FINAL STATEMENT OF REASONS

Update to the Initial Statement of Reasons:

The information contained in the Initial Statement of Reasons (ISOR) at the time of Public Notice remains unchanged with the exception of the following modifications. The ISOR is hereby incorporated by reference in the Final Statement of Reasons.

Section 6300.15: As originally noticed to the public, Section 6300.15 of the regulations defined genetic counseling as "providing information to clients regarding the medical, psychological, and familial implications of inherited risks for disease, including interpretation of family and medical histories to assess the chance of disease occurrence or recurrence, and education about inheritance, testing, management, prevention, resources and research." Commenters recommended the Department expand the definition of genetic counseling. The Department believes it is necessary to define genetic counseling to include functions such as 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 section is being amended to include the definition recommended by the National Society of Genetic Counselors (NSGC) and the College of American Pathology.

The proposed amendment to the definition in the first 15-day notice of public availability included additional functions and contained a provision in Section 6300.15(c) that nothing in the subsection "shall be construed to authorize a licensed genetic counselor to diagnose, test, or treat any genetic disease or condition or other disease or condition." The Department believes it is necessary to omit the word "test" from this provision to avoid ambiguity and not prohibit existing clinical practices. This modification to the proposed amendment was the subject of a second 15-day notice of public availability.

The Department believes that retaining "identifying and coordinating genetic laboratory tests" in the amendment to the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. The Department's amendment to the definition of genetic counseling in Section 6300.15 will provide that nothing in the subsection "shall be construed to authorize a licensed genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition." This amendment is necessary to clarify that licensed physicians and surgeons are responsible for the diagnosis and treatment of genetic diseases and conditions.

Section 6301.3: As originally noticed to the public, Section 6301.3 of the regulations referred to a temporary genetic counselor license being valid for a two-year period from the date of issue by the Department, unless at any time during that period it is revoked. The Department is amending this section of the regulations to also refer to the license expiration provisions in Health and Safety Code Section 124982, which include

expiration following failure of the American Board of Genetic Counselors (ABGC) certification examination. This is necessary so the regulation language is in accordance with the provisions of the statute.

Section 6301.9: As originally noticed to the public, Section 6301.9 of the regulations restricted the use of the titles “genetic intern” and “genetic assistant” to individuals licensed as genetic counselors. Commenters contend it is appropriate for students enrolled in an accredited genetic counseling educational program to identify themselves as a “genetic counseling intern” or “genetic intern.” These individuals provide services under the supervision of licensed genetic counselors or Board-certified physicians as part of their course of study. The Department is amending this section to delete “genetic intern” as a title that only licensed genetic counselors may use, and state that nothing in the section “shall be construed to limit the service or activities of a student or intern enrolled in a genetic counselor training program accredited by the ABGC or an ABGC-approved/equivalent organization, if practice constitutes a part of a supervised course of study and such student is designated by a title clearly indicating such student’s status as a student or intern.”

Commenters also contend the title “genetic assistant” is appropriate for use by individuals providing administrative support within a genetic clinic who do not provide clinical services and the use of the title should not be limited to individuals licensed as genetic counselors. The Department is deleting this job classification from this restricted title section of the regulations.

However, the Department is concerned that the title “genetic consultant” could be abused by unlicensed practitioners purporting to provide genetic counseling. For that reason, the Department believes it is necessary to add it to this section of the regulations as a title that only licensed genetic counselors may use.

Section 6303.1: As originally noticed to the public, Section 6303.1 of the regulations referred to failure of the ABGC certification examination as grounds for revocation of a temporary genetic counselor license. Health and Safety Code Section 124982 provides that a temporary license shall expire in cases where the licensee fails the certification exam. The Department is amending this section of the regulations to remove failure of the ABGC certification examination as a reason for revocation because it is imprecise. The expiration of a license is separate and distinct from the revocation of a license.

Proposed changes were noticed for a 15-day public availability period which began May 22, 2013, and ended June 6, 2013. A subsequent modification to remove an ambiguity concerning the function of genetic counselors in identifying and coordinating genetic laboratory tests was noticed for a second 15-day public availability period, beginning July 20, 2013, and ending August 5, 2013, for which no comments were received.

The reference citation is being amended to cite California Codes in alphabetical order, resulting in non-substantive changes.

Section 6303.3: The reference citation is being amended to cite California Codes in alphabetical order, resulting in non-substantive changes.

STATEMENTS OF DETERMINATIONS

Alternatives Determination:
The Department has determined that no reasonable alternative considered by the Department, or that has otherwise been identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which the emergency action was taken, or would be as effective and less burdensome to affected private persons than the adopted regulations, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Incorporation by Reference:
In accordance with the California Code of Regulations (CCR), Title 1, Sections 20(c)(1)(2) and (3), the Department in the adoption of 17 CCR Section 6301.1(a)(1), Section 6301.3(a)(1) and (g), and Section 6301.5(a)(1) made reference to forms: CDPH 4486 (03/12), and CDPH 4487 (03/12). The Department has incorporated these documents for the following reasons: 1) it would be cumbersome to publish the documents in the CCR; 2) the documents are available upon request; and 3) the documents are reasonably available to the affected public from the Department's website or internet search by title.

Local Mandate Determination:
The Department has determined that the regulations do 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, nor are there any other non-discretionary costs imposed.

Impact on Business:
The Department has made a determination that the regulations do not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

ADDENDUM ONE

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL 45-DAY NOTICE OF PUBLIC AVAILABILITY PERIOD

The following list is of persons commenting on the emergency regulations during the public comment period beginning on February 8, 2013, and ending at 5:00 p.m. on

March 27, 2013. A public hearing was held on March 27, 2013 from 1:30 p.m. to 3:30 p.m., in Training Room A at 1500 Capitol Avenue, Sacramento, California. The public hearing and public comment period produced comments from those noted below.

"WT"= written testimony, "OT"= oral testimony
1. WT: John Richardson, Director, Policy and Government Relations, NSGC, Washington, DC.

2. WT: Laila Rhee Morris, MS, LCGC, University of California, Davis, Department of OB/GYN, Sacramento, CA.

3. WT: Alyssa C. Snider, MS, PhD.

4. OT: Elizabeth Kearney, LCGC, California Coalition of Genetic Counselors, NSGC, San Mateo, CA.

5. OT: Nicole Mans, LCGC, Sacramento, CA.

Note: The first digit of the number designation identifies the Commenter as listed above. The digit after the decimal point indicates a specific comment if more than one comment was noted.

1. Definition of Genetic Counseling
Comment: The commenters recommend Section 6300.15 of the regulations be amended to adopt the definition of genetic counseling jointly developed by the NSGC and the College of American Pathology to be consistent with the majority of other states where licensure is being pursued.
Commenters: 1.1 and 4.1

Department Response: The Department acknowledges these comments, and is amending Section 6300.15 of the regulations to include a more comprehensive definition of genetic counseling in the regulations, which includes identifying and coordinating genetic laboratory tests. The Department is including additional language to make it clear that nothing in the regulations shall be construed to authorize a licensed genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition.

2. Restricted Use of Titles
Comment: The commenters recommend Section 6301.9 of the regulations be amended to delete the terms "genetic counseling intern," "genetic intern," and "genetic assistant" as titles that only licensed genetic counselors may use.

The commenters contend the use of these titles should not be restricted to licensed genetic counselors and should continue to be used by other groups. Students and/or interns enrolled in an ABGC accredited genetic counseling educational programs identify

themselves as a "genetic counseling intern" or "genetic intern." These individuals would be providing services under the supervision of licensed genetic counselors or Board-certified physicians, so their practice should not be putting the public at risk. Likewise, a "genetic assistant" provides administrative support within a genetic clinic or genetics department at a medical institution and does not provide clinical or genetic counseling services.
Commenters: 1.2 and 4.2

Department Response: The Department acknowledges these comments, and is amending Section 6301.9 of the regulations. The Department believes it appropriate for students enrolled in an accredited genetic counseling educational program to identify themselves as a "genetic counseling intern" or "genetic intern." The Department is deleting "genetic intern" as a title that only licensed genetic counselors may use, and adding text stating that "nothing in this section shall be construed to limit the service or activities of a student or intern enrolled in a genetic counselor training program accredited by the ABGC or an ABGC-approved/equivalent organization, if practice constitutes a part of a supervised course of study and such student is designated by a title clearly indicating such student's status as a student or intern."

The Department also accepts NSGC's interpretation of the "genetic assistant" job classification and is deleting "genetic assistant" from the regulations as a title that only licensed genetic counselors may use.

3: Continuing Education Requirements for Licensure
Comment: The commenters recommend Section 6301.7. of the regulations be amended to allow the option for professional activity credits (PACs) to be considered for the renewal of genetic counselor licenses, together with continuing education units (CEUs).

Commenters contend that the ABGC allows PACs to be considered along with CEUs for recertification as a genetic counselor.
Commenters: 1.3 and 4.3

Department Response: The Department does not support this change to the regulations. Health and Safety Code Section 124981 specifies that during every three-year period of licensure as a genetic counselor, the licensee must complete 45 hours of continuing education units, of which 30 hours shall be in genetics (defined as Category 1 CEUs in the regulations) to be eligible for license renewal. The Department believes a statutory amendment would be required to authorize the Department to allow PACs to substitute for CEUs.

The Department acknowledges that genetic counselors electing to recertify with the ABGC through CEUs and PACs may use PACs as a substitute for a certain percentage of the required CEUs. However, the ABGC's minimum requirements for the remaining CEUs that cannot be substituted are more onerous than the Department's CEU

requirements for licensure renewal in the regulations. Although the time periods for certification and licensure differ, for applicants utilizing the maximum allowable PACs as a substitute for Category 1 CEUs, the ABGC requirements may be averaged on an annual basis as follows:

Total number of CEU/PAC contact hours required: 25
- Category 1 CEUs: 10 contact hours
- PACs: 5 contact hours
- Category 2 CEUs: 10 contact hours

The requirements in the Department's regulations may be averaged on an annual basis as follows:

Total number of CEU contact hours required: 15
- Category 1 CEUs: 10 contact hours
- Category 2 CEUs: 5 contact hours

4: Expression of Support
Comment: The commenter expresses support for the regulations since they bring the Department into line with current national criteria for the licensure of genetic counselors set forth by the ABGC.
Commenter: 2

Department Response: The Department appreciates the expression of support.

5: Temporary Genetic Counselor Licenses and Certification Examination
A. Comment: The commenter recommends that the regulations be amended so that individuals holding a temporary genetic counselor license, taking the ABGC examination, and failing, be permitted to reapply for a new temporary genetic counselor license if they provide proof of active candidate status through the ABGC for a subsequent examination and work under the supervision of a licensed genetic counselor.

The commenter notes pitfalls of the current regulations include that genetic counselor licenses may be granted to individuals who have not had any genetic counseling experience for the entire year in which they were prohibited from practicing after failing the ABGC examination at their first attempt and passing at a subsequent attempt; individuals who choose to take the examination early and do not pass are assumed to be less qualified to perform duties than individuals who defer for a year because they do not feel prepared to take the examination; and individuals who defer for a year and who have been successfully employed during that period but who then fail the ABGC examination are suddenly unable to keep their job and must quit or be fired by their employer.
Commenter: 3.1

Department Response: The Department acknowledges the comment and the potential hardship that the current licensure requirements may create. However, the Department

does not believe the Health and Safety Code provides the statutory authority for the recommended changes to licensure requirements.

California Health and Safety Code Section 124981 states that one of the requirements for licensure as a genetic counselor is that the applicant has demonstrated competence by an examination administered or approved by the Department. Health and Safety Code Section 124982 has a similar provision for applicants for a temporary genetic counselor license intending to take the examination. The regulations specify that this examination is to be the ABGC certification examination.

Health and Safety Code Section 124982 provides that a temporary genetic counselor license may be issued to applicants attesting that they will apply for the first available certification examination, or for the examination in the year following the year of the first available examination. Health and Safety Code Section 124982(c)(2) states a temporary genetic counselor license expires 30 days after notification of the Department of failure of the certification examination. Individuals failing the certification examination are required to wait until they pass a subsequent examination before applying for a genetic counselor license and cannot practice as a genetic counselor prior to obtaining that license.

The commenter recommends a second temporary genetic counselor license be issued when the applicant has regained active candidate status for a subsequent ABGC certification examination following a failed attempt. Health and Safety Code Section 124982(b) states that temporary licenses are valid for a period of 24 months, unless they otherwise expire or are revoked, and may not be “extended or renewed.” A statutory amendment would be required to authorize the Department to issue more than one temporary genetic counselor license to an individual.

However, the regulations currently refer to revoking a temporary genetic license following failure of the ABGC certification examination, while Health and Safety Code Section 124982 refers to the license expiring. The Department is amending Sections 6301.3 and 6303.1 of the regulations to remove references to revocation and refer to the expiration provisions in the Health and Safety Code as it is important the regulation language be in accordance with the provisions of the statute.

B. Comment: The commenter, in noting that the ABGC examination is only offered once a year, recommends an examination be offered monthly or at least quarterly.
Commenter: 3.2

Department Response: The Department acknowledges the comment and the potential hardship that the current licensure requirements may create. However, the Department does not support amending the regulations to provide for an alternative to the ABGC certification examination for licensure requirements.

California Health and Safety Code Section 124981 states that one of the requirements for licensure as a genetic counselor is that the applicant has demonstrated competence

by an examination administered or approved by the Department. Section 124982 has a similar provision for applicants for a temporary genetic counselor license intending to take the examination. The regulations specify that this examination is to be the ABGC certification examination.

Unlike other states that may have a Board or Advisory Committee established by statute, in California the Department's Genetic Disease Screening Program (GDSP) administers the licensure program. Health and Safety Code Sections 124977 and 124996 require that GDSP activities be "fully supported from fees collected." Administering a Departmental examination as an alternative to the ABGC certification examination would place additional administrative burdens on the Department that were not included in fiscal estimates and the establishment of licensure fees.

The ABGC certification examination has traditionally been offered only once each year. The activities of the ABGC in determining the scheduling of their certification examination are outside the scope of the regulatory action. However, the Department notes the ABGC will begin offering the certification examination twice each year commencing in 2014, which has the potential to reduce the hardship experienced by genetic counselors whose temporary licenses expire due to failure at one examination attempt.

C. Comment: The commenter recommends that a temporary license not be revoked if a temporary license holder does not pass the ABGC board certification exam at their first attempt.

The commenter contends that other states have provisions that if a temporary license holder does not pass their first attempt at the board exam, they may have a second attempt and still hold a temporary genetic counseling license and practice genetic counseling in the meantime.
Commenter: 5

Department Response: The Department acknowledges the comment and the potential hardship that the current licensure requirements may create. However, the Department does not believe the Health and Safety Code provides the statutory authority for the recommended changes to licensure requirements.

California Health and Safety Code Section 124982 explicitly states that a temporary license expires 30 days after notification of the Department that an applicant has failed the certification examination. A statutory amendment would be required to prevent a temporary license from expiring after one failed examination attempt.

However, the regulations currently refer to revoking a temporary genetic license following failure of the ABGC certification examination, while Health and Safety Code Section 124982 refers to the license expiring. The Department is amending Sections 6301.3 and 6303.1 of the regulations to remove references to revocation and refer to the expiration

provisions in the Health and Safety Code as it is important the regulation language be in accordance with the provisions of the statute.

ADDENDUM TWO

COMMENTS RECEIVED DURING THE FIRST 15-DAY NOTICE OF PUBLIC AVAILABILITY PERIOD

The Department has complied with the requirements of Section 44 of Title 1 of the California Code of Regulations. The notice and modified text were e-mailed or mailed to persons testifying at the public hearing, commenters, and persons requesting notification of changes, and posted on the CDPH website. The following list is of persons commenting on the proposed amendments to the regulations during the 15-day public comment period beginning on May 22, 2013, and ending on June 6, 2013:

"WT"= written testimony

1. WT: Rebecca Nagy, President, NSGC, Chicago, IL.

2. WT: Maren T. Scheuner, MD, MPH, FACMG.

3. WT: Carin Espenschied, MS, LCGC, Assistant Director, Cancer Screening & Prevention Program, Genetic Counselor, City of Hope, Division of Clinical Cancer Genetics, Duarte, CA.

4. WT: Mark H. Lipson, MD, Clinical Geneticist, Sacramento, CA.

5. WT: Michael Aidan, Assistant Executive Director, Engineers and Scientists of California Local 20, San Francisco, CA.

6. WT: Vickie L. Venne, MS, LGC, Senior Genetic Counselor; Laurence J. Meyer, MD, PhD, National Director, VHA Central Office: Genomic Medicine Service, Department of Veterans Affairs, Salt Lake City, UT.

7. WT: Kathryn Murray, MS, CGC, Center for Genetics and Maternal-Fetal Medicine; Shelly Bosworth, MS, CGC, Center for Genetics and Maternal-Fetal Medicine; Vern Katz, MD, Maternal Fetal Medicine; Peter Kovach, MD, Medical Oncologist, Springfield, OR.

8. WT: Beth Crawford, MS, LCGC, Clinical Director, Cancer Risk Program, University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center; Robert L. Nussbaum, MD, Holly Smith Professor of Medicine, Medical Director, Cancer Risk Program, UCSF Helen Diller Family Comprehensive Cancer Center, Chief, Division of Genomic Medicine, Department of Medicine, UCSF; Katherine A. Rauen, MD, PhD,

Professor, Depts. Pediatrics, OB/Gyn & RS, Interim Chief, Division of Medical Genetics, Director, NF/Ras Pathway Clinic, Director, Medical Genetics Residency Program, Director, AFP Program, UCSF Helen Diller Family Comprehensive Cancer Center; Gerrie Shields, Administrative Director, UCSF Helen Diller Family Comprehensive Cancer Center; Janet Sabatino, RN, BSN, Administrative Nurse Manager, UCSF Helen Diller Family Comprehensive Cancer Center; Jonathan P. Terdiman, MD, Professor of Clinical Medicine and Surgery, UCSF; Gerri Berg, Director, Business Development, UCSF Medical Center; Juliane Wojciak, MS, LCGC; Robin Lee, MS, LCGC; Julie S. Mak, MSc, MS, LCGC; Amie Blanco, MS, LCGC; Nicola Stewart, MS, LCGC; Megan Myers, MS, LCGC; Kate Loranger, MS, LCGC; Lauren Ryan, MS, LCGC; Peggy Conrad, MS, LCGC; Sherri Pena, MS, LCGC, Practice Manager, Prenatal Diagnostic Center, UCSF; Kathryn Drexler, MS, LCGC; Erin Ayash, MS, LCGC; Ellen Simpson, PhD, MS, LCGC; Allyson Scott, MS, LCGC, San Francisco, CA.

9. WT: Colleen Caleshu, MS, LCGC, Genetic Counselor, Stanford Center for Inherited Cardiovascular Disease; Kyla Dunn, MS, LCGC, Genetic Counselor, Stanford Center for Inherited Cardiovascular Disease; Rachel Koff, MS, LCGC, Genetic Counselor, Stanford Center for Inherited Cardiovascular Disease; Megan Grove, MS, LCGC, Genetic Counselor, Stanford Center for Inherited Cardiovascular Disease; Euan Ashley, MRCP, DPhil, Director, Stanford Center for Inherited Cardiovascular Disease; Joshua Knowles, MD, PhD, Director, Familial Dyslipidemia Clinic, Stanford Center for Inherited Cardiovascular Disease, Medical Director, Familial Hypercholesterolemia Foundation; Marco Perez, MD, Director, Familial Arrhythmia Clinic, Stanford Center for Inherited Cardiovascular Disease; Matthew Wheeler, MD, PhD, Stanford Center for Inherited Cardiovascular Disease, Stanford, CA.

Note: The first digit of the number designation identifies the Commenter as listed above. The digit after the decimal point indicates a specific comment if more than one comment was noted.

1. Definition of Genetic Counseling: Identifying and Coordinating Genetic Laboratory Tests

The Department's proposed amendment to the definition of genetic counseling included additional functions. The proposed Section 6300.15(c) stated that genetic counseling includes "identifying and coordinating genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment. Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose, test or treat any genetic disease or condition or other disease or condition."

A. Comment: Commenters support regulations that include the ability of licensed genetic counselors in California to order genetic tests.

Several commenters support the expanded definition of genetic counseling proposed in Section 6300.15 to include additional functions, but recommend that Section 6300.15(c) be amended so that "identifying and coordinating genetic laboratory testing" include the

ability of a licensed genetic counselor to order genetic tests. These commenters concur that genetic counselors should be excluded from diagnosis and treatment of genetic conditions and diseases.

One commenter contends there are a considerable number of studies in the literature that show that incorporating genetic counselors into the testing process leads to cost-efficient risk identification and more appropriate genetic test orders, as genetic counselors make appropriate test selection whereas many non-genetics specialists do not. Other studies have demonstrated quantified savings from the involvement of genetic counselors in genetic testing by reducing the number of inappropriate tests that are not clinically indicated, ensuring test orders are in accordance with evidence-based medicine, and reducing unnecessary treatment. The commenter contends appropriately trained genetic counselors are ideally suited to provide these increasingly essential services in the most cost-effective and efficient manner, and therefore should have the ability to order tests in California.

Another commenter contends genetic counselors have the education, skills, professionalism and integrity to be responsible for ordering genetic tests, with collegial relationships with physician clinical geneticists essential for interaction as needed for complex cases.
Commenters: 1, 4, 5, 7, 8.2 and 9

Department Response: The Department acknowledges these comments and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. However, the Department is not attempting to regulate the practices of clinical geneticists, or clinical laboratories in accepting clinical test orders. The Department believes that including “identifying and coordinating genetic laboratory tests” in the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. To avoid ambiguity and not prohibit collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of physicians, the Department instituted a change to the proposed amendment to state in Section 6300.15(c) that “Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition.” The Department’s amendment to the definition includes this modified provision.

B. Comment: The commenter supports the Department’s proposed amendment to the definition of genetic counseling in Section 6300.15, particularly the language in Section 6300.15(c), since it is important to make a clear distinction between the role of genetic counselors and medical doctors involved in the care of patients with or at risk for genetic conditions.

The commenter contends genetic counselors are not trained to make diagnoses or recommend medical treatments, surveillance or management, and, to provide genetic

counseling services, must work with a physician (or nurse practitioner in some states), and the physician is the health professional responsible for developing the differential diagnosis, developing a genetic testing strategy and ordering tests, and recommending management to the patient based upon all of the available medical information, including genetic test results.
Commenter: 2.1

Department Response: The Department acknowledges this comment and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. The Department believes that including "identifying and coordinating genetic laboratory tests" in the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. To avoid ambiguity and not prohibit collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of physicians, the Department instituted a change to the proposed amendment to state in Section 6300.15(c) that "Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition." The Department's amendment to the definition includes this modified provision.

C. Comment: Commenters recommend amending Section 6300.15 to remove the sentence "Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose, test or treat any genetic disease or condition or other disease or condition."

Commenters contend the addition will potentially cause significant harm to the public, since prohibiting genetic counselors from ordering tests will significantly impede the process and negatively impact patient care.

Commenters: 6.1

Department Response: The Department acknowledges this comment and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. The Department believes that including "identifying and coordinating genetic laboratory tests" in the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. To avoid ambiguity and not prohibit collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of physicians, the Department instituted a change to the proposed amendment to state in Section 6300.15(c) that "Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition." The Department's amendment to the definition includes this modified provision.

D. Comment: Commenters recommend the regulations include a statement indicating that genetic counselors may order genetic tests under an ordering physician or allow

collaborative agreements for California organizations that recognize the value of the genetic counselors' ability to order genetic tests.

One commenter contends signing test request forms to order genetic tests under the name of an ordering physician is a regular part of the responsibilities genetic counselors perform and the proposed text in section 6300.15(c) could be interpreted to indicate that this would no longer be allowed. This would limit the efficiency and effectiveness of genetic counselors.

Other commenters contend the genetic counselors' ability to order tests has saved facilities money and helped many patients understand the nuances of genetic tests and the reasons why tests will or will not help in their medical management.
Commenters: 3 and 6.2

Department Response: The Department acknowledges these comments and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. However, the Department is not attempting to regulate the practices of clinical geneticists, or clinical laboratories in accepting clinical test orders. The Department believes that including "identifying and coordinating genetic laboratory tests" in the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. To avoid ambiguity and not prohibit collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of physicians, the Department instituted a change to the proposed amendment to state in Section 6300.15(c) that "Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition." The Department's amendment to the definition includes this modified provision.

E. Comment: Commenters support the limited ability of genetic counselors who have met the stringent guidelines of state licensure to order tests based on published guidelines for each particular sub-specialty and/or under a protocol developed and approved by Medical Geneticist physicians.
Commenters: 8.1

Department Response: The Department acknowledges this comment and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. However, the Department is not attempting to regulate the practices of clinical geneticists, or clinical laboratories in accepting clinical test orders. The Department believes that including "identifying and coordinating genetic laboratory tests" in the definition of genetic counseling is sufficient to reflect current practices of genetic counselors transmitting orders for genetic tests on behalf of physicians and with physician approval. To avoid ambiguity and not prohibit collaborative agreements or protocols in organizations allowing genetic counselors to transmit test orders on behalf of physicians, the Department instituted a change to the

proposed amendment to state in Section 6300.15(c) that "Nothing in this subsection shall be construed to authorize a genetic counselor to diagnose or treat any genetic disease or condition or other disease or condition." The Department's amendment to the definition includes this modified provision.

2. Definition of Genetic Counseling: Determining Genetic Risk

Comment: Commenter recommends Section 6300.15(a) of the proposed amendment to the definition of genetic counseling be modified to replace the phrase "to determine genetic risk" with "to assist with genetic risk assessment" to read as follows:
"(a) obtaining and evaluating individual, family, and medical histories to assist with genetic risk assessment for genetic/medical conditions and diseases in a patient, his/her offspring, and other family members."

The commenter contends important medical-decision making is necessary for a physician to develop an appropriate differential diagnosis, formulate a genetic testing strategy, and interpret the meaning of test results in the context of the patient's medical information.
Commenter: 2.2

Department Response: The Department acknowledges the comment and believes it is important to distinguish between the roles of physicians and genetic counselors in the definition of genetic counseling. However, the Department does not support the recommended modification to the proposed amendment to the regulations. While acknowledging the collaborative relationship between physicians and genetic counselors, the Department believes interpreting family and medical histories to assess the chance of disease occurrence or recurrence, and providing that information to patients, is an appropriate role for genetic counselors to perform. The Department believes the language proposed adequately reflects the training received by genetic counselors and their responsibilities in clinical practice in collaboration with physicians, and is amending the definition to include this provision.

ADDENDUM THREE

COMMENTS RECEIVED DURING THE SECOND NOTICE OF 15-DAY PUBLIC AVAILABILITY PERIOD

The Department has complied with the requirements of Section 44 of Title 1 of the California Code of Regulations. The notice and modified text were e-mailed or mailed to persons testifying at the public hearing, commenters, and persons requesting notification of changes, and posted on the CDPH website. The public availability period began July 20, 2013, and ended August 5, 2013. The Department did not receive any comments on the modified text during the availability period.