

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 § 97431. Definitions.

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

- 9 (a) "Affiliation" or "affiliate" refers to situation in which an entity controls, is controlled  
10 by, or is under common control with another legal entity in order to collaborate for  
11 the provision of health care services.
- 12 (b) "Cost and market impact review" shall mean the review conducted by the Office  
13 pursuant to section 127507.2 of the Health and Safety Code ("the Code").
- 14 (c) "Culturally competent care" means the ability of providers and organizations to  
15 effectively deliver health care services that meet the social, cultural, and linguistic  
16 needs of patients.
- 17 (d) "Department" shall mean the Department of Health Care Access and Information.
- 18 (e) "Director" shall mean the director of the Department of Health Care Access and  
19 Information.
- 20 (f) "Fully integrated delivery system" shall have the meaning set forth in section  
21 127500.2(h) of the Code.
- 22 (g) "Health care entity" shall:
- 23 (1) Have the meaning set forth in section 127500.2(k) of the Code;  
24 (2) Include pharmacy benefit managers as set forth in sections 127501(c)(12)  
25 and 127507(a) of the Code;  
26 (3) Include a management services organization, which qualifies as a "payer"  
27 for the purposes of these regulations;  
28 (4) Include any affiliates, subsidiaries, or other entities that control, govern, or  
29 are financially responsible for the health care entity or that are subject to  
30 the control, governance, or financial control of the health care entity; and  
31 (5) Exclude physician organizations with less than 25 physicians, unless  
32 determined to be a high-cost outlier, as described in 127500.2(p)(6) of the  
33 Code. For purposes of these regulations, any health care entity entering  
34 into a transaction with a physician organization of less than 25 physicians  
35 remains subject to the notice filing requirements of section 97435.
- 36 (h) "Health care services," for purposes of this Article, are services for the care,  
37 prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health  
38 (mental health or substance use disorder) condition, illness, injury, or disease,  
39 including but not limited to:
- 40 (1) Acute care, diagnostic, or therapeutic inpatient hospital services;

- 1 (2) Acute care, diagnostic, or therapeutic outpatient services;  
2 (3) Pharmacy, retail and specialty, including any drugs or devices;  
3 (4) Performance of functions to refer, arrange, or coordinate care;  
4 (5) Equipment used such as durable medical equipment, diagnostic, surgical  
5 devices, or infusion; and  
6 (6) Technology associated with the provision of services or equipment in  
7 paragraphs (1) through (5) above, such as telehealth, electronic health  
8 records, software, claims processing, or utilization systems.
- 9 (i) "Hospital" shall mean any facility that is required to be licensed under subdivision  
10 (a), (b), or (f) of section 1250 of the Code, except a facility operated by the  
11 Department of State Hospitals or the Department of Corrections and  
12 Rehabilitation.
- 13 (j) "Management services organization" means an entity that provides administrative  
14 or management services for a health care entity, not including the direct provision  
15 of health care services. Administrative or management services include, but are  
16 not limited to, claims processing, utilization management, billing and collections,  
17 customer service, provider rate negotiation, network development, and other  
18 services and support.
- 19 (k) "Material change transaction" shall mean a transaction which meets the  
20 requirements of section 97435(c).
- 21 (l) "Notice" shall refer to the notice of a material change transaction as set forth in  
22 section 97435.
- 23 (m) "Office" shall mean the Office of Health Care Affordability established by section  
24 127501 of the Code.
- 25 (n) "Payer" shall have the meaning set forth in section 127500.2(o) of the Code.
- 26 (o) "Physician organization" shall have the meaning set forth in section 127500.2(p)  
27 of the Code.
- 28 (p) "Provider" shall have the meaning set forth in section 127500.2(q) of the Code.
- 29 (q) "Transaction" includes mergers, acquisitions, affiliations, or other agreements  
30 involving the provision of health care services in California that involve a change  
31 of assets (sell, transfer, lease, exchange, option, encumber, convey, or dispose)  
32 or entail a change, directly or indirectly, to ownership, operations, or governance  
33 structure involving any health care entity.

34  
35 **Note:**

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

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

38  
39 **§ 97433. Scope.**

1 Sections 97435 through 97441 govern the procedure for filing notices of material  
2 change transactions and the Office’s criteria and procedure for review of material  
3 change transactions and cost and market impact reviews, if deemed necessary.  
4

5 *Note:*

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

7 Reference: Sections 127500.5, 127507, and 127507.2, Health and Safety Code.  
8

9 **§ 97435. Material Change Transactions.**

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

18 (b) Who must file. A health care entity shall file a written notice of a transaction with  
19 the Office if the transaction involves any parties listed in subsections (b)(1)  
20 through (b)(3) under any one or more of the circumstances set forth in subsection  
21 (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the  
22 Code:

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

26 (2) A health care entity with annual revenue, as defined in subsection (d), of  
27 at least \$10 million or that owns or controls California assets of at least  
28 \$10 million and is involved in a transaction with any health care entity  
29 satisfying subsection (b)(1); or

30 (3) A health care entity located in or serving at least 50% of patients who  
31 reside in a health professional shortage area, as defined in Part 5 of  
32 Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations  
33 (commencing with section 5.1), available at <https://data.hrsa.gov>.

34 (c) Circumstances requiring filing. A transaction is a material change pursuant to  
35 section 127507(c)(1) of the Code if any of the following circumstances exist:

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

38 (2) The transaction is likely to increase annual revenue of any health care entity  
39 that is a party to the transaction by at least \$10 million or 20% of annual  
40 revenue at normal or stabilized levels of utilization or operation.

- 1 (3) The transaction involves the sale, transfer, lease, exchange, option,  
2 encumbrance, or other disposition of 20% or more of the assets of any health  
3 care entity in the transaction.
- 4 (4) The transaction involves a transfer or change in control, responsibility, or  
5 governance of the submitter, as defined in subsection (e).
- 6 (5) The terms of the transaction contemplate an entity negotiating or  
7 administering contracts with payers on behalf of one or more providers and  
8 the transaction involves an affiliation, partnership, joint venture, accountable  
9 care organization, parent corporation, management services organization, or  
10 other organization.
- 11 (6) The transaction involves the formation of a new health care entity, affiliation,  
12 partnership, joint venture, or parent corporation for the provision of health  
13 services in California that is projected to have at least \$25 million in annual  
14 revenue at normal or stabilized levels of utilization or operation, or have  
15 control of assets related to the provision of health care services valued at \$25  
16 million or more.
- 17 (7) The transaction involves a health care entity joining, merging, or affiliating  
18 with another health care entity, affiliation, partnership, joint venture, or parent  
19 corporation related to the provision of health care services where any health  
20 care entity has at least \$10 million in annual revenue as defined in subsection  
21 (d). For purposes of this subsection, a clinical affiliation does not include a  
22 collaboration on clinical trials or graduate medical education programs.
- 23 (8) The transaction changes the form of ownership of a health care entity that is a  
24 party to the transaction, including but not limited to change from a physician-  
25 owned to private equity-owned and publicly held to a privately held form of  
26 ownership.
- 27 (9) A health care entity that is a party to the transaction has consummated any  
28 transaction regarding provision of health care services in California with  
29 another party to the transaction within ten years prior to the current  
30 transaction.
- 31 (d) Revenue. For purposes of this section, revenue means the total average annual  
32 California-derived revenue received for all health care services by all affiliates  
33 over the three most recent fiscal years, as follows:
- 34 (1) For health care service plans, revenue as reported to the Department of  
35 Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).
- 36 (2) For health insurers, revenue as reported to the Department of Insurance  
37 pursuant to Insurance Code section 931.
- 38 (3) For hospitals, net patient revenue, as reported to the Department in  
39 accordance with the "Accounting and Reporting Manual for California  
40 Hospitals," incorporated by reference in 22 CCR 97018.

- 1 (4) For long-term care facilities, net patient revenue, as reported to the  
2 Department in accordance with the “Accounting and Reporting Manual for  
3 California Long-Term Care Facilities,” incorporated by reference in 22 CCR  
4 97019.
- 5 (5) For risk-bearing organizations required to register and report to the DMHC,  
6 revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.
- 7 (6) For other providers or provider organizations, net patient revenue, which  
8 includes the total revenue received for patient care, including:  
9 (A) Prior year third-party settlements;  
10 (B) Revenue received (inclusive of withholds, refunds, insurance services,  
11 capitation, and co-payments) from a health care entity or other payer to  
12 provide health care services, for all providers represented by the provider  
13 or provider organization in contracting with payers, for all providers  
14 represented by the provider or provider organization in contracting with  
15 payers;  
16 (C) Fee for service revenue; or  
17 (D) Revenue from shared risk and all incentive programs.
- 18 (7) For management services organizations, all payments and revenue received  
19 from health care entities to provide administrative or management services.  
20 Administrative or management services include, but are not limited to, claims  
21 processing, utilization management, billing and collections, customer service,  
22 provider rate negotiation, network development, and other services and  
23 support.
- 24 (e) Control, responsibility, or governance. For purposes of this section, a transaction  
25 will transfer or change control, responsibility, or governance if:  
26 (1) There is a substitution or addition of a new corporate member or members  
27 that transfers more than 10% of the control of, responsibility for, or  
28 governance of a health care entity; or  
29 (2) There is a substitution of one or more members of the governing body of a  
30 health care entity, or any arrangement, written or oral, that would transfer full  
31 or partial voting control of the members of the governing body of a health care  
32 entity; or  
33 (3) The transaction would result in the transfer of more than 10% of the  
34 administrative or operational control or governance of at least one entity that  
35 is a party to the transaction.
- 36 (f) A transaction is not a material change transaction if the health care entity directly,  
37 or indirectly through one or more intermediaries, already controls, is controlled  
38 by, or is under common control with, all other parties to the transaction, such as a  
39 corporate restructuring.
- 40

- 1 *Note:*
- 2 Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
- 3 Reference: Section 127500.2, 127507, Health and Safety Code.
- 4

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1 **§ 97437. Pre-Filing Questions.**

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

4  
5 *Note:*

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

7 Reference: Section 127507, Health and Safety Code.

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9 **§ 97439. Filing of Notices of Material Change Transactions.**

10 (a) A notice of material change transaction pursuant to section 127507 of the Code  
11 required to be filed under this section (“notice”) shall be made under penalty of  
12 perjury using the portal on the Office’s website at [\[website and registration](#)  
13 [instructions to be provided\]](#)\_\_. In making any narrative statements in response to  
14 subsection (b), if any documents support the assertion, the health care entity  
15 making the assertion shall, pursuant to subsections (c) and (d), provide and cite  
16 the document, including the section or page of the document.

17 (b) Form and Contents of Public Notice. A health care entity submitting a notice  
18 (“submitter”) shall provide the following information to the Office for public posting  
19 on the Office’s website:

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

22 (A) Business Name

23 (B) Business Website

24 (C) Business Mailing Address

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

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

35 (ii) For health care service plans, health insurers, and risk-bearing  
36 organizations, include number of enrollees per patient zip code in the  
37 last year.

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

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



- 1 (C) A statement of why the transaction is necessary or desirable;  
2 (D) General public impact or benefits of the transaction, including quality and  
3 equity measures and impacts;  
4 (E) Narrative description of the expected competitive impacts of the  
5 transaction; and  
6 (F) Description of any actions or activities to mitigate any potential adverse  
7 impacts of the transaction on the public.
- 8 (8) The submission date and nature of any applications, forms, notices, or other  
9 materials submitted or required regarding the proposed transaction to any  
10 other state or federal agency, such as, but not limited to, the Federal Trade  
11 Commission or the United States Department of Justice.
- 12 (9) Whether the proposed transaction has been the subject of any court  
13 proceeding and, if so, the:  
14 (i) Name of the court;  
15 (ii) Case number; and  
16 (iii) Names of the parties
- 17 (10) A description of current services provided and expected post-transaction  
18 impacts on health care services, which shall include, if applicable:  
19 (A) Physical addresses where services are performed;  
20 (B) Levels and type of health care services offered, including reproductive  
21 health care services, labor and delivery services, pediatric services,  
22 behavioral health services, cardiac services, and emergency services;  
23 (C) Number and type of patients served, including but not limited to, age,  
24 gender, race, ethnicity, preferred language spoken, disability status, and  
25 payer category;  
26 (D) Community needs assessments;  
27 (E) Charity care;  
28 (F) Community benefit programs; and  
29 (G) Medi-Cal and Medicare.
- 30 (11) Description of any other prior transactions that:  
31 (A) Affected or involved the provision of health care services;  
32 (B) Involved any of the health care entities in the proposed transaction; and  
33 (C) Occurred in the last ten years.
- 34 (12) Description of potential post-transaction changes to:  
35 (A) Ownership, governance, or operational structure.  
36 (B) Employee staffing levels, job security or retraining policies, employee  
37 wages, benefits, working conditions, and employment protections.  
38 (C) City or county contracts regarding the provision of health care  
39 services between the parties to the transaction and cities or counties.

1 (D) Seismic compliance with the Alfred E. Alquist Hospital Facilities  
2 Seismic Safety Act of 1983, as amended by the California Hospital  
3 Facilities Seismic Safety Act (Health & Saf. Code, §§ 129675-  
4 130070).

5 (E) Competition within 20 miles of any physical facility offering  
6 comparable patient services.

7 (13) Description of the nature, scope, and dates of any pending or planned  
8 material changes, as used in section 97435(b), occurring between the  
9 submitter and any other entity, within the 12 months following the date of the  
10 notice.

11 (c) Documents to Be Submitted with Notice.

12 Submitters shall upload the following documents in machine-readable portable  
13 document format (.pdf), with sections bookmarked, as applicable:

- 14 (1) Copies of all current agreement(s) and term sheets (with accompanying  
15 appendices and exhibits) governing or related to the proposed material  
16 change (e.g., definitive agreements, affiliation agreements, stock purchase  
17 agreements);
- 18 (2) Contact information for any individuals signing or responsible for the  
19 transaction or side or related agreements;
- 20 (3) If applicable, any *pro forma* post-transaction balance sheet for any surviving  
21 or successor entity;
- 22 (4) A current organizational chart of the organization of any entity party to the  
23 transaction, including charts of any parent and subsidiary organization(s) and  
24 proposed organizational chart(s) for any post-acquisition or transaction;
- 25 (5) Certified financial statements for the prior three years and any documentation  
26 related to the liabilities, debts, assets, balance sheets, statements of income  
27 and expenses, any accompanying footnotes, and revenue of all entities that  
28 are parties to the transaction;
- 29 (6) Articles of organization or incorporation, bylaws, partnership agreements, or  
30 other corporate governance documents of all entities that are parties to the  
31 transaction, including any proposed updates that occur as a result of the  
32 transaction;
- 33 (7) If the submitter has filed notice of the transaction with the Federal Trade  
34 Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of  
35 1976 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and  
36 Report Form and any attachments thereto;
- 37 (8) Any documentation related to the mitigation of any potential adverse impacts  
38 of the transaction on the public; and
- 39 (9) Any analytic support for and/or documents supporting the submitter's  
40 responses to the narrative answers provided.

1 (d) Confidentiality of Documents Submitted with Notice.

2 All of the information provided to the Office by the submitter shall be treated as a  
3 public record unless the submitter designates documents or information as  
4 confidential and the Office accepts the designation in accordance with  
5 paragraphs (1) through (3) below.

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

16 (2) Marked-confidential versions of stock purchase agreements, financial  
17 documents, compensation documents, contract rates, and unredacted  
18 résumés are deemed confidential by the Office. A submitter claiming  
19 confidentiality in respect of portions of a notice, or any documents not  
20 specified above thereafter submitted in support of the notice, shall include a  
21 redaction log that provides a reasonably detailed statement of the grounds on  
22 which confidentiality is claimed and a statement of the specific time for which  
23 confidential treatment of the information is necessary. Bases for  
24 confidentiality shall include: (1) the information is proprietary or of a  
25 confidential business nature, including trade secrets, and has been  
26 confidentially maintained by the entity and the release of which would be  
27 damaging or prejudicial to the business concern; (2) the information is such  
28 that the public interest is served in withholding the information; or (3) the  
29 information is confidential based on statute or other law.

30 (3) If a request for confidential treatment is granted, the submitter will be notified  
31 in writing, the information will be marked “Confidential” and kept separate  
32 from the public file. The Office and the Department shall keep confidential all  
33 nonpublic information and documents designated as confidential pursuant to  
34 this section.

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

39 (f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by  
40 submitting a written request at any time after submission of the notice and until

1 the Office issues its final report, as described in section 97441. The Office will  
2 remain entitled to collect any costs incurred in connection with any reviews up  
3 until the first business day after the withdrawal notice is received, pursuant to  
4 127507.4 of the Code.

5  
6 *Note:*

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

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

9  
10 **§ 97441. Cost and Market Impact Reviews.**

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

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

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

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

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

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

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

28 (E) If the transaction may negatively impact the quality of care.

29 (F) If the transaction between a health care entity located in this state and an  
30 out-of-state entity may increase the price of health care services or limit  
31 access to health care services in California.

32 (b) Timing of Review of Notice.

33 For purposes of this subsection, a notice shall be deemed complete by the Office  
34 on the date when all of the information required by section 97439 of these  
35 regulations has been submitted to the Office. Within 60 days of a complete  
36 notice, the Office shall inform each party to a noticed transaction of any  
37 determination to initiate a cost and market impact review pursuant to  
38 127507.2(a)(1) of the Code, subject to the following 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 (c) Request for Review of Determination to Conduct Cost and Market Impact  
13 Review.
- 14 (1) Within 10 business days of the date of a determination that a cost and market  
15 impact review is required, a submitter may request review of the Office's  
16 determination. The request shall:
- 17 (A) Be in writing;  
18 (B) Be signed by the submitter;  
19 (C) Be sent to the Director with a copy to the Office;  
20 (D) Be provided to all other submitters involved in the transaction;  
21 (E) Set forth specifically and in full detail the grounds upon which submitter  
22 considers the determination to be in error; and  
23 (F) State the reason(s) why the submitter asserts a cost and market impact  
24 review is not warranted.
- 25 (2) The request will be denied if it contains no more than a request for a waiver of  
26 a cost and market impact review, unsupported by specific facts.
- 27 (3) Within 5 business days of receipt of a request for redetermination, the  
28 Director may:
- 29 (A) Decline review and uphold the determination that a cost and market  
30 impact review is required; or  
31 (B) Grant the request and waive a cost and market impact review.
- 32 (4) The Director may extend this period for one additional 5-day period if the  
33 Director needs additional time to complete the review.
- 34 (5) The determination of the Director, either upholding the original determination  
35 or substituting an amended determination, is final.
- 36 (d) Timeline for Completion of Cost and Market Impact Review  
37 The Office shall complete a cost and market impact review within 90 days of the  
38 final decision by the Office to conduct a cost and market impact review, subject  
39 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 the community affected by  
19 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) Whether the parties to the transaction have been parties to any other  
26 transactions in the past ten years that have been below the thresholds set  
27 forth in section 97435(b).
- 28 (6) Consumer concerns including, but not limited to, complaints or other  
29 allegations against any health care entity that is a party to the transaction  
30 related to access, care, quality, equity, affordability, or coverage.
- 31 (7) Any other factors the Office determines to be in the public interest.

32 (f) Preliminary Report of Findings.

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

39 (g) Final Report of Findings.



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

8  
9 *Note:*  
10 Authority: Sections 127501 and 127501.2, Health and Safety Code.  
11 Reference: Sections 127500.5, 127502.5, 127507, and 127507.2, Health and Safety  
12 Code.