



California
Department of
Health Services

DIANA M. BONTÁ, R.N., Dr. P.H.
Director

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



Gray Davis
Governor

**REPORT TO THE CALIFORNIA LEGISLATURE
ON “LICENSING GENETIC PERSONNEL”**

**California Department of Health Services
January 1, 2000**



Do your part to help California save energy. To learn more about saving energy, visit the following web site:
www.ConsumerEnergyCenter.org/flex/index.html

Genetic Disease Branch, 2151 Berkeley Way, Annex 4, Room 300, Berkeley, CA 94704
Phone 510-540-2534 • Fax 510-540-2966
Internet Address: www.dhs.ca.gov

Cunningham, George MD, MPH (DHS-Genetics)

From: Sabanovich, Sandra (DHS-LGA)
Sent: Thursday, April 12, 2001 10:31 AM
To: Mitchell, Tameron (DHS-PCFH)
Cc: Cunningham, George MD, MPH (DHS-Genetics)
Subject: Approval of Licensing Genetic Personnel

Ms. Mitchell,

This is to inform you that the one time Legislative Report titled "Licensing Genetic Personnel" has been approved by the Governor's office, as of 4/11/01.

If you should have any questions, please feel free to contact me.

Sandra Sabanovich

Secretary to the Deputy Director

Department of Health Services

Legislative and Governmental Affairs

714 P St, Room 1350

916 657-2843 fax 916-657-2996

e-mail: ssabanov@dhs.ca.gov

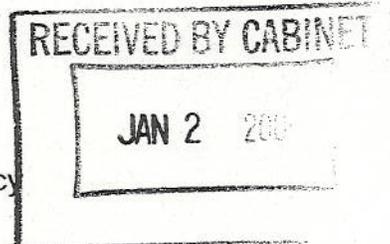
REQUEST FOR REPORT APPROVAL

20033

TO: FILE

DN3158

ATTENTION: SUSAN P. KENNEDY
Cabinet Secretary



FROM: Grantland Johnson
Secretary, Health and Human Services Agency

Prepared By: Tameron Mitchell, R.D., M.P.H.
Deputy Director/ Primary Care and Family Health
916-654-0265

*Cab-
2022*

DATE:

SUBJECT: Request for Approval of Report to the Legislature

REPORT TITLE: Licensing Genetic Personnel
AUTHORITY/MANDATE: SB 1800, Chapter 897, Statute 1998 –Health & Safety Code
Section 124980 (11)(b)

FREQUENCY: One Time Report
DUE TO THE LEGISLATURE: January 1, 2000

POLICY ISSUES ADDRESSED: Recognition of a new class of health professional, licensing of Genetic Counselors. – This report recommends the establishment of a new health care professional to provide genetic counseling. While the recommendations are a result of consultation with a multi disciplinary advisory committee, establishing education and experience requirements to deliver genetic counseling services could result in some current providers to be ineligible to continue providing such services creating a financial crisis for the providers. Even though the field of genetics is very specialized, any "turf" issue related to scope of practice for health professionals can be very contentious. Additionally, while the advisory committee was representative of many disciplines in the field of genetics, three major California organizations did not participate. It is therefore recommended that when the report and standards are approved, the Department meet with the California Medical Association, the California Nurses Association and various scientists union representatives to brief them on the Departments recommendations prior to release of the report to the Legislature.

REPORT RECOMMENDATION: Approve Report to the Legislature

[Signature]
APPROVED: _____ 8/7/00
Diana M. Bontá, R.N., Dr.P.H. Date
Director
Department of Health Services

[Signature]

Susan P. Kennedy Date
Cabinet Secretary

[Signature]

Grantland Johnson Date
Secretary
Health and Human Services Agency

[Signature]

Michael J. Gotch Date
Legislative Secretary

Gray Davis Date
Governor

Memorandum

Date: JUN 12 2000

To: Richard R. Bayquen
Chief Deputy Director
714 P Street, Room 1253

From: Tameron Mitchell, R.D., M.P.H.
Deputy Director
Primary Care and Family Health
714 P Street, Room 450
654-0265

Subject: Report to the Legislature

Attached is a copy of the report entitled Licensing Genetic Personnel for your review and approval.

Section 124980(11)(b) of the Health and Safety Code requires that this report be submitted to the Legislature by January 1, 2000.

Upon your approval, we will prepare the final report for review and approval by the Agency and Governor's Office.

Attachments

APPROVED:


Richard R. Bayquen
Chief Deputy Director

DATE: _____

Highlights of Report

Subject Matter:	Licensing of Genetic Counselors
Principal Findings:	There is need of and support for the Department of Health Services to license a new class of health professional as genetic counselors.
Principal Recommendations:	The Legislature provides legal authority for licensure and collection of licensure fees.
Controversial Areas:	None
Fiscal Impact:	If licensing authority is provided, there would be a requirement to add staff to handle the workload. The costs associated with licensing would be offset by fees collected.

Report To The Legislature – SB1800

Background

The Senate Select Committee on Genetics and Public Policy held hearings February 18, 1997 on Licensing of Genetic Counselors. The Department of Health Services (Department) testified at that hearing.

Subsequently, in February 1998, Senator Patrick Johnston introduced SB1800. (Appendix A). As originally introduced the bill would have given the Department authority to license a new class of genetic health professions and to collect a fee to support the activity. The bill was amended on August 1998 to instead require the Department to report by January 1, 2000 on “appropriate criteria and standards for licensing genetic counselors.” The Department was required to consult with medical professional organizations in developing the Department’s recommendations.

Implementation

The legislation directed the Department to “consult with a group of medical experts representing professional organizations including, but not limited to, The Medical Board of California, the California Medical Association, and organizations representing genetic counselors in California”. Invitations to participate in an advisory committee were extended to all these groups. The Department convened a broad-based advisory committee with representatives from all organizations responding to the invitation to participate. The California Medical Board attended the advisory committee meetings. Although the California Medical Association (CMA) did not actively participate in the advisory committee meetings, a member of CMA was provided with all advisory committee materials, including meeting announcements,

meeting minutes etc. The list of persons invited to participate is listed as Appendix B. The first meeting was April 1, 1999. A draft of proposed regulations to specify criteria and standards for licensure of master and doctoral level genetic health professions was discussed. The issue of whether to include some recognition of a subspecialty of genetics in nursing was also discussed. Two subcommittees were created, one for genetic counselors and a second for nursing.

The genetic professional group quickly reached consensus. The nursing group which included representatives from the Board of Registered Nursing (BRN) involved more complex issues and several meetings, phone calls and exchanges of letters were required to clarify the issues and reach consensus. The consensus was that the legislation did not address nurses who are already licensed by the BRN. The development of subspecialty recognition of nurses trained in genetics should be the responsibility of the nursing profession and the BRN.

A second meeting of the full advisory committee was held on September 27, 1999. The final recommendations for standards were presented and accepted by the entire advisory committee.

Problem Definition

The current law and the standards of practice recognized by the medical community require genetic counseling be provided to insure proper utilization of new genetic tests and to maximize the public's understanding of the risk, benefits and options available. There is a need and a demand for genetic counseling. California has master's-level genetic counselors and doctoral-level medical geneticists. Given the progress in the Human Genome Project and the massive investment in private sector research, there will be many new tests and genetic applications that will involve complex counseling.

Currently genetic counselors, although used widely, are not recognized as licensed health professionals and their services are not reimbursable. In addition, some persons are providing genetic counseling without formal training. Some patients who need counseling have not received it.

Significant Findings

The Department, based on the analysis of the Departments' Genetic Disease Branch and following the discussion and direction of the advisory committee, makes the following findings:

- (1) There is a need to create a licensure program for master's-level genetic counselors and doctoral-level medical geneticists.
- (2) Department of Health Services (DHS) is the appropriate agency to administer this licensure program.
- (3) There is agreement on specifics of the standards for licensure.
- (4) Licensed genetic counselors and doctoral medical geneticists provide valuable health care services, which should be reimbursable by health care payers.
- (5) DHS needs to obtain legislative authority to implement the standards, issue licenses, and collect a fee to support this activity.
- (6) DHS should assist the BRN in cooperation with concerned professional nursing organizations including the International Society of Nurses in Genetics (ISONG) to develop a formal program to recognize an advanced practice nurse in genetics.

Documentation in Support of Findings

Finding No. 1. The Department has conducted a licensing survey using the same data collection process used by the Department of Consumer Affairs. The data collected supported the need for a licensure program. The Department has also received endorsement of licensure by

professional organizations representing medical genetics. (See Appendix C) The advisory committee was unanimous in accepting the need for licensure.

Finding No. 2. The Department met with the Department of Consumer Affairs (DCA) and reviewed our survey. The DCA concluded that this is too small a group and would be too expensive to license via a special examination and licensing board. To ensure the input and endorsement of the Department of Consumer Affairs, the legislation mandated their participation on the Advisory Committee. They expressed no objection to DHS assuming this responsibility. The concerned groups have expressed support of DHS as the licensing agency.

Finding No 3. The consensus language for the proposed standards is included in Appendix D. These standards would still have to be formulated as regulations and be subject to public hearing and additional comments and suggestions for change. The Department needs legislative action to clarify the legislative intent and the Department's authority in this area. The Department needs clear authority for implementing regulations and collection of fees to provide a mechanism for supporting the licensure activities. The exact amount of the license fee will be set to assure that the program would be self-supporting.

Finding No. 4. The Department recognizes that nurses are already licensed health professionals. It is therefore appropriate that a subspecialty recognition of genetic nursing be done under the auspices of the BRN and within the developed procedures already approved by the nursing profession to recognize special training and experience in other critical areas. The Department would be pleased to support this effort and contribute our expertise and experience in the provision of genetic services to this project. Information provided to the advisory committee indicated an active effort to this end that is being conducted by ISONG. The nursing

representatives on the advisory committee endorsed the proposed standards as submitted.

(Appendix E)

g.gcc.gen.Report To The Legislature – SB1800

SB1800

SB 1800 Hereditary disorders: genetic counselors.**BILL NUMBER: SB 1800 CHAPTERED 09/28/98****CHAPTER 897**

FILED WITH SECRETARY OF STATE SEPTEMBER 28, 1998
 APPROVED BY GOVERNOR SEPTEMBER 27, 1998
 PASSED THE SENATE AUGUST 31, 1998
 PASSED THE ASSEMBLY AUGUST 17, 1998
 AMENDED IN ASSEMBLY AUGUST 10, 1998
 AMENDED IN ASSEMBLY JULY 7, 1998
 AMENDED IN ASSEMBLY JUNE 24, 1998
 AMENDED IN ASSEMBLY JUNE 10, 1998
 AMENDED IN SENATE MAY 5, 1998

INTRODUCED BY Senator Johnston**FEBRUARY 18, 1998**

An act to amend Section 124980 of the Health and Safety Code, relating to hereditary disorders.

LEGISLATIVE COUNSEL'S DIGEST

SB 1800, Johnston. Hereditary disorders: genetic counselors.

Existing law requires the Director of Health Services to establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety in accordance with certain principles.

This bill would require the State Department of Health Services to recommend appropriate criteria and standards for licensing genetic counselors, and would require the department to consult with a group of medical experts representing medical professional organizations during the process of developing and recommending the criteria and standards. It would further require the department to report its recommendations to the Legislature by January 1, 2000.

SECTION 1. Section 124980 of the Health and Safety Code is amended to read:

124980. (a) The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety, in accordance with the principles established pursuant to this section. These principles shall include, but not be limited to, the following:

(1) The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.

(2) The incidence, severity and treatment costs of each hereditary disorder and its perceived burden by the affected community should be considered; and that where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders be consulted by the department.

- (3) Information on the operation of all programs on hereditary disorders within the state, except for confidential information obtained from participants in the programs, be open and freely available to the public.
- (4) Clinical testing procedures established for use in programs, facilities, and projects be accurate, provide maximum information, and that the testing procedures selected produce results that are subject to minimum misinterpretation.
- (5) No test or tests shall be performed on any minor over the objection of the minor's parents or guardian, nor may any tests be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders, and is given reasonable opportunity to object to the testing.
- (6) No testing, except initial screening for PKU and other diseases that may be added to the newborn screening program, shall require mandatory participation, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions.
- (7) Counseling services for hereditary disorders be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder as a result of screening programs; the counseling is nondirective, emphasizes informing the client, and not require restriction of childbearing.
- (8) All participants in programs on hereditary disorders be protected from undue physical and mental harm, and except for initial screening for PKU and other diseases that may be added to newborn screening programs, be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease be informed of the nature, and where possible, the cost of available therapies or maintenance programs, and be informed of the possible benefits and risks associated with such therapies and programs.
- (9) All testing results and personal information generated from hereditary disorders programs be made available to an individual over 18 years of age, or to the individual's parent or guardian. If the individual is a minor or incompetent, all testing results that have positively determined the individual to either have, or be a carrier of, a heredity disorder shall be given through a physician or other source of health care.
- (10) All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, be held confidential and be considered a confidential medical record except for such information as the individual, parent, or guardian consents to be released; provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available, except for statistical data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to 45 Code of Federal Regulations Section 46.101 et seq. entitled "Protection of Human Subjects," the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value

that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

(11) An individual whose confidentiality has been breached as a result of any violation of the provisions of the Hereditary Disorders Act (Section 27) may recover compensatory damages, and in addition, may recover civil damages not to exceed ten thousand dollars (\$10,000), reasonable attorney's fees, and the costs of litigation.

(b) The department shall recommend appropriate criteria and standards for licensing genetic counselors. In the process of developing the recommended criteria and standards, the department shall consult with a group of medical experts representing medical professional organizations including, but not limited to, the Medical Board of California, the California Medical Association, and organizations representing genetic counselors in California. The department shall report its recommendations to the Legislature by January 1, 2000.

 [Senate Home Page](#)  [Search Bill Text](#)

Senate Rules Committee / California State Senate / WebMaster@sen.ca.gov

GENETIC COUNSELOR LICENSURE COMMITTEE
DEPARTMENT OF HEALTH SERVICES
GENETIC DISEASE BRANCH

Andrew Acosta
State Capital
Room 5066
Sacramento, CA 95814
Tel: 916-323-4306 or 916-445-2407
Fax: 916-323-2596
Email: andrew.acosta@sen.ca.gov

Gwen Anderson, RN, Ph.D.
Post Doctoral Fellow
Program in Genomics, Ethics and Society
Stanford Center for Biomedical Ethics
701 Welch Road, Suite 1105
Palo Alto, CA 94304
Tel: 650-725-9564
Fax: 650-725-6131
Email: gander@leland.stanford.edu

Robin Clark, M.D.
Genesis Laboratory
5750 Division Street, Suite 104
Riverside, CA 92506
Tel: 909-865-0800 or 909-781-9923
Fax: 909-865-0808 or 909-781-9924
Email: rclark@deltanet.com

David Cox, M.D., Ph.D.
Department of Genetics
Stanford University Medical Center
M-336
Stanford, CA 94305
Tel: 650-725-8042
Fax: 650-725-8058
Email: cox@shgc.stanford.edu

Beth Crawford, M.S.
Genetic Counselor
University of California, San Francisco
Mount Zion Cancer Center
2356 Sutter Street, Box 1714
San Francisco, CA 94115
Tel: 415-885-7779
Fax: 415-885-7218
Email: bcrawf@itsa.ucsf.edu

George C. Cunningham, M.D., M.P.H.
Chief, Genetic Disease Branch
State of California Health and Welfare Agency
Department of Health Services
2151 Berkeley Way, Annex 4
Berkeley, CA 94704-1011
Tel: 510-540-2553
Fax: 510-849-5102
Email: gcunning@dhs.ca.gov

Cynthia Curry, M.D.
Medical Director of Genetics
Valley Children's Hospital
Genetic Medicine -FC21
9300 Valley Children's Place
Madera, CA 93638
Tel: 209-353-6625
Fax: 209-353-6656
Email: curryc@valleychildrens.org

Charles Epstein, M.D.
Professor of Pediatrics and Genetics
University of California, San Francisco
633 Parnassus Avenue
Campus Box 0748
San Francisco, CA 94143-0748
Tel: 415-476-2981
Fax: 415-476-9976
Email: cepst@itsa.ucsf.edu

Andrea Fishbach, M.S., M.P.H.
Kaiser Permanente-Genetics
2350 Geary Blvd.
San Francisco, CA 94115
Tel: 415-202-2998
Fax: 415-202-2999
Email: andrea.fishbach@ncal.kaiperm.org

Cathi Rubin Franklin, M.S.
Quest Diagnostic Laboratories
7600 Tyrone Avenue
Van Nuys, CA 91405
Tel: 800-877-2520 ext. 6157
Fax: 818-376-6212
Email: cathi.franklin@questdiagnostics.com

James Goldberg, M.D.
Prenatal Diagnosis Center
California Pacific Medical Center
3700 California Street, Ste G-330
San Francisco, CA 94118
Tel: 415-750-6400
Fax: 415-750-2306
Email: jgoldberg@fetaldx.com

Sara Goldman, M.P.H.
California Department of Health Services
Genetic Disease Branch
2151 Berkeley Way, Annex 4
Berkeley, CA 94704-1011
Tel: 510-540-3041
Fax: 510-540-2966
Email: sgoldman@dhs.ca.gov

GENETIC COUNSELOR LICENSURE COMMITTEE
DEPARTMENT OF HEALTH SERVICES
GENETIC DISEASE BRANCH

Henry Greely, J.D.
Professor of Law/PGES Co-Director
Stanford Law School
Crown Quad, Suite 333
Stanford, CA 94305
Tel: 650-723-2517
Fax: 650-725-0253 or 650-725-7663
Email: hgreely@leland.stanford.edu

Bill Herbert, M.S.
Cedars Sinai Medical Center
444 S. San Vicente Blvd, Suite 1001
Los Angeles, CA 90048
Tel: 310-855-2211
Fax: 323-651-5381
Email: bherbert@mailgate.csmc.edu

Cindy James
Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento, CA 95825
Tel: 916-263-1080
Fax:
Email: cjames@smtp.medbd.dca.ca.gov

Patrick Johnston
Senator
5th District, California Legislature
State Capitol, Room 5066
Sacramento, CA 95814
Tel: 916-445-2407
Fax: 916-323-2304
Email: senator.johnston@sen.ca.gov

Steven Keiles, M.S.
Department of Genetics
Kaiser Permanente Medical Center
6041 Cadillac Avenue
Los Angeles, CA 90034-1702
Tel: 213-857-2074
Fax: 323-857-2239
Email: steven.b.keiles@kp.org

Rev. Dr. William Kintner, II
Alliance of Genetic Support Groups
127 East South Avenue
Redlands, CA 92373-7149
Tel: 909-335-0050
Fax: 909-793-2118
Email: Revdocwtk@juno.com

Barbara Koenig, Ph.D.
Executive Director/PGES Co-Director
Stanford Center for Biomedical Ethics
701 Welch Road, Suite 1105
Palo Alto, CA 94304
Tel: 650-725-6103
Fax: 650-725-6131
Email: bkoenig@stanford.edu

Edward Lammer, M.D.
Children's Hospital/Oakland
Medical Genetics and Prenatal Diagnosis
747 52nd Street
Oakland, CA 94609
Tel: 510-428-3550
Fax: 510-450-5874
Email: cho.dr.ela@cho.org

Melinda Lassman, M.A.
California Department of Health Services
Genetic Disease Branch
2151 Berkeley Way, Annex 4
Berkeley, CA 94704-1011
Tel: 510-540-2543
Fax: 510-540-2966
Email: mlassman@dhs.ca.gov

Deborah MacDonald, R.N., M.S.
Genetics Associate/Cancer Risk Counselor
City of Hope National Medical Center
Clinical Cancer Genetics Program
1500 E. Duarte Road
Duarte, CA 91010-3000
Tel: 626-359-8111 ext. 4330 or 4324
Fax: 626-930-5495
Email: dmacdonald@smtplink.coh.org

Aida Metzenberg, Ph.D.
Director, Genetic Counseling Program
California State University in Northridge
18111 Nordhoff Street
Northridge, CA 91330-8303
Tel: 818-677-3355
Fax: 818-677-2034
Email: aida.metzenberg@csun.edu

Angela Musial, M.S.
The Perinatal Center
Alfigen/The Genetics Institute
1455 Montego Dr. Suite 201
Walnut Creek, CA 94598
Tel: 510-937-0620
Fax: 510-937-5936
Email: bapcl@aol.com

GENETIC COUNSELOR LICENSURE COMMITTEE
DEPARTMENT OF HEALTH SERVICES
GENETIC DISEASE BRANCH

Sara L. (Sally) Tobin, Ph.D., M.S.W.
Senior Research Scholar
Program in Genomics, Ethics, and Society
Stanford Center for Biomedical Ethics
701 Welch Road, Suite 1105
Palo Alto, CA 94304
Tel: 650-725-2663
Fax: 650-725-6131
Email: Tobinsl@leland.stanford.edu

Kathleen Schmidt Yule, R.N., M.S.
American Nurses Association/California
C/o 201 Chestnut Street, Apt. A
San Francisco, CA 94133-2428
Tel: 415-421-3776 or 415-476-5048
Fax: 415-665-1314
Email: yule@itsa.ucsf.edu

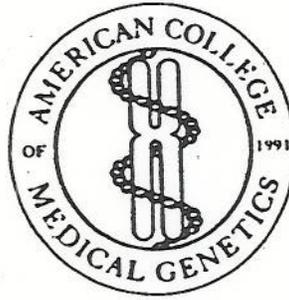
Dena Towner, M.D.
University of California, Davis
Department of OB/GYN
4860 Y Street, Ste 2500
Sacramento, CA 95817
Tel: 916-734-6918
Fax: 916-734-6025
Email: drtowner@ucdavis.edu

Tracy Trotter, M.D.
200 Porter Drive, Suite 300
San Ramon, CA 94583
Tel: 925-838-6511
Fax: 925-838-6544
Email: Ttrotter@silcon.com

Ann Walker, M.S.
Director, Genetic Counseling Program
U. C. Irvine Medical Center
Department of Pediatrics - ZQT 4482
101 The City Drive
Orange, CA 92868-3298
Tel: 714-456-5789
Fax: 714-456-5330
Email: awalker@uci.edu

Jon Weil, Ph.D.
Director, Genetic Counseling Program
University of California, Berkeley
University Hall, Room 570
Berkeley, CA 94720-1190
Tel: 510-642-6328 or 510-642-6553
Fax: 510-643-8771
Email: weilj@socrates.berkeley.edu

John Williams, M.D.
Cedars Sinai Medical Center
Prenatal Diagnosis Program
444 South San Vicenter Blvd, Suite 1002
Los Angeles, CA 90048
Tel: 310-423-9929
Fax: 310-423-9940
Email:



July 25, 1997

BOARD OF DIRECTORS

REED E. PYERITZ, M.D., Ph.D.
PRESIDENT (1998)

LEWIS B. HOLMES, M.D.
V.P. CLINICAL GENETICS (1998)
CLINICAL GENETICS (2000)

MICHAEL S. WATSON, Ph.D.
V.P. LABORATORY GENETICS (1998)
CYTOGENETICS (1998)

MARILYN C. JONES, M.D.
SECRETARY (2000)
CLINICAL GENETICS (2000)

JOE LEIGH SIMPSON, M.D.
TREASURER (2000)
CLINICAL GENETICS (2002)

R. RODNEY HOWELL, M.D.
PRESIDENT-ELECT (1998)
CLINICAL GENETICS (1998)

DAVID L. RIMON, M.D., Ph.D.
PAST PRESIDENT (1998)

DIRECTORS

MAIMON M. COHEN, Ph.D.
CYTOGENETICS (1998)

LOUIS J. ELSAS, M.D.
BIOPHYSICAL GENETICS (2000)

RICHARD A. KING, M.D., Ph.D.
CLINICAL GENETICS (2000)

BRUCE R. KORF, M.D., Ph.D.
CLINICAL GENETICS (2002)

MICHELE M. LEBEAU, Ph.D.
CYTOGENETICS (2002)

ROBERT L. NUSSBAUM, M.D.
MOLECULAR GENETICS (2002)

JOHN A. PHILLIPS, III, M.D.
MOLECULAR GENETICS (2000)

ADVISORS

KURT HIRSCHHORN, M.D.
LYNN D. FLEISHER, Ph.D., J.D.

OFFICE OF THE PRESIDENT
REED E. PYERITZ, M.D., Ph.D.
DEPARTMENT OF HUMAN GENETICS
ALLEGHENY UNIVERSITY OF THE HEALTH SCIENCES
11TH FLOOR, SOUTH TOWER
320 E NORTH AVENUE
PITTSBURGH, PA 15212-4772
TELEPHONE: 412-359-6388
FAX: 412-359-6488

George C. Cunningham, M.D., M.P.H., Chief
Genetic Disease Branch
Department of Health Service
2151 Berkeley Way, Annex 4
Berkeley, CA 94704

Dear Dr. Cunningham:

Genetic counseling is an intrinsic component of virtually all medical genetics services. Often times, genetic counseling is the most crucial and essential component and can stand by itself.

For a variety of reasons, including the fact that genetic counselors who are certified by the American Board of Genetic Counseling are capable of providing services independent of their medical genetics colleagues, should have the capability of performing services reimbursable by all medical insurers, it is essential that genetic counselors be licensed by the states in which they practice.

This is a position long held by the American College of Medical Genetics. Indeed, the College has supported the development of CPT codes specifically for genetic counseling services at the level of the CPT Advisory Committee of the American Medical Association.

Because of the large number of genetic counselors who practice in California, I, the American College of Medical Genetics and medical geneticists throughout the United States are looking to California as a beacon for instituting licensure of professional genetic counselors.

The College and I are most interested in the progression of this initiative in California and would be most pleased to provide any services that you deem appropriate.

Sincerely,

Reed E. Pyeritz, M.D., Ph.D.
Professor of Human Genetics, Medicine,
and Pediatrics
MCP•Hahnemann School of Medicine
Allegheny University of the Health Sciences

REP/vwg



August 20, 1997

George C. Cunningham, MD, MPH
Chief, Genetic Disease Branch
Department of Health Services
2151 Berkeley Way, Annex 4
Berkeley, CA 94704

Dear Dr. Cunningham:

On behalf of the National Society of Genetic Counselors (NSGC), I welcome the opportunity to comment regarding the need for licensure of genetic counselors as health care professionals.

Given the continual genetic discoveries and advances, it is imperative that safeguards be in place to prevent the misuse of genetic information. We believe that one such safeguard involves the licensure of genetic counselors in order to protect the public from potential misuse of genetic information by unqualified individuals. As you know, there is presently no mechanism for institutions, employers, and consumers to identify and therefore be cognizant of qualified master's or doctoral prepared genetic counselors. Licensure would also assure that individuals who are not properly trained cannot use the title of genetic counselor.

Since it has been estimated that the amount of genetic information doubles every 18 months, we recognize the need for continued education in order to assure that properly trained genetic counselors stay abreast of all of the new genetic technologies and unique issues that surround this technology. We support the proposed licensure protocols stating that continuing education units (CEUs) be required. However, given the fact that our upcoming short course and annual education conference in Baltimore is only 3 CEUs (1 CEU = 10 contact clock hours), your requirement of 30 CEUs seems excessive. With budget cuts across the board, many genetic counselors are limited to the number of conferences they may attend. Other cost-effective alternatives for continuing education units need to be explored before such requirements are implemented.

We agree that genetic counselors should be eligible for licensure if they are certified by either the American Board of Medical Genetics (ABMG), 1982-1990, or the American Board of Genetic Counseling (ABGC), after 1993. However, we believe that a grandfather clause should be included for our non-certified colleagues who have graduated from a recognized genetic counseling program and/or have been practicing for a certain number of years (i.e. 5-10) without a current logbook of 50 genetic counseling cases.

AUG-28-1997 18:25

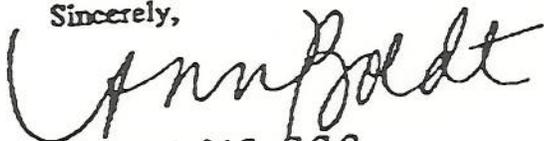
ST JOSEPH FAMILY LIVO

00 3178338 3751 P.02/83

Although we cannot predict whether licensure could possibly result in no or lower reimbursement for genetic counseling services, billing codes will not be established for unlicensed allied health professionals. Billing codes are necessary to enable genetic counselors to more appropriately bill for the time intensive genetic counseling sessions, including preparation and follow-up. This would also eliminate concerns over the possibility of medical fraud when billing under a physician's code.

I understand that many genetic counselors in California are responding favorably toward licensure. I will be anxious to learn the final results from your survey. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,



Ann Boldt, M.S., C.G.C.
President, National Society of Genetic Counselors

cc: Virginia Corson, President, American Board of Genetic Counseling
Angela Musial, Co-chair, Billing, Reimbursement & Licensure Subcommittee
LuAnn Weik, Co-chair, Billing, Reimbursement & Licensure Subcommittee
Deb Lochner Doyle, Chair, Professional Issues Committee
Andrea Fishbach, Region VI Representative
Maureen Smith, President-elect
Bea Leopold, Executive Director
Ann Walker



of Genetic Support Groups

A Coalition of Voluntary Organizations and Professionals

35 Wisconsin Circle, Suite 440 • Chevy Chase, MD 20815-7015
(800) 336-GENE • (301) 652-5553 • Fax (301) 654-0171
alliance@capaccess.org • <http://medhelp.org/www/agsg.htm>

July 30, 1997

George C. Cunningham, MD, MPH
Director
Genetic Disease Branch
Department of Health Services
2151 Berkeley Way, Annex 4
Berkeley, CA 94704

Dear Dr. Cunningham:

Thank you for your letter asking for a consumer perspective on genetic counseling licensure as the State of California considers new regulations.

The Alliance strongly supports licensure for all professional disciplines, especially genetic counseling. Making a clear statement of the minimum professional qualifications of genetic counselors can further ensure that the public receives quality care. This is particularly important now that primary care providers are being called upon more and more to give services to individual and families who have, or may have, genetic diagnoses.

Through our toll-free help lines -- by phone, e-mail and web site -- we hear from thousands of consumers each year. Whenever possible, we refer callers to genetic counselors in their own state and community, utilizing the membership directory of the National Society of Genetic Counselors. We could make these referrals with even greater confidence if, in addition to NSGC membership, we could base referrals on state licensure attainment.

There are several areas where consumer needs are focused:

(1) State licensure would raise public visibility and consumer appreciation of the genetic counseling profession. Many consumers do not know or understand the purpose of genetic counseling. While they may be concerned that inherited diseases could exist in their families, they do not know that there is a specific type of professional to whom they can turn for genetic information and support.

(2) Licensure would also result in enhanced professionalization and greater utilization of genetic counselors within the health care delivery system. The Alliance strongly supports an interdisciplinary approach to the provision of genetic services. As genetic technology continues to evolve and the primary care providers see more people with special genetic needs, the unique skills and expertise of genetic counselors can enhance the quality and sensitivity of primary care services. Medical personnel who deliver genetic information must be adequately educated about the emotional and familial aspects of genetic disease. Many calls to the Alliance help line are from patients and parents who have received a diagnosis and feel that they have been left, without support or guidance, to deal with the emotional aspects of that diagnosis.

Many calls to the Alliance focus on having received inadequate explanations of a particular diagnosis. Consumers are often given a name for what is wrong with them but they don't really understand what it means. In fairness to the professionals who deliver the diagnosis, people in shock do not always fully register what is being said to them. However, if the diagnosis were more consistently offered and more thoroughly explained by licensed professionals trained in counseling and genetics, there would be less confusion, greater clarity and the likelihood of more rapid adjustment and constructive coping. State licensure could reinforce this process.

(3) State licensure could underline the critical importance of the professional skills and experience required also for professional board certification, for example the need to communicate genetic information in an understandable, non-directive manner; demonstrate knowledge of and insight into the psychosocial and ethnocultural experiences important to each client; perform psychosocial assessments; evaluate responses to the condition; promote informed decision-making and identify and use community resources. We would hope and expect that genetic counselors would be active within the voluntary and support group community and would be equipped to make support group referrals as needed.

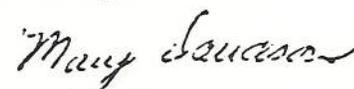
(4) State licensure of genetic counselors could help encourage health care reimbursement for genetic counseling services, the current status of which is often problematic. This would encourage expansion of graduate programs to meet expected future genetic counseling needs as genetic technology evolves.

(5) State licensure would encourage attainment of the knowledge base, skills, sensitivity and appreciation for working within regional and community ethnocultural groups, values and norms.

(6) State licensure could also reinforce the importance of sensitive attention to consumer concerns about genetic/medical privacy and discrimination. Licensure requirements should include demonstration of sound knowledge and understanding of state and federal legislative and policy issues relative to genetics. Counseling must take place within the larger context of sensitivity to the potential for misuse of genetic information. When a genetic diagnosis is placed in the medical or research record, even where no symptoms are manifested, the consumer can face potential difficulties in obtaining and maintaining insurance and employment. Genetic counselors must fully disclose the possible ramifications of genetic testing, diagnostic results and insurance reimbursement records. Although legislation aimed at prohibiting this type of discrimination is in place in California and is being proposed at the Federal level, it is rather limited in scope and does not apply to diagnosed and symptomatic conditions. Genetic counselors must be conversant with these critical discrimination and privacy issues and attentive to these problems in working with clients.

I hope these recommendations are useful and that you will feel free to call on us for further help.

Sincerely,



Mary Davidson
Executive Director

cc. Ann Boldt, MS
Joan Burns, MSW, MS

GENETIC COUNSELOR LICENSURE STANDARDS

For purposes of these standards, the following definitions shall apply:

"Active candidate" means a person who has received official recognition by the Board referenced in these standards that the candidate meets the requirements and has received formal written notification of eligibility to be admitted to examination by the Board.

"Board certified" means written documentation that all requirements for the Board referenced in these standards have been satisfactorily completed.

"Clinical geneticist" means a physician licensed to practice medicine in the state of California who has certification in clinical genetics or designation as an active candidate in clinical genetics by the American Board of Medical Genetics or Canadian College of Medical Genetics.

"Genetic counseling" means a communication process that deals with the human problems associated with the occurrence, or the risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons as defined in these standards to help the individual or family to (1) comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder and the risk of occurrence in specified relatives; (3) understand the alternatives for dealing with the risk of occurrence; (4) choose the course of action which seems appropriate to them in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and (5) to make the best possible psychosocial adjustment to the disorder in an affected family member and/or to the risk of occurrence of that disorder. Genetic counseling as used in these standards shall not be interpreted to apply to communications which occur between patients and licensed health care professionals who are operating within the scope of their license and qualifications as part of provision of general health care services.

"Genetic counselor" means a person who has been licensed as such by the Department.

"License eligible" means a person who has been approved by the Department as having met the requirements to apply for the appropriate referenced Board examination.

"Ph.D. medical geneticist" means a person who has been licensed as such by the Department.

STANDARD ONE Genetic Counselor License

Any person desiring to provide genetic counseling services as a licensed genetic counselor shall make an application and obtain a license from the Department prior to the performance of such services. Such license shall be valid for three years unless at any time during that period it is revoked or suspended.

A genetic counselor license shall be issued to an applicant who has met the following qualifications:

- (a) has been certified as a genetic counselor by the American Board of Genetic Counseling or American Board of Medical Genetics, or
- (b) has been designated an "active candidate" by the American Board of Genetic Counseling and is awaiting an opportunity to complete the certification process, or
- (c) is designated by the Department as license eligible. The license eligible status is temporary until it becomes possible to apply for active candidacy and shall not be longer than eighteen months. All license eligible personnel must apply to the American Board of Genetic Counseling at the earliest opportunity and be designated as an active candidate in accordance with the American Board of Genetic Counseling rules.

STANDARD TWO Ph.D. Medical Geneticist License

Any person desiring to provide genetic counseling services as a licensed Ph.D. medical geneticist shall make an application and obtain a license from the Department prior to the performance of such services. Such license shall be valid for three years unless at any time during that period it is revoked or suspended.

A Ph.D. medical geneticist license shall be issued to an applicant who has met the following qualifications:

- (a) has earned a doctoral degree, and
- (b)
 - (1) is certified as a Ph.D. medical geneticist by the American Board of Medical Genetics, or
 - (2) has active candidacy status as a Ph.D. medical geneticist by the American Board of Medical Genetics and is awaiting an opportunity to complete the certification process, or
 - (3) is designated by the Department as license eligible. The license eligible status is temporary until it becomes possible to apply for active candidacy and shall not be longer than eighteen months. All license eligible personnel must apply to the American Board of Medical Genetics at the earliest opportunity and be designated as an active candidate in accordance with the American Board of Medical Genetics rules.

STANDARD THREE Restricted Use of Title

Any person who does not have a valid license as a Genetic Counselor shall not use, in connection with his or her name or place of business, the title "Genetic Counselor," "Certified Genetic

Counselor,” or “ Licensed Genetic Counselor,” or any words, letters, abbreviations or insignia indicating or implying that he or she has met the qualifications for, or has the license recommended in these standards.

Any person who does not have a valid license as a Ph.D. Medical Geneticist shall not use, in connection with his or her name or place of business, the title “Medical Geneticist,” “Certified Medical Geneticist,” or “ Licensed Medical Geneticist,” or any words, letters, abbreviations or insignia indicating or implying that he or she has met the qualifications for, or has the license recommended in these standards.

STANDARD FOUR Determination of Qualifications

Whenever the Department questions the nature of the training, experience or equivalency of credentials or licenses, the Department shall appoint a panel of consultants recognized as qualified in the area in question. This panel shall conduct such investigations as are necessary and shall make a report with recommendations to the Department. The final decision shall be made by the Department.

STANDARD FIVE Supervision

Genetic counselors and Ph.D. medical geneticists work as part of a team that includes a clinical geneticist who shall supervise their work. In special circumstances, supervision shall be arranged by formal agreement with one or more clinical geneticists and shall consist of regular chart review, face-to-face interaction and referrals for further genetic consultation, if indicated.

STANDARD SIX Scope of Practice

Under the supervision of a clinical geneticist, the scope of practice for persons licensed as a genetic counselor or Ph.D. medical geneticist includes:

- (a) Assessment of the risk for a genetic disorder or birth defect, carrier status, or predisposition to a genetic disease in the referred individual or in his/her offspring by analysis of the medical, pregnancy, and family history, including previous genetic evaluations,
- (b) Patient education regarding the etiology, features, natural history and possible treatments for the disorder(s) in question,
- (c) Discussion of options for clarifying the above risks, including genetic and/or prenatal diagnostic tests or referral for specific medical evaluations, and the methods, limitations, risks and benefits of these,
- (d) Exploration of the potential psychosocial implications of a positive, negative, uninformative or equivocal diagnostic evaluation,

- (e) Post-evaluation counseling to interpret the results of a genetic test and/or to discuss the diagnosis, including the usual characteristics, variability and course of the condition, the alternatives and efficacy of available treatments, and the risk of occurrence or recurrence in other family members, and
- (f) On-going supportive counseling to explore and address psychosocial and emotional consequences of the diagnosis, test results, or genetic risk.

STANDARD SEVEN Continuing education requirement

Genetic counselors and Ph.D. medical geneticists must have 45 hours of continuing education units within a three-year period, at least 30 hours of which shall be in genetics.

STANDARD EIGHT Fees

The director of the Department shall establish fees for licenses required by the Department sufficient to cover the cost of implementing these standards.

All fees established in this article shall be collected by and paid to the Department. All such moneys shall be deposited in the Genetic Disease Testing Fund.

STANDARD NINE Reimbursement

Genetic counseling provided by a licensed genetic counselor or Ph.D. medical geneticist shall be considered a reimbursable service unless expressly prohibited by federal law or regulation.



International Society of Nurses in Genetics, Inc.

George C. Cunningham, MD, MPH, Chief
 Genetic Disease Branch
 Department of Health Service
 2151 Berkeley Way, Annex 4
 Berkeley, CA 94704

May 3, 1999

Dear Dr. Cunningham:

ISONG greatly appreciates your willingness to meet with ISONG members to discuss issues related to qualifications of the genetic advanced practice nurse (GAPN). We selected the title of GAPN to represent our role in order to be consistent with the language used in the *Statement on the Scope and Standards of Genetics Clinical Nursing Practice*, and also to reflect the title of other APNs, such as the Oncology or Pediatric APN. The GAPN title also distinguishes us from the nurse who may practice at the generalist level.

As you know, we are concerned that the language in the proposed legislation for licensing of genetic counselors could exclude nurses from providing genetic services. As we understand from Gwen Anderson's summary of the meeting, you discussed this concern with members of the public policy forum on April 1, 1999. Thank you for representing ISONG's concern to other committee members.

We would like to inform you that ISONG member Rita Monsen, DSN, MPH, RN, is the Chair of ISONG's recently established Credentialing Committee (timeline attached). Dr. Monsen, or committee members residing in CA (Gwen Anderson, RN, PhD, and/or Barbara Ferriera, RN) are available to meet with you to update you on the committee's work and plans for credentialing of the GAPN, by the year 2000. Please identify possible dates and times for that meeting. Let us know how we can best prepare so that we can provide you with the information necessary for your draft legislation that clarifies nurses' qualifications to provide genetic services. ISONG welcomes your leadership and we look forward to working with you.

Please find attached a copy of the paper slated for publication in the journal, *Nursing Outlook*. The authors outline the activities ISONG has, and is now doing, to promote certification of Genetics Advanced Practice Nurses and challenges that lie ahead for making this goal a reality. In addition, I assume you received your copy of the *Scope and Standards* monograph (Kathy Yule, RN, distributed 12 to committee



International Society of Nurses in Genetics, Inc.

members who requested them). I trust that you will find these documents helpful as you rewrite this draft legislation.

Best regards,

Deborah MacDonal, RN, MS, GAPN
ISONG President 1999

Rita Monsen, DSN, MPH, RN
Chair, Credentialling Committee

Gwen Anderson, RN, PhD
Member, Credentialling Committee

cc: Barbara Ferriera, RN
Kathy Yule, RN

**INTERNATIONAL SOCIETY OF NURSES IN GENETICS
CREDENTIALLING COMMITTEE
ACTION PLAN**

INTERNATIONAL SOCIETY OF NURSES IN GENETICS (ISONG)

VISION

Caring for people's genetic health

MISSION

To foster the scientific, professional, and personal development of members in the management of genetic information.

CREDENTIALLING COMMITTEE GOALS

1. To develop the policies and procedures for the award of a credential in Genetic Advanced Practice Nursing to Master's prepared nurses in clinical practice roles in health care services with a genetic component
2. To develop a set of requirements for submission and scoring of a portfolio (of educational and experiential qualifications) which is psychometrically sound and foundational to future certification in Genetic Advanced Practice Nursing with American Nurses Credentialing Center (ANCC, a subsidiary of the American Nurses Association)
3. To develop the policies and procedures for marketing, recruitment of candidate applicants, record maintenance, and evaluation of all credentialing activities

CREDENTIALLING COMMITTEE INTENDED OUTCOMES (1 December 2000)

Award of credential in Genetic Advanced Practice Nursing which is psychometrically sound and foundational to future certification in Genetic Advanced Practice Nursing with American Nurses Credentialing Center (potential for national recognition by the National Council of State Boards of Nursing, regional regulatory bodies, and third party reimbursement)

CREDENTIALLING COMMITTEE TIMELINE

Month/Year	Activity
1 JUNE 1999	Establishment of policies for <ul style="list-style-type: none"> • Marketing credential as Genetic Advanced Practice Nurse • Recruitment of applicant candidates • Maintenance of Credentialing records • Evaluation of Credentialing process Establishment of initial educational and experiential qualifications (draft requirements document)
1 SEPTEMBER 1999	Preparation of Credentialing Committee Report for presentation at October, 1999 ISONG Conference, includes all documents, policies, and procedures prepared to date
1 DECEMBER 1999	Pilot procedures: Recruitment and acceptance of applicant portfolios
1 MARCH 2000	Pilot procedures: Evaluation of portfolios submitted
1 JUNE 2000	Pilot procedures: Implementation of psychometric evaluation of portfolios
1 SEPTEMBER 2000	Pilot procedures: Establishment of standards for portfolio scoring Completion of scoring of pilot applicant candidate portfolios
1 DECEMBER 2000	Award of initial credential as Genetic Advanced Practice Nurse by ISONG to first set of successful candidates Formation of Certification Committee for cooperation with the American Nurses Credentialing Center (ANCC) for a nationally recognized certificate, with potential for third party reimbursement