

Significant Legislative Rule Analysis

Chapter 246-803 WAC

Rules Concerning
East Asian Medicine Practitioners

August 30, 2019

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

Chapter 246-803 WAC – East Asian medicine practitioner was opened by the Department of Health (department) to clarify, streamline, and update regulations for licensed East Asian medicine practitioners in Washington State. A comprehensive review of the chapter had not been done since 2014, and the existing rules are outdated and conflict with current law and practice. The proposed rule amendments are necessary to provide clear, current, and enforceable regulations for East Asian medicine practitioners.

In addition to the department’s decision to update chapter 246-803 WAC, RCW 43.70.041 was passed in 2013 requiring the department to conduct a formal review all of its existing rules every five years to identify ways to clarify or simplify existing rules in order to reduce the regulatory burden on businesses without compromising public health and safety. Complying with RCW 43.70.041 aligned with the department’s decision to update chapter 246-803 WAC; the proposed rules are the result of both of these efforts.

The department is proposing rule amendments to:

- Make general housekeeping and clarification changes;
- Add updated and current definitions; and
- Amend the patient notification of qualifications and scope of practice requirements.

In addition, the department is proposing new rules for:

1. Patient record content details the clinical information that is required to be included in a patient record, which must be in English and be legible, complete and accurate;
2. Patient abandonment establishes the requirement than an East Asian medicine practitioner shall respond to any reasonable request for services in the interest of public health and welfare;
3. Instrument sterilization procedure requires East Asian medicine practitioners to follow the 7th edition of “Best Practices for Acupuncture Needles Safety and Related Procedures” published by the Council of Colleges for Acupuncture and Oriental Medicine revised May 2017;
4. Preparing and maintaining a clean field for each patient. A clean field is the area that has been prepared to contain the equipment necessary for acupuncture in such a way as to reduce the possible contamination of sterile needles and other clean or sterile equipment; and
5. Expired license rule defines how an East Asian medicine practitioner with an expired license may return his or her license to an active license.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes, a significant analysis is required for the proposed rules. As defined in RCW 34.05.328, the proposed rules amend requirements for obtaining or maintaining a license, the violation of which may subject a licensee to a penalty or sanction.

However, the department has determined that no significant analysis is required for the following portions of the proposed rules:

Table 1: Non-Significant Rule Identification

#	WAC Section	Section Title	Justification
1	WAC 246-803-010 (Amended)	Definitions	The proposed rule does not meet the definition of a significant legislative rule under RCW 34.05.328(5)(c).
2	WAC 246-803-030 (Amended)	East Asian medicine	The proposed change is exempt from analysis because it made only grammatical changes for readability under RCW 34.05.328(5)(c).
3	WAC 246-803-300 (Amended)	Patient notification of qualifications and scope of practice	The proposed additions are exempt from analysis under RCW 34.05.328(5)(b)(v). It is specifically dictated in RCW 18.06.130.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Chapter 18.06 RCW establishes the requirements to practice as an East Asian medicine practitioner (EAMP). The legislative intent of chapter 18.06 RCW is to recognize that EAMP’s engage in a system of medicine, which includes more than just acupuncture, to maintain and promote wellness and to prevent, diagnose, and treat disease by drawing upon experience, learning, and traditions originating in East Asia. The statutory goal is to change the state’s professional designation of acupuncturists to EAMP’s and to incorporate current statutory provisions governing acupuncture while recognizing treatments, methods, and techniques used in East Asian medicine.

The proposed rules are used to assure the public’s health and protection by implementing the following objectives:

- Having clear and concise patient records;
- Having requirements to avoid patient abandonment;
- Having instrument sterilization procedures; and

- Preparing and maintaining a clean field.
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SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rules will achieve the authorizing statute's goals and objectives by providing up-to-date requirements that are clear, concise and necessary to assure patient safety.

The Department of Health has assessed and determined that there are no feasible alternatives to rulemaking as rules are required by statute. These standards need to be established in rule to be enforced.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the proposed amendments and new rules that are significant are analyzed below. As discussed above, other portions of the proposed rules are not significant and are therefore not included in this analysis.

It is noted that Department staff conducted a small poll of three licensed Washington EAMPs to determine the impact of the proposed rules for WAC 246-803-130, 246-803-305, 246-803-308, 246-803-320 and 246-803-325. The three licensees were members of the Acupuncture and Eastern Medicine Advisory Committee and represented large and small practices and are located in Seattle, Spokane and Yakima.

WAC 246-803-130 Application requirements for applicants from foreign schools

Rule Overview - The proposed amendment changes the credentialing evaluation company from the American Association of Collegiate Registrars and Admissions Officers (AACRAO) to the International Consultants of Delaware (ICD). The department is amending the rule to delete AACRAO as they no longer do credential evaluations.

The department requires all applicants for licensure to take and pass the applicable portions of the National Certification Commission on Acupuncture and Oriental Medicine (NCCAOM) exams. In order to sit for these exams, the NCCAOM requires all applicants from foreign schools to submit a credentialing evaluation report from ICD. The ICD is the recognized credentialing

service that reviews the transcripts to determine if an applicant's education is substantially equal to the graduates of approved schools. The department estimates that it will take approximately four to seven hours for an applicant to collect, organize and send in the required information. This is approximately the same amount of time that it took to collect, organize and send in the required information to AACRAO.

The department does not have the staff time or expertise to evaluate transcripts from foreign schools. The ICD charges \$75.00 for a general statement evaluation and \$175.00 for a course-by-course evaluation that includes the grade point average to review an applicant's records. The AACRAO charged \$75.00 for a basic statement of comparability and \$190.00 for a course-by-course evaluation to review an applicant's records. This results in a cost savings of \$15.00 to the applicant. This allows the department to make a quicker determination on if the applicant meets the minimum education requirements.

The foreign trained applicant will have an additional cost prior to licensure, but the short time frame for licensure outweighs this cost.

WAC 246-803-305 Patient record content (New section)

Rule Overview – The proposed rule details clinical information required to be included in a patient record, which must be in English and be legible, complete, and accurate.

The proposed rule requires an East Asian medicine practitioner to maintain complete treatment records for patients treated. These records shall include:

- Name of the patient;
- Patient history;
- Dates of treatment;
- Treatment given; and
- Progress made during treatment.

In addition, the proposed rules:

- Require the practitioner to maintain a patient record for six years after the last treatment, or after the patient turns 18 years of age; and
- Clarify that the practitioner shall comply with chapter 70.02 RCW and the Health Insurance Portability and Accountability Act, 45 C.F.R. destruction and privacy regulations.

Rule Cost/Benefit Analysis – The benefit of the proposed rule is enhanced patient safety. Thorough, complete, legible, and accurate patient records are vital for patient safety and appropriate regulation. Requirements for patient record content are currently not provided in law. WAC 246-803-305 contains minimal guidance for EAMP's on patient record content. Thorough records are necessary to inform other treatment providers who subsequently treat the patient, as well as for the department when investigating complaints and regulating practitioners, including EAMPs.

There are expected costs for EAMPs to comply with the proposed rule in order to store and maintain the records for six years or until the patient turns 18. Department staff conducted a small poll of licensed Washington EAMPs to determine the impact of the proposed rule. Respondents indicated that an EAMP spends approximately ten minutes per patient on charting and that complying with the proposed rule will incur very little additional time. One could reasonably assume the proposed rule could result in two additional minutes per patient for record keeping. Accurate, legible and complete record keeping is good business practice, saving time and reducing duplication of effort. In addition to the benefit of an accurate record for patient safety, the increase in efficiency would offset the minor costs to record keeping.

WAC 246-803-308 Patient abandonment (New Section)

Rule Overview – The proposed new section establishes the requirement that an East Asian medicine practitioner shall respond to any reasonable request for services in the interest of public health and welfare.

The attending EAMP, without reasonable cause, shall not neglect, ignore, abandon, or refuse to treat a patient. If the practitioner chooses to withdraw responsibility for a patient of record, the practitioner shall:

- Advise the patient in writing that treatment is being terminated;
- Advise the patient to seek another East Asian medicine practitioner for future care; and
- The East Asian medicine practitioner shall remain reasonably available for up to fifteen calendar days from the date of the notice to address clinical concerns related to the care provided.

Rule Cost/Benefit Analysis – There are minimal expected costs for EAMPs to comply with this proposed rule. The poll indicated there would be minimal impact (cost and time) on their practice to address the termination of service in writing. The public will benefit by the assurance that EAMPs will have knowledge of statutory requirements on patient abandonment and that the current EAMP shall remain reasonably available for up to fifteen calendar days to address any clinical concerns related to the patient’s care.

WAC 246-803-320 Instrument sterilization procedures (New Section)

Rule Overview – The proposed new section requires East Asian medicine practitioners to follow the 7th edition of “Best Practices for Acupuncture Needles Safety and Related Procedures” published by the Council of Colleges for Acupuncture and Oriental Medicine revised May 2017 by:

- Using sterile instruments;
- Following proper instrument sterilization procedures including the use of biological monitors;
- Keeping accurate records of sterilization cycles; and
- Maintaining equipment service as described in the manufacturer’s instruction manual.

This rule does not apply to needles, which may not be re-used or sterilized for a subsequent use on more than one patient under any circumstances.

Rule Cost/Benefit Analysis – There are minimal expected costs for East Asian medicine practitioners to comply with this proposed rule. The poll indicated there would be minimal impact (cost and time) on their practice to comply with the proposed rule. All practitioners are required to take the Clean Needle Technique Course while in their East Asian medicine educational program. They are required to follow the best practices while in their clinical rotations.

While this proposed change would create a new requirement in rule, all EAMPs have the required knowledge and education to implement this requirement if they are already licensed.

Acupuncture Practice Examples	Disinfectant Level Required before Reuse	Disinfecting Procedure
BP cuff, Stethoscope, e- stim clips.	<p>Low or intermediate disinfecting agents acceptable.</p> <p>Disinfect between each patient. This will take between 3 to 5 minutes each time.</p>	<p>Fabric equipment (BP cuffs) may be disinfected with isopropyl alcohol EPA approved solutions for non- critical items. Smooth surfaces can be disinfected through 2 steps: soap and water cleansing followed by wiping with a low or intermediate disinfecting agent.</p> <p>Step 1 Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water.</p> <p>Step 2 Soak in appropriate FDA-cleared disinfectant for the time indicated for reusable equipment. Follow label directions for use as an intermediate disinfecting agent.</p>
Cups or gua sha tools used over intact skin.	<p>Intermediate disinfecting agents required.</p> <p>Sterilize before reuse. This will take between 3 to 5 minutes per use.</p>	<p><u>Step 1</u> Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water.</p> <p><u>Step 2</u> Soak in appropriate FDA-cleared disinfectant for the time indicated for reusable equipment. Follow label directions for use as an intermediate disinfecting agent.</p>

		agent.
All cups used for wet cupping; cups and gua sha spoons used on non-intact skin.	Sterilize before reuse; or high- level disinfectant required. This will take between 3 to 5 minutes per use.	<u>Step 1</u> Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water. <u>Step 2</u> <u>Option 1</u> : Autoclave. <u>Option 2</u> : Soak in high-level disinfectant (e.g., Sporox, Sterrad, Acecide, Endospore, Peract) as per product label instructions.
Equipment that breaks the skin or enters the vascular system; <u>No acupuncture and Oriental medicine (AOM) equipment falls into this category.</u>	Must be sterilized.	Example: autoclave.

If the EAMP uses an autoclave, the tools must be sterilized weekly with the autoclave log completed each time it is used. The equipment needs to be maintained and serviced according to the manufacturer’s instruction manual.

The public will benefit by the assurance that EAMPs will have knowledge of requirements for best practices for acupuncture needle safety and related procedures and assurance that the tools being used have been sterilized.

WAC 246-803-325 Preparing and maintaining a clean field (New Section)

Rule Overview: The proposed new section requires an East Asian medicine practitioner to prepare and maintain a clean field for each patient. A clean field is the area that has been prepared to contain the equipment necessary for acupuncture in such a way as to reduce the possible contamination of sterile needles and other clean or sterile equipment. An East Asian medicine practitioner was not previously required to maintain a clean field or to disinfect the treatment room.

Rule Cost/Benefit Analysis: There are minimal expected costs for East Asian medicine practitioners to comply with this proposed rule. The poll indicated there would be minimal impact (cost and time) on their practice to comply with the proposed rule. If an EAMP is not currently preparing and maintaining a clean field for each new patient, this may add a minimum amount of time to prepare this for each new patient interaction. A clean field is the area that has been prepared to contain the equipment necessary for acupuncture in such a way as to reduce the possible contamination of sterile needles and other clean or sterile equipment. A clean field uses

a clean, dry, flat surface to place materials such as acupuncture needles, clean cotton balls or unopened swabs. The surface used for the clean field is to be cleaned with a low-level disinfectant between each patient. However, based on the risk of contamination of sterile needles and other equipment, this proposed rule creates new and important benefits to both the patient and practitioner.

WAC 246-803-410 Expired license (New Section)

Rule Overview: The proposed rule defines how an East Asian medicine practitioner with an expired license may return their license to an active license.

- A East Asian medicine practitioner whose license is expired for one year or less must:
 - Meet the requirements of chapter 246-12 WAC; and
 - Pay the applicable fees to renew. The fees consist of:

1. Renewal fee	\$196.00
2. Late Renewal Penalty	<u>\$ 50.00</u>
3. Total	\$246.00

- A East Asian medicine practitioner whose license has expired for more than one year but less than three must:
 - Meet the requirements of WAC 246-12-040(3)(b)(i) through (ix); and
 - Pay the applicable fees to renew. The fees consist of:

1. Renewal fee	\$196.00
2. Late renewal penalty	\$ 50.00
3. Expired license reissuance	<u>\$ 50.00</u>
4. Total	\$296.00

- A East Asian medicine practitioner whose license has expired for three years or more and has been engaged in practice in another state or United States jurisdiction must:
 - Provide verification of active practice from any other state or United States jurisdiction;
 - Meet the requirements of WAC 246-12-040(3)(c)(i) through (xi); and
 - Pay the applicable fees to renew. The fees consist of:

1. Renewal fee	\$196.00
2. Late renewal penalty	\$ 50.00
3. Expired license reissuance	<u>\$ 50.00</u>
4. Total	\$296.00

- A East Asian medicine practitioner whose license has expired for three years or more and has not been engaged in practice in another state or United States jurisdiction must:
 - Meet the requirements of WAC 246-12-040(3)(b)(i) through (ix);
 - Pay the applicable fee to renew. The fees consist of:

1. Renewal fee	\$196.00
2. Late renewal penalty	\$ 50.00
3. Expired license reissuance	<u>\$ 50.00</u>
4. Total	\$296.00 and

- Complete extended course work preapproved by the department or
- Successfully retake and pass the examinations required in WAC 246-803-240.

The previous reinstatement requirements only required an East Asian medicine practitioner whose license has expired for 1 year or more to pay the renewal fee, late renewal penalty fee and the expired license reissuance fee.

Rule Cost/Benefit Analysis: In addition to paying late fee, the rule does impose additional costs to the licensed East Asian medicine practitioner if they have been expired for three years or more and have not been engaged in practice in another state or United States jurisdiction. If they wish to return to active practice, they must either complete extended course work preapproved by the department or successfully retake and pass the examinations required in WAC 246-803-240.

The associated costs for the National Certification Commission on Acupuncture and Oriental Medicine (NCCAOM) three examination modules are:

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|------------------------------------|------------------|
| ● Application Fee | \$ 595.00 |
| ● Foundations of Oriental Medicine | \$ 310.00 |
| ● Acupuncture with Point Location | \$ 310.00 |
| ● Biomedicine | <u>\$ 310.00</u> |
| ● Total | \$1,245.00 |

The NCCAOM certification/examination fee to send results to a state board vary from a low of \$45.00 to a high of \$150.00.

The option of completing extended course work that is preapproved by the department is new, the associated costs could greatly vary. The cost could be as little as \$0 for some online courses to \$200.00 or \$300.00 per course depending upon the course work that is being submitted for preapproval.

The benefit to the public of proposed rule amendment is that it ensures that East Asian medicine practitioners who have been out of practice are competent before providing care. There are potential costs to the EAMP returning to practice associated with taking an exam or completing extended course work preapproved by the department. However, the benefit of ensuring patient safety outweighs the personal financial costs to the EAMP.

Total Probable Cost versus Probable Benefit

There are costs for individuals to maintain a patient record. A patient record is the only documentation of what the EAMP saw clinically, what the treatment plan proposed was, what discussion was had with the patient about treatment alternative and consent, and what treatment was actually performed. A small informal survey was conducted in 2018 of three EAMP's. All three EAMP's indicated there would be minimal impact (cost and time) on their practice to comply with the proposed rules. The record is necessary for other treatment providers who will treat the patient in the future as well as for the department when investigating complaints and regulating practitioners. A complete and accurate patient record is vital for patient safety and for appropriate regulation.

The EAMP required to pay the costs associated with an expired license can be avoided if an active license is maintained.

The probable benefits of patient safety outweigh the probable costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The department developed the proposed rules collaboratively. The collaborative process included sending notice of the rule-making to the GovDelivery stakeholders and held five open public rules workshops. Four of the workshops were held in Kent and one was held in Vancouver. All the workshops were held during committee meetings and were noted on the East Asian Medicine Advisory Committee's agenda. The agenda was sent to GovDelivery and posted to the program's website.

Prior to the workshops, the department had sent out draft language to give the stakeholders a starting point. Many ideas were proposed, thoroughly discussed, and then accepted or rejected following a lengthy rule development phase with key stakeholders and interested parties. Some of the more significant proposed rule revisions, which were ultimately rejected, include the following:

- a) A proposal was considered that the need to have a rule on patient record content was not required. This proposal was ultimately rejected as there have been complaints received regarding record keeping and there were no rules to require patient records to be kept.
- b) A proposal was considered that the proposed rule on instrument sterilization procedure be removed from the draft language. This proposal was ultimately rejected as there are currently no requirements for a practitioner to use sterile instruments.

The proposed rules are the least burdensome alternative to those previously considered and ultimately rejected because they provide clarification, establish current standards, and align with national best practices for maintaining a practice. The proposal is responsive to the statutory goals and objectives to protect the public health, safety, and welfare through the regulation of the practice of East Asian medicine while simultaneously reducing unnecessary regulatory burdens on licensees and businesses without compromising public health and safety.

SECTION 7:

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

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

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

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

The proposed rule does not differ from any federal regulation or statute applicable to the same activity or subject matter.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

Yes, the rule is coordinated to the maximum extent practicable with other applicable laws including the East Asian medicine practitioner laws (chapter 18.06 RCW), and applicable provisions of the Uniform Disciplinary Act (chapter 18.130 RCW).