Approved – Effective 8/22/24

Legend: Added text is in underline; Deleted text is in ~~strikeout~~.

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(p), 97435(c)(6), and 97438(c)(2) of these regulations, refers to a situation in which an entity ~~("affiliate")~~ 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) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in 127500.2(p)(6) of the Code. Any health care entity entering into a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435.

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

(1) Acute care, diagnostic, or therapeutic inpatient hospital services;

(2) Acute care, diagnostic, or therapeutic outpatient services;

(3) Pharmacy, retail and specialty, including any drugs or devices;

(4) Performance of functions to refer, arrange, or coordinate care;

(5) Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and

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

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

(j) “Material change transaction~~,~~” ~~as used in section 127507(c)(1) of the Code,~~ shall mean a transaction as defined in subsection (p) that meets the requirements of section 97435(c). “Material change transaction” does not include:

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

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

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

(*l*) “Office” shall mean the Office of Health Care Affordability established by section 127501 of the Code.

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

(n) “Physician organization” shall have the meaning set forth in section 127500.2(p) of the Code.

(o) “Provider” shall have the meaning set forth in section 127500.2(q) of the Code.

(p) “Transaction” includes mergers, acquisitions, affiliations, and agreements impacting the provision of health care services in California that involve a transfer (<u>including a</u> sale, lease, exchange, option, encumbrance, conveyance, or disposition) of assets or a transfer of control, responsibility, or governance of the assets or operations, in whole or in part, of any health care entity to one or more entities.

Authority cited: Sections 127501, 127501.2 and 127507, Health and Safety Code.
Reference: Sections 127500.2, 127507 and 127507.2, Health and Safety Code.

§ 97435. Material Change Transactions.

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

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

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

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

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

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

(c) Circumstances requiring filing. A transaction is a material change transaction pursuant to section 127507(c)(1) of the Code if any of the circumstances in paragraphs (1) through (8) below exist. For purposes of this subsection only, "annual California-derived revenue" means revenue from the provision of health care

services in California.

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

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

(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of the submitter(s).

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

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

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

(7) The transaction is part of a series of related transactions for the same or related health care services occurring over the past ten years involving the same health care entities or entities affiliated with the same entities. The proposed transaction and its related transactions will constitute a single transaction for purposes of determining the revenue thresholds in subsection (b) and asset and control circumstances in subsections (c)(3), (c)(4), and (c)(6).

(8) The transaction involves the acquisition of a health care entity by another entity and the acquiring entity has consummated a similar transaction(s), in the plast ten years, with a health care entity that provides the same or related health care services. The proposed transaction and its related transactions will constitute a

single transaction for purposes of determining the revenue thresholds in subsection (b) and asset and control circumstances in subsections (c)(3), (c)(4), and (c)(6).

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

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

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

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

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

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

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

(A) Prior-year third-party settlements;

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

(C) Fee-for-service revenue; and

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

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

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

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

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

Authority cited: Sections 127501, 127501.2 and 127507, Health and Safety Code. Reference: Sections 127500.2 and 127507, Health and Safety Code.

§ 97438. Filing of Notices of Material Change Transactions.

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

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

(1) General information regarding the submitter:

(A) Business Name.

(B) Business Website.

(C) Business Mailing Address.

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

(i) For health care providers or fully integrated delivery systems, include a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity (e.g., number of licensed beds) or patients served (e.g., number of patients per county) in California in the last year.

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

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

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

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

(2) List of primary languages used by submitter when providing services to the public as well as any threshold languages, as determined by the Department of Health Care Services, used when providing services to Medi-Cal beneficiaries;

(3) Identification of all ~~other~~ parties to the transaction and indication whether any health care entities who are parties to the transaction will be submitting a notice. For each ~~other~~ entity that is a party to the transaction, the submitter shall exercise reasonable diligence to ascertain and ~~to the extent the submitter has access to the information,~~ shall describe the following:

(A) The entity's business (including business lines or segments);

(B) Ownership type (corporation, partnership, limited liability company, etc.), including any affiliates, subsidiaries, or other entities that control, govern, or are financially responsible for the health care entity or that are subject to the control, governance, or financial control of the health care entity;

(C) Governance and operational structure (including ownership of or by a health care entity);

(D) Annual revenue for the three most recent fiscal years used in calculating revenue in accordance with section 97435(d);

(E) Current county or counties of operation;

(F) If a health care provider or a fully integrated delivery system is a party to, or the subject of, the transaction, include a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity (e.g., number of licensed beds) or patients served (e.g., number of patients per county) in California in the last year;

(G) Primary and threshold languages, as determined by the Department of Health Care Services, used;

(H) If a payer or a fully integrated delivery system is a party to, or the subject of, the transaction, include a list of all counties where coverage is sold, counties in which they are licensed to operate by the Department of Managed Health Care and/or the Department of Insurance, and the number of enrollees residing in each listed county in the year preceding the transaction; and

(I) Include the business addresses, if known, of all new entities that will be formed as a result of the transaction.;

(4) Proposed or anticipated date of transaction closure;

(5) Description of transaction, which shall include the following:

(A) The goals of the transaction;

(B) A summary of terms of the transaction;

(C) A statement of why the transaction is necessary or desirable;

(D) General public impact or benefits of the transaction, including quality and equity measures and impacts;

(E) Narrative description of the expected competitive impacts of the transaction; and

(F) Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public.

(6) The submission date and nature of any applications, forms, notices, or other materials submitted or required regarding the proposed transaction to any other state or federal agency, such as, but not limited to, the Federal Trade Commission or the United States Department of Justice.

(7) Whether the proposed transaction has been the subject of any court proceeding and, if so, the:

(A) Name of the court;

(B) Case number; and

(C) Names of the parties

(8) A description of current services provided by the health care entity and expected post-transaction impacts on health care services, which shall include, if applicable:

(A) Counties where services are currently performed and any post-transaction changes thereto;

(B) Levels and type of health care services currently offered, such as the full range of reproductive health care and sexual health care services, specialized services for LGBTQ+ populations, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services, and any post-transaction changes thereto;

(C) Summary that includes the number and type of patients currently served, including, but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category, and any post-transaction changes thereto;

(D) Current community needs assessments, charity care, and community benefit programs, and any post-transaction changes thereto; and

(E) Whether Medi-Cal and Medicare patients are currently accepted and any post-transaction changes thereto.

(9) If this transaction is a merger or acquisition, description of any other prior mergers or acquisitions that satisfy all of the following:

(A) Involved the same or related health care services;

(B) Involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and

(C) Were closed in the last ten years.

(10) Description of potential post-transaction changes to:

(A) Ownership, governance, or operational structure of the submitter and parties to the transaction.

(B) The submitter's employee staffing levels, job security, retraining policies, wages, benefits, working conditions, and/or employment protections.

(C) City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties.

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

(11) Description of the nature, scope, and dates of any material change transactions between the submitter and any other entity that are either pending or planned to occur within 12 months following the date of the notice.

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

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

(2) Copies of all current agreement(s) and term sheets (with accompanying appendices and exhibits) governing or related to the proposed material change (e.g., definitive agreements, affiliation agreements, stock purchase agreements);

(3) Documentation sufficient to show the valuation of transaction;

(4) Contact information for any individuals signing or responsible for the

transaction or side or related agreements, including names, addresses, telephone numbers, and e-mail addresses;

(5) Any pro forma post-transaction balance sheet for any surviving or successor entity;

(6) A current organizational chart of the organization of any entity party to the transaction, including charts of any parent and subsidiary organization(s), and proposed organizational chart(s) for the same entities after the transaction;

(7) Existing documentation identifying the number of patients per county or enrollees per county in the last year of any provider, payer, or fully integrated delivery system, as applicable, that is a subject of the transaction;

(8) Certified financial statements for the prior three years and any documentation related to the liabilities, debts, assets, balance sheets, statements of income and expenses, any accompanying footnotes, and revenue of all entities that are parties to the transaction. “Certified financial statements” mean audited financial reports, or if a health care entity does not routinely prepare audited financial reports, comprehensive financial statements. Comprehensive financial statements shall include details regarding annual costs, annual receipts, realized capital gains and losses, and accumulated surplus and accumulated reserves using the standard accounting method routinely used by the health care entity. Comprehensive financial statements must be supported by sworn written declarations by the chief financial officer, chief executive officer or other officer who has financial management and oversight responsibility, certifying the comprehensive financial statement is complete, true, and correct in all material matters to the best of their knowledge, and that the health care entity does not routinely prepare audited financial reports, or the most recent audited financial report is not available. For California-derived revenue requirements (as used in this Article), the certification under this paragraph requires that revenue be calculated as it was generated or occurred in California rather than when booked, accrued, or taxed;

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

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

(11) Any analysis and/or documents supporting the submitter's responses to the narrative answers provided pursuant to subsection (b).

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

(1) A submitter of a notice pursuant to this section or a submitter requesting expedited review pursuant to section 97439 may request confidential treatment of information or documents submitted. The submitter shall file two versions of any document for which confidentiality is requested. The nonpublic version shall be unredacted and shall be maintained as confidential by the Office and Department pending a determination of confidentiality. The public version, which may be made available to the public by the Office, shall have the confidential portions removed or redacted. Requests for confidentiality of publicly available information or documents will be denied.

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

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

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

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

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

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

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

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

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

Authority cited: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127507, 127507.2 and 127507.4, Health and Safety Code.

§ 97439. Request for Expedited Review of Notices of Material Change Transaction.

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

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

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

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

(b) A submitter must demonstrate that either of the conditions below exists:

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

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

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

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

Authority cited: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Section 127507.2, Health and Safety Code.

§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Review.

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

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

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

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

(C) The transaction may lessen competition or create a monopoly in any geographic service areas impacted by the transaction.

(D) The transaction may lessen competition for health care entities to hire workers or may negatively impact the labor market by, for instance, lowering wages or slowing wage growth, worsening benefits or working conditions, or resulting in other degradations of workplace quality.

(E) The transaction negatively impacts a general acute care or specialty hospital by, for instance, restricting or reducing the health care services offered.

(F) The transaction may negatively impact the quality of health care services available to patients from the parties to the transaction.

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

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

(I) The transaction between a health care entity located in this state and an out-of-state entity may negatively impact affordability, quality, or limit access to

health care services in California, or undermine the financial stability or competitive effectiveness of a health care entity located in this state.

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

(1) Within 10 business days after the date of a determination that a CMIR is required, the submitters of the notices for that transaction may collectively request review by the Director of the Office's determination. The request shall:

(A) Be in writing;

(B) Be signed by all requesting submitters;

(C) Be ~~sent to the Director, with a copy to the Office~~ submitted through the Office's portal;

(D) Specifically set forth the grounds upon which the submitters consider the determination to be in error; and

(E) State the reasons why a CMIR is not warranted.

(2) The request will be denied if it contains no more than a request for a waiver of a CMIR, unsupported by specific facts.

(3) Within five business days of receipt of a request for review, the Director shall either:

(A) Decline review and uphold the determination that a CMIR is required; or

(B) Grant the request and waive a CMIR.

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

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

Authority cited: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127502 and 127507.2, Health and Safety Code.

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

(a) Timeline for Completion of a Cost and Market Impact Review.

The Office shall complete a CMIR within 90 days of the final decision by the Office to conduct a CMIR, subject to subsections (a)(1) through (3):

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

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

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

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

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

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

(3) The effect of lessening competition or potentially creating a monopoly, which could result in raising costs, reducing quality or equity, or restricting access or innovation.

(4) The effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board pursuant to section 127502(n) of the Code, and as set forth at 22 CCR 97447.

(~~4~~5) The effect on competition for workers and the impact on the labor market.

(~~5~~6) Whether the transaction may foreclose competitors of any party to the transaction from a segment of the market or otherwise increase barriers to entry in any health care market.

(~~6~~7) Whether the parties to the transaction have been parties to any other transactions in the past ten years that have been below the thresholds set forth in section 97435(c).

(~~7~~8) Consumer concerns including, but not limited to, complaints or other allegations against any health care entity that is a party to the transaction related to access, care, quality, equity, affordability, or coverage.

(~~8~~9) Any other factors the Office determines to be in the public interest.

(c) Preliminary Report of Findings.

(1) Upon completion of a CMIR, the Office shall make factual findings and issue a preliminary report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code.

(2) Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report.

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

Authority cited: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127500.5, 127502, 127502.5, 127507 and 127507.2, Health and Safety Code.