

Significant Legislative Rule Analysis (SA)
New Chapter 246-825 WAC
a Rule Concerning Genetic Counselors
July 23, 2010

Section 1. What is the scope of the rule?

Human genome studies and discoveries have been significant in the last few decades with reports coming out of the Human Genome Project (HGP). The HGP was an international scientific research project that looked at DNA and mapped human genes. Several thousands of genes have been discovered in relation to genetic diseases as well as chronic diseases such as cancer and heart disease.

The Department of Health (department) is proposing rules to implement the genetic counselor profession created by the 61st Legislature. Substitute Senate Bill 5608 is now codified as Chapter 18.290 RCW.

Effective August 1, 2010, the law mandates that persons engaging in the practice of genetic counseling must be licensed by the department unless otherwise exempted in the statute. Genetic counselors offer a range of services including providing information and support to families who have members with birth defects, genetic disorders or who may be at risk of inherited conditions. Genetic counselors analyze and identify the risk of the occurrence of genetic disorders and inheritance patterns and provide families with available options and information of the potential for recurrence. Many genetic counselors are involved in research related to medical genetics, clinical practice including specialized genetic counseling (e.g. prenatal, pediatric, cancer-risk, etc), diagnostic laboratories, biotech companies, and teaching.

Providers without a license cannot legally provide services or use the title genetic counselor. Additionally, the law details the scope of practice and a mechanism to sanction genetic counselors who engage in unprofessional conduct under the Uniform Disciplinary Act.

The proposed rule, as drafted, requires genetic counselors to meet specific education and examination requirements and follow minimum standards for continuing education (CE). Genetic Counselor licenses will be renewed annually with a three-year CE reporting cycle with the first year of the cycle beginning on or after August 1, 2011.

Genetic counselors work independently within their scope of practice, but must establish a collaborative agreement for ordering genetic tests or other evaluations. The agreement memorializes the relationship with a licensed physician or osteopathic physician board certified in a specialty relevant to the practice of the genetic counselor. Specific documentation requirements regarding the written agreement are detailed in the proposed rule.

Persons meeting all licensing requirements but have not passed the certification examination may qualify for a provisional license. The proposed rule outlines eligibility standards, supervisory requirements, and applicant process.

The proposed rules establishes license fees for initial licenses, renewals, provisional licenses, late renewal penalties and expired license reissue fees. In addition, the rule provides a process for a practitioner to demonstrate continuing competency if his or her license is expired for over three years.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

The general goal of Chapter 302, Law of 2009 is to safeguard the public health, safety and welfare by assuring that only appropriately educated and trained individuals qualify for licensure as a genetic counselor.

The proposed rules implement the following objectives:

- A. Approve masters or doctorate programs in genetic counseling or medical genetics.
- B. Establish or approve a licensing examination prepared and administered by a private organization.
- C. Establish all licensing fees.
- D. Establish licensing criteria for provisional genetic counselor license.
- E. Establish requirements and fees for renewal of license.
- F. Establish standards for demonstrating competency when a license has lapsed for a period longer than three years.

Section 3. What is the justification for the proposed rule package?

RCW 18.290.020 requires the department to establish all licensing and examination requirements for the practice of genetic counseling. The proposed rules achieve the authorizing statute's goals and objectives by setting explicit education and examination requirements for qualification to practice as a licensed or provisionally licensed genetic counselor.

The department has assessed and determined that there are no feasible alternatives to rulemaking because the statute requires rules to implement the law. In addition, standards for education, examination, and practice must be in rule to be enforceable.

If the rules were not adopted, there would be no enforceable standards for the department to issue a license and provide oversight to those that practice genetic counseling.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

A. Identification of total number of rules in package

- ◆ WAC 246-825-010 Definitions.
- ◆ WAC 246-825-020 Practice parameters.
- ◆ WAC 246-825-030 Collaborative agreement.
- ◆ WAC 246-825-050 Examination required.
- ◆ WAC 246-825-060 Licensure requirements.
- ◆ WAC 246-825-080 Licensure by endorsement.
- ◆ WAC 246-825-100 Qualification for provisional license.
- ◆ WAC 246-825-105 Documentation and supervision – Provisional license.
- ◆ WAC 246-825-110 Continuing education.
- ◆ WAC 246-825-130 Auditing for compliance.
- ◆ WAC 246-825-140 Expired license.
- ◆ WAC 246-825-990 License fees.

B. Non-Significant Rule Identification Table

WAC Section	Section Title	Section Subject	Reason
WAC 246-825-010	Definitions.	Definitions- Defines terms used throughout the rule chapter.	Does not create a new policy or regulatory program.
WAC 246-825-990	License fees.	License fees	Under RCW 34.50.310, the department is not required to conduct a cost benefit analysis on fees. The department did prepare a separate fee study.

C. Significant Rule Analysis

WAC 246-285-020 Practice parameters.

Rule Overview: This new section identifies specific procedures and tasks are within a genetic counselor’s scope of practice. This section also establishes when a genetic counselor shall refer a patient to a licensed health care provider.

Rule Cost/Benefit: There are no compliance costs. The benefit is that the proposed language provides a clear understanding as to when a genetic counselor needs to refer a patient to a licensed health care provider.

WAC 246-825-030 Collaborative agreement.

Rule Overview: This section establishes the contents and requirements of the written collaborative agreement that memorializes the relationship between the genetic counselor and the physician or osteopathic physician. A genetic counselor operating under a collaborative agreement may have expanded authority to order laboratory tests or recommend other evaluations to diagnose a condition or determine the carrier status of one or more family members, including testing for inherited disorders.

Rule Cost/Benefit: There are no compliance costs. The benefit is that the proposed language provides clear guidance regarding procedures and tasks to genetic counselors to ensure they are not practicing beyond their scope of practice.

WAC 246-825-050 Examination required.

Rule Overview: This new section establishes a requirement for applicants to take and pass the American Board of Genetic Counselors (ABGC) national certification examination or have passed a national examination previously administered by the American Board of Medical Genetics (ABMG). The ABGC recognizes 31 programs in 20 states and 3 in Canada. While Washington State does not have an accredited genetic counseling program, there is an accredited program at the University of British Columbia in Vancouver, Canada.

Rule Cost/Benefit Analysis: The proposed rule imposes a cost to sit for the ABGC Certification Examination (\$1365) to those that must comply. In addition, there are minimal travel costs as there are 160 assessment centers nationwide and in Canada that administer the exam.

The probable benefit of the proposed rule is that the national organization ABGC has used its expertise to define professional standards of competency for the genetic counseling profession through a certification examination since 1996. In addition, individuals must demonstrate that they meet established standards for professional practice through documentation of specialized training and clinical experience to qualify to sit for the examination.

WAC 246-246-825-060 Licensure requirements.

Rule Overview: This new section establishes licensure requirements for applicants to include education and examination. In order to meet the requirements, applicants must hold a masters or doctorate level degree in genetic counseling or medical genetics training from programs accredited by the ABGC and ABMG or an equivalent program as determined by the secretary.

Rule Cost/Benefit Analysis: According to CollegeBoard.com, the estimated cost of a year's tuition, room and board, and fees at a private/public college and university in 2010 is \$36,717 and \$13,797 respectively. The probable benefit of the proposed rule outweighs the costs because the standards are consistent with nationally recognized standards for education for a genetic counselor. Accredited doctorate/master degree programs meet or exceed the minimum standards outlined by the accrediting body. The standards are designed to prepare genetic counselors academically and clinically to provide genetic services to individuals and families.

State licensure will make genetic counseling more available and more visible to the public. While patients/families may have concerns that an inherited disease exists in their family, they may not know that there is a health professional with specific education and training for genetic information and support. Licensure will provide oversight of the profession and a uniform process for action against unprofessional conduct.

WAC 246-246-825-080 Licensure by endorsement.

Rule Overview: This new section outlines the requirements for an individual licensed as a genetic counselor in another state to apply for licensure without examination. Applicants fitting these criteria are eligible for a temporary practice permit.

Rule Cost/Benefit Analysis: The probable benefit of the proposed rule recognizes that states that license genetic counselors have adopted equivalent licensing standards. The rule provides better mobility of practitioners eliminating the need to order transcripts. Streamlining the licensure process for these applicants may help promote access to genetic counseling services in Washington.

WAC 246-246-825-100 Qualification for provisional license.

Rule Overview: This new section outlines the requirements to qualify for a provisional genetic counselor license, the duration of the license and the number of renewals permitted.

An applicant for provisional license must:

- ◆ Meet all licensing requirements for a genetic counselor license except passing the certification examination;
- ◆ Be supervised by a fully licensed genetic counselor or physician or osteopathic physician with a current ABMG certification in clinical genetics specialty;
- ◆ Submit forms provided by the department documenting supervised practice; and
- ◆ Pay a provisional license fee.

The provisional license must be renewed annually and may be renewed up to three times. The license expires on the practitioner's birthday or 60 days after passing an approved certification examination or by the issuance of a genetic counselor license or when a notice of decision is mailed.

Rule Cost/Benefit Analysis: The proposed rule imposes a minimum cost to the applicant for the credential while providing the probable benefits of gaining clinical experience, knowledge and competency post—graduation and under the supervision of a qualified supervisor. A provisional license can be renewed three times providing the applicant sufficient time to prepare, take and pass the board certification examination.

WAC 246-246-825-105 Documentation and supervision – Provisional license.

Rule Overview: This new section outlines the supervisory requirements for which an individual may practice under the authority of a provisional genetic counselor license. The proposed rule requires the applicant for a provisional genetic counselor license send written notification of current working relationship with a qualified supervisor to the department. The new section also puts the individual practicing with a provisional license on notice that they must not practice between the end of one supervisory relationship and the department’s receipt and approval of a new supervisor.

The department has determined the need to review supervisory plans to ensure:

- a. Qualified staff practice under safe oversight; and
- b. Practitioners hold appropriate, and unrestricted current state license, and board certification if applicable.

Rule Cost/Benefit Analysis: The costs associated with this section are associated with the time needed to identify authorized supervisor(s); and to prepare a written description of supervision and mentoring plan to include a review of the genetic counselor’s services to ensure adequate professional support and standards of quality are being met.

Cost associated with developing the supervisory plan is based on human resources. Using the average wages reported by the US Department of Labor, Bureau of Labor Statistics a supervisory plan developed in collaboration with all parties is estimated to take 10 to 40 hours at a cost of \$1243 to \$4974. [Assumptions: approximately \$37.06 per hour for a Genetic Counselor (Occupation Code 29-1199 “Health Diagnosis and Treatment Practitioner, All Other”) and \$ 87.29 per hour for a Physician or Osteopathic Physician (Occupation Code 29-1069 “Physician and Surgeon, All Others).]

WAC 246-246-825-110 Continuing education.

Rule Overview: The new section establishes competency based continuing education requirements for genetic counselors. The proposed rule requires 7.5 continuing education units (CEUs) or 75 contact hours every 3 years. This new section lists organizations that approve or accredit acceptable continuing education courses or programs. These organizations are consistent with the national board recognized continuing education program

Rule Cost/Benefit Analysis: Continuing education courses/program vary in cost based on the program and the number of contact hours earned. On-line, webinar, annual education conferences and other opportunities are available to promote growth and development within the profession. Continuing education courses/programs range in cost based partly on the number CEUs earned. Costs range from approximately \$150 to \$629. The requirement in rule is

consistent with CEUs needed to maintain voluntary national certification. The probable benefits of expanding the practitioner's knowledge base and staying up-to-date on new developments are of value to public health.

WAC 246-285-130 Auditing for compliance.

Rule Overview: This new section lists documentation that genetic counselors must provide when they are audited. Acceptable documentation of continuing education includes certificates of completion or a letter provided by program sponsor. Either document must name the participant, program title, date of participation, and the number of contact hours awarded.

Rule Cost/Benefit: There may be minimal compliance costs for reproduction of certificates/letters in the event the licensee fails to maintain adequate records. The benefit is that the licensee is on notice that documentation of compliance with continuing education requirements is enforced.

WAC 246-246-825-140 Expired license.

Rule Overview: The proposed rule puts the genetic counselor on notice that they must not practice at any time when their credential is expired. The section adopts the requirements of chapter 246-12 WAC Part 2 and imposes additional requirements to demonstrate competence. Competence must be shown by documentation of active practice in another U.S jurisdiction and ABGC certification or by retaking and passing the ABGC certification examination or other examination approved by the secretary.

Rule Cost/Benefit Analysis: The cost of the certification examination is \$1365. The proposed rule benefits public health by protecting patients from potentially unqualified providers and restricting practice to only actively licensed genetic counselors.

D. Rule Package Cost-Benefit Conclusion

Although the rule analysis has shown there are costs for individuals who elect to enter this profession, these costs are necessary to ensure that individuals practicing as genetic counselors are adequately educated and trained and can demonstrate their knowledge, competence, and expertise by passing the ABGC certification examination. Therefore, the benefits of the rules exceed the costs.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

Descriptions of alternatives considered

The department developed the proposed rules in collaborative process with the Washington State Genetic Counselor Network, genetic counselors and other interested parties.

- ◆ *Alternative version 1:* Adopt the American Board Genetic Counselor “Active Candidate Status” to qualify for a provisional genetic counselor license.
- ◆ *Alternative version 2:* Require a professional enhancement plan to demonstrate continuing competency.
- ◆ *Alternative version 3:* Issue and renew licenses for two-year cycles.

Least burdensome determination

- ◆ The proposed rules are less burdensome than the alternative because applicants for provisional genetic counselor license will not be required to have “active candidate status” with ABGC. This will allow a qualified individual who has not yet passed or taken the ABGC certification exam to gain post-graduate supervised clinical experience, knowledge and competency prior to registering to take the exam.
- ◆ The proposed rules are less burdensome than the alternative in defining on-going education/competency requirements. The original draft required genetic counselors to develop a three-year professional enhancement plan. The proposed rule requires 75 CEUs to be completed every 3 years following the first license renewal cycle. This requirement is consistent with national certification requirements and takes into consideration the availability of recognized continuing education activities. In addition, the proposed rule requires individuals whose license is expired for more than three years to demonstrate continued competency by passing the ABGC re-certification exam.
- ◆ The proposed rules are less burdensome than the alternative because the license cycle is adjusted to one year to reduce the fee to renew. Health professions in Washington State must support all the cost of their regulatory program through fees (RCW 43.70.250). With only fifty genetic counselor licenses to support the cost of creating and maintaining this program the shared cost and financial burden is significant.

Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The department determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

The rule does not differ from any applicable federal regulation or statute.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

There are no other applicable laws.