

Oregon Board of Naturopathic Medicine – Injection Therapy Subcommittee
February 12, 2020 @ 1130-1pm. PSOB Room 445

Present: Mary-Beth Baptista, Ex. Director; Dr. Terrance Manning; Dr. Ryan Minarik, Dr. Sam Oltman

Present via Conference Line: Dr. Robert Strait; Dr. Don McBride

NEXT MEETING: Wednesday, February 26, 2020 @ 1130-1PM. PSOB Room 445

MINUTES:

PART 1: Meeting opened with each participant stating their desired outcomes for the meeting as well as the end product. Including:

- Rules should be separated by therapy. Rules directed at defining what training / hours / content is necessary for each therapy.
- Specific rules regarding what “counts” as CE – who is qualified to teach based on experience and frequency of engaging in the therapy, what substantively needs to be taught and how – practical / hands on training – or CE classes – or combination of both.
- Set rules that ensure minimum competency skill set of the practitioner and safety to patient / public.
- Rules should be delineated by target of the injective, to ensure the doctor is safely injecting the needle and safely engaging in the movement of the needle in that area of the body
- Rules and Board action should be proactive because this therapy is growing and will only become a larger part of the practice of the profession and want to ensure the integrity of profession with the appropriate level of training.
- Should consider rules that require hands on training as well as a practical exam.
- Should look to the Midwifery Certification process and requirements as the guide for rules / requirements for injection therapy.
- Should require CE explaining to doctors how to vet products to protect against falling for potentially abusive marketing processes.
- Rules will also need to address those that have been practicing and criteria based ways to “grandfather” current practitioners in.
- IV therapy is separate from injection therapy (and vice versa) and should remain separate in the rules. Rules IV Ozone and Injection Ozone should be separated by IV / Injection.

Executive Director Baptista (ED) explained the following:

- Guidelines – Guidelines are not rules. A licensee cannot be found in violation and disciplined for a violation of a guideline. However, guidelines inform practitioners what may be viewed as best / or standards of practice that one should adhere to ensure they are not negligently engaging in this area of practice. Some topics that arise in the subcommittee may be more appropriately handled in guideline rather than rule. Used Opioid Guidelines by way of example.

- Administrative Rules: Rule making authority rests with the Board. The process of rulemaking involves putting out a notice that solicits public comment on the rule. After a period of public comment the Board may choose to incorporate (or not) the public comment and the Board has approval authority for what is contained in the final draft of the rule.
- Rule 850-060-0212: The Board established a subcommittee of experienced stake holders to assist in proposing draft language for the aforementioned rule. The Board is the body that decides on the text of the rule, and the Board has final approval authority.
- Oregon Revised Statutes: Statutory authority rests with the legislature. The Board may submit legislative concepts to the governor for consideration of statutory changes. The next deadline to submit statutory changes for the next biennium is April 2020.
- The Board may not make rules that are contrary to Statute.
- Statutes and Rules are “the floor – not the ceiling” when regulating Licensee behavior / practice.
- The Board has developed a positive and supportive relationship with OANP. There are things that may come up in the rule making process that may be best handled by the association rather than the regulatory authority.

PART II: Subcommittee discussed their ideas on how to structure the rule. Members decided to start with delineating “levels” of skill / education / risk by both “target” and “injectate.” Members lean toward the “target” being the driver of the rules – and that the risk of harm from “injectate” may increase or decrease based on the “target” of the injection. Members created the initial frame work:

TARGET:

Level 1: Subcutaneous (Sub Q) / Intramuscular (IM)

- Facial
- Genitals
- Sub Q nerves

Level 2: Extremities / Tendons / Ligaments

- Peripheral nerve
- Ankles
- Wrists
- Elbows
- Intermuscular joints

Level 3: Spine / (TBD: Intraosseous)

- Nerve root
- Spinal nerve
- Cervical thoracic lumbar
- (TBD: Bone Marrow)

INJECTATE:

Level 1: Prepared Injectate

- Dextrose
- Antisialagogues
- Steroid
- Ozone
- Botox
- Allogeneic

Level 2: Autologous

- Platelet-rich Plasma (PRP)
- Adipose

NEXT STEPS:

1. Research and prepare to discuss proposals for how to structure the rule around intersection of both / either “target” and “injectate”
2. Research and discuss training / education regulations for competency to engage in each level of injection therapy.
3. Research and prepare to discuss proposals for regulating experience to provide training / education
4. Research and provide written explanation regarding scope of practice and statutory authority to engage Intraosseous injections
5. Research and provide written explanation regarding scope of practice and statutory authority to engage Intraosseous injections
6. Review related Administrative Rules for consistency of proposals and ORS to determine if proposals are in-line with / or contrary to Statute.

MEETING #2

Injection Therapy Subcommittee – Minutes

Wednesday, February 26, 2020 – 11:30-1pm

Portland State Building – Room 445

ATTENDANCE:

Present: ED Mary-Beth Baptista, Bd Invg. Doug Cook, Dr. Ryan Minarik, Dr. Sam Oltman, Dr. Terrance Manning II

VIA Teleconference: Dr. Robert Straight, Dr. Tyna Moore, Board Representative Dr. Tracy Erfling; Dr. Stacey Guggino, Dr. Don McBride

NEXT MEETING: Wednesday, March 11, 2020 – 11:30-1pm. Portland State Building – Room 445

1. Unanimous Approval of 2.12.2020 Injection Therapy Subcommittee – DRAFT Minutes

2. Review Public Meetings / Public Records Laws: This rules committee is a public body subject to public meeting laws. Public meeting laws require public bodies to work in public. This includes email communication. If one or more members are discussing committee business via email – it could be construed as a closed group meeting in violation of public meeting laws.

Public meeting laws allow for information to be disseminated to the group from one sender, and one member can reply to sender. In the future it is best to send all communications to ED MBB to distribute to the group.

3. Review Rules Sub-Committee Role / Advisory Committee: Rule 850-060-0212: The Board established this subcommittee of experienced stake holders to assist in proposing draft language for the aforementioned rule. The purpose of this subcommittee is to advise the Board's development of Rule OAR 850-060-0212. The Board will take the subcommittees' recommendations into consideration when they decide on the text / requirements to include in the rule. All rule making authority rests with the Board.

4. Reviewed Dr. Minarik email (Attachment A) proposing a starting point for the discussion regarding the structure and substance of the rule.

- Discussed creating “Levels” based on the difficulty / risks associated with the location of injection.
 - Level 1 – SQ / IM
 - Level 2- Extremity / Tendon / Ligament (incl joint)
 - Level 3 – Spine
- Discussed creating two “Categories” of injectate
 - Category A: Prepared (Commercially / Compounded Sterile) *Default designation
 - Category B: Autologous (of cells / tissues)

5. Discuss training / education regulations for competency to engage in each level of injection therapy of Category A:

- Level 1(A): 6 hours of training / education
 - 3 practical / 3 didactic
 - Focus: anatomy, injection technique, aseptic / sterility, palpating
- Level 2(A): Two options proposed and discussed. Group moved forward with the following:
 - Option 1: Total 32 hours required. Training / CE hours broken down as follows:
 - Foot / Ankle: 4 hours
 - Hand / Wrist: 4 hours
 - Elbow: 4 hours
 - Knee: 6 hours
 - Hip: 6 hours
 - Shoulder: 8 hours
 - Proposals for Focus / Substance of the CE Training: diagnostic, care management; didactic; medical imaging
- Level 3(A): Discussed breaking training down similarly to Level 2(A) for regions of the spine: lumbar, thoracic, cervical. Proposals for CE / Training requirements included:
 - Medical Imaging
 - Guidance Techniques
 - Preceptorship / Residency

6. ACTION ITEMS:

- Dr. Manning will research training / education requirements recommended by the Spinal Intervention Society
- MB Baptista will contact the Board of Medical Imaging

7. Agenda Items for Meeting #3 – March 11, 2020

- Continue discussion regarding education / training hours and substance of education / training for Level 2(A) and Level 3 (A) (B)
- Discuss proposals for regulating experience to offer training / provide education
- Discuss proposals for rule implementation:
 - Application of CE / training toward annually required CE for renewal
 - Maintenance / “renewal” requirements
 - Requirements for current practitioners

Mary-Beth Baptista

From: Dr. Ryan Minarik <drminarik@elixiawellness.com>
Sent: Wednesday, February 26, 2020 10:07 AM
To: Mary-Beth Baptista
Subject: Re: Injection Therapy Administrative Rule Subcommittee: Wednesday 2/26 @ 1130am-1pm (w/CALL IN #)

Hi Mary-Beth,

For what it's worth, I came up with a proposed starting point for CE requirements, as a springboard for discussion. This may be/look too confusing initially, but its an idea of how to stratify levels of injections and injectates with training requirements.

OBNM Injection Therapy

Location

- Level 1: SQ/IM
- Level 2: Extremity/Tendon/Ligament (inc joint)
- Level 3: Spine

Injectate

- Category A: Prepared (Commercially/Compounded Sterile). *Default designation
- Category B: Autologous

CE Requirements

- Questions:
 - - Initial hours required for certification?
 - Grandfathered for NDs in already in practice?
 - Maintenance/Renewal reqs?
 - What constitutes "training"?
 - Hours vs supervised patient encounters?
 - *Level trainings would automatically include category A injectates, with additional training guidelines for botox. Use of ozone has its own separate training/CE reqs, so level 1+ injections of ozone would presume appropriate training has simultaneously been met.
- Level 1A:
 - - Initial: 6 hours. (or sufficient with graduation/medial license? This might be issue with botox training)
 - Grandfathered: 5+ years in practice
 - Maintenance/Renewal: Not required
- Level 2A:
 - - Initial: 16-32 (?) hours within 2 years (2 weekend courses)
 - Grandfathered: If 5+ years in practice, evidence of 16-32 hours training over course of licensure
 - Maintenance/Renewal: 16 hours level 2 training every 5 years.
- Level 3A:

- - Initial: 16 hours within 2 years
 - Grandfathered: Proof of 8+ hours of spine specific training
 - Maintenance/Renewal: 20 hours level 2-3 total training every 5 years. *Image guidance training qualifies?
- Category B (would automatically apply to any Level achieved):
 - - Initial: 8-16 (?) hours specific to autologous products and preparation (not injection technique)
 - Grandfathered: ?
 - Maintenance/Renewal: 6 hours every 5 years

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Ryan Minarik, ND, LAc.
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On Tue, Feb 25, 2020 at 2:27 PM Mary-Beth Baptista <marybeth.baptista@state.or.us> wrote:

PLEASE DO NOT REPLY ALL – REPLY ONLY TO SENDER

Hello All,

Thank you for your participation in the injection rules subcommittee. As a reminder the second meeting is tomorrow, Wednesday, Feb 26 at 11:30am, Room 445, at the State Office Building (800 NE Oregon Street) Please see attached agenda.

Please note we will validate your parking at [Liberty Centre Building](#), 650 NE Oregon St (Lloyd District), Portland, OR 97232

For those of you that would like to participate in the meeting tomorrow by phone:

Injection Subcommittee DRAFT MINUTES 3.11.2020 – Meeting #3.

PSOB room 445; 1130-1pm

ATTENDANCE:

Present: ED Mary-Beth Baptista, Dr. Ryan Minarik, Dr. Sam Oltman, Dr. Terrance Manning II

Via Teleconference: Dr. Robert Straight, Dr. Tyna Moore, Board Representative Dr. Tracy Erfling; Dr. Stacy Guggino, Dr. Don McBride

NEXT MEETING: Wednesday, April 1, 2020 – 1130-1pm.

1. Subcommittee approved Feb. 26, 2020, without correction or addition from the Rules Subcommittee.
2. Board continued the discussion from Feb. 26, regarding training and education requirements for Level 3A and 3B – Spinal Injections: Lumbar / Thoracic / Cervical.

Dir Baptista distributed information from Richard Wendt, OHA, regarding fluoroscopy training. Dr. Manning researched training requirements from the Spinal Intervention Society (SIS). Dr. Manning relayed that SIS requires a two day training in each of the three areas of the spine. Approximately 50 total hours to be “Board Certified” in three areas.

Dr. McBride discussed Doctors in Osteopathy are required to obtain approximately 30 total hours of training prior to engaging in spinal injections. ED Baptista cautioned against the term “board certified” and discussed the difference b/w “certification” and baseline training required to engage in the practice.

Group discussion regarding DO training requirements in comparison to ND training requirements. Discussion regarding DO complete residencies, while ND’s do not. Members discussed whether or not that distinction should affect the amount of required hours of training.

3. Group started discussion regarding appropriate total hours per 3 areas of spine: a total of 14-16 hours; 8 of which practical. Plus an additional 8 hours of didactic, to include: 2.5-3 hours of Image Spine Guidance/ Ultra Sound/ Flouro / X-ray. Total 50-56 hours
4. Further discussion regarding the amount of hours exceeding DO requirements, also discussed Board history of requiring hours based on / exceeding other equivalent licensing Boards. Keeping in mind that training for Level 1 & 2 – prior to training for Level 3. Discussed a target of 32 hours. 8 hours per spinal region; and an additional 8 hours of didactic, to include: 2.5-3 hours of Image Spine Guidance/ Ultra Sound/ Flouro / X-ray.
5. PLACEHOLDER: Further discussion needed whether or not a certain amount of practical hours or number of injections required prior to entry into practice, akin to a residency / mentorship. Or whether the training required is sufficient to enter into practice. Training floor v. Practical Hours ceiling.

6. Agenda Items:

- Entry to practice requirements (if necessary)
- Discuss proposals for approval / regulating experience to offer training / provide education & training
- Discuss proposals for rule implementation:
 - Application of CE / training toward annually required CE for renewal total
 - Maintenance of education / secondary training and required time frame.
 - Adjusting requirements for current practitioners – how to implement “grandfather” clauses