

SUPPLEMENTAL STATEMENT OF REASONS
Second 15-Day Public Availability

The California Department of Public Health (Department) has instituted a change to the previously proposed amendments to the text of the emergency regulations which is discussed below. This change is in response to comments that were received during the initial 15-day public comment period, which ended on June 6, 2013.

Section 6300.15: As noticed, the Department had proposed to expand the definition of genetic counseling to include additional functions performed by genetic counselors. The proposed definition of genetic counseling included identifying and coordinating genetic laboratory tests and integrating test results with personal and family history to assess and communicate risk factors for genetic and medical conditions and diseases. It is in the public's interest that these functions be performed by licensed genetic counselors.

The proposed amendment also contained a provision stating that nothing in the regulations shall be construed to authorize a licensed genetic counselor to diagnose, test, or treat any genetic disease or condition or other disease or condition. Some commenters supported this provision since it makes a distinction between the roles of genetic counselors and medical doctors involved in the care of patients with or at risk for genetic conditions. Other commenters opposed the inclusion of the word "test" in this provision as it could be interpreted as preventing collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of supervising physicians.

The Department believes it necessary to delete the word "test" from this provision to avoid ambiguity and not prohibit existing clinical practices. The Department believes that retaining "identifying and coordinating genetic laboratory tests" in the proposed amendment to the definition of genetic counseling as previously noticed is sufficient to reflect current practices of genetic counselors working under the supervision of a physician and transmitting orders for genetic tests on behalf of the physician and with the physician's approval.

By instituting this change to the proposed amendments previously noticed, the Department is seeking to avoid the appearance of attempting to regulate the practices of clinical geneticists and clinical laboratories which are subject to the provisions of the Business and Professions Code, and regulations promulgated under the authority of that Code. It is not the intent of the Department to venture beyond what is necessary to define genetic counseling for the purposes of implementing, interpreting and making specific the genetic counselor licensure and title protection provisions of the Health and Safety Code.