

CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-05-27

RULE TITLE: Licensing of Lactation Consultants and Counselors

REASON FOR RULEMAKING: The proposed amendments are intended to address the addition of the Lactation Counselor license type and set the requirements for licensure as well as the scope of practice for licensees.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE:
N/A

TESTIMONY AND COMMENTS:

Comments Received: Expressing concern over the co-mingling of regulations. Specifically, these comments recommended that Lactation Counselors and Lactation Consultants have their own individual regulations.

Section Involved: Entire Regulations

Response: RIDOH notes that the regulations point to different scopes of practice according to the certifying bodies for these related professionals providing lactation services to the Rhode Island public. Some comments expressed concern that Lactation Counselors are not trained to provide clinical care. In response to this, RIDOH further notes that according to the ALPP's [Scope of Practice](#), "The Certified Lactation Counselor® (CLC®) is a **clinical**, professional lactation care provider who has demonstrated the necessary skills, knowledge, and abilities to provide **clinical** breastfeeding support and management to families who are thinking about breastfeeding or who have questions or problems during the course of breastfeeding/lactation...Construct and maintain conditions that predispose mothers and babies to an uncomplicated breastfeeding experience through counseling, education, **clinical** management, and support...Use counseling skills and techniques that are supportive to breastfeeding mothers and babies, practicing in a **clinically competent** manner...Ability to incorporate evidence based approaches to **clinical** practice and make appropriate referrals operating on the continuum of the health care team." Based on this, RIDOH established that it would be less confusing to keep the regulations as proposed. *No changes to the regulation are being made in response to these comments.*

Comment Received: "I recommend amending Part 27 and Section 27.1 and all other instances to use the full, statutory title "Lactation Counselors", so the wording would be changed to "for licensing of Lactation Consultants and Lactation Counselors". This ensures the rule reflects the precise language of the statute and maintains professional consistency."

Section Involved: Entire Regulations

Response: RIDOH notes that the terminology used is for brevity and to avoid confusion. *No changes to the regulation are being made in response to this comment.*

Comment Received: "We are deeply concerned that the proposed regulation — in particular, Section 27.9 (Scope of Practice for a Lactation Counselor) — risks creating dangerous confusion between two very different professions with fundamentally different education, training, and competencies."

Section Involved: Entire Regulations

Response: RIDOH notes there is a SOP for each professional that certifies them and the regulations point to the different scopes of practice according to the certifying bodies for these related professionals that would be providing lactation services to the public. All of this information regarding education, training and competencies is public knowledge and accessible to the public, and RIDOH does not believe the regulations would be a source of confusion. *No changes to the regulation are being made in response to this comment.*

Comment Received: In support of the proposed regulations.

Sections Involved: Entire regulations

Response: RIDOH acknowledges these comments.

Comment Received: Expressing concern that the ALPP Scope of Practice refers to ALCs and CLCs as clinicians and stated "Counselors do not have hands-on clinical training to prepare them."

Sections Involved: Entire Regulations

Response: RIDOH notes that R.I. Gen. Laws § 23-13.8-9 states: "...A licensed lactation counselor shall comply with the Academy of Lactation Policy and Practice; CLC, in accordance with "Scope of Practice for CLCs"; ALC, in accordance with "Scope of Practice for ALCs"; and/or a licensed lactation counselor shall limit the counselor's practice to demonstrated areas of competence as documented by relevant professional education, training, and experience." Therefore, RIDOH is required to adopt the ALPP's Scope of Practice for CLCs. *No changes to the regulation are being made in response to these comments.*

Comment Received: Expressing concern regarding changes made to the requirements for IBCLCs.

Section Involved: Entire Regulations

Response: RIDOH notes that the only changes made to the requirements for IBCLCs are to change from using the full name to the acronym and allowing them to supervise lactation counselors. *No changes to the regulations are being made in response to these comments.*

Comments Received: Expressing concern regarding the adoption of the Academy of Lactation Policy and Practice's Scope of Practice for CLCs.

Section Involved: §§ 27.2(C) and (D)

Response: RIDOH notes that R.I. Gen. Laws § 23-13.8-9 states: "...A licensed lactation counselor shall comply with the Academy of Lactation Policy and Practice; CLC, in accordance with "Scope of Practice for CLCs"; ALC, in accordance with "Scope of Practice for ALCs"; and/or a licensed lactation counselor shall limit the counselor's practice to demonstrated areas of competence as documented by relevant professional education, training, and experience." Therefore, RIDOH is required to adopt the ALPP's Scope of Practice for CLCs. *No changes to the regulation are being made in response to these comments.*

Comment Received: "We also wish to voice concern regarding the proposed list of what Lactation Consultants (IBCLCs) cannot do. A licensed clinician, by definition, is performing medical functions. Typical scopes of practice for clinical healthcare professionals do not list what they cannot do, but rather delineate what they can do."

Sections Involved: §§ 27.2(C) and (D) and other references to IBCLC scope.

Response: The section on practice limitation is as per the IBCLC (certifying body) advisory opinion approved by the IBLCE Board of Directors on 22 March 2017 which states:

"Practicing medicine means to engage, with or without compensation, in medical diagnosis, healing, treatment or surgery. A medical diagnosis is based upon a medical history and physical examination and may include additional testing which then leads to identifying a disease or disease process. Treatment may include medical, surgical or psychiatric management of a patient.

The above statements from the IBCLC Practice Guiding Documents outline the IBCLC's process of assessment, documentation, and referral. The IBCLC certificant neither practices medicine nor diagnoses a disease or disease process unless the certificant is separately licensed or authorized to perform such procedures. An IBCLC certificant does: carefully assess, document findings, and refer appropriately as needed, to obtain a medical diagnosis and possible treatment."

As such, this section in RIDOH's proposed regulations refers to this limitation in Scope of Practice for clarity and public safety's sake:

"B. Limitation of Practice. A licensed Lactation Consultant shall limit their practice to demonstrated areas of competence as documented by relevant professional education, training, and experience. Unless licensed as a doctor or nurse practitioner, a Lactation Consultant shall not:

1. Give medical advice;
2. Give a medical diagnosis;
3. Prescribe medication;
4. Perform medical procedures; or,
5. Perform medical treatment."

It is the intent of the proposed regulations that a Rhode Island licensed lactation counselor cannot practice medicine or diagnose a disease or disease process unless the lactation counselor is separately licensed or authorized to perform such procedures. In response to this comment, RIDOH has revised the proposed regulation to incorporate by reference to the IBCLC advisory opinion approved by the IBLCE Board of Directors on 22 March 2017 which RIDOH believes will ensure clarity on this matter. This change does not represent a substantive change; rather, it is a clarification.

Comment Received: Recommending the definition of “Lactation Counselor” be removed from the regulations.

Section Involved: § 27.3(A)(7)

Response: RIDOH notes that this definition is necessary to effectuate the purpose of the regulations. *No changes to the regulation are being made in response to this comment.*

Comment Received: ““I worry about the new scope's proposal for Counselors/CLC's to help patients with "normal" breastfeeding and to then refer "abnormal" or higher risk patients to Consultants/IBCLCs because this may cause a delay in care when time is of the essence. "I worry that if patients do not receive early support from Consultants with a higher level of training then it will decrease their likelihood of meeting their breastfeeding goals.”

Sections Involved: § 27.3(A)(8)

Response: RIDOH notes that based upon both professions understanding of the critical timeline of referral which is evidenced in their ethical and subject matter expertise, much as in other professions, referral should be a timely process prioritized based on the urgency. This creates an impetus on relationship building as outlined in the regs for providers (PCP's), CLC's, and IBCLC's to be able to connect with one another to the benefit of the patient's care. *No changes to the regulation are being made in response to this comment.*

Comment Received: Recommending revising the definition of “Lactation Counselor” by “removing 'addressing' and redefining as specializing in the range of normal non-medically complex breastfeeding and parental health assessment to refer for health complications.”

Sections Involved: § 27.3(A)(8)

Response: RIDOH agrees with this comment and *the definition has been revised by “replacing “addresses” with “specializing” and adding “in non-medically complex” and “parental health assessment”*

Comment Received: Regarding the use of the word “normal” in the definition of “lactation counselor” and expressed concern over its interpretation.

Section Involved: § 27.3(A)(8)

Response: RIDOH agrees with this comment and has *changed the word “normal” to “non-medically complex.”*

Comments Received: Stating that licensure should be a choice and not a requirement and that there should be distinct classifications for licensed and non-licensed practitioners.

Sections Involved: § 27.4.3

Response: RIDOH notes that R.I. Gen. Laws § 23-13.8-3 states: “(a) No individual shall practice unless the individual is licensed in accordance with the provisions of this chapter.” Therefore, licensure is required. *No changes to the regulation are being made in response to this comment.*

Comments Received: Recommending that Lactation Counselors be allowed to supervise "Lactation Educators and Certified Breastfeeding Specialists."

Sections Involved: § 27.4.3(F)

Response: RIDOH notes that this is beyond the scope of these regulations. *No changes to the regulation are being made in response to these comments.*

Comment Received: Recommending “Amending § 27.4.3(F) to include “Licensed Lactation Counselors” to ensure the rule reflects the full authority granted by the statute.”

Section Involved: § 27.4.3(F)

Response: RIDOH notes that R.I. Gen. Law § 23-13.8-3 states that “a licensed lactation counselor is authorized to supervise the following individuals: 1. Licensed lactation counselor; 2. Students, interns, or individuals preparing for practice as lactation counselor; 3. Care extenders and other team members as appropriate; and 3. Volunteers.” *Given this language in statute, RIDOH will add “lactation counselor” to § 27.4.3(F).*

Comment Received: Provided similar suggested language for § 27.9.

Section Involved: § 27.9

Response: *In response, RIDOH is revising § 27.9(C) to read “If the Lactation Counselor assisting in the lactation care of infants referenced in §§ 27.9(B)(1) or (2) is not employed by the facility, they must have a written collaborative agreement in place which lays out the terms of the collaboration with the collaborating healthcare professional.”*

Comment Received: Recommending that RIDOH remove the word "Counseling" and add "may provide independent management and must provide services" in § 27.9(A).

Section Involved: § 27.9(A)

Response: RIDOH notes that the statute (R.I. Gen. Laws § 23-13.8-9) states "A licensed lactation counselor must provide lactation counseling services within the scope of practice." Therefore, the statutory language provides the counseling services requirement. *No changes to the regulation are being made in response to this comment.*

Comment Received: "In accordance with the Academy of Lactation Policy and Practice Scope of Practice for Certified Lactation Counselors, we propose amending this rule to clarify that a L-CLC “may provide independent management and must provide counseling services within the parameters of R.I. Gen. Laws § 23-13.8-9” (27.9-A) and clarifying that L-CLCs may continue to practice independently within their scope of practice (deletion of 27.9-B-3)."

Section Involved: §§ 27.9(A) and 27.9(B)(3)

Response: RIDOH notes that while the requirements of § 27.9(B)(3) is in the Scope of Practice per the ALPP, RIDOH has included additional collaborative safeguards in the current landscape of changing SOPs for CLC's for the extreme caution for public health and safety. *No changes to the regulation are being made in response to this comment.*

Comment Received: Recommending the wording “with a collaborative agreement” be added to § 27.9(B).

Section Involved: § 27.9(B)

Response: RIDOH notes that the facility is responsible for putting together the plan for a collaborative agreement and RIDOH defers to the facility for this. *No changes to the regulation are being made in response to this comment.*

Comment Received: Recommended adding "Licensed Midwife and Physician Assistant" to the list of possible licensees that a CLC must collaborate with when caring for medically-complex infants.

Section Involved: § 27.9(B)

Response: RIDOH notes that Physician Assistants do not receive training in breastfeeding during school and do have residency training. Licensed Midwives have training in lactation but may not have the extent necessary to be able to be the expert for a medically complex infant. *For those reasons, RIDOH will not make any changes to the regulation based on this comment.*

Comment Received: Expressing concern that CLCs would be allowed to care for medically complex infants. The commenter stated: "The lack of clinical knowledge and extensive training would very likely result in inappropriate care for these dyads."

Sections Involved: § 27.9(B)(1)

Response: RIDOH notes that under the regulations, CLCs must “work with an IBCLC, Physician, or Nurse Practitioner, in accordance with facility policies for such collaboration, when assisting in the lactation care of medically complex infants.” *No changes to the regulation are being made in response to these comments.*

Comment Received: Expressing concerns over the ability of counselors, if working under a doctor or nurse practitioner, to see medically complex infants. The comment stated that Doctors and NPs may not have lactation training and look to Consultants for expertise.

Sections Involved: § 27.9(B)(1)

Response: RIDOH notes that Doctors and NP's do ultimately make the health determinations in concert with the family and would be the referring provider responsible for complex situations regardless of their lactation specific expertise and knowledge. Additionally, the goal of the regulations is to have more integration with the primary clinician, NP or doctor, and lactation specialists by encouraging that partnership especially in necessary complex clinical cases. Additionally, this is beyond the scope of these regulations as the Scope of Practice of physicians and NPs is not being discussed. *No changes to the regulation are being made in response to these comments.*

Comment Received: Recommending that the regulations “clarify that Lactation Counselors provide only education and peer support, not clinical assessment or management.”

Section Involved: § 27.9(B)(3)

Response: RIDOH notes that the regulations point to different scopes of practice according to the certifying bodies for these related professionals providing lactation services to the Rhode Island public. Some comments expressed concern that Lactation Counselors are not trained to

provide clinical care. In response to this, RIDOH further notes that according to the ALPP's [Scope of Practice](#), "The Certified Lactation Counselor® (CLC®) is a **clinical**, professional lactation care provider who has demonstrated the necessary skills, knowledge, and abilities to provide **clinical** breastfeeding support and management to families who are thinking about breastfeeding or who have questions or problems during the course of breastfeeding/lactation...Construct and maintain conditions that predispose mothers and babies to an uncomplicated breastfeeding experience through counseling, education, **clinical** management, and support...Use counseling skills and techniques that are supportive to breastfeeding mothers and babies, practicing in a **clinically competent** manner...Ability to incorporate evidence based approaches to **clinical** practice and make appropriate referrals operating on the continuum of the health care team." Based on this, RIDOH established that it would be less confusing to keep the regulations as proposed. *No changes to the regulation are being made in response to these comments.*

Comment Received: Recommended that § 27.9(C) be removed from the regulations.

Section Involved: § 27.9(C)

Response: RIDOH believes including prohibitions in clear language is important to provide clarification. *No changes to the regulation are being made in response to this comment.*

Comment Received: "[recommend] entirely removal [of § 27.9(B)(3)] as Lactation Counselors already operate independently and with scope. RI General Law 23-13.8 sets no legal precedent for supervisor or collaborative requirement, nor does the Scope of Practice as adopted by 23-13.8. Additionally due to the nature of CLC scope and practice NO licensed provider listed, such as Physician, Physician Assistant, Nurse Practitioner and Registered Nurses should be operating within the parameters of Licensed CLC, as to a higher continuity of care based on their licensure. A Physician's extensive medical education is not interchangeable with the training required to become a Licensed CLC, L-CLC, and the scope of practice for NPs is determined by state law and is distinct from that of a Licensed CLC, L-CLC."

Section Involved: § 27.9(C)

Response: RIDOH notes that the Collaborative Agreement is limited to counselors who are assisting in the lactation care of medical complex infants. *RIDOH is revising § 27.9(C) to read "If the Lactation Counselor assisting in the lactation care of infants referenced in §§ 27.9(B)(1) or (2) is not employed by the facility, they must have a written collaborative agreement in place which lays out the terms of the collaboration with the collaborating healthcare professional."*

Comment Received: "CLCs should not require a collaborative agreement to practice within their scope. We are independent professionals who refer to higher levels of care as needed. Requiring a collaborative agreement would be a burdensome additional step and would unnecessarily gatekeep services, limiting our ability to respond effectively and efficiently to families in need of crucial and timely lactation support."

Section Involved: § 27.9(C)

Response: RIDOH notes that the Collaborative Agreement is limited to counselors who are assisting in the lactation care of medical complex infants. *RIDOH is revising § 27.9(C) to read "If the Lactation Counselor assisting in the lactation care of infants referenced in §§ 27.9(B)(1) or*

(2) is not employed by the facility, they must have a written collaborative agreement in place which lays out the terms of the collaboration with the collaborating healthcare professional.”

Comment Received: Stating that although the ALPP requires 90 hours of education for CLCs, other organizations only require 45 hours.

Sections Involved: N/A

Response: RIDOH responds that the regulations require ALPP certification, so what other organizations require is not relevant to these regulations. *No changes to the regulation are being made in response to these comments.*

CHANGES TO THE TEXT OF THE RULE:

- § 27.2(G)
 - Added “These Regulations hereby adopt and incorporate “Advisory Opinion: Assessment, Diagnosis, and Referral” approved by the IBLCE Board of Directors on 22 March 2017 by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.”
- § 27.3(A)(8)
 - Revised the definition of “Lactation Counselor” by “replacing “addresses” with “specializing” and adding “in non-medically complex” and “parental health assessment”
- § 27.4.3(F)(1)(a)
 - Added “Licensed Lactation Counselor”
- § 27.9(C)
 - Revised to read: “If the Lactation Counselor assisting in the lactation care of infants referenced in §§ 27.9(B)(1) or (2) is not employed by the facility, they must have a written collaborative agreement in place which lays out the terms of the collaboration with the collaborating healthcare professional.”

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

- 1) Alternative approaches;
- 2) Overlap or duplication with other statutory and regulatory provisions; and
- 3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.