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Director

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

ACTION: NOTICE OF EMERGENCY RULEMAKING
Title 17, California Code of Regulations

SUBJECT: The Licensing of Genetic Counselors, DPH-00-067E

Notice IS HEREBY GIVEN that the California Department of Public Health (Department) has, under the authority granted by section 131200 of the Health and Safety Code, adopted the regulations described in this notice on an emergency basis. Section 124977(d)(1) of the Health and Safety Code provides that for the purpose of the Administrative Procedures Act, the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. This regulation is in effect. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent.

PUBLIC PROCEEDINGS:

Notice is hereby given that the Department will conduct a public hearing commencing on:

Date and Time: Wednesday, March 27, 2013 – 1:30 p.m. to 3:30 p.m.

Place: 1500 Capitol Ave, Training Room A
Sacramento, California 95814

Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of hearing designated above.

For individuals with disabilities, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. To request such services or copies of materials in an alternate format, please write or call: Laurel Prior, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, phone (916) 440-7673, email at lprior@cdph.ca.gov, or use the California Relay Service by dialing 711. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

WRITTEN COMMENT PERIOD:

The public comment period will close at 5:00 pm on March 25, 2013. Any person may submit public comments in writing (by mail, fax, e-mail, or in person) regarding the emergency changes. To be considered by the Department, comments must be submitted to the Department, Office of Regulations as follows:

1. By email to: regulations@cdph.ca.gov;
2. By fax transmission to: (916) 440-5747;
3. By mail to: Office of Regulations, P.O. Box 997377, Sacramento, CA 95899-7377; or
4. Hand delivered to: 1616 Capitol Avenue, Sacramento, CA 95814

AUTHORITY AND REFERENCE CITATIONS:

The Department adopts the regulations sections identified under the authority provided in Sections 124977, 124980, 124981, 124982, 131052 and 131200, Health and Safety Code. The regulations implement, interpret, or make specific Sections 124980, 124981, 124982, 124996, 131071, Health and Safety Code; Section 17520, Family Code; Section 494.5, Business and Professions Code; and Section 11522, Government Code.

The Department adopts Articles 1 through 3, Sections 6300.1, 6300.3, 6300.5, 6300.7, 6300.9, 6300.11, 6300.13, 6300.15, 6300.17, 6300.19, 6300.21, 6300.23, 6301.1, 6301.3, 6301.5, 6301.7, 6301.9, 6303.1, and 6303.3, in Title 17 of the California Code of Regulations (CCR), Division 1, Chapter 4, Subchapter 9, Group 1, Licensing of Genetic Counselors.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Health and Safety Code Section 131200 authorizes the Department to promulgate regulations for the execution of its duties. The Genetic Disease Screening Program (GDSP) is administered by the Department to serve the people of California by reducing the emotional and financial burden of disability and death caused by genetic and congenital disorders. Health and Safety Code Section 124980 requires the Department to establish regulations and standards for licensing master level genetic counselors and doctoral level medical geneticists as genetic counselors. GDSP is responsible for administering this new genetic counselor licensure program.

Section 124981 establishes the qualifications for original and renewal licenses and prohibits the use of the title “genetic counselor” unless the person has applied for and obtained a license from the Department. Section 124982 establishes the qualifications for temporary genetic counselor licenses. This emergency regulatory action expands the scope of the requirements for genetic counselor and temporary genetic counselor licensure and the application process; renewal of genetic counselor licenses; continuing education requirements; time period of licenses; reasons and procedures for denial or revocation of genetic counselor and temporary genetic counselor licenses; and license fees.

The purpose of the regulations is to establish appropriate criteria and standards for licensing genetic counselors. The requirements for a genetic counselor license include certification with the American Board of Genetic Counseling (ABGC) or the American Board of Medical Genetics (ABMG). The requirements for a temporary genetic counselor license

include the applicant being accepted as an active candidate for the ABGC certification examination, or providing a statement of intent to apply to the ABGC for active candidate status. Individuals with a temporary genetic counselor license are required to work under the general supervision of a licensed genetic counselor or licensed physician.

Genetic counselor licenses are valid for three years unless at any time they are revoked. Temporary genetic counselor licenses are valid for two years unless at any time they are revoked. To renew a genetic counselor license, the licensee is required to have completed 45 contact hours of continuing education (30 contact hours from the National Society of Genetic Counselors [NSGC] Category 1 continuing education unit [CEU] programs with the remaining 15 contact hours from either NSGC Category 1 or Category 2 CEU programs).

Health and Safety Code Sections 124977 and 124996 require that GDSP activities be “fully supported from fees collected.” The Department will charge fees to applicants applying for and renewing licenses in order to cover the cost of administering and maintaining the licensure program.

The benefits anticipated by the adoption of these regulations are the protection of public health and safety by implementing professional standards of education and experience for genetic counselors, and restricting the practice of genetic counseling to individuals meeting these standards. Genetic counseling is the practice of helping individuals and families understand the medical, psychological, social and reproductive implications of inherited and congenital conditions. Elements of the practice include: assessment of the chance for recurrence or occurrence of an inherited condition; education about inheritance, testing options, medical management, prevention, social support and research; and counseling to help clients adapt to the choices and to the psychological, familial and social issues that stem from the risk or condition in the family.

Two forms, California Genetic Counselor License Application, CDPH 4486 (03/12), and California Genetic Counselor License Payment, CDPH 4487 (03/12), are incorporated by reference.

MANDATED BY FEDERAL LAW OR REGULATION:

Currently, there are no existing federal regulations or statutes applicable to the regulations. The Department does not consider the regulations inconsistent or incompatible with existing state regulations.

OTHER STATUTORY REQUIREMENTS:

Not applicable.

LOCAL MANDATE:

The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of Division 4 of the Government Code.

FISCAL IMPACT ESTIMATE:

- A. Fiscal Impact on Local Government: None.
- B. Fiscal Impact on State Government: It is anticipated that the revenues generated from the licensure program will offset the costs to the Department associated with administering the program. Initial estimates of annual revenues are \$80,100 for fiscal year (FY) 2011-12 and \$10,200 for FY 2012-13. There are no other costs mandated for state government. There are no plans at present to require a new funding category for Medi-Cal or for other state agencies.
- C. Fiscal Impact on Federal Funding of State Programs: The regulations do not affect the loss or gain of federal matching funds and there are no additional federal funds required in conjunction with these regulations.
- D. Fiscal Impact on Private Persons or Businesses Directly Affected: The cost impacts known to the Department at the time this regulation was adopted, that a representative private person or business would necessarily incur in reasonable compliance with this regulation, are as follows: Private persons desiring to practice genetic counseling are impacted by payment of fees as defined in the Health and Safety Code, Sections 124981 and 124982, and Sections 6301.1, 6301.3, and 6301.5 of these regulations. Businesses are not directly affected by these regulations with the exception of entities that choose to pay license fees for their employees.
- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

EFFECT ON HOUSING COSTS:

The Department has determined that the regulations will have no impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE:

The Department has made an initial determination that the regulations would not have a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT:

The Department has determined that the regulations would not significantly affect:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

The Department has determined that the regulations would benefit the health and welfare of California residents as it is in the public's interest to have individuals providing genetic

counseling services meet minimum standards of education, training, and professional conduct.

The Department has determined there are no discernible benefits to worker safety or the state's environment.

BUSINESS REPORT:

Not applicable.

EFFECT ON SMALL BUSINESS:

The Department has determined that the regulation will not affect small business. None of the businesses affected by this regulation meet the criteria of small business established by section 11342.610 of the Government Code.

CONSIDERATION OF ALTERNATIVES:

In accordance with Government Code Section 11346.5(a)(13), a rulemaking agency must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

CONTACT INFORMATION:

For questions regarding the subject matter of these regulations:

**Genetic Disease Screening Program
Sara Goldman, M.P.H, Chief
Program Standards and Quality Assurance Branch
California Department of Public Health
(510) 412-1463**

For questions regarding the regulatory process described in this notice:

**Laurel Prior
Office of Regulations
(916) 440-7673**

All submitted comments should contain the regulation package identifier DPH-00-067E.

AVAILABILITY OF EXPRESS TERMS AND INITIAL STATEMENT OF REASONS:

The Department has made available the regulation text and the initial statement of reasons for the emergency regulations on the Department's website at <http://www.cdph.ca.gov>. Upon completion of the rulemaking process, the rulemaking file for this regulatory action, which contains those items and all information on which the emergency action is based, will be available to the public upon a request submitted to the Department.

AVAILABILITY OF CHANGES TO PROPOSED TEXT:

After considering all timely and relevant comments received, the Department may finalize the emergency regulations substantially as described in this Notice. If the Department makes modifications, which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department finalizes the regulations as revised. Copies of modified regulation text may be obtained from the Department's website at <http://www.cdph.ca.gov>.

FINAL STATEMENT OF REASONS:

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS:

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-00-067E

Kathleen Keeshen for



Dated: 1/23/13

**Ron Chapman, MD, MPH
Director**