Regulatory Analysis

Notice of Intended Action to be published: 653—Chapter 20
"Licensure of Genetic Counselors"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 147, 148H and 272C

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 147, 148, 148H and 272C

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 5, 2024 9 a.m.	6200 Park Avenue Des Moines, Iowa Information on virtual participation will be available on the Department of Inspections, Appeals, and Licensing's website prior to the hearing.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis, which must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking sets minimum standards for entry into the medical profession. Iowa residents, licensees and employers benefit from the rulemaking since it articulates the processes by which individuals apply for licensure as a genetic counselor in the state of Iowa, as directed in statute. This includes the processes for initial licensure, renewal, and reactivation. These requirements ensure public safety by requiring individuals entering the profession to have minimum competency.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There is no direct cost to the general public, but there is a cost to the applicant since complying with the minimum requirements to enter into the profession is at the expense of the licensee.

The licensee would also have costs related to educational requirements and examination requirements. The Board of Medicine has not identified an exact cost of education for this field since it varies depending on the school the licensee chooses to attend to meet those requirements.

Board staff review applications for initial and renewal licenses, answer inquiries on licensing, and field phone calls. Staff salaries to support the work of the Board are covered by the Licensing and Regulation Fund established in 2023 Iowa Acts, Senate File 557. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

- Classes of persons that will benefit from the proposed rulemaking:

The public and professionals benefit from the proposed rulemaking. Establishing minimum licensing requirements ensures that practitioners are competent to practice. Without having an established threshold for entry into the profession, individuals who are not appropriately trained could cause serious harm to the public during their practice. Genetic counselors and medical professionals require certain skills and training to effectively help and treat their patients.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

Educational institutions provide the academic training for genetic counselors to obtain their license in the state of Iowa. Additional private industries and educational institutions provide examinations and materials for preparation for the examination. Because the cost of education is so variable depending on the institution the person attends, the Board is unable to put an exact cost on education or examination preparation.

Licensing fees are $245 for initial licensing and $200 for renewal.

- Qualitative description of impact:

Establishing minimum requirements for licensure ensures safety for the licensee and consumer. The cost of inaction would be increasing the potential for injury to the public by a licensee who is not qualified to perform the work in the field.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Costs to the agency are for the staff time needed to manage Board activities, which include managing applications for initial licenses, renewals, and reinstatements. Staff salaries to support the work of the Board are covered by the fund. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

- Anticipated effect on state revenues:

Costs associated with implementing this rulemaking are paid by individual licensees or establishments, not the State. This rulemaking has no anticipated impact on state revenues.

Staff salaries to support the work of the Board are covered by the fund. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The Board believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. Licensure requirements could be reduced or eliminated for the purpose of lowering the bar of entry into the profession, but the Board would be concerned about the public safety of Iowans in that scenario.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The Board has not identified a more cost-effective alternative to the licensure of genetic counselors. The Board believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. Licensure requirements could be reduced or eliminated for the purpose of lowering the bar of entry into the profession, but the Board would be concerned about the public safety of Iowans in that scenario.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

The Board has not identified a more cost-effective alternative to the licensure of genetic counselors. The Board believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. Licensure requirements could be reduced or eliminated for

the purpose of lowering the bar of entry into the profession, but the Board would be concerned about the public safety of Iowans in that scenario.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

The Board has not identified a more cost-effective alternative to the licensure of genetic counselors. The Board believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. Licensure requirements could be reduced or eliminated for the purpose of lowering the bar of entry into the profession, but the Board would be concerned about the public safety of Iowans in that scenario.

Due to the state government alignment, this Board is now part of the Department. The Department's Licensing Division continues to assess and implement opportunities to increase efficiencies and standardize board processes across all professional licensing boards. The updates to this chapter support this effort. The Department is actively pursuing a single licensing platform to assist in standardizing licensing.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

The proposed chapter relates to high-stakes public safety concerns that are present whether the business is a small business or a large organization. The chapter is meant to ensure public safety in terms of licensing requirements for physicians. While some physicians likely are running a small business of their own, some also work for large corporations and hospitals. To exempt small businesses from adhering to this chapter would jeopardize any member of the public who sought services from that small business. The risk to the public is greater than the potential harm or cost to the small business. Additionally, if a licensee subject to this chapter is a small business and has identified a rule that is overly burdensome and the goals of which could be achieved in a manner that would reduce the impact on the small business, the licensee could utilize the Department's established waiver process.

Text of Proposed Rulemaking

ITEM 1. Rescind 653—Chapter 20 and adopt the following **new** chapter in lieu thereof:

CHAPTER 20
LICENSURE OF GENETIC COUNSELORS

653—20.1(148H) Scope of chapter. This chapter does not apply to any of the following:

1. A physician or surgeon or an osteopathic physician or surgeon licensed under Iowa Code chapter 148, a registered nurse or an advanced registered nurse practitioner licensed under Iowa Code chapter 152, a physician assistant licensed under Iowa Code chapter 148C, or other persons licensed

under Iowa Code chapter 147 when acting within the scope of the person's profession and doing work of a nature consistent with the person's education and training.

2. A person who is certified by the American Board of Medical Genetics and Genomics as a doctor of philosophy and is not a genetic counselor licensed pursuant to Iowa Code chapter 148H.

3. A person employed as a genetic counselor by the federal government or an agency thereof if the person provides genetic counseling services solely under the direction and control of the entity by which the person is employed.

4. A genetic counseling intern.

653—20.2(148H) Definitions. The definitions stated in Iowa Code chapter 148H, in addition to those listed below, apply to this chapter.

"American Board of Genetic Counseling" or *"ABGC"* means the United States-based commission, or its equivalent or successor organization, that validates entry-level competency in the practice of genetic counseling through professional certification.

"American Board of Medical Genetics and Genomics" or *"ABMGG"* means the United States-based commission, or its equivalent or successor organization, that validates entry-level competency in the practice of genetic counseling through professional certification.

653—20.3(148H) Titles used. A genetic counselor licensed under Iowa Code chapter 148H may use the words "genetic counselor" or "licensed genetic counselor" or the corresponding abbreviation "LGC" after the person's name. Persons who possess a provisional license shall add the designation "provisional licensed genetic counselor."

653—20.4(148H) Qualifications for licensure.

20.4(1) Each applicant for licensure under Iowa Code chapter 148H shall:

a. Submit an application form and supporting documentation.

b. Hold active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, or as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

20.4(2) A licensee shall maintain active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, or as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

653—20.5(148H) Qualifications for provisional licensure. The board may issue a provisional license to an applicant who meets all of the requirements for licensure except for the certification component and who has been granted active candidate status by the American Board of Genetic Counseling or the American Board of Medical Genetics and Genomics.

20.5(1) The applicant shall submit a provisional license application form, proof of active candidate status, and supporting documentation prescribed by the board.

20.5(2) A provisional license expires and becomes inactive upon the earliest of the following:

a. Issuance of a license as a genetic counselor by the board.

b. Loss of active candidate status.

(1) A person holding a provisional license that is inactive due to loss of active candidate status may submit an application for reactivation of the provisional license upon demonstrating that active candidate status has been reestablished.

(2) An application for extension of a provisional license shall be signed by a qualified supervisor.

c. The date printed on the provisional license.

20.5(3) A person with a provisional license shall work at all times under the supervision of a qualified supervisor.

653—20.6(147,148H) Application requirements.

20.6(1) *Application for licensure.* To apply for a license to practice genetic counseling, an applicant shall:

a. Submit the completed application, including required credentials and documents, a completed fingerprint packet, and a sworn statement by the applicant attesting to the truth of all information provided by the applicant;

b. Pay the nonrefundable initial application fee identified in 653—subrule 8.13(1) and pay the fee identified in 653—subrule 8.13(6) for the evaluation of the fingerprint packet and the national criminal history background checks by the division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI).

20.6(2) *Contents of the application form.* Each applicant shall submit the following information on the application form provided by the board:

a. The applicant's full legal name, date and place of birth, home address, mailing address, principal business address, and personal email address regularly used by the applicant or licensee for correspondence with the board;

b. A chronology accounting for all time periods from the date the applicant entered a genetic counseling training program or educational institution to the date of the application;

c. The other jurisdictions in the United States or other nations or territories in which the applicant is authorized to practice genetic counseling, including license, certificate of registration or certification number and date of issuance;

d. Full disclosure of the applicant's involvement in civil litigation related to the practice of genetic counseling in any jurisdiction of the United States or other nations or territories. Copies of the legal documents may be requested if needed during the review process;

e. A statement disclosing and explaining any informal or nonpublic actions, such as letters of warning, letters of education, any confidential retraining, or any kind of confidential action taken toward a genetic counselor's certification or license that is not public discipline; warnings issued, investigations conducted, or disciplinary actions taken, whether by voluntary agreement or formal action, by a medical, genetic counseling or professional regulatory authority, an educational institution, a training or research program, or a health facility in any jurisdiction;

f. A statement disclosing and explaining any charge of a misdemeanor or felony involving the applicant filed in any jurisdiction, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

g. A letter sent directly from the ABGC or ABMGG to the board verifying the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a letter sent directly from ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure;

h. A completed fingerprint packet to facilitate a national criminal history background check. The fee for evaluation of the fingerprint packet and the DCI and FBI criminal history background checks will be assessed to the applicant.

20.6(3) *Application cycle.* If the applicant does not submit all materials within 90 days of the board's initial request for further information, the application is inactive.

a. To reactivate the application, an applicant shall submit a nonrefundable reactivation of application fee identified in 653—subrule 8.13(2) and shall update application materials if requested by the board. The period for requesting reactivation is limited to 30 days from the date the applicant is notified that the application is inactive, unless the applicant is granted an extension in writing by the committee or the board.

b. Once the application reactivation period is expired, an applicant must reapply and submit a new, nonrefundable initial application fee and a new application, including required documents and credentials.

20.6(4) *Applicant responsibilities.* An applicant for licensure to practice genetic counseling bears full responsibility for each of the following:

a. Paying all fees charged by regulatory authorities, national certifying organizations, health facilities, and educational institutions providing the information specified in subrule 20.6(2);

b. Providing accurate, up-to-date, and truthful information on the application form including but not limited to that specified under subrule 20.6(2) related to prior professional experience, education, training, active certification, licensure, and disciplinary history.

20.6(5) *Licensure application review process.* Licensure applications will be reviewed pursuant to the process outlined in rule 653—9.8(147,148).

20.6(6) *Grounds for denial of licensure.* The board, on the recommendation of the committee, and after consultation with an Iowa-licensed genetic counselor, may deny an application for licensure for any of the following reasons:

a. Failure to meet the requirements for licensure specified in this chapter pursuant to Iowa Code section 148H.3.

b. Pursuant to Iowa Code section 147.4, upon any of the grounds for which licensure may be revoked or suspended as specified in Iowa Code sections 147.55 and 148H.7 or in rule 653—20.20(147,148H,272C).

20.6(7) *Preliminary notice of denial.* Prior to the denial of licensure to an applicant, the board issues a preliminary notice of denial that is sent to the applicant by regular, first-class mail at the address provided by the applicant. The preliminary notice of denial is a public record and cites the factual and legal basis for denying the application, notifies the applicant of the appeal process, and specifies the date upon which the denial will become final if it is not appealed.

20.6(8) *Appeal procedure.* An applicant who has received a preliminary notice of denial may appeal the denial and request a hearing on the issues related to the preliminary notice of denial by serving a request for hearing upon the executive director not more than 30 calendar days following the date when the preliminary notice of denial was mailed. The applicant's current address shall be provided in the request for hearing. The request is deemed filed on the date it is received in the board office. If the request is received with a USPS nonmetered postmark, the board considers the postmark date as the date the request is filed. The request shall specify the factual or legal errors and that the applicant desires an evidentiary hearing and may provide additional written information or documents in support of licensure.

20.6(9) *Hearing.* If an applicant appeals the preliminary notice of denial and requests a hearing, the hearing will be a contested case open to the public and conducted in accordance with 481—Chapter 506.

20.6(10) *Finality.* If an applicant does not appeal a preliminary notice of denial in accordance with subrule 20.6(8), the preliminary notice of denial automatically becomes final. A final denial of an application for licensure is a public record.

20.6(11) *Failure to pursue appeal.* If an applicant appeals a preliminary notice of denial in accordance with subrule 20.6(8) but the applicant fails to pursue that appeal to a final decision within one year from the date of the preliminary notice of denial, the board may dismiss the appeal. The appeal may be dismissed only after the board sends a written notice by first-class mail to the applicant at the applicant's last-known address. The notice will state that the appeal will be dismissed and the preliminary notice of denial will become final if the applicant does not contact the board to schedule the appeal hearing within 30 days of the date the letter is mailed from the board office. Upon dismissal of an appeal, the preliminary notice of denial becomes final. A final denial of an application for licensure under this rule is a public record.

20.6(12) *Waiver prohibited.* Provisions of this rule are not subject to waiver pursuant to 653—Chapter 3 or any other provision of law.

653—20.7(147,148H) Display of license and notification required to change the board's data system.

20.7(1) *Display of license.* Licensed genetic counselors shall display the license issued by the board in a conspicuous place in their primary place of business.

20.7(2) *Change of contact information.* Licensees shall notify the board within one month of a change in home address, address of the place of practice, home or practice telephone number, or personal email address regularly used by the applicant or licensee for correspondence with the board.

20.7(3) *Change of full legal name.* A licensee shall notify the board of any change in the licensee's full legal name within one month of making the name change. Notification requires a notarized copy of a marriage license or a notarized copy of court documents.

20.7(4) *Deceased.* A licensee's file will be closed and labeled "deceased" when the board receives a copy of the licensee's death certificate or other reliable information of the licensee's death.

653—20.8(147,148H,272C) Biennial renewal of license required. Pursuant to Iowa Code section 148H.3, a license expires on October 31 of odd-numbered years and can be renewed for the fee identified in 653—paragraph 8.14(2)*"c."*

20.8(1) *Application.* The applicant for renewal shall provide:

a. A renewal application.

b. A letter sent directly from the ABGC or ABMGG to the board verifying that the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a letter sent directly from ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure.

c. Satisfactory evidence to the board that in the period since the license was issued or last renewed, the applicant has completed 30 hours of National Society of Genetic Counselors or ABMGG continuing education units as approved by the board.

20.8(2) *Expiration date.* Certificates of licensure to practice genetic counseling expires on October 31 in odd years.

20.8(3) *Prorated fees.* The first renewal fee for a license will be prorated on a monthly basis according to the date of issue.

20.8(4) *Renewal requirements and penalties for late renewal.* The licensee is responsible for renewing the license prior to its expiration. Failure of the licensee to receive notice does not relieve the licensee of responsibility for renewing that license.

a. Upon receipt of the completed renewal application, staff will administratively issue a license that expires on October 31 of odd-numbered years. In the event the board receives adverse information on the renewal application, the board will issue the renewal license but may refer the adverse information for further consideration.

b. Every renewal shall be displayed in connection with the original certificate of licensure.

c. If the licensee fails to submit the renewal application and renewal fee prior to the expiration date on the current license, a penalty fee identified in 653—subrule 8.13(4) will be assessed for renewal in the grace period, a period up until January 1.

20.8(5) *Inactive license.* Failure of a licensee to renew by January 1 will result in inactivation of the license, and the license will become invalid.

a. Licensees are prohibited from engaging in the practice of genetic counseling with an inactive or lapsed license.

b. Having a genetic counselor license in inactive or lapsed status does not preclude the board from taking disciplinary actions authorized in Iowa Code section 147.55 or 148H.7.

653—20.9(147,272C) Reactivation of an inactive license.

20.9(1) *Reactivation requirements.* Licensees who allow their licenses to go inactive by failing to renew may apply for reactivation of a license. Pursuant to Iowa Code section 147.11, applicants for reactivation shall:

a. Submit a completed application for reactivation of a license to practice genetic counseling. The application shall include the following information:

(1) The applicant's full legal name, date and place of birth, home address, mailing address, principal business address, and personal email address regularly used by the applicant or licensee for correspondence with the board.

(2) Every jurisdiction in which the applicant is or has been authorized to practice, including license numbers and dates of issuance.

(3) Full disclosure of the applicant's involvement in civil litigation related to the practice of genetic counseling in any jurisdiction of the United States or other nations or territories. Copies of the legal documents may be requested if needed during the review process.

(4) A statement disclosing and explaining any warnings issued, investigations conducted or disciplinary actions taken, whether by voluntary agreement or formal action, by a medical, genetic counseling or professional regulatory authority; an educational institution; a training or research program; or a health facility in any jurisdiction.

(5) Verification of an applicant's hospital and clinical staff privileges and other professional experience for the past five years if requested by the board.

(6) A chronology accounting for all time periods from the date of initial licensure.

(7) A statement disclosing and explaining any charge of a misdemeanor or felony involving the applicant filed in any jurisdiction, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside.

b. Submit a completed fingerprint packet to facilitate a national criminal history background check. The fee identified in 653—subrule 8.13(6) for the evaluation of the fingerprint packet and the DCI and FBI criminal history background checks will be assessed to the applicant.

c. Pay the reactivation fee identified in 653—subrule 8.13(7) plus the fee identified in 653—subrule 8.13(6) for the evaluation of the fingerprint packet and the DCI and FBI criminal history background checks.

d. A letter sent directly from the ABGC or ABMGG to the board verifying the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a letter sent directly from the ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure.

e. Meet any new requirements instituted since the license lapsed.

20.9(2) *Reactivation for an applicant who has been out of practice for three years.* If an applicant for reactivation has not engaged in the field of genetic counseling or precision medicine in the past three years in any jurisdiction of the United States, the board may, after consultation with an Iowa-licensed genetic counselor, require an applicant to:

a. Successfully complete board-approved continuing education or remediation.

b. Successfully complete a board-approved employment-based monitoring program developed by the genetic counselor's employer, an Iowa-licensed genetic counselor and the board.

c. Successfully complete any other pathway as agreed upon by the board.

653—20.10(272C) Code of ethics. The NSGC Code of Ethics prepared and approved by the National Society of Genetic Counselors shall be utilized by the board as guiding principles in the practice of genetic counseling in this state.

653—20.11(148H,272C) Surrender of license to the board.

20.11(1) A genetic counselor whose ABGC certification has lapsed or whose certification has been revoked by the ABGC shall surrender the genetic counselor's license to the board.

20.11(2) A provisional licensee who loses active candidate status with the ABGC must immediately cease the practice of genetic counseling until the provisional licensee obtains an extension of the provisional license or obtains a new provisional license.

These rules are intended to implement Iowa Code chapters 147, 148, 148H, and 272C.