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 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.

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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.

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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" 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 parties to the transaction, such as a corporate restructuring.

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(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 (including a 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.