

PROPOSED EMERGENCY REGULATORY TEXT

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

Chapter 11.5. Promotion of Competitive Health Care Markets; Health Care Affordability

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

§ 97431. Definitions.

As used in this Article, the following definitions apply:

- (a) "Affiliation," as used in sections 97431(~~pu~~), 97435(c)(6) and 97438(c)(2) of these regulations, refers to a situation in which an entity controls, is controlled by, or is under common control with another legal entity in order to collaborate for the provision of health care services. "Affiliation" does not include a collaboration on clinical trials, graduate medical education programs, health professions training programs, health sciences training programs, or other education and research programs.
- (b) "Cost and market impact review" or "CMIR" shall mean the review conducted by the Office pursuant to section 127507.2 of the Health and Safety Code ("the Code").
- (c) "Culturally competent care" means health care services that meet the social, cultural, and linguistic needs of patients.
- (d) "Department" shall mean the Department of Health Care Access and Information.
- (e) "Director" shall mean the director of the Department of Health Care Access and Information.
- (f) "Fully integrated delivery system" shall have the meaning set forth in section 127500.2(h) of the Code.
- (g) "Health care entity" shall:
 - (1) Have the meaning set forth in section 127500.2(k) of the Code;
 - (2) Include pharmacy benefit managers as set forth in sections 127501(c)(12) and 127507(a) of the Code; and
 - (3) Include any parents, affiliates, or subsidiaries that act in California on behalf of a payer and:
 - (A) control, govern, or are financially responsible for the health care entity or are subject to the control, governance, or financial control of the health care entity, or
 - (B) in the case of a subsidiary, are a subsidiary acting on behalf of another subsidiary; but.
 - (4) Include an entity that owns, operates, or controls a provider, regardless of whether the provider is currently operating, providing health care services, or has a pending

1 or suspended license.

2 (45) Exclude physician organizations with less than 25 physicians, unless determined to
3 be a high-cost outlier, as described in 127500.2(p)(6) of the Code. Any noticing
4 and/or health care entity entering into a transaction with a physician organization of
5 less than 25 physicians remains subject to the notice filing requirements of section
6 97435.

7 (h) “Health care services” are services and payments for the care, prevention, diagnosis,
8 treatment, cure, or relief of a medical or behavioral health (mental health or substance
9 use disorder) condition, illness, injury, or disease, 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, surgical devices, or
15 infusion; and

16 (6) Technology associated with the provision of services or equipment in paragraphs (1)
17 through (5) above, such as telehealth, electronic health records, software, claims
18 processing, or utilization systems.

19 (i) “Hedge fund” shall have the meaning set forth in section 127500.2(l) of the Code.

20 (ii) “Hospital” shall mean any facility that is required to be licensed under subdivision (a),
21 (b), or (f) of section 1250 of the Code, except a facility operated by the Department of
22 State Hospitals or the Department of Corrections and Rehabilitation.

23 (k) “Management services organization” shall mean entities, as described in section
24 127500.2(o) of the Code that are additionally at least one of the following:

25 (1) Owned by a hospital and have two or more physician organizations as clients or
26 affiliates;

27 (2) Employ the physician-owner of, or otherwise have an agreement with the physician-
28 owner that defines the services to be provided and compensation for such services
29 with, one or more physician organizations;

30 (3) Share directors, officers, investors, or other natural persons with the ability to
31 exercise control with respect to a health care entity; or

32 (4) Affiliated with at least two of the following:

33 (A) A health plan;

34 (B) Two or more physician organizations; or

35 (C) A hospital.

36 (j) “Material change transaction” shall mean a transaction as defined in subsection (p) that
37 meets the requirements of section 97435(c). “Material change transaction” does not
38 include:

39 (1) Transactions in the usual and regular course of business of the health care entity,
40 meaning those that are typical in the day-to-day operations of the health care entity.

1 (2) Situations in which the health care entity directly, or indirectly through one or more
2 intermediaries, already controls, is controlled by, or is under common control with, all
3 parties to the transaction, such as a corporate restructuring.

4 (~~k~~m) "Notice" shall refer to the notice of a material change transaction as set forth in section
5 97435.

6 (n) "Noticing entity" shall mean the entities set forth in section 127507(h)(1) through (4) of
7 the Code.

8 (~~l~~o) "Office" shall mean the Office of Health Care Affordability established by section
9 127501 of the Code.

10 (~~m~~p) "Payer" shall have the meaning set forth in section 127500.2(q) of the Code.

11 (~~n~~q) "Physician organization" shall have the meaning set forth in section 127500.2(r) of the
12 Code.

13 (r) "Private equity group" shall have the meaning set forth in section 127500.2(s) of the
14 Code.

15 (~~o~~s) "Provider" shall have the meaning set forth in section 127500.2(t) of the Code.

16 (t) "Submitter" shall mean the entities that are required to provide notice of a material
17 change transaction under section 127507(c)(1) and/or (c)(2) of the Health and Safety
18 Code and these regulations or that are referred by another California state agency to
19 provide notice.

20 (~~p~~u) "Transaction" shall mean the agreements and transactions set forth in subdivisions
21 (c)(1), (c)(2)(A), and (c)(2)(B) of section 127507 of the Code, and includes mergers,
22 acquisitions, affiliations, and agreements impacting the provision of health care services
23 in California that involve a transfer (including a sale, lease, exchange, option,
24 encumbrance, conveyance, or disposition) of assets or a transfer of control,
25 responsibility, or governance of the assets or operations, in whole or in part, of any
26 health care entity and/or management services organization to one or more entities.
27 Being a subject of a transaction means the transaction will result in the transfer, as used
28 in this subsection, of a health care entity's assets, control, responsibility, governance, or
29 operations, in whole or in part to one or more entities.

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31 NOTE:

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

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

1 **§ 97432. Pre-Filing Questions.**

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

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5 NOTE:

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

7 Reference: Section 127507, Health and Safety Code.
8

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

10 (a) A health care entity or noticing entity that meets the criteria of subsection (b) shall
11 provide the Office with notice of a material change transaction as described in
12 subsection (c) at least 90 days before the closing date of the transaction. For purposes
13 of section 127507(c)(23) of the Code, the phrase “entering into the agreement or
14 transaction” refers to the closing date.

15 (b) **Who must file.** A health care entity or noticing entity ~~who is a party to, or a subject of, a~~
16 ~~material change transaction,~~ shall file a written notice of the material change transaction
17 with the Office if the health care entity (~~hereinafter referred to as a “submitter”~~) or
18 noticing entity meets any of the thresholds in subsections (b)(1) through (b)(3) under
19 any of the circumstances set forth in subsection (c), unless exempted by subdivisions
20 (d)(1) through (4) of section 127507 of the Code. ~~Being a subject of a transaction~~
21 ~~means the transaction will result in the transfer, as used in section 97431(p), of a health~~
22 ~~care entity’s assets, control, responsibility, governance, or operations, in whole or in~~
23 ~~part to one or more entities.~~

24 (1) A health care entity with annual revenue, as defined in subsection (d), of at least \$25
25 million or that owns or controls California assets of at least \$25 million and is a party
26 to, or subject of, the transaction.

27 (2) A health care entity with annual revenue, as defined in subsection (d), of at least \$10
28 million or that owns or controls California assets of at least \$10 million and is a party
29 to, or a subject of, a transaction with:

30 (A) any health care entity satisfying subsection (b)(1); or

31 (B) any entity that owns or controls a health care entity satisfying subsection (b)(1);
32 or

33 (C) any noticing entity that satisfies subsection (b)(4).

34 (3) A provider or fully integrated delivery system that is a party to, or a subject of, the
35 transaction and provides health care services in a designated primary care health
36 professional shortage area in California, as defined in Part 5 of Subchapter A of
37 Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section
38 5.1), available at <https://data.hrsa.gov>.

1 (4) A noticing entity meeting one of the following:

2 (A) A private equity group or hedge fund that is a party to a transaction identified in
3 subsection (c)(10) with a management services organization or health care entity
4 satisfying subsection (b)(1), (2), or (3).

5 (B) A management services organization that is a party to a transaction identified in
6 subsection (c)(11) with a management services organization or a health care
7 entity satisfying subsection (b)(1), (2), or (3).

8 (C) A newly created business entity created for the purpose of entering into
9 agreements or transactions with a health care entity that is a party to a
10 transaction with a health care entity satisfying subsection (b)(1), (2), or (3).

11 (c) **Circumstances requiring filing.** A transaction is a material change transaction
12 pursuant to section 127507(c)(1) of the Code if any of the circumstances in paragraphs
13 (1) through (811) below exist. For purposes of this subsection only, “annual California-
14 derived revenue” means revenue from the provision of health care services in
15 California.

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

18 (2) The transaction is more likely than not to increase annual California-derived revenue
19 of any health care entity that is a party to, or a subject of, the transaction, by either
20 \$10 million or more or 20% or more of annual California-derived revenue at normal
21 or stabilized levels of utilization or operation.

22 (3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance,
23 or other disposition of 25% or more of the total California assets of the health care
24 entity(ies) submitter(s).

25 (4) The transaction involves a transfer of control, responsibility, or governance, in whole
26 or in part, of the health care entity submitter, as defined in subsection (e).

27 (5) The transaction will result in an entity contracting with payers on behalf of
28 consolidated or combined providers and is more likely than not to increase the
29 annual California-derived revenue of any provider that is a party to, or a subject of,
30 the transaction by either \$10 million or more or 20% or more of annual California-
31 derived revenue at normal or stabilized levels of utilization or operation.

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

- 1 (7) The transaction is part of a series of related transactions for the same or related
2 health care services occurring over the past ten years involving the same health
3 care entities, same management services organizations, or entities affiliated with the
4 same entities. The proposed transaction and its related transactions will constitute a
5 single transaction for purposes of determining the revenue thresholds in subsection
6 (b) and asset and control circumstances in subsections (c)(3), (c)(4), and (c)(6).
- 7 (8) The transaction involves the acquisition of a health care entity and/or management
8 services organization by another entity and the acquiring entity has consummated a
9 similar transaction(s), in the past ten years, with a management services
10 organization or a health care entity that provides the same or related health care
11 services. The proposed transaction and its related transactions will constitute a
12 single transaction for purposes of determining the revenue thresholds in subsection
13 (b) and asset and control circumstances in subsections (c)(3), (c)(4), and (c)(6).
- 14 (9) The transaction involves a private equity group or hedge fund and does one of the
15 following:
- 16 (A) Results in the private equity group or hedge fund holding 5% or more of the
17 assets, equity, debt, or liabilities of a health care entity satisfying subsection
18 (b)(1), (2) or (3) or a management services organization. This includes groups of
19 investors, private equity firms, or hedge funds investing collectively to hold 5% of
20 the assets or equity of the health care entity; or
- 21 (B) Results in the acquisition of assets, equity, debts, or liabilities of a health care
22 entity satisfying subsection (b)(1), (2), or (3) or a management services
23 organization, including, but not limited to, by an agreement where the private
24 equity group or hedge fund has authority to do any of the following:
- 25 (i) Appoint or replace leadership or governing body member(s) of the health care
26 entity or management services organization;
- 27 (ii) Veto decisions made by a health care entity or management services
28 organization;
- 29 (iii) Alter operations by expanding or reducing health care services offered by the
30 health care entity or changing arrangements with management services
31 organization or payers;
- 32 (iv) Purchase the real property of a health care entity where services are
33 provided and lease the property back to the health care entity;
- 34 (v) Cause, require, approve, or veto the incurrence of indebtedness by the health
35 care entity or management services organization;
- 36 (vi) Manage or operate a health care entity or management services
37 organization, such as through management agreements, consulting
38 agreements, administrative services agreements, or affiliated management
39 services organizations;
- 40 (vii) Charge fees to the health care entity or management services organization;
41 or

1 (viii) Spend the capital and net income of a health care entity or management
2 services organization. Spending the capital or net income may involve
3 approving, directing, restricting, or controlling budgets, capital expenditures,
4 distributions, or the use of net income or tax reserves.

5 (10) The transaction involves a management services organization and does one of the
6 following:

7 (A) Results in a management services organization providing management and
8 administrative support services for a health care entity satisfying subsection
9 (b)(1);

10 (B) Results in a management services organization providing management and
11 administrative support services for two or more providers that collectively
12 generate \$10 million annually from California patients; or

13 (C) Involves a transfer of control, responsibility, or governance, in whole or in part, of
14 the management services organization, as defined in subsection (e), or a change
15 in 25% or more of the management services organization's ownership.

16 (11) The transaction results in the sale or transfer of real estate where a health care
17 entity provides health care services:

18 (A) To an entity other than the entity acquiring the health care entity or its direct
19 parent; and

20 (B) The surviving health care entity will be required to lease or pay rent for the real
21 estate.

22 (d) **Revenue.** For purposes of subsection (b) of this regulation only, "revenue" means the total
23 average annual California-derived revenue received for all health care services by the
24 submitter and all affiliates over the three most recent fiscal years, as follows:

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

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

29 (3) For hospitals, net patient revenue, as reported to the Department in accordance with
30 the "Accounting and Reporting Manual for California Hospitals," incorporated by
31 reference in 22 CCR § 97018.

32 (4) For long-term care facilities, net patient revenue, as reported to the Department in
33 accordance with the "Accounting and Reporting Manual for California Long-Term
34 Care Facilities," incorporated by reference in 22 CCR § 97019.

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

37 (6) For other providers or provider organizations, net patient revenue, which includes
38 the total revenue received for patient care, as it was generated or occurred in
39 California rather than when revenue is booked, accrued, or taxed, including:

40 (A) Prior-year third-party settlements;

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

5 (C) Fee-for-service revenue; and

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

7 (7) For pharmacy benefit managers, all payments and revenue received from health
8 care entities to provide pharmacy benefit management services as it was generated
9 or occurred in California rather than when revenue is booked, accrued, or taxed.

10 (e) Control, responsibility, or governance. For purposes of this section, a transaction will
11 directly or indirectly transfer control, responsibility, or governance, in whole or in part, of
12 a material amount of the assets or operations of a health care entity and/or
13 management services organization to one or more entities if:

14 (1) The transaction would result in the transfer of 25% or more of the voting power of
15 the members of the governing body of a health care entity and/or management
16 services organization, such as by adding one or more members, substituting one or
17 more members, or through any other type of arrangement, written or oral; or

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

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22 NOTE:

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

24 Reference: Sections 127500.2 and 127507, Health and Safety Code.
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27 **§ 97437. Confidentiality.**

28 (a) Confidentiality of Documents and Information Submitted to the Office.

29 All of the information provided to the Office as part of a Notice or Cost and Market
30 Impact Review shall be treated as a public record unless the submitter designates
31 documents or information as non-public or confidential when submitting through the
32 Office portal system and the Office accepts the designation in accordance with
33 subsections (b) through (d) below. For purposes of this Article, “nonpublic” means
34 information that:

35 (1) Is confidentially maintained and not shared by the holder of the information with the
36 general public; and

37 (2) Does not include information that is lawfully made available to the general public
38 from any federal, state, or local government record or disclosure, media source, or
39 any other publicly available source.

40 (b) Requests for Confidentiality. A submitter of a notice of a material change transaction, a

1 submitter requesting expedited review pursuant to section 97439, or a submitter
2 requesting review of the Office's determination to conduct a cost and market impact
3 review pursuant to section 97441, ("requestor") may request confidential treatment of
4 information or documents submitted. When requesting confidentiality of documents or
5 information:

6 (1) The requestor shall file two versions of any document for which confidentiality is
7 requested in part. The nonpublic version shall be unredacted and shall be
8 maintained as confidential by the Office and Department pending a determination of
9 confidentiality. The public version, which may be made available to the public by the
10 Office, shall have the confidential portions removed or redacted.

11 (2) A requestor requesting confidentiality in respect to portions of a notice, a request for
12 expedited review, a request to review a determination to conduct a cost and market
13 impact review, or any documents or information not specified in subsection (c)
14 thereafter submitted in support of the notice, shall include a justification that
15 provides:

16 (A) A detailed statement of the grounds enumerated in (3)(A) through (D), below, on
17 which confidentiality is claimed and an explanation of why confidentiality is
18 necessary;

19 (B) A statement of the specific time for which confidential treatment of the
20 information is necessary and an explanation for why the specific time is
21 necessary; and

22 (C) A statement describing how the information has been confidentially maintained
23 by the entity.

24 (3) The detailed statement in support of the request for confidentiality shall indicate
25 whether any of the following applies:

26 (A) Whether the information is proprietary or of a confidential business nature,
27 including trade secrets (as defined in California Civil Code section 3426.1(d)),
28 and whether the release would be damaging or prejudicial to the business
29 concern;

30 (B) Whether another state or federal agency deems the filed document confidential
31 and, if so, for what period of time;

32 (C) Whether the information is confidential based on statute or other law; or

33 (D) Whether the information is such that the public interest is served in withholding
34 the information.

35 (4) A Submitter may request confidentiality of information or documents it has obtained
36 from another party to the transaction if it lacks personal knowledge to establish their
37 confidential nature under subsection (d)(3). In this event, submitter may submit a
38 declaration from the party to meet the requirements of subsection (d)(3) to obtain
39 confidentiality for such information or document.

40 (c) Deemed Confidential Documents. Marked-confidential versions of stock purchase
41 agreements, compensation documents, contract rates, transaction valuation

1 documentation provided in response to subsection (c)(3), and unredacted résumés are
2 deemed confidential and nonpublic by the Office, pursuant to section 127507.2(c)(2) of
3 the Code. The Submitter must mark each of the documents as confidential pursuant to
4 this subsection.

5 (d) Requests for confidentiality of publicly available information or documents will be
6 denied.

7 (e) When the Office makes a determination regarding a request for confidential treatment,
8 the submitter will be notified in writing. With the exception of disclosure to the Attorney
9 General pursuant to sections 127507.2(c)(1) and 127507.2(d)(1) of the Code, the Office
10 and the Department shall keep confidential all nonpublic information and documents
11 designated as confidential pursuant to this section. If a request for confidentiality is
12 denied, a submitter may withdraw any information or documents for which it requested
13 confidentiality in its submission by submitting a request through the portal.

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15 NOTE:

16 Authority cited: Sections 127501, 127501.2, 127507, and 127507.2, Health and Safety Code.
17 Reference: Section 127507 and 127507.2, Health and Safety Code.
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20 **§ 97438. Filing of Notices of Material Change Transactions.**

21 (a) A notice of material change transaction pursuant to section 127507 of the Code
22 required to be filed under this section (“notice”) shall be made under penalty of perjury
23 using the portal on the Office’s website at www.hcai.ca.gov/login. A ~~health care entity~~
24 submitter shall also attest it used reasonable diligence to ascertain the information
25 required by this section. A ~~health care entity submitter~~ or its agent filing via the portal
26 shall create a portal account by inputting a first (given) and last name (surname), valid
27 e-mail account, display name, and password, and submit a system-generated
28 verification code. Alternatively, ~~the health care entity a submitter or agency~~ may use an
29 existing media account from Microsoft or Google to access the portal.

30 (b) Form and Contents of Public Notice. A ~~submitter health care entity submitting a notice~~
31 ~~(“submitter”)~~ shall indicate which threshold(s) and circumstance(s) are met, pursuant to
32 section 97435(b) and (c), respectively, and either note where in another entity’s
33 submission for the same transaction the following information is found or provide the
34 following information to the Office for public posting on the Office’s website:

35 (1) General information regarding the submitter:

36 (A) ~~Business~~ Entity Name.

37 (B) ~~Business~~ Entity Website.

38 (C) ~~Business~~ Entity Mailing Address.

39 (D) Description of organization, including, but not limited to, business lines or
40 segments, ownership type (corporation, partnership, limited liability company,
41 etc.), governance and operational structure (including ownership of or by a health

1 care entity). Submitters shall also include the following information:

2 (i) For health care providers or fully integrated delivery systems, include a
3 summary of provider type (hospital, physician group, etc.), facilities owned or
4 operated, the owner of any real property involved in the transaction where
5 services are provided, service lines, number of staff, geographic service
6 area(s), number of patients served per county in California in the last year,
7 and capacity (e.g., number of licensed beds) ~~or patients served (e.g., number~~
8 ~~of patients per county) in California in the last year.~~

9 (ii) For health care service plans, health insurers, risk-bearing organizations, and
10 fully integrated delivery systems, include number of enrollees per county in
11 the last year.

12 (iii) For management services organizations, include all types of services offered,
13 the types of services provided to any health care entity involved in the
14 transaction, and geographic service area(s).

15 (iv) For private equity groups or hedge funds, include names of health care
16 entities or management services organizations owned or financed by the
17 participating asset managers and funds they manage.

18 (E) Federal Tax Identification Number and tax status as for-profit or non-profit.

19 (F) If applicable, a list List of current California health care-related licenses and license
20 or registration numbers issued by regulatory agencies such as the Department of
21 Managed Health Care, the Department of Insurance, and the Department of
22 Public Health; state and local business licenses related to the provision of health
23 care services; registration(s) with the Secretary of State held by the submitter, if
24 any; and for any current health-care related license(s) held outside of California,
25 identification of license type and state of issuance. For purposes of this
26 subsection, provide the health care license type and numbers only for those
27 facilities, services, and professions involved in the transaction. Individual
28 professional license information is not required to be provided.

29 (G) Contact person, title, e-mail address, and mailing address for public inquiries.

30 (H) Names of all affiliates, parents, and subsidiaries of the submitter.

31 (I) Names of all members of the submitter's governing body such as the board of
32 directors, managing partners, or LLC managers.

33 (2) If applicable, a list List of primary languages used by submitter a provider when
34 providing services to the public as well as any threshold languages, as determined
35 by the Department of Health Care Services, used when providing services to Medi-
36 Cal beneficiaries;

37 (3) Identification of all parties to the transaction and indication whether any health care
38 entities and/or noticing entities who are parties to the transaction will be submitting a
39 notice. For each entity that is a party to (or in the case of a health care entity, the
40 subject of) the transaction, the submitter shall exercise reasonable diligence to
41 ascertain and shall describe the following:

- 1 (A) The entity's business (including all business lines or segments), any affiliation
2 with a management services organization, and relationship, if any, to any of the
3 other parties to the transaction;
- 4 (B) Ownership type (corporation, partnership, limited liability company, etc.),
5 including any affiliates, subsidiaries, or other entities that control, govern, or are
6 financially responsible for the noticing and/or health care entity or that are subject
7 to the control, governance, or financial control of the noticing and/or health care
8 entity;
- 9 (C) Governance and operational structure (including ownership of or by a health
10 care entity and/or management services organization);
- 11 (D) Annual revenue for the three most recent fiscal years used in calculating
12 revenue in accordance with section 97435(d);
- 13 (E) Current county or counties of any health care entity or management services
14 organization's operation;
- 15 (F) If a health care provider or a fully integrated delivery system is a party to, or the
16 subject of, the transaction, include a summary of provider type (hospital,
17 physician group, etc.), facilities owned or operated, service lines, number of staff,
18 geographic service area(s), and capacity (e.g., number of licensed beds) or
19 patients served (e.g., number of patients per county) in California in the last year;
- 20 (G) Primary and threshold languages of any provider, as determined by the
21 Department of Health Care Services, used;
- 22 (H) If a payer or a fully integrated delivery system is a party to, or the subject of, the
23 transaction, include a list of all counties where coverage is sold, counties in
24 which they are licensed to operate by the Department of Managed Health Care
25 and/or the Department of Insurance, and the number of enrollees residing in
26 each listed county in the year preceding the transaction; and
- 27 (I) Include the business addresses, if known, of all new entities that will be formed as
28 a result of the transaction;
- 29 (4) Proposed or anticipated date of transaction closure;
- 30 (5) Description of transaction, which shall include the following:
- 31 (A) The goals of the transaction;
- 32 (B) A summary of terms of the transaction;
- 33 (C) A statement of why the transaction is necessary or desirable;
- 34 (D) General public impact or benefits of the transaction, including quality and equity
35 measures and impacts;
- 36 (E) Narrative description of the expected competitive impacts of the transaction; and
- 37 (F) Description of any actions or activities to mitigate any potential adverse impacts
38 of the transaction on the public.

- 1 (6) The submission date and nature of any applications, forms, notices, or other
2 materials submitted or required regarding the proposed transaction to any other
3 state or federal agency, such as, but not limited to, the Federal Trade Commission
4 or the United States Department of Justice.
- 5 (7) Whether the proposed transaction has been the subject of any court proceeding
6 and, if so, the:
- 7 (A) Name of the court;
8 (B) Case number; and
9 (C) Names of the parties.
- 10 (8) ~~A description~~ Description of current services provided by the health care entity and
11 expected post-transaction impacts on health care services, which shall include, if
12 applicable:
- 13 (A) Counties where services are currently performed and any post-transaction
14 changes thereto;
- 15 (B) Levels and type of health care services currently offered, such as the full range
16 of reproductive health care and sexual health care services, specialized services
17 for LGBTQ+ populations, labor and delivery services, pediatric services,
18 behavioral health services, cardiac services, and emergency services, and any
19 post-transaction changes thereto;
- 20 (C) Summary that includes the number and type of patients currently served,
21 including, but not limited to, age, gender, race, ethnicity, preferred language
22 spoken, disability status, and payer category, and any post-transaction changes
23 thereto;
- 24 (D) Any CMS "Star Ratings" or similar quality assessments
- 25 ~~(DE)~~ Current community needs assessments, charity care, and community benefit
26 programs, and any post-transaction changes thereto; ~~and~~
- 27 ~~(EF)~~ Whether Medi-Cal and Medicare patients are currently accepted and any post-
28 transaction changes thereto; and
- 29 (G) Anticipated cost savings, quality investments, price reductions, and service
30 expansions as a result of the transaction.
- 31 (9) If this transaction is a merger or acquisition, description of any other prior mergers or
32 acquisitions by any noticing and/or health care entity that satisfy all of the following:
- 33 (A) Involved the same, similar, or related health care and/or management services
34 organization services;
- 35 (B) Involved at least one of the entities, or their parents, subsidiaries, predecessors,
36 or successors, in the proposed transaction; and
- 37 (C) Were closed in the last ten years.
- 38 (10) Description of potential post-transaction changes to:

1 (A) Ownership, governance, or operational structure of the submitter and parties to
2 the transaction, including all entities or persons with 5% or more ownership of the
3 entity for:-

4 (i) Any acquiring or merging entity, including all intermediate entities between the
5 ultimate parent company and acquiring entity, as well as any entities
6 controlled by the acquiring entity at the time of the transaction; and

7 (ii) Any acquired or merging entity, including all entities or persons with 5% or
8 more ownership of the entity and controlled entities that will exist post-
9 transaction.

10 (B) Voting rights, decision-making authority, and management and compliance
11 structures of the submitter and parties to the transaction.

12 (BC) The submitter's employee staffing levels, job security, retraining policies,
13 wages, benefits, working conditions, collective bargaining, and/or employment
14 protections.

15 (D) Real Estate where health care services are provided, including sales, transfers
16 to affiliates, encumbrances, or updates to landlord-tenant agreements.

17 (GE) If applicable, cCity or county contracts regarding the provision of health care
18 services between the parties to the transaction and cities or counties.

19 (DF) If the submitter is a provider or a fully integrated delivery system, comparable
20 health care services currently offered by other health care entities within 20 miles
21 of any location where the submitter offers health care services.

22 (11) Description of the nature, scope, and dates of any material change transactions
23 between the submitter and any other entity (including parents, subsidiaries, and any
24 entity or person with 5% or more ownership of the entity thereof) that are either
25 pending or planned to occur within 12 months following the date of the notice.

26 (c) Documents to Be Submitted with Notice. Except for documents submitted pursuant to
27 subsection (c)(1), if a submitter is submitting a document in response to either
28 subsections (b) or (c), a submitter may reference the page number or section of that
29 submission or of another entity's submission in the same transaction in response to
30 another subsection. Submitters shall upload the following documents in machine-
31 readable portable document format (.pdf), with sections bookmarked, as applicable:

32 (1) If the submitter has filed notice of the transaction with the Federal Trade
33 Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976
34 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and Report Form
35 and any attachments thereto;

36 (2) Copies of all current agreement(s), letters of intent (whether or not superseded by an
37 agreement), and term sheets (with accompanying appendices and exhibits)
38 governing or related to the proposed material change (e.g., definitive agreements,
39 affiliation agreements, stock purchase agreements);

40 (3) Copies of any lease-back agreements;

- 1 (34) Documentation sufficient to show the valuation of the transaction, such as;
2 (A) Independent valuation/appraisal reports prepared by a third party related to
3 businesses, tangible and intangible assets, services, and/or compensation
4 related to the transaction. This may include fair market value opinions, fair value
5 opinions, fairness opinions, solvency opinions, and/or strategic value opinions;
6 (B) Internal management-prepared valuation analyses related to businesses,
7 tangible and intangible assets, services, and/or compensation related to the
8 transaction;
9 (C) Previous financial and/or tax reporting valuations performed relating to the health
10 care entity within the three years prior to the contemplated transaction;
11 (D) Valuation analyses pertaining to the transaction included in board or special
12 committee presentations; and
13 (E) Analyses or reports pertaining to the anticipated value of community benefits
14 provided by any health care entity involved in the transaction;
15 (45) Contact information for any individuals signing or responsible for the transaction or
16 side or related agreements, including names, addresses, telephone numbers, and e-
17 mail addresses;
18 (56) Any pro forma post-transaction balance sheet for any surviving or successor entity;
19 ~~(6) A current organizational chart of the organization of any entity party to the~~
20 ~~transaction, including charts of any parent and subsidiary organization(s), and proposed~~
21 ~~organizational chart(s) for the same entities after the transaction;~~
22 (7) Organizational chart(s) including:
23 (A) A current organizational chart for any party to, or subject of, the transaction up
24 through the ultimate parent entity and including any subsidiary organizations;
25 (B) A current organizational chart for any health care entity or noticing entity in the
26 transaction that shows all entities or persons with 5% or more ownership of the
27 entity; and
28 (C) Proposed organizational chart(s) for the same entities after the transaction.
29 (8) For private equity groups or hedge funds, documentation showing the names of all
30 health care entities or management services organizations in the portfolios of
31 participating asset managers.
32 (79) Existing ~~d~~Documentation identifying the number of patients per county or enrollees
33 per county in the last year of any provider, payer, or fully integrated delivery system,
34 as applicable, that is a subject of the transaction;

1 (810) Certified financial statements for the prior three years and any documentation
2 related to the liabilities, debts, assets, balance sheets, statements of income and
3 expenses, any accompanying footnotes, and revenue of all entities that are parties
4 to the transaction, including the entities described in subsection (b)(10)(A)(i) and (ii)
5 of this section. “Certified financial statements” mean audited financial reports, or if a
6 health care entity does not routinely prepare audited financial reports,
7 comprehensive financial statements. Comprehensive financial statements shall
8 include details regarding annual costs, annual receipts, realized capital gains and
9 losses, and accumulated surplus and accumulated reserves using the standard
10 accounting method routinely used by the health care entity. Comprehensive financial
11 statements must be supported by sworn written declarations by the chief financial
12 officer, chief executive officer or other officer who has financial management and
13 oversight responsibility, certifying the comprehensive financial statement is
14 complete, 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, or the
16 most recent audited financial report is not available. For California-derived revenue
17 requirements (as used in this Article), the certification under this paragraph requires
18 that revenue be calculated as it was generated or occurred in California rather than
19 when booked, accrued, or taxed;

20 (11) For private equity groups or hedge funds, documentation sufficient to show the
21 ratio of debt to enterprise value or ratio of debt to equity, the source of any debt, and
22 the post-recapitalization debt ratio for any acquired health care entity or
23 management services organization.

24 (912) Articles of organization or incorporation, bylaws, partnership agreements, or other
25 corporate governance documents of all entities that are parties to the transaction,
26 including any proposed updates that occur as a result of the transaction;

27 (4013) Any documentation related to the mitigation of any potential adverse impacts of
28 the transaction on the public; and

29 (4414) Any analysis and/or documents supporting the submitter’s responses to the
30 narrative answers provided pursuant to subsection (b), including documents or
31 presentations shared with investors or the governing body of the health care entity or
32 noticing entity.

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

38
39 ~~(1) A submitter of a notice pursuant to this section, or a submitter requesting expedited~~
40 ~~review pursuant to section 97439 may request confidential treatment of information or~~
41 ~~documents submitted. The submitter shall file two versions of any document for which~~
42 ~~confidentiality is requested. The nonpublic version shall be unredacted and shall be~~
43 ~~maintained as confidential by the Office and Department pending a determination of~~
44 ~~confidentiality. The public version, which may be made available to the public by the Office,~~

1 shall have the confidential portions removed or redacted. Requests for confidentiality of
2 publicly available information or documents will be denied.

3 ~~(2) Marked confidential versions of stock purchase agreements, compensation documents,~~
4 ~~contract rates, transaction valuation documentation provided in response to subsection~~
5 ~~(c)(3), and unredacted résumés are deemed confidential and nonpublic by the Office,~~
6 ~~pursuant to section 127507.2(c)(2) of the Code.~~

7 ~~(3) A submitter claiming confidentiality in respect to portions of a notice, a request for~~
8 ~~expedited review, or any documents not specified in subsection (d)(2) thereafter submitted in~~
9 ~~support of the notice, shall include a justification that provides a detailed statement of the~~
10 ~~grounds enumerated in (A) through (D), below, on which confidentiality is claimed, a~~
11 ~~statement of the specific time for which confidential treatment of the information is~~
12 ~~necessary, and a statement that the information has been confidentially maintained by the~~
13 ~~entity. The detailed statement in support of the request for confidentiality shall indicate~~
14 ~~whether any of the following applies:~~

15 ~~(A) Whether the information is proprietary or of a confidential business nature, including~~
16 ~~trade secrets (as defined in California Civil Code section 3426.1(d)), and whether the~~
17 ~~release would be damaging or prejudicial to the business concern;~~

18 ~~(B) Whether another state or federal agency deems the filed document confidential and, if~~
19 ~~so, for what period of time;~~

20 ~~(C) Whether the information is confidential based on statute or other law; or~~

21 ~~(D) Whether the information is such that the public interest is served in withholding the~~
22 ~~information.~~

23 ~~(4) When the Office makes a determination regarding a request for confidential treatment,~~
24 ~~the submitter will be notified in writing. If a request for confidential treatment is granted, the~~
25 ~~information will be marked "Confidential" and kept separate from the public file. With the~~
26 ~~exception of disclosure to the Attorney General pursuant to sections 127507.2(c)(1) and~~
27 ~~127507.2(d)(1) of the Code, the Office and the Department shall keep confidential all~~
28 ~~nonpublic information and documents designated as confidential pursuant to this section. If a~~
29 ~~request for confidentiality is denied, a submitter may withdraw any information or documents~~
30 ~~for which it requested confidentiality in its submission by submitting a request through the~~
31 ~~portal.~~

32 ~~(ed) Notification of Changes. A submitter shall notify the Office within five business days if~~
33 ~~the transaction is amended or cancelled. The Office shall require a submitter to re-~~
34 ~~notice an amended material change transaction in accordance with the procedures set~~
35 ~~forth in section 97435.~~

36 ~~(fe) Withdrawal of Notice. A submitter may withdraw a notice for any reason by submitting a~~
37 ~~written request at any time after submission of the notice and until the Office issues its~~
38 ~~final report, as described in section 97442. The Office will remain entitled to collect any~~
39 ~~costs incurred in connection with any reviews up until the first business day after the~~
40 ~~withdrawal notice is received, pursuant to section 127507.4 of the Code.~~

1 NOTE:

2 Authority cited: Sections 127501 and 127501.2, Health and Safety Code.

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

4
5
6 **§ 97439. Request for Expedited Review of Notices of Material Change Transaction.**

7 (a) A submitter may request expedited review of a notice of a material change transaction
8 by providing the Office, concurrently with the submission required by section 97435:

9 (1) A detailed explanation, in accordance with subsection (b), of the conditions
10 necessitating expedited review;

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

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

13 (b) A submitter must demonstrate that ~~either~~ any one or more of the conditions below
14 exists:

15 (1) Severe financial distress of one or more of the parties to the transaction. “Severe
16 financial distress” means grave risk of immediate business failure, such as a
17 substantial likelihood that a party to the transaction (or an entity affected by the
18 transaction) will have to file for bankruptcy under Chapter 11 of the Bankruptcy Act
19 (11 U.S.C. Sec. 1101 *et seq.*) absent expedited review, and that the transaction is
20 necessary to ensure continued health care access in the relevant markets.

21 (2) A substantial likelihood of a significant reduction in the provision of critical health
22 care services within one or more geographic regions.

23 (3) An urgent situation exists (including, without limitation, a public health emergency,
24 natural disaster, or legal mandate), not of the submitter’s own making, in which the
25 public interest would be best served by an expedited review.

26 (c) A submitter may request that information submitted pursuant to subsection (a) be held
27 confidential in accordance with section 97438(d). If a request for confidentiality is denied
28 in any part, a submitter may withdraw a request to expedite review by submitting a
29 request through the portal.

30 (d) The Office will grant the request if the submitter has demonstrated that conditions for
31 expedited review exist and the transaction is required to address such conditions.

32
33 NOTE:

34 Authority cited: Sections 127501 and 127501.2, Health and Safety Code.

35 Reference: Section 127507.2, Health and Safety Code.

1 **§ 97440. Timing of Review of Notice and Tolling.**

2 (a) Timing of Review of Notice. For purposes of this subsection, a notice shall be deemed
3 complete by the Office on the date when all of the information required by section 97438
4 of these regulations has been submitted to the Office by all health care entities and
5 noticing entities who are parties to the transaction and required to submit under section
6 97435(b).

7 (1) Subject to subsection (b), should OHCA determine it will not conduct a CMIR, OHCA
8 will notify the submitters of this determination within 45 days after the filing of a
9 complete notice. The Office and the submitter may agree to a later date by mutual
10 agreement, which shall be in writing and specify the date on which the Office and the
11 parties have agreed.

12 (2) Subject to subsection (b), should OHCA determine it will conduct a CMIR, it will
13 notify the submitters of that determination within 60 days after the filing of a
14 complete notice.

15 (3) Should the scope of the transaction materially change from that outlined in the initial
16 notice, the 45-day and 60-day periods shall be restarted by the Office.

17 (b) Tolling of 45-day and 60-day periods.

18 (1) The 45-day and 60-day periods shall be tolled during any time period in which the
19 Office has requested and is awaiting further information from the parties to a
20 material change transaction or from or a third party necessary to complete its review.

21 (2) The Office shall toll the 45-day and 60-day periods during any time period in which
22 review of the transaction by another state agency, federal regulatory agency, or
23 court may impact the Office's determination.

24 NOTE:

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

26 Reference: Section 127507.2, Health and Safety Code.

27
28
29 **§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and**
30 **Market Impact Review.**

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

32 (1) The Office shall base its decision whether to conduct a CMIR on any of the following
33 factors:

34 (A) The transaction may result in a negative impact on the availability or accessibility
35 of health care services, including ~~the~~ a health care entity's ability to offer
36 culturally competent care.

37 (B) The transaction may result in a negative impact on costs for payers, purchasers,
38 or consumers, including the ability to meet any health care cost targets
39 established by the Health Care Affordability Board pursuant to section 127502(n)
40 of the Code, and as set forth at 22 CCR 97447.

- 1 (C) The transaction may lessen competition or create a monopoly in any geographic
2 service areas impacted by the transaction.
- 3 (D) The transaction may lessen competition for health care entities to hire workers or
4 may negatively impact the labor market by, for instance, lowering wages or
5 slowing wage growth, worsening benefits or working conditions, or resulting in
6 other degradations of workplace quality.
- 7 (E) The transaction negatively impacts a general acute care or specialty hospital by,
8 for instance, restricting or reducing the health care services offered.
- 9 (F) The transaction may negatively impact the quality of health care services
10 available to patients from the parties to the transaction.
- 11 (G) The transaction involves a real estate investment trust (REIT), the terms of
12 which could weaken the financial status of the health care entity or place access
13 to care at risk.
- 14 ~~(G)~~ (H) The transaction is part of a series of similar transactions by the health care
15 entity, noticing entity, or other entities that furthers a trend toward consolidation.
- 16 (H) The transaction may entrench or extend a dominant market position of any
17 health care entity or noticing entity in the transaction, including extending market
18 power into related markets through vertical or cross-market mergers.
- 19 (J) The transaction between a health care entity located in this state and an out-of-
20 state entity may negatively impact affordability, quality, or limit access to health
21 care services in California, or undermine the financial stability or competitive
22 effectiveness of a health care entity located in this state.

23 (b) Request for Review of Determination to Conduct a Cost and Market Impact Review.

- 24 (1) Within 10 business days after the date of a determination that a CMIR is required,
25 the submitters of the notices for that transaction may collectively request review by
26 the Director of the Office's determination. The request shall:
- 27 (A) Be in writing;
- 28 (B) Be signed by all requesting submitters;
- 29 (C) Be submitted through the Office's portal;
- 30 (D) Specifically set forth the grounds upon which the submitters consider the
31 determination to be in error; and
- 32 (E) State the reasons why a CMIR is not warranted.
- 33 (2) The request will be denied if it contains no more than a request for a waiver of a
34 CMIR, unsupported by specific facts.
- 35 (3) Within five business days of receipt of a request for review, the Director shall either:
- 36 (A) Decline review and uphold the determination that a CMIR is required; or
- 37 (B) Remand the determination based upon new information submitted in (b)(1)(E); or
- 38 (C) Grant the request and waive a CMIR.

1 (4) If the Director remands pursuant to (b)(3)(B), the Office will have up to 30 calendar
2 days to conduct an additional review as directed in the remand order. This period
3 may be tolled if the Office needs additional information or documents from the
4 parties to conduct the review or if the Office receives voluminous information or
5 documents and needs additional time to conduct the review. At the conclusion of this
6 review, the Director may uphold the determination or issue a waiver.

7 (45) The Director may extend this period by an additional five business days if the
8 Director needs additional time to complete the review.

9 (56) The determination of the Director, either upholding the original determination or
10 waiving the determination, is final.

11 NOTE:

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

13 Reference: Sections 127502 and 127507.2, Health and Safety Code.

14 **§ 97442. Cost and Market Impact Review; Timeline and Factors; Preliminary and Final**
15 **Reports.**

16 (a) Timeline for Completion of a Cost and Market Impact Review. The Office shall complete
17 a CMIR within 90 days of the final decision by the Office to conduct a CMIR, subject to
18 subsections (a)(1) through (3):

19 (1) The Office may extend the 90-day period by an additional 30 days if it needs
20 additional time to complete its review.

21 (2) Should the Office determine it requires additional documentation or information
22 necessary to complete its review, it shall toll either of the time periods set forth in
23 subsection (a)(1) for any time period in which it is awaiting the provision of such
24 documentation or information from the parties to the transaction or is awaiting the
25 provision of information necessary to complete its review subpoenaed pursuant to
26 section 127507.2(a)(4) of the Code.

27 (3) The Office shall toll either of the time periods set forth in subsection (a)(1) during any
28 time period in which other state agencies, federal regulatory agencies, or courts are
29 reviewing the subject transaction and their review may impact the review of the
30 transaction by the Office.

31 (b) Documents Submitted After Determination to Conduct CMIR. After its determination to
32 conduct a CMIR, the Office may request the submitter or other entities to submit
33 documents and information through the submitter portal or designated secure file share.

34 (1) When submitting documents and information to the Office, submitter and entities
35 shall include a response log that outlines all documents and information produced to
36 the Office and their location in the submitter portal or designated secure file share.
37 Based on the information or documents being sought by the Office, the Office may
38 request additional details to be noted in the log.

39 (2) Submitter and entities may also request confidential treatment of documents and
40 information.

1 information provided to OHCA. These requests will be made in the log by indicating
2 which documents should be subject to confidential treatment and specifying why the
3 document is nonpublic. Confidentiality requests shall be made in accordance with
4 section 97437.

5 (3) With the exception of disclosure pursuant to sections 127507.2(c)(1) and
6 127507.2(d)(1) of the Code, the Office and the Department shall keep confidential all
7 nonpublic information and documents designated as confidential pursuant to this
8 section.

9 (bc) Factors Considered in a Cost and Market Impact Review. A CMIR shall examine
10 factors relating to a health care entity's or noticing entity's business and its relative
11 market position, including, but not limited to:

- 12 (1) The effect on the availability or accessibility of health care services to any
13 community affected by the transaction, including the accessibility of culturally
14 competent care.
- 15 (2) The effect on the quality of health care services provided to any of the communities
16 affected by the transaction.
- 17 (3) The effect of lessening competition or potentially creating a monopoly, which could
18 result in raising costs, reducing quality or equity, or restricting access or innovation.
- 19 (4) The effect on any health care entity's ability to meet any health care cost targets
20 established by the Health Care Affordability Board pursuant to section 127502(n) of
21 the Code, and as set forth at 22 CCR 97447.
- 22 (5) The effect on competition for workers and the impact on the labor market.
- 23 (6) Whether the transaction may foreclose competitors of any party to the transaction
24 from a segment of the market or otherwise increase barriers to entry in any health
25 care market.
- 26 (7) Whether the parties to the transaction have been parties to any other transactions in
27 the past ten years that have been below the circumstances set forth in section
28 97435(c).
- 29 (8) Consumer concerns including, but not limited to, complaints or other allegations
30 against any noticing and/or health care entity that is a party to the transaction related
31 to access, care, quality, equity, affordability, or coverage.
- 32 (9) Any other factors the Office determines to be in the public interest.

33 (ed) Preliminary Report of Findings.

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

40 (de) Final Report of Findings. The Office shall issue a final report of its findings pursuant to

1 subdivision (a)(5) of section 127507.2 of the Code within 15 days of the close of the
2 comment period in subsection (c)(2), unless the Office extends this time for good cause
3 shown. Good cause means a finding based upon a preponderance of the evidence that
4 there is a factual basis and substantial reason for the extension. Good cause may be
5 found, for instance, when the Office requires additional time to review and evaluate
6 written comments regarding the preliminary report.

7
8 NOTE:

9 Authority cited: Sections 127501 and 127501.2, Health and Safety Code.

10 Reference: Sections 127500.5, 127502, 127502.5, 127507 and 127507.2, Health and Safety
11 Code.