

1 Title 22, California Code of Regulations
2 Division 7. Health Planning and Facility Construction

3
4 Chapter 11.5. Promotion of Competitive Health Care Markets;
5 Health Care Affordability
6 Article 1. Material Change Transactions and Pre-Transaction Review.
7

8 *Note to reader:* This is a revised draft, based on the original draft dated 7/27/23.
9 Deletions are shown in ~~strikeout~~; additions are show in underline.

10 *If you would like to comment on this draft, send your comments to*
11 CMIR@HCAI.CA.GOV by 5 p.m. on Tuesday, October 17, 2023.

12
13 **§ 97431. Definitions.**

14 As used in this Article, the following definitions apply:

- 15 (a) "Affiliation" or "affiliate" refers to a situation in which an entity controls, is
16 controlled by, or is under common control with another legal entity in order to
17 collaborate for the provision of health care services. For purposes of this Article,
18 a clinical affiliation does not include a collaboration on clinical trials, graduate
19 medical education programs, health professions training programs, health
20 sciences training programs, or other education and research programs.
- 21 (b) "Cost and market impact review" shall mean the review conducted by the Office
22 pursuant to section 127507.2 of the Health and Safety Code ("the Code").
- 23 (c) "Culturally competent care" means the ability of providers and organizations to
24 effectively deliver health care services that meet the social, cultural, and linguistic
25 needs of patients.
- 26 (d) "Department" shall mean the Department of Health Care Access and Information.
- 27 (e) "Director" shall mean the director of the Department of Health Care Access and
28 Information.
- 29 (f) "Fully integrated delivery system" shall have the meaning set forth in section
30 127500.2(h) of the Code.
- 31 (g) "Health care entity" shall:
32 (1) Have the meaning set forth in section 127500.2(k) of the Code;
33 (2) Include pharmacy benefit managers as set forth in sections 127501(c)(12)
34 and 127507(a) of the Code;
35 ~~(3) Include a management services organization, which qualifies as a "payer"~~
36 ~~for the purposes of these regulations;~~
37 ~~(4) (3) Include any parents, affiliates, subsidiaries, or other entities that~~
38 ~~perform the functions of a health care entity and either:~~
39 ~~(i) control, govern, or are financially responsible for the health care entity~~
40 ~~or~~

1 (ii) ~~that~~ are subject to the control, governance, or financial control of the
2 health care entity, such as an organization that acts as an agent of a
3 provider(s) in contracting with payers, negotiating for rates, or
4 developing networks; and

5 ~~(5)~~ (4) Exclude physician organizations with less than 25 physicians, unless
6 determined to be a high-cost outlier, as described in 127500.2(p)(6) of the
7 Code. ~~For purposes of these regulations, any~~ Any health care entity
8 entering into a transaction with a physician organization of less than 25
9 physicians remains subject to the notice filing requirements of section
10 97435.

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

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

24 (i) "Hospital" shall mean any facility that is required to be licensed under subdivision
25 (a), (b), or (f) of section 1250 of the Code, except a facility operated by the
26 Department of State Hospitals or the Department of Corrections and
27 Rehabilitation.

28 ~~(j) "Management services organization" means an entity that provides administrative~~
29 ~~or management services for a health care entity, not including the direct provision~~
30 ~~of health care services. Administrative or management services include, but are~~
31 ~~not limited to, claims processing, utilization management, billing and collections,~~
32 ~~customer service, provider rate negotiation, network development, and other~~
33 ~~services and support.~~

34 (k) (i) "Material change transaction," as used in section 12507(c)(1) of the Code,
35 shall mean a transaction (as defined in this section), which meets the
36 requirements of section 97435(c).

37 "Material change transaction" does not include:

- 38 (1) Transactions in the usual and regular course of business of the health
39 care entity, meaning those that are typical in the day-to-day operations
40 of the health care entity.
- 41 (2) Situations in which the health care entity directly, or indirectly through
42 one or more intermediaries, already controls, is controlled by, or is under

1 [common control with, all other parties to the transaction, such as a](#)
2 [corporate restructuring.](#)

3 (k) "Notice" shall refer to the notice of a material change transaction as set forth
4 in section 97435.

5 (l) "Office" shall mean the Office of Health Care Affordability established by
6 section 127501 of the Code.

7 (m) "Payer" shall have the meaning set forth in section 127500.2(o) of the Code.

8 (n) "Physician organization" shall have the meaning set forth in section
9 127500.2(p) of the Code.

10 (o) "Provider" shall have the meaning set forth in section 127500.2(q) of the
11 Code.

12 (p) "Transaction" includes mergers, acquisitions, affiliations, or ~~other~~ agreements
13 involving [a health care entity, or](#) the provision of health care services in California,
14 that involve a ~~change-transfer~~ of assets (sell, ~~transfer~~, lease, exchange, option,
15 encumber, convey, or dispose) or ~~entail a change, directly or indirectly, to~~
16 ~~ownership, operations, or governance structure involving any health care entity.~~
17 [control, responsibility, or governance of the assets or operations of the health care](#)
18 [entity in whole or in part to one or more entities.](#)

19
20 *Note:*

21 Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.

22 Reference: Sections 127500.2, 127507, and 127507.2, Health and Safety Code.

23 24 **§ 97433. Scope.**

25 Sections 97435 through 97441 govern the procedure for filing notices of material
26 change transactions and the Office's criteria and procedure for review of material
27 change transactions and cost and market impact reviews, if deemed necessary.

28
29 *Note:*

30 Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.

31 Reference: Sections 127500.5, 127507, and 127507.2, Health and Safety Code.

32 33 **§ 97435. Material Change Transactions.**

34 (a) [A health care entity \(hereinafter referred to as a "submitter"\) who meets the](#)
35 [criteria of subsection \(b\) shall provide the Office with notice of a transaction at](#)
36 [least 90 days before the closing date of the transaction, for those transactions](#)
37 [expected to close on or after April 1, 2024.](#)

38 ~~Effective January 1, 2024, pursuant to section 127507 of the Code, a health care~~
39 ~~entity who meets any threshold in subsection (b) (hereinafter referred to as a~~
40 ~~"submitter") shall provide the Office with at least 90 days' advance notice of~~
41 ~~transactions that will be entered into on or after April 1, 2024.~~

42 For purposes of section 127507(c)(2) of the Code, the phrase "entering into the

1 agreement or transaction” refers to the closing date. ~~any parties’ respective~~
2 ~~rights vest in a binding agreement or all contingencies to the agreement or~~
3 ~~transaction are met or waived.~~

4
5 (b) Who must file. A health care entity who is a party to a transaction shall file a
6 written notice of ~~a~~ the transaction with the Office if the party meets the thresholds
7 ~~if the transaction involves any parties listed~~ in subsections (b)(1) through (b)(3)
8 under any one or more of the circumstances set forth in subsection (c), unless
9 exempted by subdivisions (d)(1) through (4) of section 127507 of the Code.

10 (1) A health care entity with annual revenue, as defined in subsection (d), of at
11 least \$25 million or that owns or controls California assets of at least \$25
12 million; or

13 (2) A health care entity with annual revenue, as defined in subsection (d), of at
14 least \$10 million or that owns or controls California assets of at least \$10
15 million and is involved in a transaction with any health care entity satisfying
16 subsection (b)(1); or

17 (3) A health care entity located in ~~or serving at least 50% of patients who reside~~
18 ~~in~~ a designated mental health or primary care health professional shortage
19 area, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the
20 Code of Federal Regulations (commencing with section 5.1), available at
21 <https://data.hrsa.gov>.

22
23 (c) Circumstances requiring filing. A transaction is a material change transaction
24 pursuant to section 127507(c)(1) of the Code if any of the ~~following~~
25 circumstances in paragraphs (1) through (10) below exist:.

26 (1) The proposed fair market value of the transaction is \$25 million or more and
27 the transaction concerns the provision of health care services.

28 (2) The transaction is more likely than not to increase annual California-derived
29 revenue of any health care entity that is a party to the transaction by either at
30 ~~least~~ \$10 million or more or 20% or more of annual California-derived revenue
31 at normal or stabilized levels of utilization or operation.

32 (3) The transaction involves the sale, transfer, lease, exchange, option,
33 encumbrance, or other disposition of ~~20~~ 25% or more of the total California
34 assets of any health care entity in the transaction.

35 (4) The transaction involves a transfer ~~or change in~~ of control, responsibility, or
36 governance of the submitter, in whole or in part, as defined in subsection (e).

37 ~~The terms of the transaction contemplate an entity negotiating or~~
38 ~~administering contracts with payers on behalf of one or more providers and~~
39 ~~the transaction involves an affiliation, partnership, joint venture, accountable~~
40 ~~care organization, parent corporation, management services organization, or~~

1 ~~other organization.~~

2 The transaction will result in an entity contracting with payers on behalf of
3 consolidated or combined providers and is more likely than not to increase
4 the annual California-derived revenue of any providers in the transaction by
5 either \$10 million or more or 20% or more of annual California-derived
6 revenue at normal or stabilized levels of utilization or operation.

7 (6) The transaction involves the formation of a new health care entity, affiliation,
8 partnership, joint venture, or parent corporation for the provision of health
9 services in California that is projected to have at least \$25 million in
10 California-derived annual revenue at normal or stabilized levels of utilization
11 or operation, or ~~have-transfer~~ control of California assets related to the
12 provision of health care services valued at \$25 million or more.

13 (7) The transaction involves a health care entity joining, merging, or affiliating
14 with another health care entity, affiliation, partnership, joint venture, or parent
15 corporation related to the provision of health care services where any health
16 care entity has at least \$10 million in annual California-derived revenue as
17 defined in subsection (d).

18 ~~For purposes of this subsection, a clinical affiliation does not include a~~
19 ~~collaboration on clinical trials or graduate medical education programs.~~

20 (8) The transaction changes the form of ownership of a health care entity that is a
21 party to the transaction, including but not limited to change from a physician-
22 owned to private equity-owned and publicly held to a privately held form of
23 ownership.

24 (9) ~~A health care entity that is a party to the transaction has consummated any~~
25 ~~transaction regarding provision of health care services in California with~~
26 ~~another party to the transaction within ten years prior to the current~~
27 ~~transaction.~~

28 The transaction is part of a series of related transactions for the same or
29 related health care services occurring over the past ten years involving the
30 same health care entities or entities affiliated with the same entities. The
31 proposed transaction and its related transactions will constitute a single
32 transaction for purposes of determining the revenue thresholds in subsection
33 (b) and asset and control circumstances in subsection (c).

34 (10) The transaction involves the acquisition of a health care entity by another
35 entity and the acquiring entity has consummated a similar transaction(s), in
36 the last ten years, with a health care entity that provides the same or related
37 health care services. The proposed transaction and its related transactions
38 will constitute a single transaction for purposes of determining the revenue
39 thresholds in subsection (b) and asset and control circumstances in
40 subsection (c).

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(d) Revenue. For purposes of subsection (b) of this section, “revenue” means the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years, as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed, as follows:

- (1) For health care service plans, revenue as reported to the Department of Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).
- (2) For health insurers, revenue as reported to the Department of Insurance pursuant to Insurance Code section 931.
- (3) For hospitals, net patient revenue, as reported to the Department in accordance with the “Accounting and Reporting Manual for California Hospitals,” incorporated by reference in 22 CCR 97018.
- (4) For long-term care facilities, net patient revenue, as reported to the Department in accordance with the “Accounting and Reporting Manual for California Long-Term Care Facilities,” incorporated by reference in 22 CCR 97019.
- (5) For risk-bearing organizations required to register and report to the DMHC, revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.
- (6) For other providers or provider organizations, net patient revenue, which includes the total revenue received for patient care, including:
 - (A) Prior year third-party settlements;
 - (B) Revenue received (inclusive of withholds, refunds, insurance services, capitation, and co-payments) from a health care entity or other payer to provide health care services, for all providers represented by the provider or provider organization in contracting with payers, for all providers represented by the provider or provider organization in contracting with payers;
 - (C) Fee for service revenue; or
 - (D) Revenue from shared risk and all incentive programs.
- ~~(7) For pharmacy benefit managers management services organizations, all payments and revenue received from health care entities to provide administrative or management pharmacy benefit management services. Administrative or management services include, but are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.~~

1 (e) Control, responsibility, or governance. For purposes of this section, a transaction
2 will directly or indirectly transfer ~~or change~~ control, responsibility, or governance
3 in whole or in part of a material amount of the assets or operations of a health
4 care entity to one or more entities if:

5
6 (1) ~~There is a substitution or addition of a new corporate member or members~~
7 ~~that transfers more than 10% of the voting power control of, responsibility for,~~
8 ~~or governance of a health care entity; or~~

9 The transaction would result in the transfer of 25% or more of the voting
10 power of the members of the governing body of a health care entity, such as
11 by adding one or more members, substituting one or more members, or
12 through any other type of arrangement, written or oral; or

13 (2) ~~There is a substitution of one or more members of the governing body of a~~
14 ~~health care entity, or any arrangement, written or oral, that would transfer full~~
15 ~~or partial voting control of the members of the governing body of a health care~~
16 ~~entity; or~~

17 The transaction would vest voting rights significant enough to constitute a
18 change in control such as supermajority rights, veto rights, and similar
19 provisions even if ownership shares or representation on a governing body
20 are less than 25%; or

21 (3) The transaction would result in the transfer of ~~more than 10~~25% or more of
22 the administrative or operational control or governance of the management
23 and policies of at least one health care entity that is a party to the transaction.

24 ~~(f) A transaction is not a material change transaction if the health care entity~~
25 ~~directly, or indirectly through one or more intermediaries, already controls, is~~
26 ~~controlled by, or is under common control with, all other parties to the~~
27 ~~transaction, such as a corporate restructuring.~~

28
29 *Note:*

30 Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.

31 Reference: Section 127500.2, 127507, Health and Safety Code.

32
33 **§ 97437. Pre-Filing Questions.**

34 Health care entities that are unsure if they must file a notice under this Article may
35 contact the Office at CMIR@hcai.ca.gov.

36
37 *Note:*

38 Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.

39 Reference: Section 127507, Health and Safety Code.

1 **§ 97439. Filing of Notices of Material Change Transactions.**

2 (a) A notice of material change transaction pursuant to section 127507 of the Code
3 required to be filed under this section (“notice”) shall be made under penalty of
4 perjury using the portal on the Office’s website at www.hcai.ca.gov/login. A health
5 care entity or its agent filing in the portal shall create a portal account by inputting
6 a first and last name, valid email account, display name, and password, and
7 submit a system-generated verification code. Alternatively, the health care entity
8 or agency may use an existing media account from Microsoft or Google to access
9 the portal. In making any narrative statements in response to subsection (b), if any
10 documents support the assertion, the health care entity making the assertion
11 shall, pursuant to subsections (c) and (d), provide and cite the document,
12 including the section or page number of the document.

13 (b) Form and Contents of Public Notice. A health care entity submitting a notice
14 (“submitter”) shall indicate which threshold(s) and circumstance(s) are met,
15 pursuant to section 97435(b) and (c), respectively, and provide the following
16 information to the Office for public posting on the Office’s website:

17 (1) General information about the transaction and entities in the transaction,
18 including the following information regarding the submitter:

19 (A) Business Name

20 (B) Business Website

21 (C) Business Mailing Address

22 (D) Description of organization, including, but not limited to, business lines or
23 segments, ownership type (corporation, partnership, limited liability
24 corporation, etc.), governance and operational structure (including
25 ownership of or by a health care entity).

26 (i) For health care providers or fully integrated delivery systems, include a
27 summary of provider type (hospital, physician group, etc.), facilities
28 owned or operated, service lines, number of staff, geographic service
29 area(s) ~~including zip code and county~~, and capacity or patients served
30 in California (e.g., number of licensed beds, number of patients per
31 ~~patient zip code county~~ in the last year, ~~quantity/type of services~~
32 ~~provided annually~~).

33 (ii) For health care service plans, health insurers, ~~and~~ risk-bearing
34 organizations, or fully integrated delivery systems, include number of
35 enrollees per ~~patient zip code county~~ in the last year.

36 (E) Federal Tax ID # and tax status as for-profit or non-profit

37 (F) California health care licenses held by the submitter, if any, and
38 identification of any other states where health care-related licenses are
39 held ~~and~~, license type, ~~and numbers~~. For purposes of this subsection,
40 provide the health care license type and numbers only for those facilities,
41 services, and professions involved in the transaction.

- 1 (G) Contact person, title, e-mail address, and mailing address for public
2 inquiries.
- 3 ~~(2) County(ies) in California currently served by submitter~~
4 ~~(3) Other states currently served by submitter~~
5 ~~(4) (2) Primary languages used by submitter and all other health care entities in~~
6 ~~the transaction~~ when providing services to the public ~~and as well as~~ the
7 threshold languages used when providing services to Medi-Cal beneficiaries,
8 as determined by the Department of Health Care Services;
- 9 ~~(5) (3) Description of all other entities involved in transaction and if any other~~
10 ~~health care entities will be submitting a notice.~~ For each entity involved in the
11 transaction, describe to the extent the submitter has access to the
12 information, the following:
- 13 (A) The entity's business (including business lines or segments);
14 (B) Ownership type (corporation, partnership, limited liability corporation, etc.),
15 including any affiliates, subsidiaries, or other entities that control, govern,
16 or are financially responsible for the health care entity or that are subject
17 to the control, governance, or financial control of the health care entity;
18 (C) Governance and operational structure (including ownership of or by a
19 health care entity);
20 (D) Annual revenues for prior three years;
21 (E) Current county or counties geographic areas (including zip code and
22 county) of operation;
23 (F) If a health care provider is involved in the transaction, include a summary
24 description of each provider type(s), physical address of facilities owned,
25 operated, or leased where patient services are provided, service lines,
26 number of staff, ~~zip codes and county(ies) served~~, capacity, and patients
27 served in California (e.g., number of licensed beds, number of patients,
28 quantity of services provided annually in the prior year), ~~and number of~~
29 ~~patient visits by county and zip code in the year preceding the transaction;~~
30 (G) Primary and threshold languages, as determined by the Department of
31 Health Care Services, used;
- 32 ~~(G) (H) If a payer, describe include a description of~~ the county(ies) where
33 coverage is sold, counties in which they are licensed to operate by the
34 Department of Managed Health Care and/or the Department of Insurance,
35 and the number of enrollees residing in the California county ~~and zip code~~
36 in the year preceding the transaction; and
- 37 ~~(H) (I) For all health care entities, include a description of~~ the business
38 addresses, if known, of any new entity(ies) that will be formed as a result
39 of the transaction.
- 40 ~~(6) (4) Proposed or anticipated date of transaction closure;~~
41 ~~(7) (5) Description of transaction, which shall include the following:~~
42 (A) The goals of the transaction;

- 1 (B) A summary of terms of the transaction;
 2 (C) A statement of why the transaction is necessary or desirable;
 3 (D) General public impact or benefits of the transaction, including quality and
 4 equity measures and impacts;
 5 (E) Narrative description of the expected competitive impacts of the
 6 transaction; and
 7 (F) Description of any actions or activities to mitigate any potential adverse
 8 impacts of the transaction on the public.
- 9 ~~(8)~~ (6) The submission date and nature of any applications, forms, notices, or other
 10 materials submitted or required regarding the proposed transaction to any other
 11 state or federal agency, such as, but not limited to, the Federal Trade
 12 Commission or the United States Department of Justice.
- 13 ~~(9)~~ (7) Whether the proposed transaction has been the subject of any court
 14 proceeding and, if so, the:
 15 (i) Name of the court;
 16 (ii) Case number; and
 17 (iii) Names of the parties
- 18 ~~(10)~~ (8) A description of current services provided by the health care entity and
 19 expected post-transaction impacts on health care services, which shall include, if
 20 applicable:
 21 (A) ~~Physical addresses~~ Counties where services are performed;
 22 (B) Levels and type of health care services offered, ~~including such as the full~~
 23 range of reproductive health care and sexual health care services,
 24 specialized services for LGBTQ+ populations, labor and delivery services,
 25 pediatric services, behavioral health services, cardiac services, and
 26 emergency services;
 27 (C) Summary of the nNumber and type of patients served, including but not
 28 limited to, age, gender, race, ethnicity, preferred language spoken,
 29 disability status, and payer category;
 30 (D) Community needs assessments, charity care, and community benefit
 31 programs; and
 32 ~~(E) Charity care;~~
 33 ~~(F) Community benefit programs; and~~
 34 ~~(G) (E) Medi-Cal and Medicare.~~
- 35 ~~(11)~~ (9) If this transaction is a merger or acquisition, ~~d~~ Description of any other prior
 36 ~~transactions~~ mergers or acquisitions that satisfy all of the following:
 37 (A) ~~Affected or involved the provision of health care services~~ Involved the
 38 same or related health care services;
 39 (B) ~~Involved any of the health care entities in the proposed transaction;~~
 40 Involved at least one of the entities, or their parents, subsidiaries,
 41 predecessors, or successors, in the proposed transaction; and
 42 (C) ~~Occurred~~ Were closed in the last ten years.

- 1 ~~(12)~~ (10) Description of potential post-transaction changes to:
- 2 (A) Ownership, governance, or operational structure.
- 3 (B) Employee staffing levels, job security or retraining policies, employee
- 4 wages, benefits, working conditions, and employment protections.
- 5 (C) City or county contracts regarding the provision of health care
- 6 services between the parties to the transaction and cities or counties.
- 7 (D) Seismic compliance with the Alfred E. Alquist Hospital Facilities
- 8 Seismic Safety Act of 1983, as amended by the California Hospital
- 9 Facilities Seismic Safety Act (Health & Saf. Code, §§ 129675-
- 10 130070).
- 11 (E) Competition within 20 miles of any physical facility offering
- 12 comparable patient services.
- 13 (2) Description of the nature, scope, and dates of any pending or planned
- 14 material changes, as used in section 97435(b), occurring between the
- 15 submitter and any other entity, within the 12 months following the date of the
- 16 notice.
- 17 (c) Documents to Be Submitted with Notice.
- 18 Except for documents submitted pursuant to subsection (c)(1), if a submitter is
- 19 submitting a document in response to either subsections (b) or (c), a submitter
- 20 may reference the page number or section of that submission in response to
- 21 another subsection. Submitters shall upload the following documents in machine-
- 22 readable portable document format (.pdf), with sections bookmarked, as
- 23 applicable:
- 24 (1) If the submitter has filed notice of the transaction with the Federal Trade
- 25 Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of
- 26 1976 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and
- 27 Report Form and any attachments thereto;
- 28 ~~(1)~~ (2) Copies of all current agreement(s) and term sheets (with accompanying
- 29 appendices and exhibits) governing or related to the proposed material
- 30 change (e.g., definitive agreements, affiliation agreements, stock purchase
- 31 agreements);
- 32 (3) Documentation related to valuation of transaction;
- 33 ~~(2)~~ (4) Contact information for any individuals signing or responsible for the
- 34 transaction or side or related agreements;
- 35 ~~(3)~~ (5) If applicable, any *pro forma* post-transaction balance sheet for any
- 36 surviving or successor entity;
- 37 ~~(4)~~ (6) A current organizational chart of the organization of any entity party to the
- 38 transaction, including charts of any parent and subsidiary organization(s) and
- 39 proposed organizational chart(s) for any post-acquisition or transaction;
- 40 (7) Existing documentation identifying the number of patients per zip code or
- 41 enrollees per zip code in the last year.

- 1 ~~(5)~~ (8) Certified financial statements for the prior three years and any
2 documentation related to the liabilities, debts, assets, balance sheets,
3 statements of income and expenses, any accompanying footnotes, and
4 revenue of all entities that are parties to the transaction. Certified financial
5 statements mean audited financial reports, or if a health care entity does not
6 routinely prepare audited financial reports, a comprehensive financial
7 statement. The comprehensive financial statement shall include details
8 regarding annual costs, annual receipt, realized capital gains and losses, and
9 accumulated surplus and accumulated reserves using the standard
10 accounting method routinely used by the health care entity and must be
11 supported by sworn written declarations by the chief financial officer, chief
12 executive officer or other officer who has financial management and oversight
13 responsibility, certifying the comprehensive financial statement is complete,
14 true, and correct in all material matters to the best of their knowledge, and
15 that the health care entity does not routinely prepare audited financial reports,
16 or the most recent audited financial report is not available. For California-
17 derived revenue requirements (as used in this Article), the certification under
18 this paragraph requires that revenue be calculated as it was generated or
19 occurred in California rather than when revenue is booked, accrued, or taxed;
20 ~~(6)~~ (9) Articles of organization or incorporation, bylaws, partnership agreements,
21 or other corporate governance documents of all entities that are parties to the
22 transaction, including any proposed updates that occur as a result of the
23 transaction;
24 ~~(7) If the submitter has filed notice of the transaction with the Federal Trade~~
25 ~~Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of~~
26 ~~1976 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and~~
27 ~~Report Form and any attachments thereto;~~
28 ~~(8)~~ (10) Any documentation related to the mitigation of any potential adverse
29 impacts of the transaction on the public; and
30 ~~(9)~~ (11) Any analytic support for and/or documents supporting the submitter's
31 responses to the narrative answers provided.

32 (d) Confidentiality of Documents Submitted with Notice.

33 All of the information provided to the Office by the submitter shall be treated as a
34 public record unless the submitter designates documents or information as
35 confidential when submitting through the Office portal system and the Office
36 accepts the designation in accordance with paragraphs (1) through (3) below.

- 37 (1) A submitter of a notice pursuant to this section may designate portions of a
38 notice and any documents or information thereafter submitted by the
39 submitter in support of the notice as confidential. The submitter shall file two
40 versions of the notice. One shall be marked as "Confidential" and shall
41 contain the full unredacted version of the notice or supporting materials and
42 shall be maintained as such by the Office and Department. The second

1 version of the notice shall be marked as “Public” and shall contain a redacted
2 version of the notice or supporting materials (from which the confidential
3 portions have been removed or redacted) and may be made available to the
4 public by the Office.

5 (2) Marked-confidential versions of stock purchase agreement(s), ~~financial~~
6 ~~documents~~, compensation documents, contract rates, and unredacted
7 résumés are deemed confidential by the Office.

8 (3) A submitter claiming confidentiality in respect of portions of a notice, or any
9 documents not specified above thereafter submitted in support of the
10 notice, shall include a ~~redaction log~~ justification that provides a reasonably
11 detailed statement of the grounds enumerated in (i) through (iv) of this
12 paragraph, below, on which confidentiality is claimed, ~~and~~ a statement of
13 the specific time for which confidential treatment of the information is
14 necessary, and a statement that the information has been confidentially
15 maintained by the entity. ~~Bases~~ A request for confidentiality shall state
16 whether any of the following applies ~~include~~:

17 (4) (i) Whether the information is proprietary or of a confidential business
18 nature, including trade secrets (as defined in California Civil Code
19 section 3426.1(d)), ~~and has been confidentially maintained by the~~
20 ~~entity~~ and whether the release ~~of which~~ would be damaging or
21 prejudicial to the business concern;

22 (i) Whether another state or federal agency deems the filed
23 document confidential and, if so, for what period of time;

24 (ii) ~~(2) the information is such that the public interest is served in~~
25 ~~withholding the information; or (3) Whether~~ the information is
26 confidential based on statute or other law; or

27 (iii) Whether the information is such that the public interest is served
28 in withholding the information.

29 (3) (4) If a request for confidential treatment is granted or denied, the submitter
30 will be notified in writing. If a request for confidential treatment is granted,
31 the information will be marked “Confidential” and kept separate from the
32 public file. With the exception of the Attorney General as provided in
33 section 127502.5(c)(4) of the Code, the Office and the Department shall
34 keep confidential all nonpublic information and documents designated as
35 confidential pursuant to this section.

36 (e) Notification of Changes. A submitter shall notify the Office within five business
37 days if the transaction is amended, altered, or cancelled. The Office may require a
38 submitter to re-notice any material changes in accordance with the procedures set
39 forth in section 97435.

40 (f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by
41 submitting a written request at any time after submission of the notice and until
42 the Office issues its final report, as described in section 97441. The Office will

1 remain entitled to collect any costs incurred in connection with any reviews up
2 until the first business day after the withdrawal notice is received, pursuant to
3 127507.4 of the Code.

4
5 **Note:**

6 Authority: Sections 127501 and 127501.2, Health and Safety Code.

7 Reference: Sections 127507, 127507.2, and 127507.4, Health and Safety Code.

8
9 **§ 97440. Request for Expedited Review.**

10 (a) A submitter may request the Office expedite its review of a notice of a material
11 change transaction by providing the Office, concurrently with the submission
12 required by section 97435:

13 (1) A detailed explanation of the conditions necessitating expedited review;

14 (2) Any documentation substantiating the necessity of expedited review; and

15 (3) The date by which the submitter requests the Office complete its review.

16 (b) A submitter shall demonstrate that either of the conditions in subsections (b)(1)
17 or (2) exist to obtain expedited review:

18 (1) Severe financial distress of one or more of the parties to the transaction; or

19 (2) Any significant reduction in the provision of critical health care services
20 within a geographic region or regions.

21 (3) As used in subsection (b)(1), “severe financial distress” shall be shown by a
22 grave risk of immediate business failure and the demonstration of a
23 substantial likelihood any party to the transaction (or an entity affected by
24 the transaction) will have to file for bankruptcy under Chapter 11 of the
25 Bankruptcy Act (11 U.S.C. Sec. 1101 *et seq.*) absent the waiver and the
26 transaction is necessary to ensure continued health care access in the
27 relevant markets.

28 (c) A submitter may request information to be held confidential in accordance with
29 section 97439(d).

30 (d) The Office will grant or deny the request based on whether the submitter has
31 sufficiently demonstrated conditions for expedited review exist and the
32 transaction is immediately required to mitigate such conditions.

33
34 **Note:**

35 Authority: Sections 127501 and 127501.2, Health and Safety Code.

36 Reference: Sections 127507.2 Health and Safety Code.

1 **§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost**
2 **and Market Impact Reviews; Findings.**

3 (a) Office Determination Whether to Conduct a Cost and Market Impact Review.

4 (1) In determining whether to conduct a cost and market impact review based on
5 ~~a market failure or market power or~~ the Office's finding a noticed material
6 change is likely to have a risk of a significant impact on market competitions,
7 the state's ability to meet cost targets, or costs for purchasers and
8 consumers, the Office will consider the factors set forth in subsection (a)(2).

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

11 (A) If the transaction may result in a negative impact on the availability or
12 accessibility of health care services, including the health care entity's
13 ability to offer culturally competent care.

14 (B) If the transaction may result in a negative impact on costs for payers,
15 purchasers, or consumers, including the ability to meet any health care
16 cost targets established by the Health Care Affordability Board.

17 (C) If the transaction may lessen competition or tend to create a monopoly in
18 any geographic service areas impacted by the transaction.

19 (D) If the transaction may lessen competition for workers or may negatively
20 impact the labor market.

21 ~~(D)~~ (E) If the transaction directly affects a general acute care or specialty hospital.

22 ~~(E)~~ (F) If the transaction may negatively impact the quality of care.

23 (G) If the transaction is part of a series of similar transactions by the health
24 care entity or entities or furthers a trend toward consolidation.

25 (H) If the transaction may entrench or extend a dominant market position of
26 any health care entity in the transaction, including extending market power
27 into related markets through vertical or cross-market mergers.

28 ~~(F)~~ (I) If the transaction between a health care entity located in this state and an
29 out-of-state entity may negatively impact affordability, quality, or limit access
30 to health care services in California ~~increase the price of health care services,~~
31 ~~or undermine the financial stability or competitive effectiveness of a health~~
32 ~~care entity located in this state, or limit access to health care services in~~
33 ~~California.~~

34 (b) Timing of Review of Notice.

35 For purposes of this subsection, a notice shall be deemed complete by the Office
36 on the date when all of the information required by section 97439 of these
37 regulations has been submitted to the Office by all health care entities who are
38 parties to the transaction and required to submit under section 97435(b) (the
39 complete filing by all required parties is deemed receipt of a complete notice).

40 Within 60 days of a complete notice, the Office shall inform each party to a
41 noticed transaction of any determination to initiate a cost and market impact

1 review pursuant to 127507.2(a)(1) of the Code, subject to the following
2 conditions, if applicable:

3 (1) The Office and the submitter may agree to a later date by mutual agreement
4 which shall be in writing and specify the date to which the Office and the
5 parties have agreed.

6 (2) The 60-day period shall be tolled during any time period in which the Office
7 has requested further information from the parties to a material change
8 transaction and it is awaiting the provision of such information.

9 (3) The Office may choose to toll the 60-day period during any time period in
10 which other state or federal regulatory agencies or courts are reviewing the
11 subject transaction.

12 (4) Should the scope of the transaction materially change from that outlined in
13 the initial notice, the 60-day period may be restarted by the Office.

14 (5) Should the Office grant a request to expedite pursuant to section 97440.

15 (c) Request for Review of Determination to Conduct Cost and Market Impact
16 Review.

17 (1) Within 10 business days of the date of a determination that a cost and market
18 impact review is required, ~~a submitter~~ the submitters of the notices for the
19 same transaction may collectively request review of the Office's
20 determination. The request shall:

21 (A) Be in writing;

22 (B) Be signed by ~~the~~ all requesting submitters;

23 (C) Be sent to the Director with a copy to the Office;

24 (D) Be ~~provided to~~ consolidated with all other submitters involved in the
25 transaction;

26 (E) Set forth specifically and in full detail the grounds upon which submitter(s)
27 considers the determination to be in error; and

28 (F) State the reason(s) why the submitter(s) asserts a cost and market impact
29 review is not warranted.

30 (2) The request will be denied if it contains no more than a request for a waiver of
31 a cost and market impact review, unsupported by specific facts.

32 (3) Within 5 business days of receipt of a request for redetermination, the
33 Director may:

34 (A) Decline review and uphold the determination that a cost and market
35 impact review is required; or

36 (B) Grant the request and waive a cost and market impact review.

37 (4) The Director may extend this period for one additional 5-day period if the
38 Director needs additional time to complete the review.

39 (5) The determination of the Director, either upholding the original determination
40 or substituting an amended determination, is final.
41

1 (d) Timeline for Completion of Cost and Market Impact Review

2 The Office shall complete a cost and market impact review within 90 days of the
3 final decision by the Office to conduct a cost and market impact review, subject
4 to subsections (d)(1) through (3):

5 (1) The Office may extend the 90-day period by one additional 45-day period if it
6 needs additional time to complete the review.

7 (2) Should the Office determine it requires additional documentation or
8 information to complete its review, it may toll either of the time periods set
9 forth in subsection (d)(1) for any time period in which it is awaiting the
10 provision of such documentation or information from the parties to the
11 transaction or is awaiting the provision of information subpoenaed pursuant to
12 section 127507.2(a)(4) of the Code.

13 (3) The Office may choose to toll either of the time periods set forth in subsection
14 (d)(1) during any time period in which other state or federal regulatory
15 agencies or courts are reviewing the subject transaction.

16 (e) Factors Considered in a Cost and Market Impact Review

17 A cost and market impact review shall examine factors relating to a health care
18 entity's business and its relative market position, including, but not limited to:

19 (1) The effect on the availability or accessibility of health care services to the
20 community affected by the transaction, including the accessibility of culturally
21 competent care.

22 (2) The effect on the quality of health care services to any of the communities
23 affected by the transaction.

24 (3) The effect of lessening competition or tending to create a monopoly which
25 could result in raising prices, reducing quality or equity, restricting access, or
26 innovating less.

27 (4) The effect on any health care entity's ability to meet any health care cost
28 targets established by the Health Care Affordability Board.

29 (5) The effect on competition for workers and the impact on the labor market.

30 (6) Whether the transaction may foreclose competitors of any party to the
31 transaction from a segment of the market or otherwise increase barriers to
32 entry in any health care market.

33 ~~(5)~~ (7) Whether the parties to the transaction have been parties to any other
34 transactions in the past ten years that have been below the thresholds set
35 forth in section 97435(b).

36 ~~(6)~~ (8) Consumer concerns including, but not limited to, complaints or other
37 allegations against any health care entity that is a party to the transaction
38 related to access, care, quality, equity, affordability, or coverage.

39 ~~(7)~~ (9) Any other factors the Office determines to be in the public interest.

40 (f) Preliminary Report of Findings.

41 (1) Upon completion of a cost and market impact review, the Office shall make
42 factual findings and issue a preliminary report of its findings pursuant to

1 subdivision (a)(5) of section 127507.2 of the Code.
2 (2) Within 10 business days of the issuance of the preliminary report, the parties
3 to the transaction and the public may submit written comments in response to
4 the findings in the preliminary report.

5 (g) Final Report of Findings.

6 The Office shall issue a final report of its findings pursuant to subdivision (a)(5) of
7 section 127507.2 of the Code within 30 days of the close of the comment period
8 in paragraph (f)(2) of this regulation, unless the Office extends this time for good
9 cause shown. Good cause means a finding based upon a preponderance of the
10 evidence there is a factual basis and substantial reason for the extension. Good
11 cause may be found, for instance, when the Office requires additional time to
12 review and evaluate written comments regarding the preliminary report.

13
14 *Note:*

15 Authority: Sections 127501 and 127501.2, Health and Safety Code.

16 Reference: Sections 127500.5, 127502.5, 127507, and 127507.2, Health and Safety
17 Code.

18
19 **§ 97442. Market Power or Market Failure Determinations.**

20 This Article does not preclude the Office from conducting a cost and market impact
21 review of any health care entity based on the Director's request pursuant to sections
22 127502.5 and 127507.2 of the Code.

23
24 *Note:*

25 Authority: Sections 127501 and 127501.2, Health and Safety Code.

26 Reference: Sections 127500.5, 127501, 127502.5, 127507, and 127507.2, Health and
27 Safety Code.