

4695.0800 FACTORS FOR DETERMINING THE NECESSITY OF REGULATION.

Subpart 1. **Consideration of factors.** In the review of an applicant group questionnaire, the subcommittee, council, and commissioner shall base their recommendation or decision as to whether or not the applicant group shall be regulated upon the factors contained in Minnesota Statutes, section 214.001, subdivision 2.

Subp. 2. **Factor of unregulated practice.** In applying the factor of whether the unregulated practice of an occupation may harm or endanger the health, safety, and welfare of citizens of the state and whether the potential for harm is recognizable and not remote, at a minimum the relevance of the following shall be considered:

A. harm shall be construed to be a condition representative of physical, emotional, mental, social, financial, or intellectual impairment resulting from the functions rendered or failed to be rendered by the applicant group;

B. potential for harm may be recognizable when evidenced by at least one or more of the following: expert testimony; client, consumer, or patient testimony; research findings; legal precedents, financial awards, or judicial rulings;

C. potential for harm may be recognizable when evidenced by at least one or more of the following characteristics of the applicant group;

(1) inherently dangerous nature of the applicant group's functions;

(2) dangerous nature of devices or substances used in performing applicant group's functions;

(3) exercise by practitioners of the applicant groups of an observable degree of independent judgment when: identifying or evaluating a consumer's or client's symptoms; formulating a plan for consumer or client care, service delivery or treatment; and/or providing consumer or client care, delivering service, or implementing a plan of treatment;

D. potential for harm may be remote when evidenced by at least one or more of the following: infrequent or rare instances of impairment; impairment which is minor in nature; or secondary or tertiary effects of the applicant group's function.

Subp. 3. **Occupation requiring special skill factor.** In applying the factor of whether the practice of an occupation requires specialized skill or training and whether the public needs and will benefit by assurances of initial and continuing occupational ability, the existence of the following items shall be considered as indicating that specialized skill or training or their continuation is required:

A. that the functions performed by the practitioner are several and their performance necessitates a thorough understanding of the complex relationship between those functions;

B. that the one or more functions performed by the practitioner requires a detailed understanding of the specific components of the function and the relationship between the functions and the symptoms, problem, or condition that function is intended to address or ameliorate;

C. that the absence of specialized skill or training is likely to increase the incidence and/or degree of harm as defined in subpart 2 to the consumer as client; and

D. that there occur frequent or major changes in areas of skilled knowledge and technique of which the practitioner must keep informed in order to meet current standards.

Subp. 4. **Factor of more effective means.** In applying the factor of whether the citizens of this state are or may be effectively protected by other means, at a minimum the relevance of the following shall be considered:

- A. Indicators of protection by other means shall include but not be limited to:
- (1) supervision by practitioners in a regulated occupation;
 - (2) existence of laws governing devices and substances used in the occupation;
 - (3) existence of laws governing the standard of practice;
 - (4) existence of standards for professional performance;
 - (5) employment in licensed human service facilities which are required to employ competent staff;
 - (6) existence of federal licensing as credentialing mechanism;
 - (7) existence of civil service procedures which effectively screen potential employees for competence;
 - (8) graduation of members of the applicant group from an accredited educational institution or training program;
 - (9) mandatory participation in on-the-job training programs which are required by law or by professional organization of the occupation;
 - (10) existence of professional credentials and standards of performance which effectively sanction malpractice; and
 - (11) existence of a national certification process which effectively attests to the competency of recognized professionals.

B. Indicators of protection by other means shall be assessed and evaluated at least in view of the extent to which they:

- (1) address all practitioners within an occupational group;

(2) appear sufficient to protect the general public from harm caused by the practice of the occupation in question; and

(3) appear to be permanent and ongoing mechanisms.

Subp. 5. **Overall cost-effectiveness and economic impact.** In determining whether the overall cost-effectiveness and economic impact would be positive for citizens of the state, the following shall be considered:

A. Positive cost-effectiveness and economic impact results where the benefits expected to accrue to the public from a decision to regulate an occupation are greater than the costs resulting from that decision.

(1) Cost-effectiveness means the relationship of the benefits anticipated from a decision to regulate an occupation to the overall costs to the public resulting from that decision.

(2) Economic impact means the direct and indirect effects on the price and supply of services provided by the occupation under consideration for regulation. Direct effects include impacts on the cost and supply of practitioners who would be regulated. Indirect effects include: the degree to which the existing practitioners will be precluded from practice because of regulation; the degree to which persons aspiring to practice the occupation, who if not for regulation could practice the occupation successfully, but will be prohibited because of inability to meet entry requirements; impact on ability of minorities or protected classes to enter the occupation; or impact on innovations in the delivery of care or services as a result of regulation.

(3) Costs of a decision to regulate include the estimated costs to state and local governments of administering the proposed regulatory program; educational requirements and training costs including costs associated with experiential requirements of the proposed mode of regulation; and costs to the public such as reduced or increased access by potential or existing providers to labor markets.

(4) Benefits of a decision to regulate an occupation include access to less expensive but similar providers; measurable improvements in quality of care; reductions in costs of services; process for seeking redress for injury from malpractice, or other unprofessional conduct, and reduction in the potential for public harm from unregulated practice.

B. Cost-effectiveness and economic impact can be evaluated through consideration of the following factors:

(1) degree to which regulation directly or indirectly impacts the costs and prices of goods or services provided by applicant group;

- (2) impact upon the current and future supply of practitioners of the regulated occupation;
- (3) degree to which the existing practitioners will be precluded from practice because of regulation;
- (4) impact, if any, on innovations in the delivery of care or services as a result of regulation;
- (5) costs of additional education and training required as a result of the regulation of the occupation;
- (6) manner in which and degree to which regulation will result in improvement in the quality of care;
- (7) degree to which services of the applicant group substitute for currently regulated occupations and estimated comparative costs of applicant group and currently regulated practitioners;
- (8) degree to which services of the applicant group supplement currently regulated occupations;
- (9) whether regulation confers or facilitates access to reimbursement for government assistance programs such as medicare and medicaid; estimated impact on program budgets; and
- (10) impact on expenditures by government and private third-party payors, if any, resulting from regulation of the occupation.

Subp. 6. **Nonlimiting guidelines.** Subparts 2 to 5 shall be considered nonlimiting guidelines to be used in applying the statutory factors contained in Minnesota Statutes, section 214.001, subdivision 2. Additional elements may be considered if necessary to permit a thorough review and evaluation of an applicant group questionnaire in light of the statutory factors; provided, however, that the additional elements shall be identified during the course of the review and evaluation process, all interested persons given the opportunity to comment thereon, and shall be specifically addressed in the commissioner's written decision required by part 4695.1500.

Statutory Authority: *MS s 214.13*

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