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HEALTH AND SAFETY CODE - HSC

DIVISION 101. ADMINISTRATION OF PUBLIC HEALTH [100100 - 101997] (*Division 101 added by Stats. 1995, Ch. 415, Sec. 3.*)

PART 1. CALIFORNIA DEPARTMENT OF HEALTH SERVICES [100100 - 100922] (*Part 1 added by Stats. 1995, Ch. 415, Sec. 3.*)

CHAPTER 4. Regulation of Laboratory Services [100700 - 100922] (*Chapter 4 added by Stats. 1995, Ch. 415, Sec. 3.*)

ARTICLE 4. Freestanding Cardiac Catheterization Laboratories [100921 - 100922] (*Article 4 heading added by Stats. 1996, Ch. 1023, Sec. 301.8.*)

100921. The Legislature finds and declares that:

- (a) A pilot program was established by the Office of Statewide Health Planning and Development to test the feasibility of performing high quality, safe diagnostic cardiac catheterization procedures in a freestanding cardiac catheterization laboratory.
- (b) Evaluation of this pilot program by the office demonstrated that it is feasible to conduct these procedures in nonhospital settings and that these laboratories maintain the quality of the diagnostic procedures while also reducing the cost of care.
- (c) Based on this evaluation, it is the intent of the Legislature that those freestanding cardiac catheterization laboratories that are in active status in the pilot program be licensed.

(*Added by renumbering Section 128525 by Stats. 1996, Ch. 1023, Sec. 368. Effective September 29, 1996.*)

100922. (a) Notwithstanding any other provision of law, a freestanding cardiac catheterization laboratory that as of December 31, 1993, was in active status in the Health Care Pilot Project established pursuant to former Part 1.85 (commencing with Section 444) of Division 1, and that meets the requirements specified in this section, may be licensed by the State Department of Public Health as a freestanding cardiac catheterization laboratory. The license shall be subject to suspension or revocation, or both, in accordance with Article 5 (commencing with Section 1240) of Chapter 1 of Division 2. An application for licensure or annual renewal shall be accompanied by a Licensing and Certification Program fee set in accordance with Section 1266.

(b) A laboratory granted a license pursuant to this section shall be subject to the department's regulations that govern cardiac catheterization laboratories operating in hospitals without facilities for cardiac surgery, any similar regulations that may be developed by the department specifically to govern freestanding cardiac catheterization laboratories, and to the following regulations: subdivisions (a) and (d) of Section 70129 of; paragraphs (1), (2), (3), and (4) of subdivision (a) of, and subdivision (i) of Section 70433 of; paragraphs (1), (3), (4), and (5) of subdivision (a) of Section 70435 of; subparagraphs (A), (B), and (D) of paragraph (1) of, and paragraphs (5) and (7) of, subdivision (b) of Section 70437 of; subdivision (a) of Section 70439 of; Sections 70841, 75021, and 75022 of; subdivision (a) of Section 75023 of; Sections 75024, 75025, and 75026 of; subdivisions (a), (b), and (c) of Section 75027 of; subdivision (b) of Section 75029 of; Section 75030 of; subdivision (b) of Section 75031 of; Sections 75034, 75035, 75037, 75039, 75045, and 75046 of; subdivision (a) of Section 75047 of; and Sections 75050, 75051, 75052, 75053, 75054, 75055, 75057, 75059, 75060, 75061, 75062, 75063, 75064, 75065, 75066, 75071, and 75072 of; Title 22 of the California Code of Regulations.

(c) A laboratory granted a license pursuant to this section shall have a system for the ongoing evaluation of its operations and the services it provides. This system shall include a written plan for evaluating the efficiency and effectiveness of the health care services provided that describes the following:

- (1) The scope of the services provided.
- (2) Measurement indicators regarding the processes and outcomes of the services provided.
- (3) The assignment of responsibility when the data from the measurement indicators demonstrates the need for action.

(4) A mechanism to ensure followup evaluation of the effectiveness of the actions taken.

(5) An annual evaluation of the plan.

(d) A laboratory granted a license pursuant to this section is authorized to perform only the following diagnostic procedures:

(1) Right heart catheterization or angiography, or both.

(2) Left heart catheterization or angiography, or both.

(3) Coronary catheterization and angiography.

(4) Electrophysiology studies.

(e) A laboratory granted a license pursuant to this section shall only perform its procedures on adults, on an outpatient basis. Each laboratory shall define patient characteristics that are appropriate for safe performance of procedures in the laboratory, and include evaluation of these criteria in its quality assurance process.

(f) Notwithstanding the requirements already set forth in this chapter, freestanding cardiac catheterization laboratories shall comply with all other applicable federal, state, and local laws.

(g) This section shall become operative on January 1, 1995, and does not require the department to adopt regulations.

(Amended by Stats. 2007, Ch. 483, Sec. 20. Effective January 1, 2008.)