

# Office of Health Care Affordability Overview of Proposed Regulations for Assessing Market Consolidation (CMIR)

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# Statute to Implementing Regulations



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# Who Must File Notice of a Material Change Transaction?



Health Care Entities (HCE) defined in statute as payers, providers, or fully integrated delivery systems (§127500.2(k).)

## Statute



## Proposed Regulation

**Regulations Clarify HCEs Who Must File Material Change Notice (MCN):**  
§97431(g)

- All Payers, Providers, and Fully Integrated Delivery Systems
- Pharmacy Benefit Managers (PBMs) defined as payer per statute
- Management Service Organizations (MSOs) qualify as “payers”
- Affiliates, subsidiaries, or entities that control, govern, or are financially responsible for the HCE
- Affiliates, subsidiaries, or entities subject to control, governance or financial control of the HCE
- Any HCE entering into a transaction with a physician organization of less than 25 physicians (Less than 25 is exempt, but greater than 25 remains subject to requirement.)

# Do the Health Care Entities (HCEs) Meet the Thresholds?



## Statute

OHCA shall adopt regulations for proposed material changes that warrant a notification, establish appropriate fees, and *consider appropriate thresholds, including, but not limited to annual gross and net revenues and market share in a given service or region.* (§127507(c)(3).)



## Proposed Regulation

### **Regulations Define the Thresholds for Filing MCN:**

§97435(b)(1)-(3)

- HCE has annual revenue of at least \$25M or owns or controls California assets of at least \$25M, **or**
- HCE has annual revenue of at least \$10M or owns or controls California assets of at least \$10M and are involved in a transaction with any HCE satisfying the above \$25M threshold, **or**
- HCE is located in or serving at least 50% of patients residing in a health professional shortage area (HPSA), as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations <https://data.hrsa.gov>

Revenue means total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years calculated and reported by type of HCE specified in the regulation. § 97435(d)(1)-(7)

# Do the Circumstances of the Proposed Transaction Require the HCEs to File?



## Statute

OHCA shall adopt regulations for proposed *material changes that warrant a notification*, establish appropriate fees, and consider appropriate thresholds, including, but not limited to annual gross and net revenues and market share in a given service or region. (§127507(c)(3).)



## Proposed Regulation

### **Regulations Specify Transaction Circumstances that Trigger Filing Requirement** §97435(c)(1)-(9)

- (1) The fair market value is \$25M or more and involves provision of health care services (specifically defined in the regulation)
- (2) Is likely to increase annual revenue of any HCE (that is a party to the transaction) by at least \$10M or 20% of annual revenue
- (3) Involves the sale, transfer lease, exchange, option, encumbrance, or disposition of 20% or more of assets of any HCE (that is a party to the transaction)
- (4) Involves the transfer or change in control, responsibility, or governance of the submitting HCE

# Do the Circumstances of the Proposed Transaction Require the HCEs to File? *(continued)*



## Proposed Regulation

### ***Proposed Regulations Specify Transaction Circumstances that Trigger Filing Requirement §97435(c)(1)-(9)***

- (5) The terms contemplate an entity negotiating or administering contracts with payers on behalf of one or more providers and the transaction involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, MSO, or other organization
- (6) Involves the formation of a new HCE, affiliation, partnership, joint venture, or parent corporation for the provision of health care services in California projected to have at least \$25M in annual revenue or have control of assets related to the provision of health care services valued at \$25M or more
- (7) Involves a HCE joining, merging, or affiliating with another HCE, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services where any HCE has at least \$10M in annual revenue (Affiliations for clinical trials or graduate medical education excluded)
- (8) Changes the form of ownership of a HCE, including but not limited to change from physician-owned to private equity-owned and publicly held to privately held
- (9) A HCE that is a party has consummated any transaction regarding provision of health care services in California with another party within the prior ten years

# Health Care Services Defined for Purposes of the Regulation



## Proposed Regulation §97431(h)

“Health care services,” for purposes of this Article, are services for the care, prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health (mental health or substance use disorder) condition, illness, injury, or disease, including but not limited to:

- (1) Acute care, diagnostic, or therapeutic inpatient hospital services;
- (2) Acute care, diagnostic, or therapeutic outpatient services;
- (3) Pharmacy, retail and specialty, including any drugs or devices;
- (4) Performance of functions to refer, arrange, or coordinate care;
- (5) Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and
- (6) Technology associated with the provision of services or equipment in paragraphs (1) through (5) above, such as telehealth, electronic health records, software, claims processing, or utilization systems.

# When Do the HCEs Need to File their MCNs?



## Statute

A HCE shall provide OHCA with written notice of agreements or transactions that will occur on or after April 1, 2024, that transfer material amount of assets or operations. Written notice *shall be provided to OHCA at least 90 days prior to entering into the agreement or transaction.* (§127507(c)(1)-(2).)



## Proposed Regulation

***Regulations Define “entering into the agreement or transaction” so HCEs may calculate the date for 90-day advance notice.***

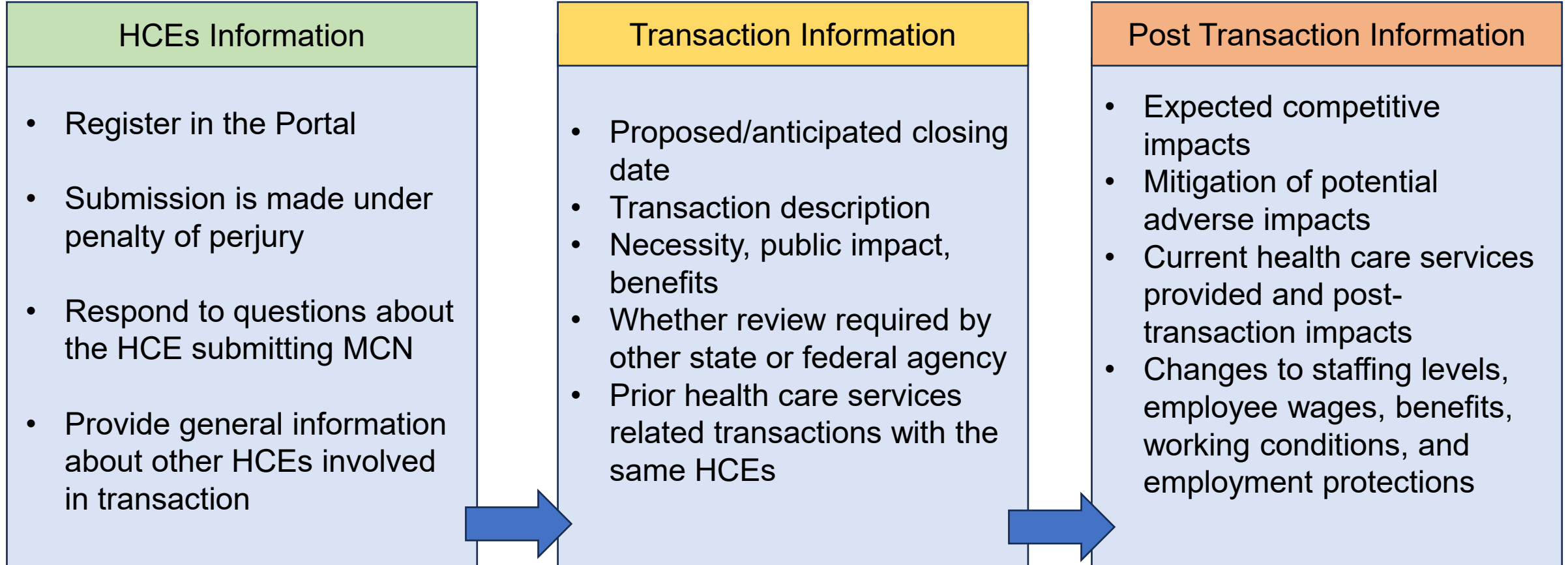
§97435(a)

Effective January 1, 2024, pursuant to section 127507 of the Code, a HCE who meets any threshold in subsection (b) (hereinafter referred to as a “submitter”) shall provide the Office with at least 90 days’ advance notice of transactions that will be entered into on or after April 1, 2024. For purposes of section 127507(c)(2) of the Code, the phrase “entering into the agreement or transaction” refers to **the date any parties’ respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived.**



# Filing the Material Change Notice via OHCA's Electronic Submission Portal – Required Information

## Proposed Regulation



# What Happens After the HCEs Submit their MCN?

## Proposed Regulation



Preliminary 60-day Review of MCN - Upon determination the MCN is complete, OHCA will post the MCN on its website and begin 60-day review to determine whether the transaction must undergo a Cost and Market Impact Review (CMIR). The 60-day clock can be tolled if additional information is required. OHCA may complete review in less than 60 days.

Determination: Waiver or CMIR Required – At conclusion of 60-day review (or sooner), OHCA notifies HCEs of Waiver or CMIR. The HCEs have 10 business days to request a review of the determination to conduct CMIR and the HCAI Director has 5 business days to respond that CMIR will proceed or will be waived.

OHCA will post the MCN Supporting Documentation on its website and conduct the CMIR within 90 days but may extend for 45 days if needed. (This time frame may be tolled if OHCA is waiting on documents requested from the parties or impacted parties outside the transaction.) OHCA will issue a Preliminary Report. Parties and the public may submit comments for 10 business days. OHCA will issue its Final Report within 30 days of the close of the comment period. The HCEs may not implement the transaction until 60 days after the Final Report.

# OHCA's Decision to Issue Waiver or Conduct CMIR



## Statute §127507.2(a)(1)

- If the office finds that a material change noticed pursuant to Section 127057 is likely to have a risk of significant impact on
  - Market competitions,
  - The state's ability to meet cost targets, or
  - Costs for purchasers and consumers,the office shall conduct a cost and market impact review.

# OHCA's Determination To Conduct CMIR - Factors



## Proposed Regulation §97441(a)(2)

(2)The Office may base its decision to conduct a cost and market impact review on any one or more of the following factors:

- (A) If the transaction may result in a negative impact on the availability or accessibility of health care services, including the HCE's ability to offer culturally competent care.
- (B) If the transaction may result in a negative impact on costs for payers, purchasers, or consumers, including the ability to meet any health care cost targets established by the Health Care Affordability Board.
- (C) If the transaction may lessen competition or tend to create a monopoly in any geographic service areas impacted by the transaction.
- (D) If the transaction directly affects a general acute care or specialty hospital.
- (E) If the transaction may negatively impact the quality of care.
- (F) If the transaction between a HCE located in this state and an out-of-state entity may increase the price of health care services or limit access to health care services in California.

# Factors Considered in the CMIR



## Statute

§127507.2(a)(1)-(2)

- A CMIR will examine factors relating to a health care entity's business and relative market position, including changes in size and market share in a given service/geographic region, prices for services compared to other providers for the same services, quality, equity, cost, access, or other factors OHCA determines to be in the public interest.
- OHCA will also consider the benefits of the material change to consumers of health care services, where those benefits could not be achieved without that transaction, including increased access to health care services, higher quality, and more efficient health care services where consumers benefit directly from those efficiencies.

# Factors Considered in the CMIR



## Proposed Regulation §97441(e)

A CMIR shall examine factors related to the HCE's business and its relative market position, including, but not limited to:

-The effect on:

- the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care,
- the quality of health care services to the community affected by the transaction,
- the lessening competition or tending to create a monopoly which could result in raising prices, reducing quality or equity, restricting access, or innovating less.
- any health care entity's ability to meet any health care cost targets established by the Board.

-Whether the parties to the transaction have been parties to any other transactions in the past ten years that have been below the thresholds set forth in section 97435(b).

-Consumer concerns including, but not limited to, complaints or other allegations against any health care entity that is a party to the transaction related to access, care, quality, equity, affordability, or coverage.

-Any other factors the Office determines to be in the public interest

# Timeframes for Material Change Notice (MCN) Review and CMIR Preliminary and Final Reports

## Proposed Regulation

