

DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
1799 GENETIC COUNSELOR ADVISORY COUNCIL
Statutory Authority: 24 Delaware Code, Section 1799I(c) (24 Del.C. §1799I(c))
24 DE Admin. Code 1799

FINAL

ORDER

1799 Genetic Counselor Advisory Council

After due notice in the *Register of Regulations* and two Delaware newspapers, a public hearing was held on September 1, 2017 at a scheduled meeting of the Genetic Counselor Advisory Council ("the Council") of the Board of Medical Licensure and Discipline ("the Board") to receive comments regarding proposed amendments to the Council's rules and regulations. The Council proposed revisions to its rules and regulations to add a new Section 7.0 setting forth standards for the use of telehealth in the practice of genetic counseling.

The proposed changes to the rules and regulations were initially published in the *Register of Regulations*, Volume 20, Issue 11, on May 1, 2017 for a June 2, 2017 hearing. The hearing was subsequently rescheduled and took place on September 1, 2017 at a scheduled Council meeting. Notice of the September 1, 2017 hearing was published in the *Register of Regulations*, Volume 21, Issue 1 on July 1, 2017. Notice was also published in the *News Journal* (Exhibit 1) and the *Delaware State News*. Exhibit 2. Pursuant to 29 Del.C. §10118(a), the date to receive final written comments was September 16, 2017, 15 days following the public hearing. The Council deliberated on the proposed revisions at its regularly scheduled meeting on November 30, 2017.

Summary of the Evidence and Information Submitted

The following exhibits were made a part of the record:

Council Exhibit 1: *News Journal* Affidavit of Publication.

Council Exhibit 2: *Delaware State News* Affidavit of Publication.

The Council received no written or public comment.

Findings of Fact and Conclusions

The public was given notice and an opportunity to provide the Council with comments in writing and by testimony on the proposed amendments to the Council's rules and regulations. The Council did not receive any written comments and no members of the public attended the hearing to offer testimony.

Pursuant to 24 Del.C. §1799I(c), the Council has the statutory authority to promulgate rules and regulations governing the practice of genetic counseling after a public hearing and subject to the approval of the Board. Given the absence of comments, either by testimony or in writing, the Council recommends to the Board that it approve the rules and regulations as published, attached hereto as Exhibit A.

RECOMMENDATION TO THE BOARD OF MEDICAL LICENSURE AND DISCIPLINE

By the unanimous affirmative vote of the undersigned members, the Genetic Counselor Advisory Council hereby adopts the rules and regulations as published in the *Register of Regulations* on May 1, 2017, Volume 20, Issue 11 and recommends approval of such rules and regulations to the Board of Medical Licensure and Discipline.

If approved by the Board, these rules and regulations will be effective ten days after publication of the Board's final order in the *Register of Regulations*.

Respectfully submitted this 30th day of November, 2017.

Zohra J. Ali-Khan Catts, Chairperson

Sara Ennis Mora, Vice Chairperson (absent)

Angela Duker

Becky Milewski

Garrett H. Colmorgen, M.D. (absent)

AND NOW, this 2nd day of January, 2018;

WHEREAS, the Board of Medical Licensure and Discipline has considered the attached recommendation of the Genetic Counselor Advisory Council for approval of amended rules and regulations related to the use of telehealth in the practice of genetic counseling; and

WHEREAS, the Board has determined to approve the aforesaid rules and regulations as proposed by the Genetic Counselor Advisory Council and attached hereto as Exhibit A.

NOW THEREFORE IT IS ORDERED by the Board of Medical Licensure and Discipline:

1. The rules and regulations recommended by the Genetic Counselor Advisory Council governing the use of telehealth in the practice of genetic counseling are hereby approved by the Board of Medical Licensure and Discipline.
2. The rules and regulations shall be effective ten days after publication of this Final Order in the *Register of Regulations*.

IT IS SO ORDERED this 2nd day of January, 2018:

Karyl Rattay, M.D., President	George A. Dahr, M.D.
Joseph M. Parise, D.O.	Stephen G. Cooper, M.D. (absent)
Gregory D. Adams, M.D. (absent)	Garrett H. Colmorgen, M.D.
Sharon Williams-Mayo, Public Member	Janice Truitt, Public Member
Malvine Richard, Public Member	Barry L. Bakst, D.O.
Bryan D. Villar, M.D.	Mary Lomax, Public Member
Stephen Lawless, M.D. (absent)	N. C. Vasuki, Public Member

1799 Genetic Counselor Advisory Council

1.0 Source of Authority

The Rules and Regulations herein contained constitute, comprise, and shall be known as the Rules and Regulations of the Genetic Counselor Advisory Council of the Board of Medical Licensure and Discipline, and are hereby promulgated, pursuant to 24 **Del.C.** §1799I(c).

2.0 Definitions

Whenever used in these Rules and Regulations unless expressly otherwise stated, or unless the context or subject matter requires a different meaning, the following terms shall have the respective meanings hereinafter set forth or indicated.

"**Board**" means Delaware Board of Medical Licensure and Discipline.

"**Council**" means the Genetic Counselor Advisory Council of the Board of Medical Licensure and Discipline.

"**Crime Substantially Related to the Practice of Genetic Counseling**" means those crimes identified in Section 15.0 of the Rules and Regulations of the Board of Medical Licensure and Discipline.

20 DE Reg. 190 (09/01/16)

3.0 Purpose

The purpose of the rules and regulations is to establish minimal acceptable levels of safe practice to protect the general public and to serve as a guide for the Council and Board to evaluate the safe and effective practice of genetic counseling.

4.0 Renewal of License

- 4.1 Each license shall be renewed biennially. The failure of the Council and/or Board to notify a licensee of his/her expiration date and subsequent renewals does not, in any way, relieve the licensee of the requirement to renew his/her certificate pursuant to the regulations of the Council and 24 **Del.C.** Ch. 17, Subchapter 11.
- 4.2 License renewal shall be accomplished online at www.dpr.delaware.gov and shall include:
 - 4.2.1 attestation of completion of the continuing education required by Section 5.0; and
 - 4.2.2 payment of fees as determined by the Division of Professional Regulation.
- 4.3 As a condition of renewal, each licensee shall maintain his/her certification with the American Board of Genetic Counseling, the American Board of Medical Genetics, or an organization that is recognized as equivalent.
- 4.4 As a condition of renewal, the licensee shall provide the Council with any other information as may be required by the Council to ascertain the licensee's good standing.
- 4.5 Failure of a licensee to renew his/her license shall cause his/her license to expire. A licensee whose license has expired may renew his/her license within one (1) year after the expiration date upon fulfilling subsections 4.2 - 4.4 above, certifying that he/she has not practiced genetic counseling in Delaware while his/her license has expired, and paying the renewal fee and a late fee as determined by the Division of Professional Regulation.

- 4.6 No licensee will be permitted to renew his/her license once the one (1) year period has expired.
- 4.7 The former licensee may re-apply under the same conditions that govern applicants for new licensure under 24 **Del.C.** Ch. 17, Subchapter 11.
- 4.8 No genetic counselor shall practice in the State of Delaware during the period of time that his/her Delaware license has expired.

20 DE Reg. 190 (09/01/16)

5.0 Continuing Education

5.1 Continuing Education Credit Hours Required for Renewal

- 5.1.1 Licensees are required to complete three (3) Continuing Education Units (CEU) biennially. A continuing education unit is equivalent to ten contact hours (a contact hour is 60 minutes). Licensees shall retain all certificates and other documented evidence of participation in an approved/accredited continuing education program for a period of at least (5) five years.
- 5.1.2 Proof of continuing education is satisfied with an attestation by the licensee that he or she has satisfied the Requirements of Section 5.0.
- 5.1.3 Attestation must be completed electronically at the time of renewal.
- 5.1.4 Licensees selected for random audit pursuant to Section 6.0 will be required to supplement the attestation with attendance verification.
- 5.1.5 CEU hours shall be prorated for new licensees. A licensee for renewal shall follow the following schedule of reporting CEUs: if, at the time of renewal, you have been licensed for less than one year, NO continuing education is required; licensed for more than one year, but less than two years, half of the continuing education (1.5 CEUs) is required, all of which shall be Category 1 CEUs pursuant to subsection 5.3.2; licensed for two or more years, the full amount (3 CEUs) is required.

5.2 Exemptions

- 5.2.1 A licensee who because of a physical or mental illness during the license period could not complete the continuing education requirement may apply through the Council to the Board of Medical Licensure and Discipline for a waiver. A waiver would provide for an extension of time or exemption from some or all of the continuing education requirements for one (1) renewal period. Should the illness extend beyond one (1) renewal period, a new request must be submitted.
- 5.2.2 A request for a waiver may be submitted up to the time of renewal

5.3 Acceptable Activities /Continuing Education Program Offerings

- 5.3.1 The overriding consideration in determining whether a specific activity/program qualifies as acceptable continuing education shall be that it is a planned program of learning which contributes directly to professional competence in the practice of Genetic Counseling
- 5.3.2 Licensees shall demonstrate that they have obtained CEUs in the categories and according to the criteria established by the American Board of Genetic Counselors (ABGC) for recertification, as may be amended from time to time.
 - 5.3.2.1 CEUs must be completed during the biennial renewal cycle.
 - 5.3.2.2 The breakdown of CEUs shall be as follows: at least 2 Category 1 CEUs and up to but no more than 1 Category 2 CEU. PACs may substitute for up to 0.6 Category 1 CEU.

16 DE Reg. 652 (12/01/12)

20 DE Reg. 190 (09/01/16)

6.0 Audit of Continuing Education Unit Hours

6.1 Audits Each Biennium

- 6.1.1 The Division of Professional Regulation shall randomly select from the list of renewed licensees a percentage of licensees, determined by the Council to be audited. The Council may also audit based on complaints or charges against an individual license, relative to compliance with continuing education requirements or based on a finding of past non-compliance during prior audits.

6.2 Documentation.

- 6.2.1 When a licensee is selected for audit, the licensee shall be required to submit documentation showing detailed accounting of the various CEUs claimed by the licensee. Licensees selected for random audit are required to supplement the attestation with supporting materials which may include a syllabus, agenda, itinerary or brochure published by the sponsor of the activity and a document showing proof of attendance (i.e., certificate, a signed letter from the sponsor attesting to attendance, report of passing test score).The Council shall attempt to verify the CEUs shown on the documentation provided by the licensee. Upon

completion of the review, the Council will decide whether the licensee's CEUs meet the requirements of these regulations.

- 6.2.2 Any continuing education not meeting all provisions of these regulations shall be rejected in part or in whole by the Council.
 - 6.2.3 Any incomplete or inaccurate documentation of continuing education may be rejected in part or in whole by the Council
 - 6.2.4 Any continuing education that is rejected must be replaced by acceptable continuing education within a reasonable period of time established by the Council. This continuing education will not be counted towards the next renewal period.
- 6.3 Council Review and Hearing Process.
- 6.3.1 The Council shall review all documentation requested of any licensee shown on the audit list. If the Council determines the licensee has met the requirements, the licensee's license shall remain in effect. If the Council determines the licensee has not met the requirements, the licensee shall be notified and a hearing may be held pursuant to the Administrative Procedures Act. This hearing will be conducted to determine if there are any extenuating circumstances justifying the apparent noncompliance with these regulations. Unjustified noncompliance with these regulations shall be considered unprofessional conduct and grounds for discipline pursuant to 24 **Del.C.** §1799P(a)(5), subject to final approval of the Council's written recommendation by the Board.

7.0 Telehealth

- 7.1 For the purpose of this Section, "telehealth" means the practice of genetic counseling by distance communication technology such as but not necessarily limited to telephone, Internet-based communications, and videoconferencing.
- 7.2 In order to practice telehealth one must hold a current, valid license as a genetic counselor issued by the Board.
- 7.3 Licensees shall understand that this Section does not provide licensees with authority to practice telehealth in service to clients domiciled in any jurisdiction other than Delaware, and licensees bear responsibility for complying with laws, rules, and/or policies for the practice of telehealth set forth by other jurisdictional boards.
- 7.4 Licensees practicing telehealth shall comply with this Section and with requirements in state and federal statutes relevant to the practice of genetic counseling.
- 7.5 Licensees shall establish and maintain current competence in the professional practice of telehealth through continuing education, consultation, or other procedures, in conformance with prevailing standards of scientific and professional knowledge. Licensees shall establish and maintain competence in the appropriate use of the information technologies utilized in the practice of telehealth.
- 7.6 Licensees shall recognize that telehealth is not appropriate for all genetic indications and clients, and decisions regarding the appropriate use of telehealth shall be made on a case-by-case basis. Licensees practicing telehealth shall be aware of additional risks incurred when practicing genetic counseling through the use of distance communication technologies and take special care to conduct their professional practice in a manner that protects the welfare of the client and ensures that the client's welfare is paramount. Licensees practicing telehealth shall:
 - 7.6.1 Conduct a risk-benefit analysis:
 - 7.6.1.1 To ensure that the genetic counseling indication is consistent with the use of telehealth to the client's benefit; and
 - 7.6.1.2 To determine whether the client has sufficient knowledge and skills in the use of the technology involved in rendering the service or can use a personal aid or assistive device to benefit from the service.
 - 7.6.2 Not provide telehealth services to any person or persons when the outcome of the analysis required in subsections 7.6.1.1 and 7.6.1.2 is inconsistent with the delivery of telehealth services, whether related to clinical or technological issues.
 - 7.6.3 Upon initial and subsequent contacts with the client, make reasonable efforts to verify the identity of the client.
 - 7.6.4 Obtain alternative means of contacting the client.
 - 7.6.5 Provide to the client alternative means of contacting the licensee;
 - 7.6.6 Whenever feasible, use secure communications with clients and obtain and document consent for the use of non-secure communications.

7.6.7 Prior to providing telehealth services, obtain the written informed consent of the client, in language that is likely to be understood and consistent with accepted professional and legal requirements, relative to:

7.6.7.1 The limitations and innovative nature of using distance technology in the provision of genetic counseling;

7.6.7.2 Potential risks to confidentiality of information due to the use of distance technology;

7.6.7.3 Potential risks of sudden and unpredictable disruption of telehealth services and how an alternative means of re-establishing electronic or other connection will be used under such circumstances;

7.6.7.4 When and how the licensee will respond to routine electronic messages;

7.6.7.5 Under what circumstances the licensee and client will use alternative means of communications under emergency circumstances;

7.6.7.6 Who else may have access to communications between the client and the licensee;

7.6.7.7 Specific methods for ensuring that a client's electronic communications are directed only to the licensee or supervisee; and

7.6.7.8 How the licensee stores electronic communications exchanged with the client.

7.6.8 Ensure that confidential communications stored electronically cannot be recovered and/or accessed by unauthorized persons when the licensee disposes of electronic equipment and data.

7.7 In the context of a face-to-face professional relationship, the following are exempt from this Section:

7.7.1 Electronic communication used specific to appointment scheduling, billing, and/or the establishment of benefits and eligibility for services; and,

7.7.2 Telephone or other electronic communications made for the purpose of ensuring client welfare in accord with reasonable professional judgment.

78.0 Crimes Substantially Related to the Practice of Genetic Counseling

Pursuant to 24 Del.C. §1799P(a)(6) the crimes determined by the Board to be substantially related to the practice of medicine are also determined to be substantially related to the practice of genetic counseling and may result in the denial of a license and/or disciplinary action against a licensee.

15 DE Reg. 544 (10/01/11)

16 DE Reg. 652 (12/01/12)

20 DE Reg. 190 (09/01/16)

21 DE Reg. 644 (02/01/18) (Final)