Report to the Legislature

Colon Hydrotherapy



Prepared by Medical Assistant Program Office of Health Professions



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Contents

Executive Summary	1
Background	2
Methodology	2
Current Practice in Other States	3
Current Practice in Washington	5
Recommendations	5
Education Requirements	9
Standards of Practice	9
Conclusion	10

Executive Summary

Colon hydrotherapy, also known as colonic irrigation, is a procedure to remove waste from the large intestine using temperature-controlled water. In 2008, the Washington Court of Appeals ruled that colonic irrigation is a practice of medicine. This ruling restricts the practice to physicians and their licensed delegates.

In 2020, the legislature introduced <u>Engrossed Substitute House Bill (ESHB) 2775</u>. This bill provided an avenue for non-physicians to practice colon hydrotherapy. Although the bill did not pass, the legislature included a budget proviso in <u>Engrossed Substitute Senate Bill 6168</u>. This directed the Department of Health (department) to review current statutes and qualification standards for colon hydrotherapy. The department was also instructed to study the certification of practices in other states. Finally, the department was directed to produce recommendations to create a colon hydrotherapy certification program in Washington.

As a result, the department identified several options to establish certification and qualification standards in Washington.

Credentialing Options

- 1. Expand the medical assistant-registered scope of practice to include colon hydrotherapy.
- 2. Create a new colon hydrotherapy certification under the Board of Naturopathy statute.
- 3. Create a new medical assistant profession: medical assistant-colon hydrotherapist. This is similar to the approach taken by ESHB 2775.

Education and Standard of Care Requirements

The department recommend specific education and training requirements to ensure appropriate standards are met. These include adopting national or international certifications or other equivalent trainings and education plans.

The department also found that standard of care requirements are necessary to ensure patient safety.

Background

Colon hydrotherapy—also known as colonic irrigation—is the removal of waste from the large intestine using warm water. Typically, modern colon hydrotherapists use prescription medical devices approved by the U.S. Food and Drug Administration (FDA).

In 2008, the Washington Court of Appeals affirmed a ruling by the department that colonic irrigation is a medical practice in <u>Yow v. The Department of Health Unlicensed Practice Program</u>. The department reflected this decision in a <u>January 2009 sunrise review</u> of colon hydrotherapy. The department found that the procedure is within the scope of practice of allopathic, osteopathic, and naturopathic physicians.

Physicians may delegate colon hydrotherapy procedures to other licensed persons, in limited circumstances. The delegating physician needs to ensure the appropriate training, competence, and supervision of the person. The procedure must also be within the scope of practice of the person performing the task.

In Washington, colon hydrotherapy procedures may be delegated, within the training and scopes of practice, to the following professions:

- allopathic physician assistants,
- osteopathic physician assistants,
- nurse practitioners,
- registered nurses,
- and licensed practical nurses.

Under current law, a person not licensed in one of the professions listed above may not perform or delegate colon hydrotherapy. Many working colon hydrotherapists in Washington do not hold a health care credential that allows them to perform the procedure.

During the 2020 legislative session, the legislature considered ESHB 2775. This bill proposed to establish a new type of medical assistant credential: a medical assistant-colon hydrotherapist. The bill failed to pass the Senate Rules Committee.

On April 3, 2020, the governor signed ESSB 6168, an act relating to fiscal matters. A proviso in this act, located in section 221 subsection 70, tasked the department to work with stakeholders to:

- Review current statutes, qualification standards, and certification practices in other states.
- Produce recommendations for implementing a certification program in Washington.

Methodology

The department invited the following stakeholders to participate in discussions on these topics:

- Washington Association of Colon Hydrotherapy,
- Washington Association of Naturopathic Physicians,

- National Board for Colon Hydrotherapy,
- International Association for Colon Hydrotherapy,
- International Register of Integrative Colon Hydrotherapists and Trainers,
- and other advocates and stakeholders of the naturopathic, massage, and colon hydrotherapy community.

The department's first workshop, on June 11, 2020, focused on:

- statutes and certification practices in other states,
- the current practice of colon hydrotherapy in Washington,
- recommendations for qualification standards for credentialing in Washington.

The department held a second workshop on June 23, 2020, focused on credentialing options for colon hydrotherapists in Washington.

Current Practice in Other States

Department staff conducted research with other states to learn about the current regulation of colon hydrotherapy practice. The department found that colon hydrotherapy is not a regulated function in most states. States regulating the practice of colon hydrotherapy have various forms, without one prevalent model. Below is a summary of current regulation of the practice of colon hydrotherapy in other states.

Summary

State	Summary	Reference
Arizona	Colon hydrotherapy is an authorized procedure for medical assistants under Naturopathic Physicians Medical Board Title 4 Chapter 18 R4-18-605(A)(7)(h). The medical assistant must be under the direct supervision of a physician.	AAC Title 4 Chapter 18 R4- 18-605(A)(7)(h)
California	Colon hydrotherapy is within the scope of practice of naturopaths, but not within the scope of practice of a registered nurse when not performed under the direction of a licensed physician.	CBPC Section 3640(c)(2)
	Historically, colon hydrotherapy is considered a complementary and alternative health care practice falling under California Business and Professional Code 2053.5 and 2053.6 effective 2002.	
	Licensing of colon hydrotherapy was proposed in 2008 <u>Legislative Bill AB311</u> , but failed.	
Colorado	Under the Colorado Natural Health Consumer Protection Act (2013), an unlicensed person may perform colonic irrigation as a complimentary, and alternative health care practitioner, provided they maintain certification through the <u>International Association of Colon Hydrotherapy</u> or the <u>National Board for Colon Hydrotherapy</u> . The practitioner must disclose they are not a physician and	CRS 6-1- 724(6)(g)

State	Summary	Reference
	recommend that the patient have an established relationship with a primary care provider.	
Connecticut	A licensed naturopathic practitioner may delegate the provision of colon hydrotherapy services to a colon hydrotherapist, provided the naturopathic physician evaluated the patient and determined such services are appropriate. The colon hydrotherapist provides services under the supervision and control of the naturopathic physician. The state does not certify or license the colon hydrotherapist.	CGS Chapter 373 Sec. 20-42a
	The colon hydrotherapist must maintain certification in good standing as a colon hydrotherapist from the International Association for Colon Hydrotherapy, the National Board for Colon Hydrotherapy, or the Global Professional Association for Colon Therapy.	
Florida	Colon hydrotherapy is regulated as an upgrade (endorsement) to a massage therapist license.	FAC 64B7- 25.001
	To qualify for the upgrade a massage therapist must complete a course of study in colonic irrigation at a board-approved massage school, or a course of study equal to or more stringent than the course of study in colonic irrigation with an approved provider or school in another state, or a colonic irrigation apprenticeship; and successfully complete the National Board for Colon Hydrotherapy exam.	Examination Requirements FAC 64B7- 26.003 Massage Establishment Operations FAC 64B7-
	Establishments that provide colonic irrigation must maintain colonic irrigation equipment in safe and sanitary condition and maintain sterilization equipment if non-disposable colonic attachments are used.	32.005 Minimum Standards for Colonics Irrigation Training
Texas	The administration of colonic irrigations is identified as a nonsurgical medical cosmetic procedure.	TAC Title 22 Part 9 Chapter
	Qualified unlicensed personnel may perform the procedure only after a patient has been evaluated and diagnosed by a physician, or a midlevel practitioner acting under the delegation of a physician; and only if a physician or midlevel practitioner is onsite during the procedure; or a delegating physician is available for emergency consultation in the event of an adverse outcome, and if the physician considers it necessary, be able to conduct an emergency appointment with the patient.	193 Rule 193.17
	The delegating physician must ensure that a person performing a procedure has appropriate training in, at a minimum: techniques for the procedure, cosmetic or cutaneous medicine, indications and contraindications for the procedure, pre-procedural and post-procedural care, recognition and acute management of potential complications that may result from the procedure, and infectious	

State	Summary	Reference	
	disease control involved with each treatment. The physician must have a written office protocol for the person performing the procedure.		
	The colon hydrotherapist must use colon hydrotherapy devices under the supervision of a licensed physician and must maintain a written order on file for each procedure.		
State	Colon Hydrotherapy included in medical practice, no other regulation		
Illinois	Illinois considers colon hydrotherapy a medical practice but does not have specific licensure for it. Licensing of colon hydrotherapy was proposed in 2013, Senate Bill SB 1651, but failed.		
Minnesota	The practice of colon hydrotherapy is included in the state statute definition of naturopathic physical medicine, <u>Statute Chapter 147E.01 Subd. 11</u> . It is not listed in <u>Statute Chapter 147E.05</u> – the Registered Naturopathic Doctors Scope of Practice.		

Current Practice in Washington

The department worked with stakeholders to understand current colon hydrotherapy practices in Washington. The department learned that about 70 independent practices provide colon hydrotherapy in Washington. Most of those practices have been in business for 15 to 20 years. Over half of those practitioners are certified through one of the colon hydrotherapies certifying bodies. Stakeholders believed that colon hydrotherapists in Washington were highly trained in the practice. Though many colon hydrotherapists have working relationships with a health care practitioner, such as a naturopathic physician, the majority work independently. Independent colon hydrotherapists receive clients from medical referrals for treatment. They also treat walk-in clients seeking colon hydrotherapy as a wellness service.

Recommendations

The department crafted recommendations based upon research findings and stakeholder input. The recommendations will require changes in statute for implementation. There are benefits and drawbacks to each recommended approach.

The department sought the best ways to ensure the physical and psychological safety of patients. The department finds it may be appropriate for non-physician health care providers to perform colon hydrotherapy under the supervision of a higher-level health care professional. This will require:

- proper training,
- appropriate equipment,
- patient safety and consent procedures,
- background checks for credential applicants.

The Department sees three viable pathways for this to occur. The first creates a new certification under the authority of the Board of Naturopathy. The others involve modifications to the medical assistant profession. Each option has benefits and challenges for current practitioners that are not credentialed in health care.

OPTION 1

Add colon hydrotherapy to the scope of practice of a medical assistant - registered.

The medical assistant registration is an entry level credential that simply requires an endorsement from a health care practitioner to qualify. This credential requires the endorsing health care practitioner to train or verify the competence of the medical assistant-registered before allowing them to perform a delegated task. This option provides colon hydrotherapists a simple pathway to become credentialed. However, the option does not allow the colon hydrotherapist to work independently. Patients could not self-refer to the colon hydrotherapist. Current independent practitioners will need to find a health care practitioner willing to supervise and delegate procedures to them.

To implement this option, the department suggests the following statutory changes.

Statutory Changes

- Add colon hydrotherapy to the scope of practice of a medical assistant-registered listed in RCW 18.360.050(4). The department recommends that education and training requirements are established to perform the task.
- Update the delegation law in RCW 18.360.060 to provide specific delegation standards for colon hydrotherapy practice.
- Update the definitions in RCW 18.360.010 to define colon hydrotherapy and update the supervision requirements to allow offsite supervision.
- Update RCW 18.360.090 to allow currently practicing colon hydrotherapists to continue to practice for a reasonable time. During this time, they can obtain any required education, training, or other requirements for practice.
- Amend RCW 18.360.060 to include separate delegation requirements for colon hydrotherapy.

Rule Changes

The department may need to implement rules for training and education standards for the practice of colon hydrotherapy.

OPTION 2

Create a new colon hydrotherapist certification within the naturopathy statute and under the authority of the Board of Naturopathy.

For this option, a new colon hydrotherapist certification would be created under the authority of the Board of Naturopathy (board). Colon hydrotherapists would work under the delegation and

supervision of licensed naturopathic physicians. The board would be responsible for writing rules for education, examination, supervision, delegation, equipment, sanitation, record keeping, and other topics. The board would have oversight of the credentialed colon hydrotherapists, including disciplinary matters.

A key benefit of this option is that naturopathic physicians understand the practice of colon hydrotherapy and the necessary standards of care. Colon hydrotherapy is included within the scope of practice for naturopathic physicians. Naturopathic physicians can already prescribe use of colonic irrigation systems.

As with Option 1, this option would not allow colon hydrotherapists to practice independently. Naturopathic physicians would need to delegate the procedure to a colon hydrotherapist.

This idea was introduced late, which lead to a very short timeline. Consequently, the department was unable to conduct an extensive review of this option with stakeholders in the naturopathic community. The Washington Association of Naturopathic Physicians (WANP) thought the concept of a certification under the Board of Naturopathy could be a regulatory solution. However, they felt the solution would be more applicable to colon hydrotherapy practitioners already working in a naturopathic practice. WANP suggests that any legislation includes clear expectations about supervision and delegation so naturopathic physicians understand their responsibilities.

The Board of Naturopathy expressed a desire for patients to be able to safely access the procedure. But, they want to learn more about the effects to the naturopathic profession before expressing an opinion about alignment with colon hydrotherapy certifications.

To implement this option, the department suggests the following statutory changes.

Statutory Changes

- Add a section to 18.36A RCW to include a colon hydrotherapist certification under the authority of the Board of Naturopathy. This would create a colon hydrotherapist profession under the authority of the board.
- Include a provision that a certified colon hydrotherapy provider may provide services under the supervision and delegation of a naturopathic physician.
- Grant the Board of Naturopathy the authority to write rules in order to implement the law.

Rule Changes

The board will need to develop requirements for training and education, credentialing, delegation, supervision, standards of care, and other topics.

OPTION 3

Create a new medical assistant profession: medical assistant - colon hydrotherapist.

This option would create a new medical assistant-colon hydrotherapist credential. They could work under the supervision of all health care practitioners that delegate to medical assistants (allopathic, osteopathic and naturopathic physicians, nurse practitioners, and physician assistants). Similar to the approach taken by ESSB 2775 (2020), this option would provide colon hydrotherapists a simple way to become credentialed. A health care practitioner would need to delegate the treatment to a colon hydrotherapy provider. Patients could not self-refer to the colon hydrotherapist.

To implement this option, the department suggests the following statutory changes.

Statutory Changes

- Update the definitions in <u>RCW 18.360.010</u> to define the terms colon hydrotherapy and medical assistant-colon hydrotherapist. Update supervision requirements to not require the supervisor to be physically present in the facility when supervising colon hydrotherapy procedures.
- Update the minimum qualification requirements in <u>RCW 18.360.030</u> to provide minimum qualifications to obtain a medical assistant-colon hydrotherapist credential. Or allow the secretary of health to adopt rules for qualifications, training and competency requirements.
- Update the delegation requirements in RCW 18.360.060 to provide specific delegation standards to a medical assistant-colon hydrotherapist.
- Update RCW 18.360.090 to allow currently practicing colon hydrotherapists to continue to practice for a reasonable time. During which, they may obtain any required education, training, or other requirements for practice.
- Amend RCW 18.360.060 to include separate delegation requirements for colon hydrotherapy.

Rule Changes

- The department would need to implement rules for application requirements.
- The department may need to implement rules for training and education standards for the
 practice of colon hydrotherapy. The legislature may request this be done in conjunction
 with the Board of Naturopathy.
- The department may need to implement rules for standards of practice.

The following are recommendations for the delegation of colon hydrotherapy:

- The medical assistant-colon hydrotherapist has a written emergency protocol to address urgent needs that may occur as a result of colon hydrotherapy.
- That colon hydrotherapy may be performed by a medical assistant at a facility other than the supervising health care practitioner's office.

OTHER OPTIONS CONSIDERED

The department also considered the following options but determined them less feasible after further review and discussion.

- Create a stand-alone colon hydrotherapy credential as a profession under the authority of the secretary of health.
 - Since there are likely fewer than 100 colon hydrotherapists practicing in
 Washington, the fees to obtain and maintain this credential could be very expensive.
 Small professions have fewer credential holders to share the cost of regulation.
- Add a colon hydrotherapy endorsement to the massage therapy credential. This option would allow massage therapists to perform colon hydrotherapy with proper education and training.
 - This option would allow independent massage therapists to practice colon hydrotherapy with a license endorsement. Currently, some practicing colon hydrotherapists are licensed as massage therapists. This is the regulatory model for colon hydrotherapy in Florida.
 - The massage community was not in favor of this option. They believe that colon hydrotherapy is not part of the definition of the practice of massage, but a separate profession.
- Add colon hydrotherapy to the scope of practice of a nursing assistant.
 - This option would cause conflict with other statutes that define the facilities where nursing assistants work.

Education Requirements

The department and stakeholders suggest the following requirements are included in law, or delegated to the appropriate authority to write in rule:

- Maintain a minimum of I-ACT Foundation Level certification; or
- Maintain National Board for Colon Hydrotherapist (NBCHT) credential; or
- Other training and education equivalent to the above.

Standards of Practice

The department's research found that most potential colon hydrotherapy harm comes from:

- the use of non-FDA-approved equipment,
- FDA equipment that is not properly maintained, or
- performing colon hydrotherapy when not advised for the patient.

The department and stakeholders suggest the following standards of practice are included in law, or delegated to the appropriate authority to write rules:

- Colon hydrotherapy devices must be FDA-approved.
- Colon hydrotherapists must follow the manufacturer's guidelines for sanitation and maintenance of devices.
- Any additives to filtered water must be prescribed by a delegating health care practitioner.
 Further stakeholder input may determine if any substances besides water filtered with an FDA-approved device are allowed without a prescription.
- Require health history forms and standard contraindications.

• Require health records to be maintained for five years.

Conclusion

In response to the legislature's budget proviso included in ESSB 6168, the department worked with stakeholders to review current statutes and qualifications for colon hydrotherapy and study the certification practices in other states. The product is a set of recommendations to create a colon hydrotherapy certification program in Washington.

This report includes information from eight states that regulate colon hydrotherapy or colonic irrigation.

The department recommends three credentialing options for colon hydrotherapy in Washington:

- 1. Expand the medical assistant-registered scope of practice to include colon hydrotherapy.
- 2. Create a new colon hydrotherapy credential under the Board of Naturopathy statute.
- 3. Create a new medical assistant profession—medical assistant-colon hydrotherapist. A similar option was put forward in the prior legislative session as ESHB 2775.

The department also recommends the following training and education standards to be required for credentialing of colon hydrotherapists:

- Maintain a minimum of I-ACT Foundation Level certification; or
- Maintain National Board for Colon Hydrotherapist (NBCHT) credential; or
- Other training and education equivalent to those above.

Finally, the department recommends other standards of practice to be implemented in statute or rule to ensure the safe practice of colon hydrotherapy in Washington.

