# Massachusetts: New Year, New Law — Governor Signs "An Act enhancing the market review process" (House Bill No. 5159)

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On January 8, 2025, Governor Maura Healey signed into law <u>H.B. 5159</u>, "an Act enhancing the market review process." This new law promises sweeping reform to reshape how health care businesses operate and grow. With stricter oversight, expanded reporting obligations, and new licensing requirements, the legislation signals an uptick in regulatory oversight of health care transactions and operations in Massachusetts. These changes have wide-ranging implications for stakeholders across the health care space. Many provisions of the new law will become effective once the applicable agencies issue implementing regulations. This is an expansive set of statutory changes, and this blog highlights only a few of the material provisions. Foley will provide several issue-specific analyses in the coming weeks, including implications for investors.

Here is what stakeholders need to know — and how to prepare.

### **Key Changes at a Glance**

Increased Oversight of Health Care Transactions: The Massachusetts Attorney General, the Health Policy Commission (HPC), and the Center for Health Information and Analysis (CHIA), have greater authority to scrutinize mergers, acquisitions, and other significant market changes. The HPC will now have oversight over a number of other actors and activities in the local market, including private equity players, sale/leaseback transactions.

**New Licensing Categories:** Office-based surgical centers and urgent care centers face stricter licensing requirements. Implementing regulations must be issued by October 1, 2025.

Massachusetts False Claims Act: Imposes liability on owners and investors that know about and fail to disclose violations of the Massachusetts False Claims Act.

**Required Assessments from Health Care Entities:** Non-hospital provider organizations, pharmaceutical manufacturing companies and pharmacy benefit managers are now

required to pay estimated expenses of the HPC (in addition to acute hospitals and ambulatory surgical centers).

**Expanded Reporting Obligations:** Requirements to include additional information regarding private equity (PE) investors, management services organizations (MSOs) relationships, and real estate leaseback arrangements in 2025 Provider Organization Registration Program renewals and registrations to enhance market transparency throughout the Commonwealth.

Office for Health Resource Planning: A new office will be established within the HPC to develop a state health resource plan. The office will be tasked with studying many aspects of the sector, including "health care resources", which are expansively defined to include "any resource, whether personal or institutional in nature and whether owned or operated by any person, the commonwealth or political subdivision thereof, the principal purpose of which is to provide, or facilitate the provision of, services for the prevention, detection, diagnosis or treatment of those physical and mental conditions, which usually are the result of, or result in, disease, injury, deformity or pain; provided, however, that the term "treatment", as used in this definition, shall include custodial and rehabilitative care incident to infirmity, developmental disability or old age."

**Expanding Studies on Health Care:** Establishes a primary care task force to address access, provider, and payment issues in the primary care setting that shall issue its first report to legislature by September 15, 2025, and expands the scope of CHIA's functions.

Prohibitions on Hospitals Leasing its Main Campus from a real estate investment trust ("REIT"). This exempts hospitals that had a main campus/REIT arrangement prior to April 1, 2024.

These sections reflect the legislature's efforts to balance the changing landscape of health care and consumer protection, but they also create challenges for businesses navigating this complex regulatory environment.

## **HPC's Expanded Role in Oversight Measures**

For the past decade, the HPC has overseen health care transactions in the Commonwealth through the Notice of Material Change process. "Providers" or "Provider Organizations" (including organizations in the business of health care management) that plan to undergo "Material Changes" to their operations or governance structure must submit notice to the HPC 60 days prior to closing. "Material Changes" include:

A Provider or Provider Organization entering into a merger or affiliation, or acquisition of, by, or with a carrier or involving a hospital or hospital system;

Any other acquisition, merger, or affiliation of, by, or with another Provider or Provider Organization that would result in:

- an increase in annual Net Patient Services Revenue of the Provider or Provider
  Organization of US\$10 million dollars or more, or
- the Provider or Provider Organization having a near-majority of market share in a given service or region.

A clinical affiliation between two or more Providers or Provider Organizations that each had annual Net Patient Service Revenue of US\$25 million or more in the preceding fiscal year; or

Creating an organization to administer contracts with carriers or third-party administrators or perform current or future contracting on behalf of one or more Providers or Provider Organizations.

Upon receipt of a completed notice to the HPC, the HPC is required, within 30 days, to conduct a preliminary review to ascertain whether the Material Change may result in a "significant impact" on the Commonwealth's health care cost growth benchmark goals, or on the competitive market. If the HPC determines that there will be a significant impact by the Material Change on the health care cost growth benchmark, or on the market, the HPC may initiate a cost and market impact review.

The new law expands the scope of regulated transaction by revising "Materials Changes" to also include:

Significant expansions in provider or provider organization's capacity;

Transactions that involve a significant equity investor, which result in a change of ownership or control of a Provider or Provider Organization;

Significant acquisitions, sales, or transfers of assets including, but not limited to, real estate sale lease-back arrangements; and

Conversion of a Provider or Provider Organization from a non-profit entity to a for-profit entity.

While the new law has not set thresholds for these new categories, we expect additional clarity in forthcoming guidance and regulations.

The HPC will be also seeking far more intrusive access to the financial and operational conditions of significant equity investors, including but not limited to "information regarding the significant equity investor's capital structure, general financial condition, ownership and management structure and audited financial statements."

Notably, the statute exempts from the definition of "significant equity investor" venture capital firms "exclusively funding startups or other early-stage businesses," which terms are not defined.

The role of the HPC is expanding well-beyond the state legislature's initial intent. Rather than just being an advisory review body that looks at initial material change transactions, it will now have ongoing oversight for a period of five years following the completion of a material change, including the right to request additional documentation "to assess the post-transaction impacts of a material change." Cost and market impact reviews are also being tasked to ask deeper questions than before including quality of care and patient experience as well as referral patterns. Similarly, the statute empowers CHIA to require registered provider organizations to provide additional annual internal and financial and operational information to the HPC.

# Massachusetts False Claims Act Liability of Owners and Investors

In a broad statutory challenge to the historic protections of the corporate veil that insulates shareholders from underlying liability, the new law imposes liability under the state false claims act on shareholders with an ownership or investment interest in a violating entity, who knows about the violation, and fail to disclose the violation to the Commonwealth within 60 days of identifying the violation. This change is directly related to a <a href="https://linearch.night-profile-case-brought-by-the-Office-of-the-Attorney-General resulting in \$25MM settlement">https://linearch.night-profile-case-brought-by-the-Office-of-the-Attorney-General resulting in \$25MM settlement</a> paid by investors in a behavioral health company in Massachusetts in 2021. Investors will now have a more direct risk of liability for the activities of their portfolio companies.

# **Licensing Changes**

The law also established two new license types: Office-Based Surgical Centers and Urgent Care Centers. The law has delegated broad discretion to the Massachusetts Department of Public Health (DPH) to create and implement specific licensure requirements for each of the new categories. Many medical practices historically offered urgent care under the historic exception to licensure for physician practices. This new law will require physician-based urgent care centers to submit to DPH regulatory and licensure oversight. Once regulations are drafted and implemented, any person or entity that "advertises, announces, establishes, or maintains an office-based surgical center [or urgent care center] without a license" will be subject to a fine of up to US\$10,000.

(1) Office-Based Surgical Centers, which provide:

"ambulatory surgical or other invasive procedure requiring: (i) general anesthesia; (ii) moderate sedation; or (iii) deep sedation and any liposuction procedure, excluding minor procedures and procedures requiring minimal sedation, where such surgical or other invasive procedure or liposuction is performed by a practitioner at an office- based surgical center."

This category is distinct from ambulatory surgical centers, which are already subject to clinic licensure by DPH and follow the federal definition. [1] Licensed hospitals are also exempt from obtaining an office-based surgical center license, though their affiliated physician organizations may need to be exempted through rulemaking.

(2) Urgent Care Centers, which are clinics not affiliated with a licensed hospital that provide urgent care services:

"a model of episodic care for the diagnosis, treatment, management or monitoring of acute and chronic disease or injury that is: (i) for the treatment of illness or injury that is immediate in nature but does not require emergency services; (ii) provided on a walk-in basis without a prior appointment; (iii) available to the general public during times of the day, weekends or holidays when primary care provider offices are not customarily open; and (iv) is not intended and should not be used for preventative or routine services."

Licensed hospitals (and entities "corporately affiliated with hospitals"), clinics, limited service clinics, and community health centers receiving federal grants are exempt from obtaining an urgent care center license. In other words, this new oversight is directed to urgent care centers offered in a freestanding physician office and "friendly PC" environment.

#### Other Notable Provisions and Exclusions

It appears that the New Year brought about a spirit of compromise, as some of the changes previewed this summer in S.B. 2881, "an Act enhancing the market review process" discussed in our prior blog, "Massachusetts Health Care Act Dies at the End of Legislative Session But Previews Sweeping Changes for the Health Care Industry," were excluded from the new law. Most notably, restrictions on (i) who can employ registered practicing clinicians (physicians, advanced practice providers, psychiatric nurse mental health clinical specialists, nurse anesthetists, nurse-midwives, psychologists, and licensed clinical social workers) and (ii) the corporate practice of medicine were excluded from the enacted version of the law.

While the emphasis of the law expands the scope and scale of what stakeholders are subject to state oversight, the law also establishes and expands the Commonwealth's ability to monitor and study primary care services, access, delivery, cost, and payment, to name a few.

# What Happens Next?

Stakeholders should apprise themselves of these new requirements and be on the lookout for forthcoming regulations as increased governmental scrutiny has come to the Commonwealth. Foley will monitor agency activity in the Commonwealth to help Massachusetts-based health care organizations prepare for implementing regulations.

Foley is here to help you address the short and long-term impacts in the wake of regulatory changes. We have the resources to help you navigate these and other important legal considerations related to business operations and industry-specific issues. Please reach out to the authors, your Foley relationship partner, or to our <a href="Health Care Practice Group">Health Care Practice Group</a> and <a href="Health Care Sciences Sector">Health Care Sciences Sector</a> with any questions.

[1] 42 CFR 416.2 "Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part."

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