliminate services and/or participation in specific plan networks;
- the desired closing date; and
- a brief description of the nature and purpose of the proposed transaction.

When reviewing the proposed transaction, DOH would consider several factors (Review Factors), such as:

- if positive potential impacts of the transaction outweigh potential negative impacts;
- if there are any potential anticompetitive effects of the transaction;
- the parties' financial conditions;
- the character and competence of the parties, their officers, and their directors;
- the source of funds or assets involved in the transaction; and
- the fairness of the exchange.

In the event the proposed notice and application process moves forward, the Review Factors offer a roadmap of the scope of DOH review that parties should be thinking about in developing transaction structures and drafting agreements. These factors can serve as a helpful tool for parties as they evaluate and develop pro formas and analyses for a transaction. This could put them a step ahead in their health care transactions should the legislation go forward.

After the initial notice and application is submitted, DOH is permitted to request additional information from the parties, retain actuaries and accountants (at the expense of the parties), and seek public input to fully assess the transaction. If DOH decides to disapprove the transaction, it must notify the parties within 30 days. DOH is also empowered to grant approval of the transaction subject to certain conditions, which can include, but are not limited to, requiring investment in communities that the transaction affects, implementing competition protections, or requiring contributions to state-controlled funds, such as the health care transformation fund. If DOH disapproves or approves the transaction subject to certain conditions, DOH can notify the New York State Attorney General's Office (Attorney General). The Attorney General can conduct an investigation to determine if the parties have engaged in unfair competition or anti-competitive behaviors.

If the DOH does not engage in the above-discussed behavior, the transaction is approved upon expiration of the 30-day period. The parties must also provide DOH with notice upon closing of the transaction.

Extended DOH Review

During the 30-day review period, DOH will be required to provide public notice of the proposed transaction for public comment, which, at minimum, will require:

- a summary of the proposed transaction;
- an explanation of the groups or individuals likely to be impacted by the transaction;
- information about the services currently provided by the health care entity, commitments by the health care entity to continue such services and any services that will be reduced or eliminated; and
- details about how to submit comments.

DOH may determine to conduct a thorough examination of the transaction that extends past the 30-day period. The examination could include requests for additional information and other actions to seek public input and engage the public before making its determination. The implications of public notice will require thoughtful planning for the parties. For example, the parties need to determine if they will sign definitive agreements in advance or hold off pending DOH review. It is not clear in the proposal if DOH will require signed agreements or if it will accept pencils-down versions, creating uncertainty for parties. If the parties sign in advance, definitive agreements should include not only the customary covenants for "sign with delayed closing" deals, but also several covenants specific to the DOH review. The definitive agreements should address the parties' obligations to cooperate and assist with responding to questions and follow-up during the DOH review. Relatedly, parties should include a process for evaluating any conditions that DOH may impose on its approval, and how to resolve disagreements regarding how and whether to accept the conditions. The public notice also adds a layer of considerations with respect to notifying employees, vendors, suppliers, and other third parties who may be impacted by the proposed transaction.

Increased Costs

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 health care 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.

Enforcement

If passed, the proposed law will enable the DOH to impose a civil penalty of up to ten thousand dollars ($10,000) for each day that a transaction is out of compliance (seemingly, until the required application is filed). The legislation does not specify whether DOH would impose the penalty on both parties. The DOH will also have the authority to pursue an injunction against the closing of a material transaction if the applicant did not correctly follow the application process.

Future Implications

It is unclear whether the bill will pass, but it does signal the DOH's increasing concern regarding the implications of unlicensed individuals' involvement in the provision of health care. This could result in additional scrutiny of manager relationships with health care providers through current enforcement mechanisms, regardless of whether the proposed law is enacted. For example, there may be increased DOH review of MSO relationships with physicians for corporate practice of medicine (CPOM) violations. As a result, MSOs should revisit arrangements with clinical providers to confirm the manager's responsibilities do not run afoul of New York's CPOM prohibitions, which are established by a combination of statutes, regulations, case law, and Attorney General and licensing board opinions.

The proposed legislation states that certain investor-backed entities bear resemblance to "diagnostic and treatment centers under article 28 of this chapter." These centers are required to consult DOH's Policy on Development of Service Contracts for Article 28 Facilities to confirm the manager's responsibilities are appropriate. Although this guidance is for agreements submitted as part of a CON application for an article 28 facility, it provides insight into the powers that need to remain with the established operator of the facility and includes a comprehensive list of actions that cannot be delegated to another party. These actions should be specified as reserved to the established

operator in the management agreement and operating agreement. If this legislation is enacted, private equity, venture capital, and other health care investors should:

- review potential increased transaction costs and update budgets accordingly;
- take the Review Factors into account when developing pro forma reports and analyses for transactions;
- adjust deal timelines to accommodate for the new review and approval process (simultaneous sign and close will not be an option for material transactions);
- update due diligence lists and processes to identify issues that could result in disapproval;
- prepare a notice and application checklist to ensure compliance with New York requirements;
- conduct a thorough review of materials that will submitted with the application for health care regulatory compliance; and
- consult counsel in order to be prepared for new levels of transparency and potential scrutiny that results from the review process.

We will continue to monitor and report on this proposal and other state legislative efforts geared at broadening the scope of government review of health care transactions as part of health care cost containment measures.

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