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Susan M. Flanagan-Cahill
Deputy General Counsel
Massachusetts Health Policy Commission
50 Milk Street, 8th Floor
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Submitted via email to: hpc-testimony@mass.gov

Re: Written Comments on Proposed Amended Regulations – 958 CMR 6.00 (Registration of Provider Organizations) and 958 CMR 7.00 (Notices of Material Change and Cost and Market Impact Reviews)

Dear Deputy General Counsel Flanagan-Cahill:

Dana-Farber Cancer Institute ("**Dana-Farber**") respectfully submits these written comments in response to the Massachusetts Health Policy Commission's (the "**Commission**") proposed amendments to 958 CMR 6.00 (Registration of Provider Organizations) and 958 CMR 7.00 (Notices of Material Change and Cost and Market Impact Reviews) (together, the "**Proposed Regulations**"). Dana-Farber is a leading Massachusetts non-profit cancer care and research institution and a Registered Provider Organization under 958 CMR 6.00. Dana-Farber pursues its mission to provide expert, compassionate care to patients with cancer while advancing the understanding, diagnosis, treatment, cure, and prevention of cancer and related diseases through the dedicated efforts of clinicians, researchers, and staff who serve patients from across Massachusetts, New England, and beyond.

Dana-Farber acknowledges the Commission's expanded authority under Chapter 343 of the Acts of 2024 and recognizes the legitimate policy goals underlying the Proposed Regulations. The Commission's heightened oversight of private equity and for-profit actors in the health care market — particularly in the wake of the Steward Health Care bankruptcy and its profound impact on patient access and care delivery across the Commonwealth — reflects an appropriate and necessary policy response.

However, Dana-Farber is concerned that the Proposed Regulations substantially exceed the scope of Chapter 343, imposing significant regulatory burden and uncertainty on non-profit, mission-driven institutions that were not the source of the market failures the Act was designed to remedy. As a

universal comment, and as detailed further below, several provisions in the Proposed Regulations employ open-ended "including, but not limited to" formulations that leave regulated entities unable to determine with reasonable certainty what transactions and operational changes require advance filing. Others extend the Commission's jurisdiction in ways that may lack express statutory authorization and that will, in practice, chill beneficial arrangements essential to patient access.

Dana-Farber's overarching recommendation is that the Commission adopt a differentiated regulatory framework to apply heightened requirements primarily to for-profit and private equity-backed entities and replace open-ended catchall formulations with specific, defined trigger lists in its regulations. Such an approach would better serve the purposes of Chapter 343 while avoiding unnecessary regulatory burden on non-profit institutions that are central to the Commonwealth's health care system.

I. Expanded Triggers for Filing a Notice of Material Change

A. The $10 Million Revenue Increase Threshold Is Too Low

The $10 million revenue increase threshold for expansions in capacity will trigger meaningless and burdensome reporting. It is far too low and must be raised substantially. For many providers, including Dana-Farber, $10 million in incremental revenue can result from routine service expansions, such as extending weekend clinic hours or opening an additional infusion suite, that have no meaningful market impact. The new increase threshold is also inconsistent with the established MCN filing threshold, set at $25 million. Dana-Farber recommends that the Commission raise this threshold substantially.

B. "Including but not limited to" Creates Uncertainty in Section 7.03(1)(f) — Increases in Capacity

The open-ended catchall in Section 7.03(1)(f) leaves regulated entities unable to determine with reasonable certainty what operational changes require a MCN filing. This uncertainty impairs operational planning and creates a chilling effect on beneficial service expansions. Such uncertainty could weigh equally on the Commission as well, as a lack of clear standards might result in a deluge of MCN filings, thereby impairing the Commission's ability to provide timely and appropriate responses to regulated entities. Dana-Farber respectfully recommends that the Commission replace this formulation with an exhaustive list of triggering events, providing regulated entities with clear, administrable standards.

C. Emergency DoN Applications Must Be Expressly Excluded

Section 7.03(1)(f)(i) explicitly captures "Emergency" Department of Public Health Determination of Need ("**DoN**") applications within the MCN trigger. Combined with the concurrent filing requirement in Section 7.04(1), this provision effectively eliminates the utility of the Emergency DoN pathway — the very mechanism designed for time-sensitive, patient-critical capital projects, such as the emergency replacement of oncology equipment. For a cancer center, delays in such projects can negatively impact care continuity and could result in delays that could impact clinical outcomes.

Dana-Farber recommends that the Commission expressly exclude Emergency DoN filings from the MCN requirements. Any appropriate oversight of emergency-designated capital projects is already regulated by the Department of Public Health and can further occur through post-transaction review under Section 7.15, not through pre-transaction delay that undermines the purpose of the Emergency

DoN pathway. The fallout from the Steward Health Care bankruptcy itself demonstrates the importance of preserving a flexible, time-sensitive emergency pathway to ensure health care entities can promptly take action to ensure adequate access and the safety and well-being of patients.

II. Section 7.03(1)(h) — Asset Sales and Transfers

The "including, but not limited to" formulation in Section 7.03(1)(h) renders this provision overbroad, potentially capturing routine inter-affiliate transfers and non-clinical asset dispositions far beyond the real estate lease-back arrangements that appear to have motivated Chapter 343. Applying MCN requirements to such ordinary-course transactions imposes administrative burdens disproportionate to any market impact and diverts institutional resources from patient care.

Dana-Farber recommends that the Commission limit the scope of this provision to transactions with for-profit or private equity-backed entities and replace the open-ended language with a defined and exhaustive list of covered transaction types that reflects the actual harms Chapter 343 was designed to address.

III. Sections 7.03(1)(c) and (e) — Out-of-State Entity Affiliations

Sections 7.03(1)(c)(i)(2) and (c)(ii) extend MCN requirements to affiliations with out-of-state entities, raising concerns with overbreadth.

Regulatory authority over out of state affiliations appears overbroad based on the statutory authority provided by Chapter 343. Out-of-state patients are excluded from the Commission's need assessments and market analyses, yet affiliations with out-of-state providers that serve those patients would nonetheless require MCN review. This asymmetry lacks clear policy rationale. Such authority may also have a chilling effect on important clinical affiliations. For example, for a specialized cancer center like Dana-Farber, regional affiliations with out-of-state community hospitals are essential to ensure patient access. As cancer incidence rates continue to increase, relationships with out-of-state community providers will be key to ensure patients in New England and beyond are able to access the latest and most effective evidence-based practices and standards in cancer treatment and research. Mandatory MCN review of these affiliations will deter beneficial partnerships without corresponding benefit to the Commonwealth's health care market.

Dana-Farber recommends that the Commission at minimum limit out-of-state MCN requirements to affiliations with for-profit or private equity-backed entities.

IV. Section 7.03(1)(d) — Clinical Affiliations: Co-Branding

The definition of "Clinical Affiliation" in Section 7.03 includes co-branding as a standalone trigger for MCN filing obligations. A co-branding or name-licensing arrangement that involves no operational, financial, or governance integration should not require a formal MCN filing. Such arrangements do not present the market concentration risks that the MCN process is designed to evaluate and subjecting them to full MCN review imposes costs and delays with no corresponding oversight benefit.

Section 7.04(1) — Concurrent DoN/MCN Filing Requirement

Requiring simultaneous MCN and DoN filings is operationally impracticable where project scope, planning timelines, or emergency designation makes concurrent readiness impossible. Institutions undertaking complex capital projects frequently do not have the information required for a complete MCN filing at the time a DoN application is submitted — and emergency-designated projects, by definition and as discussed above, cannot await the preparation of a comprehensive MCN package.

Dana-Farber recommends that the Commission allow sequential filing where concurrent submission is impracticable and expressly exclude Emergency DoN applications from the concurrent filing requirement.

V. Section 7.06 — CMIR Factors

The 15-factor Cost and Market Impact Review ("**CMIR**") list — capped by the open-ended catch-all in Section 7.06(15) authorizing consideration of "any other factors the Commission determines to be in the public interest" — provides insufficient predictability for regulated entities evaluating their MCN exposure. Without clearer guidance on factor weighting and the evidentiary standard for a referral to the Attorney General, regulated entities cannot meaningfully assess their regulatory risk or plan transactions accordingly.

Dana-Farber recommends that the Commission issue guidance explaining factor weighting and the evidentiary standard applicable to Attorney General referrals, and narrow Section 7.06(15) to factors consistent with the purposes of Chapter 343.

VI. 958 CMR 6.00 — Registration: "Uppermost Corporate Parent" and "Control"

<u>Uppermost Corporate Parent (Sections 6.02 and 6.03(2))</u>

Requiring registration and reporting at the level of the "Uppermost Corporate Parent" may sweep in non-profit holding entities and affiliated foundations with no direct patient care operations, extending well beyond prior practice and likely beyond Chapter 343's intent. Non-profit health systems frequently include entities that provide financial, philanthropic, or administrative support but have no meaningful role in the provision of patient care or the transactions the regulations are designed to monitor.

Dana-Farber recommends that the Commission provide clear guidance on the application of the "Uppermost Corporate Parent" definition to non-profit organizational structures.

<u>"Control" at 10% (Sections 6.02 and 7.02)</u>

Deeming control to exist at 10% of voting securities is far below standard corporate law norms and may inadvertently capture minority investment relationships and non-controlling governance arrangements that are common in non-profit health systems — including relationships arising from charitable gifts, philanthropic partnerships, and research collaborations. This threshold risks sweeping in arrangements that bear no resemblance to the kind of controlling private equity investment that Chapter 343 targeted.

Dana-Farber recommends that the Commission clarify the intended application of this definition to non-profit structures and confirm expressly that standard charitable and philanthropic relationships are not captured.

VII. Conclusion

Dana-Farber greatly appreciates this opportunity to review and comment, and respectfully urges the Commission to adopt the modifications prior to finalizing the Proposed Regulations as provided above.

Taken together, these recommendations would produce a regulatory framework that is better calibrated to the purposes of Chapter 343 — focusing the most burdensome requirements on the for-profit and private equity actors that the Act was designed to address, while preserving the ability of non-profit, mission-driven institutions like Dana-Farber to continue serving patients efficiently and without unnecessary regulatory delay.

Please do not hesitate to contact us if we can provide any additional information.

Respectfully submitted,

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