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Naturopathic Medicine Task Force to the Joint Standing
Committee on Business and Economic Development
("the Report")

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February 1, 1996

HAND DELIVERED

Representative G. Steven Rowe
State House Station 2
Augusta, ME 04333

Senator Philip E. Harriman
State House Station 3
Augusta, ME 04333

Re: Naturopathic Task Force Report

Dear Senator Harriman and Representative Rowe:

Consistent with L.D. 1532, enclosed is the majority report from the Governor's Naturopathic Task Force and minority comments from Dr. John Garafolo, a Task Force member. In submitting this report, I would like to emphasize that since October the Committee has met on regular basis, devoted a considerable amount of research time to the issues and, in good faith, has attempted to reach well-reasoned recommendations. In so doing, the Committee took into consideration economic factors, overlapping practice areas, and concerns as to educational training and professional competence. The report is not without compromises from each contingency represented on the Task Force.¹

In addition to the majority reports, the Task Force was asked to submit draft legislation and its own answers to the Sunrise Questions required under 5 M.R.S.A. § 12015(3). Proposed legislation is currently being drafted by Christina Valar, Esq., the Task Force representative from the Department of Professional and Financial Regulation. We anticipate this proposed legislation will be available shortly.

¹ Dr. Lani Graham, an active member of the Task Force, was on vacation and unavailable to review this final submission. She would like the Committee to understand that upon her return, she may have additional comments for the Committee's consideration.

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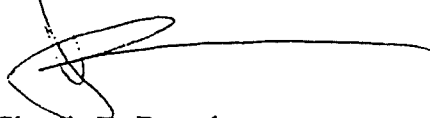
Senator Philip E. Harriman
Representative G. Steven Rowe
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With respect to the Sunrise Questions, the answers submitted by the naturopathic practitioners last legislative session were reviewed. Resulting from both issues of time and the difficulty in answering such questions without a more definitive direction as to how the legislation will precede, the Task Force was unable to come to a clear consensus on recommended language. It is fair to say, however, that as currently drafted it is unclear whether a majority of the Task Force would endorse the proposed answers.

In addition to the written report, it is our understanding from the Resolution that the Committee may wish to have an opportunity to speak with the members of the Task Force. If advised as to a date and time, representative members of the Task Force will be available.

We appreciate your consideration of the enclosures.

Sincerely,

A handwritten signature in black ink, appearing to read 'Claudia D. Raessler', with a long horizontal line extending to the right.

Claudia D. Raessler
Chairman, Naturopathic Task Force

CDR/rdl

cc: Naturopathic Task Force
Sarah C. Tubbesing, Executive Director,
Legislative Council
Representative Elizabeth Mitchell,
Vice Chair, Legislative Council
John Knox, Policy Analyst
Law & Legislative Reference Library

Naturopathic Medicine Task Force Report to the Joint Standing Committee on Business and Economic Development ("the Report")

History of the Task Force

The Task Force was appointed in the fall of 1995 and met originally on October 18, 1995. Consistent with the resolve in connection with L.D. 1532 approved by the Governor on July 3, 1995 ("the Resolution"), representatives to the Task Force were appointed from the areas of health care policy, education, allopathic and osteopathic medicine, naturopathic medicine, state government and a naturopathic consumer. A list of the Task Force members is attached. See Ex.1

Meeting on a regular basis from October through January, the Task Force spent two initial meetings educating the members as to the training and scope of practice for allopathic and osteopathic physicians and naturopathic doctors. Information was obtained from Task Force members, interested representatives and other states that have studied the issue of regulating and/or licensing naturopathic doctors.

Subsequent meetings were devoted to the areas identified in Section 5 of the Resolution. In connection with certain issues and for purposes of this Report, proposed statutory language has been suggested that will be reflected in legislation currently being drafted by legal counsel to the Commissioner of the Department of Professional and Financial Regulation. In other instances, the answers are designed to provide the Committee with some insight as to the discussions that occurred and the basis behind the Task Force's ultimate decisions. For those issues requiring a formal vote by the Task Force, the vote has been included in the answer.

Since the Task Force was unable to reach a complete consensus in support of this majority report, it is anticipated this Report will be supplemented with minority comments.

Study Subjects

1. The method of regulation, including practice license, title license, certification and registration.

Recommendation

A threshold consideration was whether or not this health care practice area should be subject to regulation. Although there was some debate as to whether or not this was an issue properly before the Task Force, it was discussed with a vote in favor of regulating. (Vote 5 in favor, 1 opposed, 1 abstention).

In considering the method of regulation, the Task Force voted in favor of licensure of naturopathic doctors as opposed to some type of registration process. In reaching this conclusion, the factors considered were the relative burden to state government in maintaining a licensure function, potential benefits derived both with respect to the doctors and the public, and the ability to more closely monitor the quality of naturopathic practice. Significant to the Task Force's consideration was the fact that the Assistant Attorney General advising the Department of Professional and Financial Regulation expressed the opinion that the ability to regulate and maintain professional accountability for the services provided was more difficult under a registration process as opposed to licensure. (Vote 6 in favor, 1 opposed, 2 abstentions).

It is worth noting that issue of licensure is important from a financial/reimbursement perspective. Both in representations made by naturopathic doctors on the Task Force and from preliminary research, state licensure can be a threshold requirement permitting naturopathic doctors to obtain reimbursement through third-party payor programs. Due to the time constraints, the Task Force was unable to explore and address all reimbursement issues, the possibility of reimbursement was considered relevant but not controlling.

2. The regulatory and oversight bodies.

Recommendation

There was a unanimous vote by the Task Force to recommend the establishment of a consolidated board for the purpose of regulating "complementary health care providers". In addition to the economies of scale to be achieved in consolidating overlapping practice areas, the Task Force discussed the importance to the public for health care doctors to both practice collaboratively and with the necessary peer oversight to ensure accountability with in the various practice areas. A more integrated board would appear to further these public policy considerations.

The Task Force envisions that in creating this type of board, the initial step is for the Department of Professional and Financial Regulation to determine and recommend to the Legislature which existing boards have overlapping and complementary practice areas and, as a consequence, could logically be regulated through a consolidated board process. In addition, we would anticipate a proposal from the Department as to the possible administrative structure.

From the Task Force's perspective, a consolidated health care board should have representation including, but not necessarily limited to, an allopathic or osteopathic physician, licensed doctors from the professions to be regulated and the public. (Vote 7 in favor, 0 opposed, 1 abstention).

3. The scope of practice, including, but not limited to, the following:

Recommendations

(a) natural childbirth;

This area of practice was the subject of considerable discussion. The issues involved the safety of home deliveries (in emphasizing the philosophy of patient choice, a delivery by a naturopathic doctor typically involves a home or birth center delivery), the scope of practice for nurses in advanced practice (currently pending rule making pursuant to 32 M.R. S. A. Sec. 2102), educational background and consumer choice. With respect to the first issue, the osteopathic and allopathic physician members of the Task Force expressed a significant public policy concern for endorsing any legislation that would encourage home deliveries. Although this concern was addressed by the naturopathic representatives to the Task Force, certain studies addressing the safety issues, the issues remained unresolved with a clear divergence of opinion among certain Task Force members. In addition, the "home delivery" concern was balanced against the interest that certain Task Force members had in achieving parity between doctors with equivalent or similar training. was balanced against the interest that certain Task Force members had in achieving parity between doctors with equivalent or similar training.

In light of the statements above, the Task Force voted in favor of the following proposal as to the inclusion of childbirth in a naturopathic doctor's scope of practice:

A naturopathic doctor must:

- (I) complete an accredited specialty certification program approved by the Council on Naturopathic Medical Education;
- (ii) pass a specialty certification exam as approved by the Board;
- (iii) for at least twenty-four months, practice under the supervision of a licensed physician with specialty training in obstetrics, or be employed by a clinic or hospital that has a program in place for obstetrical oversight by a licensed physician with specialty training in obstetrics. Upon completion of this period, written evidence of satisfactory completion must be submitted to the Board; and
- (iv) subsequent to the twenty-four months, to be licensed in obstetrics a naturopathic doctor must have (a) a documented back-up relationship with a licensed physician with specialty training in obstetrics and (b) comply with such other requirements as

are consistent with the standards established for regulating the obstetrical practice of certified nurse midwives.¹

(Vote 4 in favor, 2 opposed and 3 abstentions).

- (b) diagnostic procedures;

The Task Force agreed by consensus to the following proposed statutory language:

“A naturopathic doctor may use for diagnostic purposes physical examinations including phlebotomy, clinical laboratory tests, speculum exams and physiological function tests, excluding all endoscopies and physiological function tests requiring infusion, injection, inhalation or ingestion of medications to perform tests. A doctor may order ultrasound, x-ray and electrocardiograms, and must refer for test performance and interpretation.”

- (c) prescription and administration of medicines and therapies, including natural antibiotics;

Consistent with the scope of practice recommended by the Task Force, there was a consensus that naturopathic doctors should have a limited scope of prescriptive authority. Although the emphasis is to be placed on the use of “naturally occurring substances” as is further defined by statute, the Task Force agreed as follows:

- (1) Authorization of naturopathic doctors to use Category V legend drugs in those areas consistent with their educational training through initial training and continuing education.
- (2) Prior to full prescriptive authority and the permitted use of Category V² drugs, a naturopathic doctor shall establish a twelve (12) month relationship with a licensed allopathic or osteopathic physician, the terms of such relationship to be further defined by the Board.³

¹ Although this criteria was stated, without regulations it is unclear how relevant these requirements would be. The Task Force emphasis, however, was on the need for a defined “relationship” to exist that would both be supporting and minimize any risk of harm to a mother delivering in a home setting.

² Subsequent to the last Task Force meeting, there appears to be an issue as to whether Category V is the appropriate nomenclature. This will be addressed in drafting the legislation.

³ The nature of this relationship “supervisory” v. “consulting” needs further clarification. The language of the Task Force minutes from the January 24, 1996, meeting which are pending final approval use the word “supervisory”. The mechanics of the relationship were not developed.

- (3) Further restrictions as to the scope of permissible Category V legend drugs should be handled through the rulemaking process.
- (4) Use of Category I, II, III, and IV drugs is prohibited.
- (5) The use of controlled substances is prohibited.
- (6) Use of those substances that can be considered naturally occurring, herbal and homeopathic is permissible without restriction.

Vote: (6 in favor, 1 opposed, 2 abstentions).

- (d) surgical procedures;

By consensus, the Task Force agreed that the term "surgical procedures" would not be used for purposes of defining a naturopathic doctor's scope of practice, but rather "office procedures". The statutory language recommended by the Task Force is as follows:

"Office procedures means methods for the repair and care incidental to superficial lacerations and abrasions, superficial lesions and the removal of foreign bodies located in the superficial tissues. Use of antiseptics and local anesthetics in connection with those methods is permitted. Not permitted is the use of general, regional or spinal anesthetics, major surgery, surgery of the body cavities or specialized surgeries such as plastic surgery, surgery involving the eye or surgery when tendons are involved."

- (e) acupuncture.

The recommendation of the Task Force was that specialty certification in acupuncture would comply with current licensing requirements for acupuncturists. This would include completion of a accredited certification program and the passing of an exam as approved by the Board.

4. The authorized professional title, for example, "doctor" or "physician" and the use of the term "medical".

Recommendation:

In defining a naturopathic practice, the Task Force consider two primary issues. First, was the definition of the practice itself with the Task Force recognizing that naturopathic practice should be distinguished from the "practice of medicine and/or surgery". Second, was the issue of title for individual doctors.

For purposes of the practice issue, the Task Force recommends that in connection with any statutory language the term naturopathic medicine is permissible.

In addition, however, it is the Task Force's recommendation that statutory language expressly state that the practice of naturopathic medicine is not the practice of medicine and excludes surgical procedures, the application of x-rays, and the prescribing, dispensing or use of prescription drugs except as provided for by statute.

With respect to the second issue and the titling of a naturopathic doctor, discussed and rejected by the Task Force was the use of the term "physician" by naturopathic doctors. Although not controlling from a legislative perspective, relevant to this determination was a 1980 Maine Attorney General Opinion concluding that only those individuals licensed by the Board of Medicine are authorized to use the term "physician."

With respect to other titles, however, by majority vote the Task Force agreed upon the use of the following titles and references to practice:

naturopathic doctor
naturopathic
doctor of naturopathic medicine
naturopathic medicine
naturopathic health care
naturopathy
N.D.

(Vote 7 in favor, 1 opposed).

5. Qualifications for licensure, certification or registration.

Recommendation:

In reaching a consensus as to the qualifications for licensure, the Task Force considered practices in other jurisdictions, information as to the NPLEX exam, (the national certifying exam) as presented by Task Force members and Lara Litov, Secretary of NPLEX; and literature regarding educational programs.

Based upon this review, the basic requirements recommended for licensure are as follows:

- (a) Graduation from a naturopathic medical school as accredited by an agency recognized by the federal government; and
- (b) Completion of a national exam as approved by the Board (e.g., NPLEX).

In addition, the Task Force considered the fact that certain doctors in the State may have only completed a portion of the NPLEX exam. Consequently, it was recommended that provision be made for those doctors practicing in Maine since January of 1994. The recommendation is as follows:

- (a) A conditional license will be granted to a naturopathic doctor consistent with the doctor's current scope of practice. This will exclude any prescriptive authority and/or specialty certification.
- (b) Within three years from the date of enactment of the licensing law, a naturopathic doctor must satisfactorily complete all sections of the national certifying exam. Upon satisfactory completion of the exam, the twelve (12) months of supervisory practice⁴ must be completed before full prescriptive authority consistent with the statute will be granted.

(Vote: 7 in favor, 0 opposed, 1 abstention).

6. Grandfathering of current doctors.

Recommendation:

By a majority vote, the recommendation was to not permit grandfathering outside of the guidelines discussed above.

(Vote: 5 in favor, 0 opposed, 3 abstentions).

7. Practice by out-of-state licenses.

Recommendation:

See answers to Questions 5 and 6.

8. The grounds for refusing to license, certify or register.

Recommendation:

Although not formally discussed, it is anticipated that a refusal for licensure would occur in those instances where a doctor does not meet the basic qualifications and/or is found not to be qualified as a result of prior unethical or illegal conduct.

⁴ See comments in Footnote 3.

9. Continuing education requirements and the means of ensuring continuing competence.

Recommendation:

In reviewing recommendations as to continuing education, the Task Force supports the initial statutory language as follows with the following additions:

“When renewing a license, a naturopathic doctor must submit to the Board evidence of successful completion of the requisite hours of continuing education approved by the Board during the biannual period. The minimum requirement for license renewal that the Board may consider permissible is:

- (a) 50 hours of continuing education during any two year licensure period;
- (b) 14 of the 50 hours must be in pharmacology; and
- (c) if the doctor holds an obstetrical specialty certification, an additional 8 hours of continuing education is required annually.”

(Vote: 8 in favor, 0 opposed).

10. Reciprocity with other states.

Recommendation

As discussed above, the basic licensure requirements must be met.

In addition to the points noted above, the Task Force considered and recommends the following statutory language as to patient disclosures:

“A person who practices naturopathic medicine shall clearly disclose the person’s training and practice by displaying the appropriate licensure in their place of business. In addition, a person who practices naturopathic medicine without being covered by malpractice insurance, shall disclose to each patient that the person does not have such insurance.”

Other issues were:

- (1) public health reporting obligations; and
- (2) sale of pharmaceuticals.

With respect to public health obligations, it was the recommendation of the Task Force that reporting obligations similar to other licensed doctors should be included in the statutory language.

Similarly, the authority for dispensing and selling of prescription drugs as authorized by statute should be the same as for any other health care professional.

cc: Executive Director of the Legislative Council
Law and Legislative Reference Library

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**Minority Report for Naturopathic Task Force
by John Garofalo, M.D.**

This minority report for the Naturopathic Task Force is written primarily to express an opinion concerning the Committee's lack of ability to come to consensus on answers to the Sunrise Questions re: creation of a Licensing Board supervising naturopathic practitioners. The Committee did come to a majority opinion to require licensure and the subsequent report and proposed legislation were arrived at by both majority and consensus vote. There is no specific dissent from that final report, but whereas the Committee was unable to come to consensus on the Sunrise Questions, it is felt that an independent minority opinion concerning those questions is necessary. It is clear that whether or not the issue of licensure is decided negatively or positively depends somewhat on the answers to the Sunrise Questions and if positive answers are accepted to those questions, then the licensure and regulation as proposed by the Task Force would be the most appropriate. However, it is not clear that positive answers will necessarily be accepted. With that in mind, the following answers to the Sunrise Questions are proposed and submitted as a minority report.

L.D. 1532: Sunrise Questions and Answers

- A. What is the nature of the potential harm to the public if the occupation or activity is not regulated and the extent to which there is a threat to the public health or safety?**

If the practice of naturopathy is strictly limited to the use of natural medicines and health maintenance practices, there is little potential harm. Those activities are already regulated by the federal Food and Drug Administration (FDA).

- B. What is the extent to which existing legal remedies are inadequate to prevent or redress the kinds of harm potentially resulting from nonregulation?**

Tort action for negligence or harm are available to the consumer as means of redress. In addition any action that constitutes the practice of medicine can be redressed by legal action initiated by the Board of Licensure in Medicine.

The Attorney General's office, as well as regional District Attorneys also have the ability to bring cases of criminal negligence against practitioners. These criminal statutes have been considered in the past for action against unlicensed by lay midwives who have carelessly and recklessly jeopardized the lives of mothers and infants.

These three well-established means of redress are adequate to protect the public from any potential harm, particularly when one considers the minimal risk associated with the use of natural medicines (non-surgical and non-drug therapies).

- C. What is the extent to which the public is guided in selecting competent practitioners by**

private certification, membership in professional or occupational associations or academic credentials.

In general, the public does not often use certification, education, or academic credentials as their primary reason for choosing a practitioner. It is true that a certification, regulation or licensure will provide a member of the public an additional place to file a complaint. It does not necessarily follow that that licensure in any way confirms academic credentials or professional competence as the public does not understand what individual criteria are applied by the Board.

- D. What is the extent to which the occupation or profession has made efforts to regulate itself by adoption of standards of performance, a code of ethics or methods of resolving disputes with consumers of their services?**

The only effort to date of which we are aware is the development of draft standards of practice by the American Association of Naturopathic Physicians. These standards of practice have not been officially adopted and are not universally in use.

- E. What is the nature of the standard proposed for granting a license, as compared with the standards adopted in other jurisdictions, and the authority of the proposed regulatory board to amend those standards or establish new standards?**

Refer to Standards for Licensure as submitted in the proposed legislation.

- F. What are the qualifications of members of the proposed board?**

Refer to the Legislation for the Composition of the Board.

- G. The extent to which the harms expected to result from continued nonregulation may reasonably be expected to be reduced by the program of regulation proposed?**

There are proven instances of harm in states by practitioners claiming to be naturopathic practitioners, both those who have met standards of licensing in other states and those who have not. Licensing or regulation does not prevent inappropriate or negligent actions by an individual in any profession or other activity. Licensing or regulation in itself does not reduce these actions.

Thank you very much for the submission of this report.

Maine Association of Naturopathic Physicians

4 Milk Street
Portland, Maine 04101
(207) 773-2517

January 31, 1996

Dear Senator Harriman, Representative Rowe and Members of the Joint Standing Committee on Business and Economic Development:

We wish to address the report that is being submitted by the Task Force on Naturopathic Licensure. We respect the significant amount of time and effort put into this report by all the task force members. Although the task force worked hard to reach agreement on the many issues that were discussed, this was not always possible, and the majority report represents a tremendous compromise for the naturopathic physicians.

There are important items we do not agree with that diverge from the original bill. The original bill reflects the current education and training that naturopathic physicians receive at the federally accredited naturopathic medical schools. The recommendations of the task force in those areas where we disagree do not reflect either this level of education and training or the standards adopted by other states which have modern naturopathic licensure laws.

However, if the Business and Economic Development Committee chooses to adopt the majority report and the associated legislation, we will support the majority report due to the enormous amount of labor that went into its creation. Should the committee choose to revisit the particulars of the report, we will bring our concerns forward at that time.

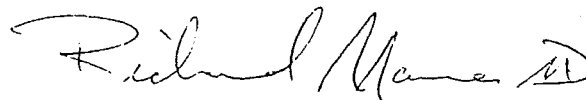
There is one section of the majority report which we will mention now. Section 3(c), dealing with prescriptive authority, contains an acknowledged factual error concerning nomenclature. Where the term "Category V" appears in relation to legend drugs the correct term should be either "DEA Schedule 6" or "non-controlled". Either of these terms would accurately represent the concept agreed to by the task force.

We look forward to working with the committee and reaching a final conclusion on an appropriate means of licensing naturopathic physicians and providing an avenue for public health, safety and welfare.

Sincerely,



Devra Krassner, N.D.
Naturopathic Task Force



Richard Maurer, N.D.
Naturopathic Task Force

cc: Members of the Naturopathic Task Force
Sarah Tubbesing, Executive Director, Legislative Council
Rep. Elizabeth Mitchell, Vice Chair, Legislative Council
John Knox, Policy Analyst
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