

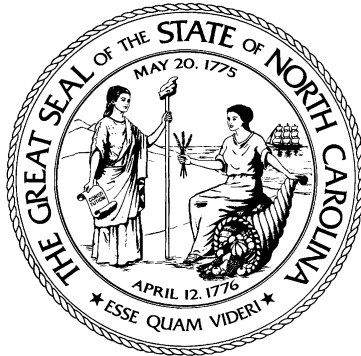
LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS

Final Assessment Report

For

COLON HYDROTHERAPY LICENSURE/FEEES

House Bill 1122



LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS

June 3, 2009

The Legislative Committee on New Licensing Boards is pleased to release this assessment report on the licensure of Colon Hydrotherapists. This report constitutes both the preliminary and final assessment report.

Representative Earline W. Parmon

**LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS
(2009-2010)**

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PREFACE

The Legislative Committee on New Licensing Boards is a 9-member joint committee of the House and Senate created and governed by statute (Article 18A of Chapter 120 of the General Statutes). The primary purpose of the Committee is to evaluate the need for a new licensing board or the proposed licensing of previously unregulated practitioners by an existing board. The Committee has been in existence since 1985.

The Committee solicits written and oral testimony on each licensing proposal in carrying out its duty to determine whether the proposal meets the following criteria:

- 1) Whether the unregulated practice of the profession can substantially endanger the public health, safety, or welfare, and whether the potential for such harm is recognizable and not remote or dependent upon tenuous argument.
- 2) Whether the profession possesses qualities that distinguish it from ordinary labor.
- 3) Whether practice of the profession requires specialized skill or training.
- 4) Whether a substantial majority of the public has the knowledge or experience to evaluate the practitioner's competence.
- 5) Whether the public can effectively be protected by other means.
- 6) Whether licensure would have a substantial adverse economic impact upon consumers of the practitioner's good or services.

The Committee issues an assessment report on its findings and recommendations. The recommendation in the report is not binding upon other committees considering the proposal.

HOUSE BILL 1122
COLON HYDROTHERAPY LICENSURE/FEEES

BACKGROUND¹

Current Standards.

Currently in North Carolina there are approximately 120 to 200 practicing colon hydrotherapists. Its use has grown in popularity throughout the state for several years, and continues to do so. Many medical doctors and health practitioners are recommending it as a complimentary treatment for their patients.

There is a great need for legislation of colon hydrotherapy in the state of North Carolina. As the demand of colon hydrotherapy services continues to grow, there also exists the need to insure the safety of those seeking this service. Without regulations regarding education, equipment, and best practices, there exists the potential for harm to the recipient of such a service in regards to sanitation and negligence caused by ignorance.

Colon hydrotherapy is a natural method of cleansing the colon using a soothing flow of warm, sterilized, and purified water instilled gently into the colon. This procedure cleans out toxins in addition to hydrating the lower colon.

While some form of colon cleansing has been practiced for thousands of years, an article extolling its benefits by J. H. Kellogg, M.D. (the same one who invented corn flakes) in the Journal of the American Medical Association is viewed as the impetus for its use in the modern era.

Leonard Smith, MD, of Gainesville, Florida, a board-certified gastrointestinal surgeon with over 25 years of experience, states “Without any reservation, I declare that my wish is to see it become an established procedure for many kinds of gastrointestinal problems. If medical centers, hospitals, and clinics installed colon hydrotherapy departments, they would find such departments just as efficacious for patients as their present treatment areas which are devoted to physiotherapy. Such is my true belief, and I do endorse this therapeutic program.”

¹ **Source:** *Response to Questionnaire for the Legislative Committee for New Licensing Boards.* A copy of the questionnaire is attached to this report.

Several states, including California and Alabama, are also considering licensure. In Florida, licensure has been required for 40 years. During this time there have been no reported complaints filed against any duly licensed therapist.

LICENSING REQUIREMENTS

§ 90-710. Title; legislative findings.

This Article may be cited as the 'North Carolina Colon Hydrotherapy Licensure Act.'

The General Assembly finds that the practice of colon hydrotherapy is an area of health care that is continually evolving to include more sophisticated and demanding client care activities. The General Assembly further finds that the practice of colon hydrotherapy by unauthorized, unqualified, unprofessional, and incompetent persons is a threat to public health, safety, and welfare, and therefore it is necessary to establish minimum standards of education, training, and competency for persons engaged in the practice of colon hydrotherapy.

"§ 90-712. License required; exemptions.

Except as otherwise provided in this Article, no person shall engage in the practice of colon hydrotherapy, use the designation 'Colon Hydrotherapist,' or advertise using any title or description that implies licensure as a colon hydrotherapist unless the person is licensed as a colon hydrotherapist as provided by this Article. A violation of this section is a Class 2 misdemeanor.

- The provisions in this Article shall not apply to:
- Any person licensed or approved by the North Carolina Medical Board to practice medicine or perform medical acts, tasks, or functions pursuant to Article 1 of Chapter 90 of the General Statutes or any person employed and working under the direct supervision of a physician licensed to practice medicine pursuant to Article 1 of Chapter 90 of the General Statutes.
- A student enrolled in an accredited colon hydrotherapy education program if colon hydrotherapy services performed by the student are an integral part of the student's course of study and are performed under the direct supervision of a licensed colon hydrotherapist.

"§ 90-713. The North Carolina Colon Hydrotherapy Licensing Board.

Composition and Terms. – The North Carolina Colon Hydrotherapy Licensing Board is created. The Board shall consist of seven members who shall serve staggered terms. Four members shall be

licensed colon hydrotherapists, one member shall be a physician licensed under Article 1 of Chapter 90 of the General Statutes, and two members shall represent the public at large.

The initial Board members shall be selected on or before October 1, 2009, as follows:

- The General Assembly, upon the recommendation of the President Pro Tempore of the Senate, shall appoint two licensed colon hydrotherapists and one public member, each to serve for a term of three years.
- The General Assembly, upon the recommendation of the Speaker of the House of Representatives, shall appoint two licensed colon hydrotherapists and one public member, each to serve for a term of two years.
- The Governor shall appoint a physician licensed under Article 1 of Chapter 90 of the General Statutes for a one-year term.

Upon the expiration of the terms of the initial Board members, each member shall be appointed by the appointing authorities designated in subdivisions of this subsection for a three-year term and shall serve until a successor is appointed and qualified. No member may serve more than two consecutive full terms.

Qualifications. – Members of the Board shall be residents of this State. The colon hydrotherapist members shall have been in practice as colon hydrotherapists for at least two consecutive years before serving on the Board and shall meet the requirements for licensure under this Article and remain in good standing with the Board during their terms. The public member of the Board shall not be: (i) trained or experienced in colon hydrotherapy; (ii) an agent or employee of a person engaged in the practice of colon hydrotherapy; or (iii) the spouse of an individual who may not serve as a public member of the Board.

Vacancies. – Any vacancy on the Board created by death, resignation, or otherwise shall be filled in the same manner as the original appointment, except that all unexpired terms of Board members appointed by the General Assembly shall be filled in accordance with G.S. 120-122. Appointees to fill vacancies shall serve the remainder of the unexpired term and until their successors are appointed and qualified.

Removal. – The Board may remove any of its members for neglect of duty, incompetence, or unprofessional conduct. A member subject to disciplinary proceedings in the member's capacity as a licensed colon hydrotherapist shall be disqualified from participating in the official business of the Board until the charges have been resolved.

Officers and Meetings. – The Board shall elect annually a chair and other officers as it deems necessary to carry out the purposes of this Article and shall hold meetings at least twice a year. A majority of the Board shall constitute a quorum.

Compensation. – Each member of the Board may receive per diem and reimbursement for travel and subsistence as set forth in G.S. 93B-5.

Assistance. – The Board shall be entitled to the services of the Attorney General in connection with the affairs of the Board or may, in its discretion, employ an attorney to assist or represent it in the enforcement of this Article.

"§ 90-714. Powers and duties.

The Board shall have the following powers and duties:

- To administer and enforce the provisions of this Article.
- To adopt, amend, or repeal rules to carry out the provisions of this Article.
- To examine and determine the qualifications and fitness of applicants for licensure and licensure renewal.
- To issue, renew, deny, restrict, suspend, or revoke licenses.
- To reprimand or otherwise discipline licensees under this Article.
- To receive and investigate complaints from members of the public.
- To conduct investigations to determine whether violations of this Article exist or constitute grounds for disciplinary action against licensees under this Article.
- To conduct administrative hearings in accordance with Article 3A of Chapter 150B of the General Statutes.
- To seek injunctive relief through any court of competent jurisdiction for violations of this Article.

- To collect fees required by G.S. 90-718 and other monies permitted by law to be paid to the Board.
- To establish and approve continuing educational requirements for persons licensed under this Article.
- To employ a secretary-treasurer and any other clerical personnel the Board deems necessary to carry out the provisions of this Article and to fix compensation for employees.
- To maintain a record of all proceedings conducted by the Board and make available to licensees and other concerned parties an annual report of all Board actions.
- To adopt and publish a code of professional conduct and practice for all persons licensed under this Article.
- To adopt a seal containing the name of the Board for use on licenses and official reports issued by the Board.

"§ 90-715. Requirements for licensure; issuance; limitations.

Upon application to the Board and payment of the required fees, an applicant may be licensed as a colon hydrotherapist if the applicant meets all of the following qualifications:

- Has obtained a high school diploma or its equivalent.
- Is 18 years of age or older.
- Is of good moral character as determined by the Board.
- Has successfully completed one semester of a three-credit hour course in anatomy and physiology from a postsecondary education school.
- Has successfully completed a minimum of 100 hours of training in colon hydrotherapy approved by the International Association for Colon Hydrotherapy.
- Passes an examination that has been approved by the National Board of Colon Hydrotherapy, meets generally accepted colon hydrotherapy principles and standards, and is approved by the Board.

When the Board determines that an applicant has met all the requirements for licensure, the Board shall issue a license to the applicant.

A colon hydrotherapist licensed under this Article shall not dispense or administer medication or provide advice regarding the use of medication, whether prescription or over-the-counter, in connection with the provision of colon hydrotherapy services.

All colon hydrotherapists licensed under this Article shall use colon hydrotherapy equipment registered with the federal Food and Drug Administration and shall comply with all applicable federal regulations, State laws, and rules adopted by the Board. Water is the only substance that may be used with the equipment unless another substance is approved for use under the direction of a person licensed to practice medicine pursuant to Article 1 of Chapter 90 of the General Statutes. Any licensed colon hydrotherapist violating this subsection shall have the license revoked by the Board.

"§ 90-716. Reciprocity.

The Board may issue a license, without examination, to any person who is a colon hydrotherapist licensed, certified, or registered in another state or country if the requirements for licensure, certification, or registration in the other state or country are substantially equivalent to the requirements for licensure in this State.

"§ 90-717. License renewal and continuing education.

Every license issued under this Article shall be renewed on or before December 31 of each year. Any person who desires to continue to practice shall apply for license renewal and shall submit the required fees. Licenses that are not renewed shall be automatically revoked. A license may be renewed at any time within one year after its expiration, if: (i) the applicant pays the required renewal fee and late renewal fee; (ii) the Board finds that the applicant has not used the license in a manner inconsistent with the provisions of this Article or engaged in the practice of colon hydrotherapy after notice of revocation; and (iii) the applicant is otherwise eligible for licensure under the provisions of this Article. When necessary, the Board may require a licensee to demonstrate continued competence as a condition of license renewal.

As a condition of license renewal, a licensee shall meet continuing education requirements set by the Board. Each licensee shall complete 12 continuing education units per year. Failure to obtain

continuing education units shall result in the forfeiture of a license. Upon forfeiture, a person shall be required to submit a new application and retake the examination as provided in this Article.

"§ 90-718. Expenses and fees.

The Board may impose the following fees not to exceed the amounts listed below:

- Application fee \$150.00
- Examination fee \$200.00
- License renewal \$100.00
- Late renewal fee \$50.00
- License by reciprocity \$250.00
- Duplicate license \$25.00

When the Board uses a testing service for the preparation, administration, or grading of examinations, the Board may charge the applicant the actual cost of the examination services.

"§ 90-719. Disciplinary action.

The Board may deny, restrict, suspend, or revoke a license or refuse to issue or renew a license if a licensee or applicant:

- Employs the use of fraud, deceit, or misrepresentation in obtaining or attempting to obtain a license or the renewal of a license.
- Practices or attempts to practice colon hydrotherapy by fraudulent misrepresentation.
- Commits an act of gross malpractice or incompetence as determined by the Board.
- Has been convicted of or pled guilty or no contest to a crime that indicates that the person is unfit or incompetent to practice as a colon hydrotherapist or that indicates that the person has deceived or defrauded the public.
- Has been declared incompetent by a court of competent jurisdiction.
- Has willfully violated any provision in this Article or any rules adopted by the Board.
- Uses or attempts to use the seal in a fraudulent or unauthorized manner.

"§ 90-720. Civil penalties.

In addition to taking any of the actions permitted under G.S. 90-719, the Board may assess a civil penalty not in excess of two thousand dollars (\$2,000) for each violation of any section of this Article or the violation of any rules adopted by the Board. The clear proceeds of any civil penalty assessed under this section shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.

Before imposing and assessing a civil penalty and fixing the amount of the penalty, the Board shall, as a part of its deliberations, take into consideration the following factors:

- The nature, gravity, and persistence of the particular violation.
- The appropriateness of the imposition of a civil penalty when considered alone or in combination with other punishment.
- Whether the violation was willful and malicious.
- Any other factors that would tend to mitigate or aggravate the violation found to exist.

Schedule of Civil Penalties. – The Board shall establish a schedule of civil penalties for violations of this Article and rules adopted by the Board.

"§ 90-721. Injunction to prevent violation; notification of complaints.

If the Board finds that a person who does not have a license issued under this Article is engaging in the practice of colon hydrotherapy, the Board may appear in its own name in superior court in actions for injunctive relief to prevent any person from violating the provisions of this Article or rules adopted by the Board.

A licensed colon hydrotherapist shall notify the Board by registered mail of any complaints filed against the colon hydrotherapist within 30 days from the date the complaint is filed."

SECTION 2. Any person who is currently a member of the International Association for Colon Hydrotherapy (IACT), is certified at the Foundation Level of IACT, and is using colon hydrotherapy equipment registered with the federal Food and Drug Administration on the effective date of this act shall be issued a colon hydrotherapist license without the requirement of examination.

SECTION 3. This act is effective when it becomes law.

FINDINGS AND RECOMMENDATIONS
COLON HYDROTHERAPY LICENSURE/FEES

Findings. The Joint Legislative Committee on New Licensing Boards finds that the sponsors have met the six criteria by which the Committee judges licensure proposals. Specifically, the Committee finds that:

- The unregulated practice of colon hydrotherapy can substantially harm or endanger the public health, safety, or welfare as there is no regulatory body to investigate complaints, and no state laws, rules or guidelines to regulate the profession. The most probable potential form of injury or harm to a patient is from individuals who lack the appropriate professional credentials to perform the procedure and properly operate the required FDA registered equipment but nevertheless are engaging in the direct delivery of colon hydrotherapy procedures.
- The profession possesses qualities that distinguish it from ordinary labor due to the requirement that an applicant use FDA licensed equipment and successful completion of a manufacturer training course, the implementation of proposed mandatory continuing education and an evolving knowledge of sanitation regulations and requirements.
- The intimate practice of colon hydrotherapy makes dedicated skill and training necessary.
- A substantial majority of the public does not have the knowledge or experience to evaluate or assess the competence of colon hydrotherapists.
- The public cannot be effectively protected by other means.
- Licensure would not have a substantial adverse economic impact upon the recipient of the hydrotherapy services.

Recommendation. The Legislative Committee on New Licensing Boards recommends that the practice of colon hydrotherapy be performed by a licensed professional. This assessment report constitutes both the preliminary and final assessment report for the licensure of colon hydrotherapists. The report is based on the proposed licensing as set out in House Bill 1122, the response to the Committee's questionnaire (Attachment), and testimony before the Committee on June 3, 2009.

ATTACHMENT

Response to Questionnaire for the Legislative Committee on New Licensing Boards

QUESTIONS FOR THE
LEGISLATIVE COMMITTEE ON
NEW LICENSING BOARDS

- **In what ways has the marketplace failed to regulate adequately the profession or occupation?**

The demand for colon hydrotherapy has dramatically increased, and it vital that only trained and educated professionals performs the service.

- **Have there been any complaints about the unregulated profession or occupation?** *Please give specific examples including (unless confidentiality must be maintained) complainants' names and addresses.*

While there have been no formal complaints, there have been complaints of people practicing colon hydrotherapy without proper knowledge and education.

- **In what ways has the public health, safety, or welfare sustained harm or is in imminent danger of harm because of the lack of state regulation?** *Please give specific examples.*

Currently in North Carolina, there are no regulations, guidelines or state laws that regulate this profession. Although the FDA regulates the equipment, each state must regulate the profession. Without regulation, practitioners may use equipment not registered with the FDA and thereby place the public in jeopardy. There is also imminent danger due to non-regulated or consistent standards of education, no in-state regulations in place and no continuing education requirements.

- **Is there potential for substantial harm or danger by the profession or occupation to the public health, safety, or welfare? How can this potential for substantial harm or danger be recognized?**

There is the potential for substantial harm by the profession through the use of non FDA registered equipment and lack of proper sterilization with such equipment, possibly leading to cross contamination to the client. Without standardized and higher levels of education, there is potential harm regarding pressure within the colon, contraindications and sanitation to list a few. These potentials for harm can be recognized, remedied and the consumer protected by raising the level of professional training and continued education.

- **Has this potential harm or danger to the public been recognized by other states or the federal government through the licensing or certification process?** *Please list the other states and any applicable federal law (including citations).*

Yes, Florida has been requiring licensing for over 30 years. Other states are now considering licensure.

- **What will be the economic advantage of licensing to the public?**

Colon hydrotherapy can be cost effective in conjunction with medical procedures with licensed physicians. Additional economic advantage for licensing to the public is the potential for job/opportunities. There is also the potential for health insurance companies to cover colon hydrotherapy as a preventive modality, or in conjunction with required medical procedures.

- **What will be the economic disadvantage of licensing to the public?**

There are no economic disadvantages of licensing for the public.

- **What will be the economic advantages of licensing to the practitioners?**

The economic advantage of licensing for the practitioner is providing a secure, established profession within our state with the protection of the consumer as paramount importance.

- **What will be the economic disadvantages of licensing to the practitioners?**

There are no financial disadvantages of licensing to the practitioner.

- **Please give other potential benefits to the public of licensing that outweigh the potential harmful effects of licensure such as a decrease in the availability of practitioners and higher cost to the public.**

Licensure should actually increase awareness of the procedure and thus increase the number of practitioners. As for the potential for higher costs to the consumer due to this decrease; as a service, the cost can not exceed what the market will bear. With the previously mentioned regulations attached to licensing, the practitioner seeking this profession will have a commitment to colon hydrotherapy as a valuable service rather than just for financial gain. With a standardized level of education and continuing education requirements the knowledge of the therapist is increased thereby providing a higher quality of service to the consumer coupled with a high standard for public safety. With this level of professionalism, more therapists will market themselves thus giving the consumer more choices. Licensure also provides the consumer with positive comfort level and sense of assurance for their safety and well being knowing there are regulations and protection mechanisms in place for their benefit.

- **Please detail the specific specialized skills or training that distinguish the occupation or profession from ordinary labor.**

The specialized skills and training that make the profession of colon hydrotherapy different from ordinary labor are: knowledge of Anatomy and Physiology, completion of training which is approved by the manufacturer of the equipment, safety training for the protection of the consumer, educational requirements, state approved schools for training, ethics guidelines across the board, sanitation regulations, required practical hours, state and national exams and continuing education requirements, depth of knowledge in the use and maintenance and disinfecting of the equipment, the awareness of contraindications for the protection of the public.

- **What are other qualities of the profession or occupation that distinguish it from ordinary labor?**

Other qualities of the profession that are distinguishable from ordinary labor are public relations skills, communications skills and personal interaction with the consumer, and education standards.

- **Will licensing requirements cover all practicing members of the occupation or profession? If any practitioners will be exempt, what is the rationale for the exemption?**

Yes, licensing requirements cover all practicing members with the only exemption being medical doctors.

- **What is the approximate number of persons who will be regulated and the number of persons who are likely to utilize the services of the occupation or profession?**

There are approximately 120 therapists currently practicing in North Carolina. Information from other related sources suggests that number may be closer to 200. The number of people likely to utilize the services of this profession is unlimited.

- **What kind of knowledge or experience does the public need to evaluate the services offered by the practitioner?**

The public needs to know the practitioner is properly trained to a standardized level of education, using FDA registered equipment, maintaining that equipment according to manufacturer guidelines, the equipment is cleaned and disinfected after each client and the practitioner is using single use, disposable tubing. Licensure will provide a sense of security for the consumer in knowing the profession is regulated to a higher standard.

- **Does the occupational group have an established code of ethics, a voluntary certification program, or other measures to ensure a minimum quality of service?**

The code of ethics for the International Association of Colon Hydrotherapists (“IACT”) is as follows:

The health, welfare, and comfort of our clients is our primary concern. We will treat our clients as we would treat ourselves. We will obtain comprehensive education in colon hydrotherapy and will assist schools in maintaining the highest standard of education for this purpose. We recognize the ever-changing nature of, approach to, and attitude towards health care. We will continue our education accordingly thereby keeping abreast of all new developments and advancements in this field. We will share our knowledge and awareness with others in the colon hydrotherapy profession. We recognize the necessity of maintaining a professional relationship with healthcare practitioners in other fields and of keeping pace with the latest developments in health care. We will work as a colon hydrotherapist as our education and training allows and demands and we will not infringe upon other professions we are not qualified to practice. We honor this profession and promise to uphold these tenants.

IACT has a voluntary certification program. There is also quality training available through independent manufacturers, instructors and schools approved by IACT. The North Carolina Colon Hydrotherapy Safety Association has been formed and is functioning as the governing body seeking licensure for the safety of the consumer.
