

AMENDED IN ASSEMBLY MARCH 25, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 822

Introduced by Assembly Member Fletcher
(Coauthor: Senator Wyland)

February 26, 2009

An act to amend Section 1276 of, and to add Chapter 2 (commencing with Section 101990) to Part 6 of Division 101 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 822, as amended, Fletcher. Health facilities: program flexibility.

Under existing law, the State Department of Public Health has licensing authority over several categories of clinics and health facilities, including hospital. Existing law requires the building standards published in the California Building Standards Code and the regulations adopted by the department to prescribe standards for adequacy, safety, and sanitation of the physical plant, of appropriate staffing, and of services, based on the type of health facility and the needs of the persons served. These regulations are required to permit program flexibility in various contexts, as long as statutory requirements are met, and the use has the prior written approval of the department or of the Office of Statewide Health Planning and Development.

Existing law requires the department to develop a standardized form and format for requests by health facilities for program flexibility. Health facilities shall thereafter apply to the department for program flexibility in the prescribed manner. After the department receives a complete application requesting program flexibility, it is required to approve, approve with conditions or modifications, or deny the

application within 60 days. Denials and approvals with conditions or modifications are required to be accompanied by an analysis and a detailed justification for any conditions or modifications imposed.

This bill would require the department to approve or approve with conditions or modifications a complete application requesting program flexibility for the use of alternate concepts, methods, procedures, techniques, or equipment by a general acute care hospital whenever the hospital demonstrates to the department that this use meets or exceeds the quality of care and patient safety in effect on January 1, 2010.

The bill would also require the department to establish a pilot program to gather clinical data on, and provide general acute care hospitals experience with, the use of alternate concepts, methods, procedures, techniques, equipment, and care from what is authorized pursuant to specified regulations, but meet certain statutory requirements. It would require, by January 1, ~~2012~~ 2014, the department to prepare a ~~specified~~ report to the Legislature *on the pilot program*.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. (a) The Legislature hereby finds and declares
- 2 all of the following:
- 3 (1) The provision of health care in general acute care hospitals
- 4 has improved dramatically in recent years, due in part to
- 5 technological and methodological advances in health care that
- 6 have greatly improved patient outcomes.
- 7 (2) California's hospital licensing regulations, found in Division
- 8 5 of Title 22 of the California Code of Regulations, were adopted
- 9 in 1976. Although there have been limited revisions over the past
- 10 decades, the regulations have not kept pace with state-of-the art
- 11 technology, equipment, and practices now available to provide
- 12 optimum patient care.
- 13 (3) Due to these outdated regulations, California hospitals are
- 14 not able to provide patients with some of the cutting-edge
- 15 technology, equipment, procedures, and care that are available
- 16 elsewhere.
- 17 (4) It is appropriate to gather clinical data and experience in
- 18 California regarding the state-of-the-art technology, equipment,
- 19 procedures, and care now available.

1 (b) It is the intent of the Legislature that the State Department
2 of Public Health develop and implement a pilot program for the
3 purposes specified in subdivision (a).

4 SEC. 2. Section 1276 of the Health and Safety Code is amended
5 to read:

6 1276. (a) The building standards published in the State
7 Building Standards Code by the Office of Statewide Health
8 Planning and Development, and the regulations adopted by the
9 department shall, as applicable, prescribe standards of adequacy,
10 safety, and sanitation of the physical plant, of staffing with duly
11 qualified licensed personnel, and of services, based on the type of
12 health facility and the needs of the persons served thereby.

13 (b) These regulations shall permit program flexibility by the
14 use of alternate concepts, methods, procedures, techniques,
15 equipment, personnel qualifications, bulk purchasing of
16 pharmaceuticals, or conducting of pilot projects as long as statutory
17 requirements are met and the use has the prior written approval of
18 the department or the office, as applicable. The approval of the
19 department or the office shall provide for the terms and conditions
20 under which the exception is granted. A written request plus
21 supporting evidence shall be submitted by the applicant or licensee
22 to the department or office regarding the exception, as applicable.

23 (c) While it is the intent of the Legislature that health facilities
24 shall maintain continuous, ongoing compliance with the licensing
25 rules and regulations, it is the further intent of the Legislature that
26 the department expeditiously review and approve, if appropriate,
27 applications for program flexibility. The Legislature recognizes
28 that health care technology, practice, pharmaceutical procurement
29 systems, and personnel qualifications and availability are changing
30 rapidly. Therefore, requests for program flexibility require
31 expeditious consideration.

32 (d) (1) The department shall, on or before April 1, 1989,
33 develop a standardized form and format for requests by health
34 facilities for program flexibility. Health facilities shall thereafter
35 apply to the department for program flexibility in the prescribed
36 manner. After the department receives a complete application
37 requesting program flexibility, it shall have 60 days within which
38 to approve, approve with conditions or modifications, or deny the
39 application. Denials and approvals with conditions or modifications
40 shall be accompanied by an analysis and a detailed justification

1 for any conditions or modifications imposed. Summary denials to
2 meet the 60-day timeframe shall not be permitted.

3 (2) Notwithstanding paragraph (1), the department shall approve
4 or approve with conditions or modifications a complete application
5 requesting program flexibility for the use of alternate concepts,
6 methods, procedures, techniques, or equipment by a general acute
7 care hospital whenever the hospital demonstrates to the department
8 that this use meets or exceeds the quality of care and patient safety
9 in effect on January 1, 2010.

10 (e) Notwithstanding any other provision of law or regulation,
11 the department shall provide flexibility in its pharmaceutical
12 services requirements to permit any state department that operates
13 state facilities subject to these provisions to establish a single
14 statewide formulary or to procure pharmaceuticals through a
15 departmentwide or multidepartment bulk purchasing arrangement.
16 It is the intent of the Legislature that consolidation of these
17 activities be permitted in order to allow the more cost-effective
18 use and procurement of pharmaceuticals for the benefit of patients
19 and residents of state facilities.

20 SEC. 3. Chapter 2 (commencing with Section 101990) is added
21 to Part 6 of Division 101 of the Health and Safety Code, to read:

22
23 CHAPTER 2. HEALTH FACILITY INNOVATION
24

25 101990. (a) The State Department of Public Health shall
26 establish a pilot program to gather clinical data on, and provide
27 general acute care hospitals, as defined in subdivision (a) of Section
28 1250, experience with, the use of alternate concepts, methods,
29 procedures, techniques, equipment, and care to what is authorized
30 pursuant to regulations adopted pursuant to Chapter 2 (commencing
31 with Section 1250) of Division 2 in effect on January 1, 2010, but
32 otherwise meet the statutory requirements of that chapter.

33 (b) The department shall identify alternate concepts, methods,
34 procedures, techniques, equipment, or care that the department
35 determines will promote innovation and improvements in services
36 and patient care. The department shall also solicit and receive
37 proposals from general acute care hospitals to use alternate
38 concepts, methods, procedures, techniques, equipment, and care
39 that will promote innovation and improvements in services and
40 patient care.

1 (c) The department shall, by July 1, ~~2010~~ 2011, authorize at
2 least two, but not more than 10, general acute care hospitals to use
3 an alternate concept, method, procedure, technique, equipment,
4 or care that was identified by the department or proposed by a
5 hospital pursuant to subdivision (b). At least one general acute
6 care hospital shall be located within the County of San Diego and
7 shall be associated with a two-hospital system operated by a health
8 care district. A general acute care hospital participating in the pilot
9 program shall staff the alternate concepts, methods, procedures,
10 techniques, equipment, and care with licensed nurses pursuant to
11 the requirements of Section 1276.4.

12 (d) The department may charge a general acute care hospital
13 authorized to participate in the program an annual fee to participate
14 in the pilot program that does not exceed the amount of the direct
15 costs to the department of overseeing and evaluating the pilot
16 program. The moneys collected from this fee shall be deposited
17 in the State Department of Public Health Licensing and
18 Certification Program Fund.

19 (e) By January 1, ~~2012~~ 2014, the department shall prepare and
20 submit a report to the Legislature on the results of the pilot program
21 and its impact upon the quality of service and patient care.