**CONCISE EXPLANATORY STATEMENT**

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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-40-05-1

**RULE TITLE:** Licensure and Discipline of Physicians

**REASON FOR RULEMAKING:** The Rhode Island Department of Health ("RIDOH"; "The Department") is proposing to amend "Licensure and Discipline of Physicians" [216-RICR-40-05-1] to amend the definition of surgery to add "Notwithstanding the above, injection of the following medications and autologous plasma products for cosmetic purposes is not considered surgery: Onabotulinumtoxin A, hyaluronic acid, Platelet-Rich Fibrin, and Platelet-Rich Plasma."

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

**TESTIMONY AND COMMENTS:**

**Comment Received:** "[The] current proposal only lists three procedures and one medication, which does not reflect the full scope of services safely performed by qualified licensed providers…The proposed language also omits many commonly performed, evidence-based treatments used in modern medical aesthetics, creating ambiguity around what is permissible and around what is permissible and potentially restricting safe, established care…Any regulation that relies on enumerating specific drugs or procedures will quickly become obsolete and will fail to provide meaningful guidance or protection…In contrast, a procedure- or product-based regulatory model introduces ambiguity, limits adaptability, and does not meaningfully improve safety."

**Response:** The proposed regulatory change is specific to certain injection-based procedures for cosmetic purposes This change does not affect the scope of practice for non-physicians performing any other procedures. However, as noted below, changes were made to the language based on comments received.

**Change to the text of the rule:** The language has been clarified to not name specific agents other than botulinum toxin. As there have been numerous recent reports of complications (including botulism) from injection of non-FDA approved toxin, the term "FDA-approved" has been added for patient and public safety reasons. In addition, we have removed the specific reference to hyaluronic acid and now use the more comprehensive term "dermal fillers." The

proposed language will now read as follows: “Notwithstanding the above, the following injection procedures are not considered surgery: FDA-approved Botulinum toxin type A (BoNT-A) products for cosmetic purposes, FDA-approved dermal filler for cosmetic purposes, Platelet-Rich Fibrin for cosmetic purposes, and Platelet-Rich Plasma for cosmetic purposes.”

**Comment Received:** "[The] Rhode Island proposal adopts an unusually narrow interpretation of medical aesthetic practice by identifying only a small subset of procedures and a single medication, while continuing to assert that such services fall outside the scope of practice for NPs, PAs and RNs. [T]his position is not only inconsistent with national standards, but it also stands in direct contrast to the regulatory environment in Massachusetts, where similarly trained and licensed providers are recognized as competent to perform these services within appropriate supervisory frameworks." The commenter urged RIDOH to revise the regulations to better align with the care model used in Massachusetts and other neighboring states.
**Response:** These regulatory changes are designed narrowly to address certain injection-based procedures for cosmetic purposes and to carve them out of the definition of surgery. These changes would allow those providers who do not have the ability to operate within their scope but who may inject medications within their scope, education, and experience to perform these injection-based procedures for cosmetic purposes, subject to a valid order and consistent with the standards of practice for their profession. RIDOH has reviewed regulatory schemes in other states in drafting these amendments. This regulatory proposal brings Rhode Island more in line with Massachusetts than it was previously.
**Change to the text of the rule:** Based upon feedback, RIDOH made a change from originally listing only one formulation of Botox and only one type of dermal filler, to including the names of the most common formulations of Botox as well as language to allow for new FDA-approved formulations and other FDA-approved dermal fillers to be included.

**Comment Received:** “Limiting the scope fails to reflect the intent of the legislation and creates unnecessary barriers to patient care. [The] recently passed legislation was intended to recognize and appropriately regulate the role of qualified healthcare professionals in medical aesthetics.”
**Response:** The regulatory change is not limiting any scope (it expands the scope for non-physicians) and is consistent with the series of steps the Department is taking in response to the legislation to safely address the evolving practice of cosmetic procedures. The legislation explicitly expanded scope for ablative laser procedures for PAs and NPs but did not address any other expansion or change of scope. The definition of surgery in this regulation is one of the rules that articulates the types of procedures that providers who have it within their scope to “operate” can perform. This is an existing regulation which we are proposing to amend so that certain injection-based procedures for cosmetic purposes may be performed by providers who do not have it within their scope to operate or inject pharmacological agents.
**Change to the text of the rule:** N/A

**Comment Received:** “These regulations would have serious consequences on many small healthcare businesses resulting in closure and job loss. This would reduce access to safe, regulated, [supervised] care for patients.”

**Response:** This regulatory change represents an expansion of scope which will increase the number of providers who can legally perform these procedures. This regulation is an expansion and not a limitation.
**Change to the text of the rule:** N/A

**Comment Received:** Commenters urged RIDOH to reconsider the regulations or revise them to reflect the scope of practice and the statute.
**Response:** RIDOH is in the process of implementing a comprehensive regulatory framework regarding Medical Spas, cosmetic procedures, and scopes of practice.
**Change to the text of the rule:** N/A

**Comment Received:** "The proposed restrictions fail to recognize the education, training and clinical standards that licensed estheticians are required to meet."
**Response:** This proposal does not apply to estheticians. Estheticians are specifically trained, educated, and licensed to perform specific procedures and that specificity within the law supersedes the general restrictions of the surgery definition. Any limitations for other providers as a result of the surgery definition is not new but was already in place. This proposed change is a slight dialing back of some of the limitations. While this change removes certain injection-based procedures for cosmetic purposes from the definition of surgery, it does not allow all providers to perform these procedures. Instead, those providers who may inject medications within their scope, education, and experience will be able to perform these injection-based procedures for cosmetic purposes subject to a valid order and consistent with the standards of practice for their profession.

**Change to the text of the rule:** N/A

**Comment Received:** "These competencies are not setting-dependent. The skills, training, and decision-making required to safely perform procedures do not change based on whether care is delivered in a primary care office or an aesthetics practice."
**Response:** This is an expansion of scope for some providers, but is limited to certain cosmetic procedures that are deemed to be lower risk. The limitation allows for more predictable outcomes and reduced risk.
**Change to the text of the rule:** N/A

**Comment Received:** Commenters indicated that those actively practicing in the field should have more input in the regulatory language.
**Response:** The Department always welcomes input from the industry on regulations.
**Change to the text of the rule:** N/A

**Comment Received:** "The current model allows for safe delegation, oversight, and collaboration among healthcare professionals. By limiting the recognize[d] scope so significantly, the proposed regulations risk disrupting this collaborative model of care."
**Response:** This proposed regulation does not alter delegation, oversight, and collaboration.
**Change to the text of the rule:** N/A

**Comment Received:** The commenters expressed “concern regarding the accessibility of the rulemaking process. The limited visibility of the public notice and the requirement for submission of comments by traditional mail present barriers to meaningful stakeholder engagement."
**Response:** RIDOH notes that the public notice was available in multiple locations including the RIDOH website, the Rhode Island Code of Regulations website, and through the Department’s email distribution list. Furthermore, there was no requirement to submit comments by mail, as all notices contained an email address where comments could be submitted. The public notice of proposed rulemaking contains the following language: “All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until April 1, 2026 by contacting the appropriate party at the address listed below: Department of Health, 3 Capitol Hill, Room 403, Providence, RI 02908, zachary.garceau@health.ri.gov.”
**Change to the text of the rule:** N/A

**Comment Received:** "More concerning is the Department's apparent position that these procedures fall outside the scope of practice for Nurse Practitioners, Physician Assistants, and Registered Nurses. This position is inconsistent with long-standing practice in Rhode Island and across the United States. These same providers are entrusted to perform far more invasive and higher-risk procedures in hospitals, surgical centers, and other medical settings."
**Response:** This proposed regulation is an expansion of scope recognizing evolving cosmetic industry.
**Change to the text of the rule:** N/A
**Comment Received:** "Is the Department suggesting that these licensed professionals should no longer be permitted to perform procedures within their training and competency? If so, the implications for access to care in Rhode Island would be significant and detrimental. The Department cannot simultaneously rely on these providers in broader healthcare delivery while excluding them from aesthetic practice without a rational, evidence-based justification."
**Response:** This proposed regulation is an expansion, not a reduction of scope. It is a requirement for all license types to only practice within their scope, and also within the training and experience for each practice being performed under that scope.
**Change to the text of the rule:** N/A

**Comment Received:** "Cosmetic Medical Procedures are *medical procedures* with benefits, risks and complications. Creating different definitions, scope of practice and safety guidelines in for cosmetic settings is a formula that risks injury to patients. A few serious complications include blindness, blood vessel damage, scarring and discoloration."
**Response:** RIDOH agrees that these are medical procedures. RIDOH (through the Center for Healthcare Facility Regulation and the Center for Professional Boards and Licensing) continues to address any complaints from patients or healthcare providers about care received as part of cosmetic procedures or in medical spas. Licensing these facilities will allow RIDOH to sanction facilities, their practitioner owners, and the practitioners themselves should the standard of care not be met. This definition change is an expansion, of scope for some license holders but is

limited to certain injection-based procedures for cosmetic purposes that are deemed to be lower risk. The limitation allows for more predictable outcomes and reduced risk. Further, the providers who will now be able to perform these procedures are already able to inject medications within scope so there is some overlap with the training and education needed to safely perform the certain injection-based procedures for cosmetic purposes. Additionally, the department is in the process of creating medical spa facility regulations, which will provide more expectations on training, experience, and competency, including contraindications to and possible complications of these procedures.
**Change to the text of the rule:** N/A

**Comment Received:** "Physicians, surgeons, the AMA and the national surgical organizations like the American Society of Plastic Surgery ought to be the ones who define surgery. All of these groups would challenge the proposed regulation change. The terminology used in the proposed rule is inaccurate and incomplete."
**Response:** The Department, when creating regulations, consults experts and takes into account many perspectives.
**Change to the text of the rule:** N/A

**Comment Received:** "Every package of hyaluronic acid filler carries a label that [it] contains an "injectable implant," and inserting an implant is surgery. The changes proposed do not align with national standards determined by Surgeons! PRP and PRF/PRFM gel thus classifies as a surgical procedure. Hyaluronic acid is also used in gel form by Orthopedic specialists for intra-articular injection, typically for knees or shoulders. Again, these prescription compounds will indeed change structure and function and would therefore be classified as surgical interventions."
**Response:** RIDOH has made amendments to the proposed regulatory language that clarifies that this does not apply to PRP and PRF used for non-cosmetic purposes, which is surgery.
**Change to the text of the rule:** The proposed language will now read as follows: “Notwithstanding the above, the following injection procedures are not considered surgery: FDA-approved Botulinum toxin type A (BoNT-A) products for cosmetic purposes, FDA-approved dermal filler for cosmetic purposes, Platelet-Rich Fibrin for cosmetic purposes, and Platelet-Rich Plasma for cosmetic purposes.”

**Comment Received:** "If Rhode Island wants to align with Massachusetts, where the Nursing board, not plastic surgery and dermatology physician experts, has determined scope of cosmetic practice, how about RI lining up medical reimbursement rates with Massachusetts?"
**Response:** This comment is not germane to the proposed regulatory change and therefore will not be addressed at this time.
**Change to the text of the rule:** N/A

**Comment Received:** "We have a primary care crisis in RI! During the course of my career, midlevels like PAs and APRNs were promoted as a way to increase the primary care workforce. A recent AMA study state[s], "Nationwide data from the American Association of Nurse Practitioners shows the 89% of APRNs are trained and certified in primary care, yet multiple

workforce studies show that only 1/4 to 1/3 practice in primary care," The most common practice setting for the remainder is cosmetic and non[-]traditional practices. In States where APRNs have independent practice authority, many APRNs seem to specifically train so they can open medical spas…Physician practices are also small businesses, except our overhead is greater given the costs of longer, comprehensive training, debt, and malpractice insurance (which shockingly is not required for NPs?!) referenced above. RI physicians deserve respect for their expertise and support for their small business."
**Response:** This comment is not germane to the proposed regulatory change and therefore will not be addressed at this time.
**Change to the text of the rule:** N/A

**Comment Received:** "Inspection of facilities and monitoring for compliance is complaint-driven, thus it is challenging to identify problem practitioners before patients are harmed. Complaint driven safety policy places a heavy burden on our Department of Health."
**Response:** This comment is not germane to the proposed regulatory change and therefore will not be addressed at this time.
**Change to the text of the rule:** N/A

**Comment Received:** "Redefining surgery may be a ploy to allow non-physicians to perform more invasive procedures. Is this a strategy by non[-]physicians to avoid being sued for performing surgery?"
**Response:** This is action by RIDOH and not any particular group. This comment is not germane to the proposed regulatory change.
**Change to the text of the rule:** N/A

**Comment Received:** "In addition, studies demonstrate that patients who visit medical spas support More regulation, not less."
**Response:** The Department is in the process of creating regulations related to medical spa facilities.
**Change to the text of the rule:** N/A

**Comment Received:** "Allowing non-physicians more scope in cosmetic practices is a slap in the face for RI physicians."
**Response:** The Department, when creating regulations, consults experts and takes into account many perspectives.
**Change to the text of the rule:** N/A

**Comment Received:** “The definition of surgery is established in Rhode Island statute governing the practice of medicine and has long been interpreted and applied by the Board of Medical Licensure and Discipline (BMLD) as the standard for what constitutes surgical practice in this state. Any effort to modify or narrow that definition through regulatory change raises significant concerns, particularly when driven by stakeholders outside of physician licensure and oversight. Altering this definition in regulation, rather than through the appropriate statutory and clinical channels, risks creating inconsistency and confusion in how medical care is

defined, delivered, and regulated....We are also concerned about the broader implications of redefining surgery in a piecemeal way. Once the definition begins to shift based on setting or business model, it creates a precedent that may gradually erode appropriate safeguards around procedures that carry meaningful risk."
**Response:** Surgery is not defined in state statute and is currently defined in regulations promulgated by RIDOH. These changes are not based on the setting in which the procedures are performed.
**Change to the text of the rule:** N/A

**Comment Received:** "We also note that the proposed approach does not align with how other states are addressing these issues. While some states, such as Massachusetts, have issued guidance through nursing boards on cosmetic procedures, those frameworks still recognize clear limitations, training requirements, and the role of prescribers and supervising clinicians in patient care. Rhode Island should be cautious about adopting changes that may weaken, rather than clarify, accountability and oversight."
**Response:** RIDOH notes that accountability and oversight over cosmetic procedures is provided the same way as all medical procedures, through the supervision of compliance of both professional licenses and facility licenses by the Department and its boards.
**Change to the text of the rule:** N/A

**Comment Received:** "The medical procedures described which use Food and Drug Administration (FDA)-regulated devices, such as those that can alter or cause biologic change or damage, should only be performed by a physician or appropriately trained non-physician personnel under the direct, onsite supervision of an appropriately trained physician."
**Response:** The Department, when creating regulations, consults experts and takes into account many perspectives.
**Change to the text of the rule:** N/A

**Comment Received:** "This amendment jeopardizes patient safety and disregards what is considered adequate and appropriate medical education and training. Quality patient care includes evaluating a patient's needs and condition(s), selecting an appropriate course of treatment and providing adequate follow-up care....As with other cutaneous procedures, it is necessary to receive adequate training before using soft-tissue augmentation agents."
**Response:** This is outside the scope of the proposed amendments for a definition.
**Change to the text of the rule:** N/A

**Comment Received:** "Studies have shown an increase in patient complications from non-physicians performing cosmetic medical procedures at med spas. Respondents reported a higher rate of moderate adverse events when having cosmetic medical procedures done by a non-physician provider, at 73.3%, compared to a physician provider, at 41.8%. There is less physician involvement in procedures and higher complication rates of certain cosmetic medical procedures, including minimally invasive skin tightening and nonsurgical fat reduction, at medical spas compared to physician's offices."

**Response:** These regulations do not speak to setting, whereas the department is in the process of creating medical spa facility regulations.
**Change to the text of the rule:** N/A

**Comment Received:** "patients should be assured that individuals who perform these types of surgery are licensed physicians who meet appropriate professional standards. The public and medical community rely on the Department of Health to put in place guardrails to protect patient safety and give them confidence that medical procedures will be performed as safely and competently as possible. It is in all of our best interest that the DOH continue to perform that independent role and maintain the current regulations."
**Response:** This regulatory change has a limited expansion of scope for non-physicians. Patient safety is one of the primary concerns of the Department, when creating or amending regulations.
**Change to the text of the rule:** N/A

**Comment Received:** "The author(s) included only one specific neurotoxin: Onabotulinumtoxin A (Botox Cosmetic). There are 4 other FDA approved neurotoxins, and this omission speaks to the limited understanding of the author(s). Are the proponents nonphysicians seeking to avoid liability for practicing surgery?"
**Response:** The FDA-approved neurotoxins are addressed by the amendments to the language. Any provider practicing any procedure must carry malpractice insurance.
**Change to the text of the rule:** N/A

**Comment Received:** "With respect to the use of botulinum toxin, policy makers must acknowledge that inappropriate use and complications from the procedure occur at higher rates in medical spas than in tradition[al] medical office settings."
**Response:** These regulations do not speak to setting, whereas the department is in the process of creating medical spa facility regulations.
**Change to the text of the rule:** N/A

**Comment Received:** "The specialties of dermatology, orthopedics, pain medicine and genitourinary each use PRP and PRF at different concentrations and various blood donor amounts. The procedure requires removal of blood from the patient, centrifuging it and separating the resultant layers, i.e. a process that requires care, training and awareness of the risks of blood borne pathogens."
**Response:** The department is in the process of creating medical spa facility regulations, which will provide more expectations on training, experience, and competency, including contraindications to and possible complications of these procedures.
**Change to the text of the rule:** N/A

**Comment Received:** "We ask does a regulation that makes PRP and PRF/PRFM non-surgical open its use for joint injection and off-label injection for other purposes to non-physicians?"
**Response:** The carve out from surgery of PRP and PRF/PRFM for cosmetic purposes is limited to the definition of “cosmetic procedures” provided in R.I. Gen. Laws § 23-105-1(4).

**Change to the text of the rule:** N/A

**Comment Received:** "The standards for training, practice, malpractice insurance and management of complications should not be lower than those in a traditional medical setting."
**Response:** These regulations do not speak to setting, whereas the department is in the process of creating medical spa facility regulations. The standards for these limited procedures are not being changed.
**Change to the text of the rule:** N/A

**Comment Received:** "Expanding what non-physicians can do in a medical spa is also diluting the primary care workforce."
**Response:** The Department is aware of the various challenges that the state faces in recruiting and retaining its primary care workforce.
**Change to the text of the rule:** N/A

**CHANGES TO THE TEXT OF THE RULE:**

The proposed language is being revised to read as follows:

Notwithstanding the above, the following injection procedures ~~of the following medications and autologous plasma products for cosmetic purposes is~~ are not considered surgery: FDA-approved ~~Ona~~Bb otulinum toxin type A (BoNT-A) products for cosmetic purposes, FDA-approved ~~hyaluronic acid~~ dermal filler for cosmetic purposes, Platelet-Rich Fibrin for cosmetic purposes, and Platelet-Rich Plasma for cosmetic purposes.¶

**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.