

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; Health Care  
5 Affordability

6 Article 1. Material Change Transactions and Pre-Transaction Review.  
7

8 *Note to reader: This is a clean copy of the revised 10/9/23 draft.*

9 *If you would like to comment on this draft, send your comments to*  
10 [CMIR@HCAI.CA.GOV](mailto:CMIR@HCAI.CA.GOV) *by 5 p.m. on Tuesday, October 17, 2023.*

11 **§ 97431. Definitions.**

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

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

- 1 (4) Exclude physician organizations with less than 25 physicians, unless  
2 determined to be a high-cost outlier, as described in 127500.2(p)(6) of the  
3 Code. Any health care entity entering into a transaction with a physician  
4 organization of less than 25 physicians remains subject to the notice filing  
5 requirements of section 97435.
- 6 (h) "Health care services," for purposes of this Article, are services for the care,  
7 prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health  
8 (mental health or substance use disorder) condition, illness, injury, or disease,  
9 including but not limited to:
- 10 (1) Acute care, diagnostic, or therapeutic inpatient hospital services;  
11 (2) Acute care, diagnostic, or therapeutic outpatient services;  
12 (3) Pharmacy, retail and specialty, including any drugs or devices;  
13 (4) Performance of functions to refer, arrange, or coordinate care;  
14 (5) Equipment used such as durable medical equipment, diagnostic,  
15 surgical devices, or infusion; and  
16 (6) Technology associated with the provision of services or equipment in  
17 paragraphs (1) through (5) above, such as telehealth, electronic health  
18 records, software, claims processing, or utilization systems.
- 19 (i) "Hospital" shall mean any facility that is required to be licensed under subdivision  
20 (a), (b), or (f) of section 1250 of the Code, except a facility operated by the  
21 Department of State Hospitals or the Department of Corrections and  
22 Rehabilitation.
- 23 (j) "Material change transaction," as used in section 12507(c)(1) of the Code, shall  
24 mean a transaction (as defined in this section), which meets the requirements of  
25 section 97435(c). "Material change transaction" does not include:
- 26 (1) Transactions in the usual and regular course of business of the health  
27 care entity, meaning those that are typical in the day-to-day operations  
28 of the health care entity.  
29 (2) Situations in which the health care entity directly, or indirectly through  
30 one or more intermediaries, already controls, is controlled by, or is under  
31 common control with, all other parties to the transaction, such as a  
32 corporate restructuring.
- 33 (k) "Notice" shall refer to the notice of a material change transaction as set forth in  
34 section 97435.
- 35 (l) "Office" shall mean the Office of Health Care Affordability established by section  
36 127501 of the Code.
- 37 (m) "Payer" shall have the meaning set forth in section 127500.2(o) of the Code.
- 38 (n) "Physician organization" shall have the meaning set forth in section 127500.2(p)  
39 of the Code.
- 40 (o) "Provider" shall have the meaning set forth in section 127500.2(q) of the Code.
- 41 (p) "Transaction" includes mergers, acquisitions, affiliations, or other agreements  
42 involving a health care entity, or the provision of health care services in California,

1 that involve a transfer of assets (sell, lease, exchange, option, encumber, convey,  
2 or dispose) or control, responsibility, or governance of the assets or operations of  
3 the health care entity in whole or in part to one or more entities.  
4

5 *Note:*

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

7 Reference: Sections 127500.2, 127507, and 127507.2, Health and Safety Code.  
8

9 **§ 97433. Scope.**

10 Sections 97435 through 97441 govern the procedure for filing notices of material  
11 change transactions and the Office's criteria and procedure for review of material  
12 change transactions and cost and market impact reviews, if deemed necessary.  
13

14 *Note:*

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

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

18 **§ 97435. Material Change Transactions.**

19 (a) A health care entity (hereinafter referred to as a "submitter") who meets the  
20 criteria of subsection (b) shall provide the Office with notice of a transaction at  
21 least 90 days before the closing date of the transaction, for those transactions  
22 expected to close on or after April 1, 2024. For purposes of section 127507(c)(2)  
23 of the Code, the phrase "entering into the agreement or transaction" refers to the  
24 closing date.

25 (b) Who must file. A health care entity who is a party to a transaction shall file a  
26 written notice of the transaction with the Office if the party meets the thresholds  
27 in subsections (b)(1) through (b)(3) under any one or more of the circumstances  
28 set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of  
29 section 127507 of the Code.

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

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

37 (3) A health care entity located in a designated mental health or primary care  
38 health professional shortage area, as defined in Part 5 of Subchapter A of  
39 Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with  
40 section 5.1), available at <https://data.hrsa.gov>.

- 1 (c) Circumstances requiring filing. A transaction is a material change transaction  
2 pursuant to section 127507(c)(1) of the Code if any of the circumstances in  
3 paragraphs (1) through (10) below exist.
- 4 (1) The proposed fair market value of the transaction is \$25 million or more and  
5 the transaction concerns the provision of health care services.
- 6 (2) The transaction is more likely than not to increase annual California-derived  
7 revenue of any health care entity that is a party to the transaction by either  
8 \$10 million or more or 20% or more of annual California-derived revenue at  
9 normal or stabilized levels of utilization or operation.
- 10 (3) The transaction involves the sale, transfer, lease, exchange, option,  
11 encumbrance, or other disposition of 25% or more of the total California  
12 assets of any health care entity in the transaction.
- 13 (4) The transaction involves a transfer of control, responsibility, or governance of  
14 the submitter, in whole or in part, as defined in subsection (e).
- 15 (5) The transaction will result in an entity contracting with payers on behalf of  
16 consolidated or combined providers and is more likely than not to increase  
17 the annual California-derived revenue of any providers in the transaction by  
18 either \$10 million or more or 20% or more of annual California-derived  
19 revenue at normal or stabilized levels of utilization or operation.
- 20 (6) The transaction involves the formation of a new health care entity, affiliation,  
21 partnership, joint venture, or parent corporation for the provision of health  
22 services in California that is projected to have at least \$25 million in  
23 California-derived annual revenue at normal or stabilized levels of utilization  
24 or operation, or transfer control of California assets related to the provision of  
25 health care services valued at \$25 million or more.
- 26 (7) The transaction involves a health care entity joining, merging, or affiliating  
27 with another health care entity, affiliation, partnership, joint venture, or parent  
28 corporation related to the provision of health care services where any health  
29 care entity has at least \$10 million in annual California-derived revenue as  
30 defined in subsection (d).
- 31 (8) The transaction changes the form of ownership of a health care entity that is a  
32 party to the transaction, including but not limited to change from a physician-  
33 owned to private equity-owned and publicly held to a privately held form of  
34 ownership.
- 35 (9) The transaction is part of a series of related transactions for the same or  
36 related health care services occurring over the past ten years involving the  
37 same health care entities or entities affiliated with the same entities. The  
38 proposed transaction and its related transactions will constitute a single  
39 transaction for purposes of determining the revenue thresholds in subsection  
40 (b) and asset and control circumstances in subsection (c).
- 41 (10) The transaction involves the acquisition of a health care entity by another  
42 entity and the acquiring entity has consummated a similar transaction(s), in

1 the last ten years, with a health care entity that provides the same or related  
2 health care services. The proposed transaction and its related transactions  
3 will constitute a single transaction for purposes of determining the revenue  
4 thresholds in subsection (b) and asset and control circumstances in  
5 subsection (c).

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

11 (1) For health care service plans, revenue as reported to the Department of  
12 Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).

13 (2) For health insurers, revenue as reported to the Department of Insurance  
14 pursuant to Insurance Code section 931.

15 (3) For hospitals, net patient revenue, as reported to the Department in  
16 accordance with the “Accounting and Reporting Manual for California  
17 Hospitals,” incorporated by reference in 22 CCR 97018.

18 (4) For long-term care facilities, net patient revenue, as reported to the  
19 Department in accordance with the “Accounting and Reporting Manual for  
20 California Long-Term Care Facilities,” incorporated by reference in 22 CCR  
21 97019.

22 (5) For risk-bearing organizations required to register and report to the DMHC,  
23 revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.

24 (6) For other providers or provider organizations, net patient revenue, which  
25 includes the total revenue received for patient care, including:

26 (A) Prior year third-party settlements;

27 (B) Revenue received (inclusive of withholds, refunds, insurance services,  
28 capitation, and co-payments) from a health care entity or other payer to  
29 provide health care services, for all providers represented by the provider  
30 or provider organization in contracting with payers, for all providers  
31 represented by the provider or provider organization in contracting with  
32 payers;

33 (C) Fee for service revenue; or

34 (D) Revenue from shared risk and all incentive programs.

35 (7) For pharmacy benefit managers, all payments and revenue received from  
36 health care entities to provide pharmacy benefit management services.

37 (e) Control, responsibility, or governance. For purposes of this section, a transaction  
38 will directly or indirectly transfer control, responsibility, or governance in whole or  
39 in part of a material amount of the assets or operations of a health care entity to  
40 one or more entities if:

41 (1) The transaction would result in the transfer of 25% or more of the voting  
42 power of the members of the governing body of a health care entity, such as

- 1 by adding one or more members, substituting one or more members, or  
2 through any other type of arrangement, written or oral; or  
3 (2) The transaction would vest voting rights significant enough to constitute a  
4 change in control such as supermajority rights, veto rights, and similar  
5 provisions even if ownership shares or representation on a governing body  
6 are less than 25%; or  
7 (3) The transaction would result in the transfer of 25% or more of the  
8 administrative or operational control or governance of the management and  
9 policies of at least one health care entity that is a party to the transaction.

10  
11 *Note:*

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

13 Reference: Section 127500.2, 127507, Health and Safety Code.  
14

15 **§ 97437. Pre-Filing Questions.**

16 Health care entities that are unsure if they must file a notice under this Article may  
17 contact the Office at CMIR@hcai.ca.gov.  
18

19 *Note:*

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

21 Reference: Section 127507, Health and Safety Code.  
22

23 **§ 97439. Filing of Notices of Material Change Transactions.**

24 (a) A notice of material change transaction pursuant to section 127507 of the Code  
25 required to be filed under this section (“notice”) shall be made under penalty of  
26 perjury using the portal on the Office’s website at [www.hcai.ca.gov/login](http://www.hcai.ca.gov/login). A health  
27 care entity or its agent filing in the portal shall create a portal account by inputting  
28 a first and last name, valid email account, display name, and password, and  
29 submit a system-generated verification code. Alternatively, the health care entity  
30 or agency may use an existing media account from Microsoft or Google to access  
31 the portal. In making any narrative statements in response to subsection (b), if any  
32 documents support the assertion, the health care entity making the assertion  
33 shall, pursuant to subsections (c) and (d), provide and cite the document,  
34 including the section or page number of the document.

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

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

41 (A) Business Name

42 (B) Business Website

- 1 (C) Business Mailing Address
- 2 (D) Description of organization, including, but not limited to, business lines or
- 3 segments, ownership type (corporation, partnership, limited liability
- 4 corporation, etc.), governance and operational structure (including
- 5 ownership of or by a health care entity).
- 6 (i) For health care providers or fully integrated delivery systems, include a
- 7 summary of provider type (hospital, physician group, etc.), facilities
- 8 owned or operated, service lines, number of staff, geographic service
- 9 area(s), and capacity or patients served in California (e.g., number of
- 10 licensed beds, number of patients per county in the last year).
- 11 (ii) For health care service plans, health insurers, risk-bearing
- 12 organizations, or fully integrated delivery systems, include number of
- 13 enrollees per county in the last year.
- 14 (E) Federal Tax ID # and tax status as for-profit or non-profit
- 15 (F) California health care licenses held by the submitter, if any, and
- 16 identification of any other states where health care-related licenses are
- 17 held and license type. For purposes of this subsection, provide the health
- 18 care license type and numbers only for those facilities, services, and
- 19 professions involved in the transaction.
- 20 (G) Contact person, title, e-mail address, and mailing address for public
- 21 inquiries.
- 22 (2) Primary languages used by submitter when providing services to the public as
- 23 well as the threshold languages used when providing services to Medi-Cal
- 24 beneficiaries, as determined by the Department of Health Care Services;
- 25 (3) Description of all other entities involved in transaction and if any other health
- 26 care entities will be submitting a notice. For each entity involved in the
- 27 transaction, describe, to the extent the submitter has access to the
- 28 information, the following:
- 29 (A) The entity's business (including business lines or segments);
- 30 (B) Ownership type (corporation, partnership, limited liability corporation, etc.),
- 31 including any affiliates, subsidiaries, or other entities that control, govern,
- 32 or are financially responsible for the health care entity or that are subject
- 33 to the control, governance, or financial control of the health care entity;
- 34 (C) Governance and operational structure (including ownership of or by a
- 35 health care entity);
- 36 (D) Annual revenues for prior three years;
- 37 (E) Current county or counties of operation;
- 38 (F) If a health care provider is involved in the transaction, include a summary
- 39 description of provider type(s), physical address of facilities owned,
- 40 operated, or leased where patient services are provided, service lines,
- 41 number of staff, capacity, and patients served in California (e.g., number

- 1 of licensed beds, number of patients, quantity of services provided in the  
2 prior year);
- 3 (G) Primary and threshold languages, as determined by the Department of  
4 Health Care Services, used;
- 5 (H) If a payer, include a description of the county(ies) where coverage is sold,  
6 counties in which they are licensed to operate by the Department of  
7 Managed Health Care and/or the Department of Insurance, and the  
8 number of enrollees residing in the California county in the year preceding  
9 the transaction; and
- 10 (I) For all health care entities, include a description of the business  
11 addresses, if known, of any new entity(ies) that will be formed as a result  
12 of the transaction.
- 13 (4) Proposed or anticipated date of transaction closure;
- 14 (5) Description of transaction, which shall include the following:
- 15 (A) The goals of the transaction;
- 16 (B) A summary of terms of the transaction;
- 17 (C) A statement of why the transaction is necessary or desirable;
- 18 (D) General public impact or benefits of the transaction, including quality and  
19 equity measures and impacts;
- 20 (E) Narrative description of the expected competitive impacts of the  
21 transaction; and
- 22 (F) Description of any actions or activities to mitigate any potential adverse  
23 impacts of the transaction on the public.
- 24 (6) The submission date and nature of any applications, forms, notices, or other  
25 materials submitted or required regarding the proposed transaction to any  
26 other state or federal agency, such as, but not limited to, the Federal Trade  
27 Commission or the United States Department of Justice.
- 28 (7) Whether the proposed transaction has been the subject of any court  
29 proceeding and, if so, the:
- 30 (i) Name of the court;
- 31 (ii) Case number; and
- 32 (iii) Names of the parties
- 33 (8) A description of current services provided by the health care entity and  
34 expected post-transaction impacts on health care services, which shall  
35 include, if applicable:
- 36 (A) Counties where services are performed;
- 37 (B) Levels and type of health care services offered, such-as the full range of  
38 reproductive health care and sexual health care services, specialized  
39 services for LGBTQ+ populations, labor and delivery services, pediatric  
40 services, behavioral health services, cardiac services, and emergency  
41 services;



- 1 (C) Summary of the number and type of patients served, including but not  
2 limited to, age, gender, race, ethnicity, preferred language spoken,  
3 disability status, and payer category;
- 4 (D) Community needs assessments, charity care, and community benefit  
5 programs; and  
6 (E) Medi-Cal and Medicare.
- 7 (9) If this transaction is a merger or acquisition, description of any other prior  
8 mergers or acquisitions that satisfy all of the following:  
9 (A) Involved the same or related health care services; and  
10 (B) Involved at least one of the entities, or their parents, subsidiaries,  
11 predecessors, or successors, in the proposed transaction; and  
12 (C) Were closed in the last ten years.
- 13 (10) Description of potential post-transaction changes to:  
14 (A) Ownership, governance, or operational structure.  
15 (B) Employee staffing levels, job security or retraining policies, employee  
16 wages, benefits, working conditions, and employment protections.  
17 (C) City or county contracts regarding the provision of health care  
18 services between the parties to the transaction and cities or counties.  
19 (D) Seismic compliance with the Alfred E. Alquist Hospital Facilities  
20 Seismic Safety Act of 1983, as amended by the California Hospital  
21 Facilities Seismic Safety Act (Health & Saf. Code, §§ 129675-  
22 130070).  
23 (E) Competition within 20 miles of any physical facility offering  
24 comparable patient services.
- 25 (11) Description of the nature, scope, and dates of any pending or planned  
26 material changes, as used in section 97435(b), occurring between the  
27 submitter and any other entity, within the 12 months following the date of the  
28 notice.
- 29 (c) Documents to Be Submitted with Notice.  
30 Except for documents submitted pursuant to subsection (c)(1), if a submitter is  
31 submitting a document in response to either subsections (b) or (c), a submitter  
32 may reference the page number or section of that submission in response to  
33 another subsection. Submitters shall upload the following documents in machine-  
34 readable portable document format (.pdf), with sections bookmarked, as  
35 applicable:  
36 (1) If the submitter has filed notice of the transaction with the Federal Trade  
37 Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of  
38 1976 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and  
39 Report Form and any attachments thereto;  
40 (2) Copies of all current agreement(s) and term sheets (with accompanying  
41 appendices and exhibits) governing or related to the proposed material

- 1 change (e.g., definitive agreements, affiliation agreements, stock purchase  
2 agreements);
- 3 (3) Documentation related to valuation of transaction;
- 4 (4) Contact information for any individuals signing or responsible for the  
5 transaction or side or related agreements;
- 6 (5) If applicable, any *pro forma* post-transaction balance sheet for any surviving  
7 or successor entity;
- 8 (6) A current organizational chart of the organization of any entity party to the  
9 transaction, including charts of any parent and subsidiary organization(s) and  
10 proposed organizational chart(s) for any post-acquisition or transaction;
- 11 (7) Existing documentation identifying the number of patients per zip code or  
12 enrollees per zip code in the last year.
- 13 (8) Certified financial statements for the prior three years and any documentation  
14 related to the liabilities, debts, assets, balance sheets, statements of income  
15 and expenses, any accompanying footnotes, and revenue of all entities that  
16 are parties to the transaction. Certified financial statements mean audited  
17 financial reports, or if a health care entity does not routinely prepare audited  
18 financial reports, a comprehensive financial statement. The comprehensive  
19 financial statement shall include details regarding annual costs, annual  
20 receipt, realized capital gains and losses, and accumulated surplus and  
21 accumulated reserves using the standard accounting method routinely used  
22 by the health care entity and must be supported by sworn written declarations  
23 by the chief financial officer, chief executive officer or other officer who has  
24 financial management and oversight responsibility, certifying the  
25 comprehensive financial statement is complete, true, and correct in all  
26 material matters to the best of their knowledge, and that the health care entity  
27 does not routinely prepare audited financial reports, or the most recent  
28 audited financial report is not available. For California-derived revenue  
29 requirements (as used in this Article), the certification under this paragraph  
30 requires that revenue be calculated as it was generated or occurred in  
31 California rather than when revenue is booked, accrued, or taxed;
- 32 (9) Articles of organization or incorporation, bylaws, partnership agreements, or  
33 other corporate governance documents of all entities that are parties to the  
34 transaction, including any proposed updates that occur as a result of the  
35 transaction;
- 36 (10) Any documentation related to the mitigation of any potential adverse  
37 impacts of the transaction on the public; and
- 38 (11) Any analytic support for and/or documents supporting the submitter's  
39 responses to the narrative answers provided.
- 40 (d) Confidentiality of Documents Submitted with Notice.
- 41 All of the information provided to the Office by the submitter shall be treated as a  
42 public record unless the submitter designates documents or information as

1 confidential when submitting through the Office portal system and the Office  
2 accepts the designation in accordance with paragraphs (1) through (3) below.

3 (1) A submitter of a notice pursuant to this section may designate portions of a  
4 notice and any documents or information thereafter submitted by the  
5 submitter in support of the notice as confidential. The submitter shall file two  
6 versions of the notice. One shall be marked as "Confidential" and shall  
7 contain the full unredacted version of the notice or supporting materials and  
8 shall be maintained as such by the Office and Department. The second  
9 version of the notice shall be marked as "Public" and shall contain a redacted  
10 version of the notice or supporting materials (from which the confidential  
11 portions have been removed or redacted) and may be made available to the  
12 public by the Office.

13 (2) Marked-confidential versions of stock purchase agreement(s), compensation  
14 documents, contract rates, and unredacted résumés are deemed confidential  
15 by the Office.

16 (3) A submitter claiming confidentiality in respect of portions of a notice, or any  
17 documents not specified above thereafter submitted in support of the notice,  
18 shall include a justification that provides a reasonably detailed statement of  
19 the grounds enumerated in (i) through (iv) of this paragraph, below, on which  
20 confidentiality is claimed, a statement of the specific time for which  
21 confidential treatment of the information is necessary, and a statement that  
22 the information has been confidentially maintained by the entity. A request for  
23 confidentiality shall state whether any of the following applies:

- 24 (i) Whether the information is proprietary or of a confidential  
25 business nature, including trade secrets (as defined in California  
26 Civil Code section 3426.1(d)), and whether the release would be  
27 damaging or prejudicial to the business concern;
- 28 (ii) Whether another state or federal agency deems the filed  
29 document confidential and, if so, for what period of time;
- 30 (iii) Whether the information is confidential based on statute or other  
31 law; or
- 32 (iv) Whether the information is such that the public interest is served  
33 in withholding the information.

34 (4) If a request for confidential treatment is granted or denied, the submitter will  
35 be notified in writing. If a request for confidential treatment is granted, the  
36 information will be marked "Confidential" and kept separate from the public  
37 file. With the exception of the Attorney General as provided in section  
38 127502.5(c)(4) of the Code, the Office and the Department shall keep  
39 confidential all nonpublic information and documents designated as  
40 confidential pursuant to this section.

41 (e) Notification of Changes. A submitter shall notify the Office within five business  
42 days if the transaction is amended, altered, or cancelled. The Office may require a

1 submitter to re-notice any material changes in accordance with the procedures set  
2 forth in section 97435.

- 3 (f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by  
4 submitting a written request at any time after submission of the notice and until  
5 the Office issues its final report, as described in section 97441. The Office will  
6 remain entitled to collect any costs incurred in connection with any reviews up  
7 until the first business day after the withdrawal notice is received, pursuant to  
8 127507.4 of the Code.

9  
10 *Note:*

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

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

13  
14 **§ 97440. Request for Expedited Review.**

- 15 (a) A submitter may request the Office expedite its review of a notice of a material  
16 change transaction by providing the Office, concurrently with the submission  
17 required by section 97435:

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

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

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

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

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

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

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

- 33 (c) A submitter may request information to be held confidential in accordance with  
34 section 97439(d).

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

38  
39 *Note:*

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

41 Reference: Sections 127507.2 Health and Safety Code.

1 **§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost**  
2 **and Market Impact Review; 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 the Office's finding a noticed material change is likely to have a risk of a  
6 significant impact on market competitions, the state's ability to meet cost  
7 targets, or costs for purchasers and consumers, the Office will consider the  
8 factors set forth in subsection (a)(2).

9 (2) The Office shall base its decision to conduct a cost and market impact review  
10 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 (E) If the transaction directly affects a general acute care or specialty hospital.

22 (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 (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  
30 access to health care services in California, or undermine the financial  
31 stability or competitive effectiveness of a health care entity located in this  
32 state.

33 (b) Timing of Review of Notice.

34 For purposes of this subsection, a notice shall be deemed complete by the Office  
35 on the date when all of the information required by section 97439 of these  
36 regulations has been submitted to the Office by all health care entities who are  
37 parties to the transaction and required to submit under section 97435(b) (the  
38 complete filing by all required parties is deemed receipt of a complete notice).  
39 Within 60 days of a complete notice, the Office shall inform each party to a  
40 noticed transaction of any determination to initiate a cost and market impact  
41 review pursuant to 127507.2(a)(1) of the Code, subject to the following  
42 conditions, if applicable:

- 1 (1) The Office and the submitter may agree to a later date by mutual agreement
- 2 which shall be in writing and specify the date to which the Office and the
- 3 parties have agreed.
- 4 (2) The 60-day period shall be tolled during any time period in which the Office
- 5 has requested further information from the parties to a material change
- 6 transaction and it is awaiting the provision of such information.
- 7 (3) The Office may choose to toll the 60-day period during any time period in
- 8 which other state or federal regulatory agencies or courts are reviewing the
- 9 subject transaction.
- 10 (4) Should the scope of the transaction materially change from that outlined in
- 11 the initial notice, the 60-day period may be restarted by the Office.
- 12 (5) Should the Office grant a request to expedite pursuant to section 97440.

13 (c) Request for Review of Determination to Conduct Cost and Market Impact  
14 Review.

- 15 (1) Within 10 business days of the date of a determination that a cost and market
- 16 impact review is required, the submitters of the notices for the same
- 17 transaction may collectively request review of the Office's determination. The
- 18 request shall:
- 19 (A) Be in writing;
- 20 (B) Be signed by all requesting submitters;
- 21 (C) Be sent to the Director with a copy to the Office;
- 22 (D) Be consolidated with all other submitters involved in the transaction;
- 23 (E) Set forth specifically and in full detail the grounds upon which submitter(s)
- 24 consider the determination to be in error; and
- 25 (F) State the reason(s) why the submitter(s) asserts a cost and market impact
- 26 review is not warranted.
- 27 (2) The request will be denied if it contains no more than a request for a waiver of
- 28 a cost and market impact review, unsupported by specific facts.
- 29 (3) Within 5 business days of receipt of a request for redetermination, the
- 30 Director may:
- 31 (A) Decline review and uphold the determination that a cost and market
- 32 impact review is required; or
- 33 (B) Grant the request and waive a cost and market impact review.
- 34 (4) The Director may extend this period for one additional 5-day period if the
- 35 Director needs additional time to complete the review.
- 36 (5) The determination of the Director, either upholding the original determination
- 37 or substituting an amended determination, is final.

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

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

- 1 (1) The Office may extend the 90-day period by one additional 45-day period if it  
2 needs additional time to complete the review.
- 3 (2) Should the Office determine it requires additional documentation or  
4 information to complete its review, it may toll either of the time periods set  
5 forth in subsection (d)(1) for any time period in which it is awaiting the  
6 provision of such documentation or information from the parties to the  
7 transaction or is awaiting the provision of information subpoenaed pursuant to  
8 section 127507.2(a)(4) of the Code.
- 9 (3) The Office may choose to toll either of the time periods set forth in subsection  
10 (d)(1) during any time period in which other state or federal regulatory  
11 agencies or courts are reviewing the subject transaction.

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

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

- 15 (1) The effect on the availability or accessibility of health care services to the  
16 community affected by the transaction, including the accessibility of culturally  
17 competent care.
- 18 (2) The effect on the quality of health care services to any of the communities  
19 affected by the transaction.
- 20 (3) The effect of lessening competition or tending to create a monopoly which  
21 could result in raising prices, reducing quality or equity, restricting access, or  
22 innovating less.
- 23 (4) The effect on any health care entity's ability to meet any health care cost  
24 targets established by the Health Care Affordability Board.
- 25 (5) The effect on competition for workers and the impact on the labor market.
- 26 (6) Whether the transaction may foreclose competitors of any party to the  
27 transaction from a segment of the market or otherwise increase barriers to  
28 entry in any health care market.
- 29 (7) Whether the parties to the transaction have been parties to any other  
30 transactions in the past ten years that have been below the thresholds set  
31 forth in section 97435(b).
- 32 (8) Consumer concerns including, but not limited to, complaints or other  
33 allegations against any health care entity that is a party to the transaction  
34 related to access, care, quality, equity, affordability, or coverage.
- 35 (9) Any other factors the Office determines to be in the public interest.

36 (f) Preliminary Report of Findings.

- 37 (1) Upon completion of a cost and market impact review, the Office shall make  
38 factual findings and issue a preliminary report of its findings pursuant to  
39 subdivision (a)(5) of section 127507.2 of the Code.
- 40 (2) Within 10 business days of the issuance of the preliminary report, the parties  
41 to the transaction and the public may submit written comments in response to  
42 the findings in the preliminary report.

1 (g) Final Report of Findings.

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

9  
10 *Note:*

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

12 Reference: Sections 127500.5, 127502.5, 127507, and 127507.2, Health and Safety  
13 Code.

14  
15 **§ 97442. Market Power or Market Failure Determinations.**

16 This Article does not preclude the Office from conducting a cost and market impact  
17 review of any health care entity based on the Director's request pursuant to sections  
18 127502.5 and 127507.2 of the Code.

19  
20 *Note:*

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

22 Reference: Sections 127500.5, 127501, 127502.5, 127507, and 127507.2, Health and  
23 Safety Code.