State of New Hampshire

GENERAL COURT

CONCORD

MEMORANDUM

DATE: October 22, 2015

TO: Honorable Margaret Wood Hassan, Governor
Honorable Shawn N. Jasper, Speaker of the House
Honorable Chuck W. Morse, President of the Senate
Honorable Paul C. Smith, House Clerk
Honorable Tammy L. Wright, Senate Clerk
Michael York, State Librarian

FROM: Representative Stephen J. Schmidt, Chairman

SUBJECT: Final Report on RSA 318:16-c, HB 190, Chapter 190:2, Laws of 2015 Commission to Study the Standards for Collaborative Pharmacy Practice

Pursuant to RSA 318:16-c, enclosed please find the Final Report of the Commission to Study the Standards for Collaborative Pharmacy Practice.

If you have any questions or comments regarding this report, please do not hesitate to contact me.

I would like to thank those members of the commission who were instrumental in this study. I would also like to acknowledge all those who testified before the commission and assisted the commission in our study.

SJS/dm
Enclosures

cc. Commission Members

Commission to Study the Standards for Collaborative Pharmacy Practice

HB 190, RSA Chapter 318:16-c, Laws of 2015

Final Report

The Commission met on September 8, 2015, for an Organizational Meeting.

Rep. Stephen Schmidt was elected Chair, Rep. James MacKay was elected Vice Chair, and Rep. John Sytek was elected Clerk.

They met again on September 22, 2015, and October 8, 2015 (minutes attached).

The Commission talked about the areas of their charge which included looking at the current collaborative practice law, looking at national standards for best practice of collaborative practice, and discussing how to expand access to collaborative practice pharmacy services to New Hampshire citizens in order to provide greater access to cost-effective care.

After discussion and collaboration among stakeholders, the commission proposes draft legislation to be submitted for the 2016 legislative session (incorporated in October 8, 2015 minutes, also attached).

Attachments

Minutes of Study Committee on HB-190 – Collaborative Pharmacy Practice
Wednesday, September 8, 2015

Members present:
Michael Dupuis, R.PH., MHA, representing NH Board of Pharmacy
Mary-Beth Gardner, ARNP, representing NH Nurse Practitioners Association.
James P. Glass, Rite Aid, representing Coalition of NH Chain Drug Stores.
Rob Glew, Elliot Hospital, representing NH Hospital Association.
Kerri Johnson, Parkland Hospital, representing NH Society of Health-System Pharmacists.
Kate Langlais-McNutt, Penacook Pharmacy, representing NH Independent Pharmacy Association.
Representative James R. MacKay, prime sponsor
Representative Stephen J. Schmidt
Representative John Sytek

This was the first meeting of the statutory commission ("committee") to study the standards for collaborative pharmacy practice established by HB-190.

Representative Schmidt, first named, called the meeting to order at 10AM, as the quorum requirement of five members was met. The first order of business was the election of a Chairman. Rep. Sytek moved that Rep. Schmidt be Chairman, with Rep. MacKay seconding. The motion carried unanimously. Rep. Schmidt then asked for a volunteer to clerk the committee. Rep. Sytek volunteered and was unanimously chosen.

Rep. Schmidt opened by pointing out that the committee had a tight "time line" since our report was due November 1. Rep. MacKay was recognized to explain the need for the study. He recalled that Dartmouth-Hitchcock used to invite Representatives to observe collaborative practice. He felt that there was an increased respect by doctors for the input from pharmacists in specific instances. He said that both he and the Pharmacy Association want to see expansion of areas of collaborative practice.

Rep. Schmidt asked for input and rationale from the various individuals present. Stuart Trachy (lobbyist for the NH Chain Drug Stores) and Fran Wendelboe (lobbyist for NH Ass'n of Independent Pharmacists) both spoke in support of expanded collaborative practice. She cited the administering of vaccinations as is done in other states.

Rep. MacKay asked the present status of collaborative practice. Ms. Johnson answered that collaborative practices occurs only in hospital settings, with a physician present (leading to a discussion of exactly what "present" meant) and with many restrictions. She was seeking to remove barriers and to expand collaboration.

Mr. Glass discussed his three major points: an accountable pharmacist, expandability, and affordability.

Ms. Gardner and Ms. Johnson discussed specifics about how collaboration could be expanded in a retail setting.

Rep. Schmidt raised several concerns: are all pharmacists capable of collaboration if their scope of practice were to increase? What about controls and patient accountability? Who is the reporting agency?

Mr. Glass, in answer, discussed education requirements and that some collaborative practices required little training, whereas others had more "intensive" requirements.

Mr. Glew emphasized that the scope of collaborative practice was very limited citing diabetes medication as an example. Both he and Ms. Johnson said they would provide the committee with relevant literature. Ms. Johnson actually did distribute some of these materials to the committee.

Rep. Schmidt asked the various participants to have specific proposals at the next meeting. The next meeting would be on Tuesday, September 22 at 9:30AM. The meeting adjourned at 10:55AM.

Respectfully submitted,

John Sytek

Minutes of Study Commission on HB-190 – Collaborative Pharmacy Practice
Tuesday, September 22, 2015

Members present:
John Butterly, MD, representing NH Medical Society
Michael Dupuis, R.PH., MHA, representing NH Board of Pharmacy
Cheryl Durand, NH Pharmacists Association
Mary-Beth Gardner, ARNP, representing NH Nurse Practitioners Association.
James P. Glass, Rite Aid, representing Coalition of NH Chain Drug Stores.
Linda Horton, Lakes Region General Hospital, Collaborative Practice Pharmacist
Kerri Johnson, Parkland Hospital, representing NH Society of Health-System Pharmacists.
Kate Langlais-McNutt, Penacook Pharmacy, representing NH Independent Pharmacy Association.
Representative James R. MacKay, prime sponsor
Representative Stephen J. Schmidt
Representative John Sytek
Nancy Wiggin, Huggins Hospital, representing the Board of Nursing
And, at the invitation of the Chairman, Nick Perencevich, MD, Physician Investigator, Board of Medicine

Chairman Schmidt opened the meeting at 9:40AM. At the first meeting of the commission, Representative Schmidt had asked the participants to return with specific proposals.

In reply, Kerri Johnson distributed a "white paper" (which she had e-mailed to the commission the previous day). She said that she had gotten together with the other pharmacy representatives Rather than have several separate presentations to the commission, she had prepared a synthesis of their "collaborative" thinking for proposed legislation.

Kerri Johnson pointed out that the number of Collaborative Practice Agreements (CPA) continues to increase since their early days in 2006. She pointed out that it was a current restriction that the provider and the collaborative pharmacist had to have the same employer. There were six proposed changes and the remainder of the meeting was her presentation of them and the discussion that followed each.

The first proposal was to change the educational requirements. At present, she said they were arbitrary; not all were necessary or useful for some collaborative practice and that the provider could make the determination of the competence of the collaborative pharmacist. Dr. Butterly wanted to see a more formal credentialing process. Mary-Beth Gardner pointed out that the NIH had documentation with tightening language. Dr. Perencevich wanted the CPA and other documentation to be filed with the provider. Linda Horton said that this was, in fact, being done and walked the commission through the documentation path.

At this point, Chairman Schmidt noted that pharmacists wanted their CPA to not necessarily be under the same roof as the provider. Mary-Beth noted that many states presently allowed this. Fran Wendelboe said that removing this restriction would improve access.

The second proposal sought to more clearly define which providers may authorize a pharmacist to see patients under a CPA.

The third proposal would allow CPA – one document - between multiple providers and pharmacists instead of many one-on-one CPA. This would be useful where there are group practices. Dr. Butterly was concerned that this would lead to a diffusion of responsibilities, putting it as: "Co-chief means no-chief." Linda Horton gave an example of how accountability would be ensured. In particular, the protocol could be written in any way that the provider feels necessary and finally, the whole arrangement is voluntary for the provider.

The fourth proposal was concerned with the manner in which notification of patient conditions and events would be sent to the provider. Dr. Butterly was concerned that in an anticoagulant situation timing was critically important. Linda Horton said that the protocol could specify this and that the wording of the proposal could include explicit mention of time line along with manner of notification.

The fifth proposal was to replace the mandatory 2 year review of CPA with definite beginning and end dates. While this could be made a part of the CPA, it was felt that some language regarding the timing of reviews should be put into statute.

The sixth proposal sought to end the restriction on the places where a pharmacist can perform his/her CPA. For example, a pharmacist could work in the home of the patient. It was pointed out that the experience in other states showed that this led to increased number of visits to providers. Instead of waiting for an arbitrarily scheduled appointed, a pharmacist working in the patient's home could see with immediacy that the patient's condition might warrant prompt medical attention.

Chairman Schmidt observed that there was a sense of cooperation and mutual respect among the parties and requested that they get together and work on wording in time for the next meeting. He scheduled the next meeting for Thursday, October 8 at 9AM.

The meeting adjourned at 10:45AM.

Respectfully submitted,

John Sytek

Minutes of Study Commission on HB-190 – Collaborative Pharmacy Practice
Thursday, October 8, 2015

Members present:
John Butterly, MD, representing NH Medical Society
Susan DeLeo, alternate for James P. Glass, Rite Aid, representing Coalition of NH Chain Drug Stores.
Michael Dupuis, R.PH., MHA, representing NH Board of Pharmacy
Cheryl Durand, NH Pharmacists Association
Mary-Beth Gardner, ARNP, representing NH Nurse Practitioners Association.
Rob Glew, Elliot Hospital, representing NH Hospital Association.
Linda Horton, Lakes Region General Hospital, Collaborative Practice Pharmacist
Kerri Johnson, Parkland Hospital, representing NH Society of Health-System Pharmacists.
Kate Langlais-McNutt, Penacook Pharmacy, representing NH Independent Pharmacy Association.
Representative James R. MacKay, prime sponsor
Representative John Sytek
Nancy Wiggin, Huggins Hospital, representing the Board of Nursing
And, at the invitation of the Chairman, Nick Perencevich, MD, Physician Investigator, Board of Medicine

In the scheduled absence of Chairman Stephen Schmidt, Representative MacKay, Vice-Chairman opened the meeting at 9:00AM. Rep. MacKay asked for introductions from the stake holders. Kerri Johnson handed out a proposed re-write of RSA 318:16-a (Standards for Collaborative Pharmacy Practice). This codified the consensus of the previous meeting.

The remainder of the meeting was a review by all parties of the language, with appropriate redrafts, of the proposed re-write. Among the considerations discussed were: With CPA to be filed in multiple locations, it appeared that keeping track of paperwork could become burdensome (Dr. Perencevich suggested "available on request"); a continued discussion as to the nature of liability sharing; as a result of a BOM meeting, Dr. Perencevich alerted the commission to the possibility of future complaints, that individuals should be named, rather than systems for liability reasons, reimbursement issues [on this latter point, Kerri Johnson pointed out that reimbursement issues were deliberately not addressed so as not to distract from the merits of the recommendations].

Ms. Johnson provided the following summary of the updates:

- Strengthening the educational requirement for the pharmacist wording and making it clear this is part of the Board of Pharmacy approval process;
- Adding wording that requires the agreement to contain a timeframe in which the pharmacist must notify the referring practitioner (and making it clear it is the referring practitioner who must be notified if the agreement is with multiple practitioners);
- Adding wording that in addition to the pharmacist keeping a copy of the agreement, the provider (or his/her administrative office) must also keep a copy of the agreement on file and that the agreement must be made available upon request/inspection;
- Adding a requirement for ongoing metrics for quality assurance and safety to be part of the agreement (the understanding being that most existing collaborative practices are already doing this);

- A discussion concerning the last section which would prohibit both parties from accepting inducements. While everyone on the committee wished that this weren't necessary, most felt in this day and age of aggressive drug manufacturer marketing it was still necessary (note: this is not new language, it is language from the original statute except for the adding of "inducement" to personal financial gain);

- A discussion about pharmacist reimbursement. There are currently mechanisms in place for pharmacists to obtain reimbursement such as "incident-to" billing codes, private contracts with practitioners or their offices for services or negotiating contracts with individual companies and insurers. There is general agreement there could be better reimbursement mechanisms in place. This is likely best reviewed at a later time after seeing the effects of pending federal legislation; and,

- Accepting the Board of Medicine's recommendation that expansion of electronic access to patient records by pharmacists should be highly encouraged – and practices should ensure compliance with HIPAA regulations. The Board of Medicine does not want to get complaints/suits around violation of privacy. Referrals signed by patients should continue to include an acknowledgement of this as is currently required in the Board of Pharmacy administrative rules pursuant to this RSA.

These updates have been incorporated into the proposed RSA 318:16-a which appears below:

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Fifteen

To repeal and re-enact:

TITLE XXX
OCCUPATIONS AND PROFESSIONS
CHAPTER 318
PHARMACISTS AND PHARMACIES
Licensed Pharmacists
Section 318:16-a

I. For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:
   a. Hold an unrestricted and current license to practice as a pharmacist in New Hampshire.
   b. Have at least $1,000,000 of professional liability insurance coverage.
   c. The pharmacist shall have the knowledge base necessary for proper monitoring: including, but not limited to, associated disease states, relevant laboratory tests, adverse events, drug and food interactions, safety and efficacy. Depending upon the complexity of the services being provided, the pharmacist may have additional credentials or training and shall demonstrate approval by the Board of Pharmacy.

II. Any practitioner(s) with prescriptive authority who hold an active, unrestricted license in the state of New Hampshire may enter into a collaborative practice agreement. An authority authorized to be performed by a pharmacist by a practitioner under a collaborative practice agreement must be within the practitioner's current scope of practice.

III. Collaborative pharmacy practice agreements may be between single or multiple pharmacists and a single or multiple practitioners.

IV. Collaborative pharmacy practice agreements shall meet the following general requirements:

a. Each protocol developed, pursuant to the collaborative pharmacy practice agreement, shall contain detailed direction concerning the services that the pharmacist may perform for patients. The protocol shall include, but not be limited to:
    i. The specific drug or drugs to be managed by the pharmacist(s).
    ii. The terms and conditions under which drug therapy may be implemented, modified, or discontinued.
    iii. The conditions and events upon which the pharmacist(s) is required to notify the collaborating practitioner(s) and the manner and time frame in which notification will occur.
    iv. The laboratory tests that may be ordered in accordance with medication therapy management.
    v. All activities performed by the pharmacist in conjunction with the protocol shall be documented as specified in the protocol.
    vi. A statement of the expected amount of time the pharmacist will dedicate to performing duties specified under the protocol.
    vii. Collaborative pharmacy practice agreements shall state the beginning and ending dates of the period of time during which the agreement is in effect, and may be terminated, in writing, by either party at any time. Collaborative pharmacy practice agreements shall be renewed at a minimum every two years. When collaborative pharmacy practice agreements are terminated, the patient(s) shall be informed and provided with details to allow for the uninterrupted continuation of their medication therapy management regimen.

b. Ongoing metrics for quality assurance and safety monitoring will be agreed upon by the practitioner(s) and pharmacist(s) and will be included in the collaborative practice agreement. These metrics will be consistent with metrics put in place or enforced by regulatory bodies.

V. Supervision of the collaborative practice shall occur on two levels:
    a. Protocols developed shall be developed based on evidence-based guidelines for best practices.
    b. The referring practitioner shall receive progress visit notes from each patient encounter in a time specified in the agreement.
    c. The referring practitioner shall provide supervision for the treatment management of the referred patient.
    d. The collaborative pharmacy practice agreement and protocols shall be on file at the pharmacist's place of practice, at the practitioner's administrative office or place of practice, and shall be available upon request.

VI. Neither the attending practitioner(s) nor the pharmacist(s) in a collaborative practice agreement may seek to gain personal financial benefit by participating in any incentive-based program or accept any inducement that influences or encourages therapeutic or product changes or the ordering of tests or services.

Dr. Butterworth moved and Ms. Wiggin seconded that the above re-write of RSA 318:16-a be the recommendation the commission. Unanimously accepted.

At 10:00 AM, Rep. Sytek moved adjournment with Dr. Butterly seconding. Unanimously accepted. Respectfully submitted, John Sytek