State of New Hampshire

GENERAL COURT

CONCORD

MEMORANDUM

DATE: **December 1, 2017**

TO: **Honorable Chris Sununu, Governor**
Honorable Gene Chandler, 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 Mariellen MacKay, Chair**

SUBJECT: **Final Report of the commission to study allowing pharmacists to prescribe or make available via protocol oral contraceptives and certain related medications.**
RSA 318:47(HB 264, Chapter 23:1, Laws of 2017)

Pursuant to RSA 318:47 (HB 264, Chapter 23, Laws of 2017), enclosed please find the Final Report of the commission to study allowing pharmacists to prescribe or make available via protocol oral contraceptives and certain related medications.

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.

Enclosures

cc: Members of the Commission

FINAL REPORT

Commission to study allowing pharmacists to prescribe or make available via protocol oral contraceptives and certain related medications.
RSA 318:47-k (HB 264, Chapter 23:1, Laws of 2017)
December 1, 2017

Commission Charge and Study Purpose

The commission was charged with (but not limited to) allowing pharmacists to prescribe or make available via protocol oral contraceptives and certain related medications. The commission was also directed to solicit information from any person or entity the commission deems relevant to its study.

Commission Membership

Representative Mariellen MacKay, *Chair*
Representative Peter Schmidt
Representative William Marsh, *Vice-Chair*
Senator Donna Soucy
Patricia Tilley, NH DHHS, *Clerk*
April Kvetkosky, NH Society of Health-System Pharmacists
Christopher Lopez, NH Pharmacists Association
Michael Bullek, NH Board of Pharmacy
Brenden Rock, Coalition of NH Chain Drug Stores
Robert Stout, NH Independent Pharmacy Association
Gary Sobelson, NH Medical Society
Lindsay Schommer, Board of Nursing
Joyce Cappiello, NH Nurse Practitioner Association
Amy Schneider, Board of Medicine Appointed Family Physician
Sara Kellogg Meade, NH Nurses Association
Ellen Joyce, American Congress of Obstetricians and Gynecologists
Mellissa Martinez-Adorno, NH Hospital Association
Jennifer Frizzell, Planned Parenthood of Northern New England
Diane Trowbridge, Bi-State Primary Care

Issue

Numerous professional groups including American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians (AAFP) believe it would be desirable to expand access to birth control by making birth control pills available without a prescription for the public health goal of preventing unintended pregnancy. Until and unless the Food and Drug Administration (FDA) permits birth control pills to be sold without a prescription, this is impossible. Other states have developed alternative methods of expanding access by making hormonal contraception available behind the counter. In this report "hormonal contraceptives" means pills, patches, and rings which the United States Food and Drug Administration (FDA) classifies as available by prescription for the purpose of contraception or emergency

contraception. It does not include similar items classified as "over the counter" by the FDA, intrauterine devices, shots, or intradermal implants.

Process

The Committee organized on Thursday, September 14th and elected Mariellen MacKay as Chair. The Chair appointed Patricia Tilley as Commission Clerk. The Commission met seven times in total (see attached minutes).

Testimony was presented by representatives of:

- The New Hampshire Insurance Department
- The New Hampshire Department of Health and Human Services
- The Commission to Study the Standards of Collaborative Practice
- The New Hampshire Attorney General

Members of the Commission presented testimony from:

- Planned Parenthood of Northern New England
- The New Hampshire Independent Pharmacy Association
- The New Hampshire Board of Pharmacy
- The NH Medical Society
- The NH Pharmacists Association
- The NH Hospital Association

Documents were reviewed including:

- SB 30 (2005)
- Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing Hormonal Contraceptive Patches and Oral Contraceptives
- HB 270 (2015)
- SB 222 (2017)
- The Final Report of the Commission to Study the Standards for Collaborative Pharmacy Practice Massachusetts SB 499 (2017)
- A listing of Pharmacist clinical care remuneration programs from Can Pharm J (Ott). 2014 Jul; 147(4): 209-232
- Washington SB 5557 (2015)
- CMS Informational Bulletin regarding State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols (Jan 17, 2017)

Findings

The Commission considered several methods of expanding access to contraception, with various advantages and disadvantages. The following methods are listed in order from least restrictive to most restrictive. At this time the Commission has decided to recommend standing orders with a model statewide protocol (option five), with the understanding that the optimal goal in the future would be a standing order signed by DHHS (option four).

1) **Over the counter (non-prescription) birth control**. The Commission recognized this required FDA action and is outside the scope of NH law.

2) **Prescriptive Authority for Pharmacists.** This would allow pharmacists to prescribe hormonal contraceptives. The Commission recognizes this option could expand access and pharmacist reimbursement, and would require a change in insurance laws. While the representatives of pharmacist groups favored this approach, the NH Medical Society and others opposed it on the grounds that it would remove the oversight of physicians and nurse practitioners in the prescribing process, and it could lead to other disruptions to current medical home environments. Whether this approach would raise concerns regarding patient safety was a matter of dispute.

3) **Statewide protocol.** This would empower a state agency to develop a statewide protocol, creating a statewide standard of care regarding training requirements, reporting requirements, and evaluation tools for uniformity of care. Pharmacists would be allowed to prescribe and dispense hormonal contraceptives. Representatives of the pharmacy groups favored this approach, but at this time pharmacists do not have provider status to bill Medicaid. The Medical Society also had concerns over proper patient oversight.

4) **Standing order signed by DHHS.** The Commission felt that this was the ultimate goal, but recognized that DHHS is unable to implement a statewide protocol at this time. The Commission also acknowledges that the absence of a Medicaid enrolled provider at DHHS would have the undesirable unintended consequence of eliminating Medicaid coverage of this enhanced form of access for hormonal contraceptive prescriptions.

5) **Standing orders with a model statewide protocol (commission recommendation).** The Commission felt a model statewide protocol would add uniformity and help establish the standard of care, thereby minimizing liability and increasing the likelihood providers would agree to sign standing orders. DHHS, the Boards of Nursing, Medicine and Pharmacy would collaborate with other stakeholders to establish to draft model language.

6) **Standing Orders with no model statewide protocol**. The Commission felt this would increase access but lack uniformity, have different educational, screening and reporting requirements. Pharmacies, particularly independent pharmacies, might have difficulty finding providers willing to sign standing orders. If a provider was willing to sign, the pharmacy's implementation would be largely controlled by the provider. It would be desirable for the legislature to establish minimum requirements by statute or rule to ensure that important elements of the program be met in any agreement developed.

7) **Collaborative Practice Agreements.** The Commission felt this could already be done under current law, but would lack statewide uniformity and do little to improve access.

Recommendations

1) The Commission endorses LSR 2018-3030, submitted by Representatives M. MacKay, J. MacKay, Marsh, P. Schmidt, Knirk, Hinch, L. Ober, LeBrun and Senators Soucy, Carson, Bradley, Feltes and Reagan.

2) The Commission desires that the pharmacy access to contraception enabled in its

endorsed legislation also be available through the Medicaid program. The Commission was advised by DHHS that no new legislation would be required so long as an enrolled Medicaid provider is authorizing the prescription.

The Commission recognized the importance of assisting the uninsured with greater access to contraception. The Commission expects that pharmacists will provide written information and referrals to safety-net health care providers and family planning centers where low and no-cost care is available.

3) The Commission recommends that if or when DHHS is able to sign a statewide protocol, that a subsequent bill be submitted to advance from the standing order with a model statewide protocol model (as in LSR 2018-3030) to a statewide protocol model.

4) The Commission endorses LSR 2018-2993 submitted by Sen. Soucy requiring that public and private insurance plans cover a 12 month supply of prescribed, self-administered hormonal contraception and receive such supply at one time.

These recommendations and report were unanimously agreed to by the Commission via a roll call vote at its final meeting on November 16, 2017.

Roll call vote to recommend this report, LSR 2018-3030 and LSR 2018-2993: Representative Mariellen MacKay, Representative Peter Schmidt, Representative William Marsh, Senator Donna Soucy, Patricia Tilley, April Kvetkosky, Christopher Lopez, Michael Bullek, Robert Stout, Gary Sobelson, Lindsay Schommer, Joyce Cappiello, Amy Schneider, Sara Kellogg Meade, Ellen Joyce and Jennifer Frizzell

Absent: Brenden Rock, Mellissa Martinez-Adorno, Diane Trowbridge

Respectfully submitted,

Rep. Mariellen MacKay

Representative Mariellen MacKay, Chair

CC: Senate President
Speaker of the House
Senate Clerk
House Clerk
State Librarian

Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
September 14, 2017

Opening

The first meeting of the Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order on September 14, 2017 in Room 306, Legislative Office Building by Representative Mariellen MacKay.

Present

Robert Stout; Michael Bullek; Gary Sobelson; Christopher Lopez; Brendan Rock; Rep Peter Schmidt; Rep Mariellen MacKay; Rep William Marsh; Sen Donna Soucy; Jennifer Frizzell; Sara Kellogg Meade; April Kvetkosky; Patricia Tilley; Melissa Martina Adorno.

New Business

Representative Marsh made a motion for Rep Mariellen MacKay to Chair the Commission. Motion passed unanimously.

Rep Mariellen MacKay appointed Rep William Marsh as Vice-chair and Patricia Tilley as Clerk.

Rep Keith Murphy was asked to describe HOUSE BILL *264 :* AN ACT establishing a commission to study allowing pharmacists to prescribe or make available via protocol oral contraceptives and certain related medications as introduced and as amended.

The bill as introduced did not provide enough detail to address FDA authority of over-the-counter designation; insurance issues; and the complex logistics and policies regarding prescribing and/or collaborative practice. The amended version of the Bill enabled the Commission to study these issues and make recommendations for future policy.

Rep Marsh led a discussion to determine if Commission members were in consensus with the broad aim of supporting increased access to affordable oral contraception.

Sara Kellogg Meade asked for further clarification of the scope of the Commission.

The general consensus was that the Commission would focus on:

- Prescribing status among pharmacists
- Scope of products/contraceptives covered
- Logistics of collaborative practice agreements or enhanced prescriber status

Final recommendations due by December 1, 2017

Jennifer Frizzell suggested that there may be lessons learned from NH's experience prior to FDA approval of the emergency contraceptive drug Plan B as an over-the-counter (OTC) option for women aged 18 and older.

> **ACTION ITEM- Jennifer Frizell will bring information about that experience and related policies to the September 28th Commission meeting.**

There was further discussion about NH's more recent experience with increased access to Naloxone and policies regarding pharmacist dispensing.

> **ACTION ITEM- Patricia Tilley will ask someone from DHHS to describe the experience with HB 270 and 271 that increased access to Naloxone.**

> **ACTION ITEM- Patricia Tilley will request that Tyler Brannen from the NH Insurance Department to come to the September 28th Commission meeting to discuss insurance implications of collaborative practice agreements and increased pharmacist prescribing authority.**

Meeting dates were tentatively set for Thursdays, 10AM-Noon every other week through November 2017.

Agenda for Next Meeting
Presentations on:

- NH's experience prior to FDA approval of the emergency contraceptive drug Plan B as an over the counter option
- NH's experience with increasing access to naloxone through standing orders for pharmacy
- NH Insurance Department perspective on collaborative

Adjournment

Meeting was adjourned at 11:15 AM by Representative Mariellen MacKay. The next general meeting will be at 10:00AM-Noon on September 28, 2017, in the Legislative Office Building, Concord.

Minutes submitted by: Patricia Tilley

Approved by: [Name]

Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
September 28, 2017

Opening

The second meeting of the Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order at 10AM on September 28, 2017 in Room 205, Legislative Office Building by Representative Mariellen MacKay.

Present

Rep Mariellen MacKay; Rep William Marsh; Robert Stout; Michael Bullek; Gary Sobelson; Christopher Lopez; Brenden Rock; Jennifer Frizzell; Sara Kellogg Meade; April Kvetkosky; Patricia Tilley; Melissa Martina-Adorno; Lindsay Schommer; Joyce Cappiello; Amy Schneider; Ellen Joyce; Diane Trowbridge.

Approval of minutes

Gary Sobeloson motioned to accept the minutes from September 14, 2017. Rep William Marsh seconded the motion. Minutes approved.

Presentations

NH Insurance Department Perspective-

Tyler Brannen, NH Insurance Department

Tyler Brannen discussed the NH Department of Insurance's role in the regulation of all insurance companies, agents and adjusters including the commercial insurers that support Expanded Medicaid population. The NH Department of Insurance does not regulate public insurance such as Medicaid and Medicare, but works closely with NH Department of Health and Human Services (DHHS) and Centers for Medicare and Medicaid Services (CMS).

Mr. Brannen described the role of Pharmacy Benefit Managers (PBMs) as the entities primarily responsible for developing and maintaining prescription drug formularies, contracting with pharmacies, and processing and paying prescription drug claims. Insurance carriers subcontract with PBMs to manage the pharmacy expenditures of insurance plans while also improving health care outcomes.

It is important to note that in 2017, NH enacted HB 455 which states that pharmacy benefit managers shall not require accreditation, credentialing, or licensing of providers/pharmacists other than by the New Hampshire pharmacy board or other state or federal entity. Insurance companies have the authority to extend credentialing to pharmacists and thus making them eligible to receive third party reimbursement, but whether they would move in that direction would require further consideration. There is no logistical problem for insurers to develop reimbursement (beyond what is covered through a PBM contract) although they may be reluctant.

Questions/Comments:

Representative Marsh asked: *Could insurers potentially be interested in extending provider status to pharmacists for the discrete use of prescribing and dispensing hormonal contraception since it appears that contraception will remain a covered service under the Affordable Care Act (ACA)?*

Insurers typically consider the cost of the service, the number of people that use or access that service, and if that service could lead to reductions in cost for other services.

Christopher Lopez commented *that in a clinic setting pharmacists are currently being reimbursed by insurers, but it is unclear how that would translate to a retail pharmacy setting.*

Gary Sobelson asked: *Why was HB 455 brought forward in the last legislative session?*

Some PBMs were requiring accreditation requirements for pharmacists that were very costly. There was some suspicion that the PBMs were engaging in "pay to play" by requiring accreditation.

Robert Stout commented: *Other states have recognized the pharmacists and given them provider status. It is not unprecedented in NH to add provider types. This has been done for providers such as chiropractors, dieticians, Advance Practice Registered Nurses, etc.*

Jennifer Frizzell asked: *Is there a way to incent increasing access by ensuring that women could receive more than one cycle of products/pills?*

The Commission could address that if so inclined.

NH Emergency Contraception Collaboration Practice Program (2005-2007)

Jennifer Frizzell, PPNNE

Jennifer Frizzell described that in 1998 Emergency Contraception (EC) methods were approved by the FDA and in 1999 Plan B was approved by FDA with an additional prescription option. In 2003 an application was filed with FDA to switch Plan B from prescription to over the counter status. In 2006 FDA approved Plan B for over the counter status for individuals 18 and over. In 2013 the US Court of Appeals ordered FDA to remove age restrictions for over the counter access.

In 1998 the State of Washington began dispensing EC via their existing collaborative practice act. NH did not have this authority in place so in the 2005 legislative session, SB 30, the Collaborative Practice for Emergency Contraception was introduced, passed and signed into law by Gov. John Lynch. NH was the fourth state in the country to move a Collaborative Practice Act forward. No funds were appropriated for implementation so Planned Parenthood of Northern New England (PPNNE) secured private funding for training and provider and patient education.

The NH Board of Pharmacy established procedures and protocols for certifying eligibility and registering agreements between prescribers and pharmacists. Participating pharmacists were required to receive training about contraception. SB 30 also required that there be a private space available in retail pharmacies for consultation (this was far less common in 2005 than it is in current pharmacies in 2017). Public education and patient materials needed to be developed to increase awareness among women throughout the state.

In partnership with the Board of Pharmacy and NH DHHS, and using private funds, PPNNE organized training and developed marketing materials. They worked with organizations such as the NH Medical Society, Bi State Primary Care and other community health centers to identify MDs and APRNs interesting in collaborating with pharmacists. They developed electronic mapping features to ensure access statewide. After 18 months, 265 pharmacists were trained, but only 22 pharmacies had trained staff and were able to dispense via collaboration.

In 2005 and 2006 there were different challenges specific to large chain retailers and independent pharmacies. Pharmacists expressed concern with the amount of time they felt they needed with patient counselling and the SB30 requirement for referral to healthcare providers. Others experienced challenges with inconsistent corporate policy

and barriers. There was uneven reimbursement- and no opportunity for reimbursement for time intensive counseling.

Women and medical providers had difficulty knowing what pharmacies were participating. Because policies at participating pharmacies were inconsistent all patient materials included the disclaimer to "Always call ahead". The cost of EC was also a challenge for low income uninsured women and pharmacists were ill equipped to advise women of Medicaid eligibility.

The program disbanded in 2007 after FDA approved Plan B for over the counter status for individuals 18 and over. In 2013, the US Court of Appeals ordered FDA to remove age restrictions for over the counter access.

Questions/Comments:

Robert Stout commented: *It was very difficult to establish a collaborative practice agreement then. The times have changed especially with experience such as Flu Immunizations.*

Rep Mariellen MacKay asked: *It appears that there is a triad- physicians, pharmacists and insurers. Did you see turf battles then?*

Yes, there are boundaries and questions that still need to be addressed. However, a decision was made at that time through SB30 to move forward to increase access to EC.

Gary Sobelson commented: *The Medical Associations were in favor of addressing the public health need. But it was recognized that there are boundaries, questions and potentially unintended consequences.*

Sara Kellogg Meade asked: *Are we talking about just oral contraception or hormonal contraception?*

While the official charge of the Commission is to address "Oral Contraceptives and Certain Related Medications", the Commission will use a working definition of "hormonal contraception".

> ACTION ITEM- Christopher Lopez will develop a list of hormonal contraceptives and related devices for the Commission.

Additional Discussion Regarding Collaborative Practice Agreements:

While the foundation for collaborative practice agreements exists, these types of arrangements have not been put in place for hormonal contraceptives. There may be opportunities to further address collaborative practice within Board of Pharmacy Administrative Rules.

Commission members suggested that the group needs further information about collaborative practice acts.

The Commission should remain focused on how any potential solution (e.g. collaborative practice or standing orders) impacts low income populations, uninsured patients, and retail pharmacy.

ACTION ITEM- Michael Bullek and/or the Board of Pharmacy should prepare information for the Commission on Collaborative Practice.

New Hampshire's Experience with Naloxone –

Leigh Cheney& Adnela Alic, NH DHHS

Following the passage of House Bill 271 in June 2015, the New Hampshire Department of Health and Human Services (NH DHHS) began a Naloxone Kit distribution campaign. Kits are distributed through public events through the Regional Public Health Networks and through retail pharmacies that have a standing order for dispensing.

HB 271 allows New Hampshire physicians to prescribe, dispense or distribute naloxone to a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose, as well as to persons who are themselves at risk of overdose.

The NH Board of Medicine worked closely with NH Board of Pharmacy, NH DHHS and the NH Attorney General's Office to revise its Administrative Rules in response to HB271. As part of the implementation of Naloxone distribution, the NH Medical Society stated that a standing order in the context of naloxone distribution means "an order provided by a physician that authorizes a pharmacist to dispense naloxone to any persons at risk or persons in a position to assist in the event of an opioid overdose without specification of a particular individual".

New Hampshire Board of Medicine Statement on House Bill 271: "HB 271 authorizes licensees to prescribe naloxone pursuant to a non-patient specific standing order with a pharmacy that authorizes naloxone to be dispensed to persons whom a pharmacist understands to be at risk of opioid overdose or in a position to assist a person at risk of overdose."

Doctors with prescriptive authority issue a written order that Naloxone can be distributed by a pharmacist. Under this scenario, someone can receive naloxone without ever meeting the doctor who officially prescribed it. In New Hampshire, many of the standing orders for naloxone were signed by a physician under contract with NH DHHS.

Currently any New Hampshire resident can buy Naloxone at an over-the-counter pharmacy that has standing orders for this service.

New Business

Rep Marsh brought the Commission's attention to the LSR that he drafted. There is an opportunity to revise the language based upon the recommendations of the Commission.

The primary question for the Commission revolves around the mechanism for increasing access to hormonal contraception at the retail pharmacy setting. There appear to be three options:

- Collaborative Practice Agreements
- Standing Orders
- Provider Status Change

The Commission will also need to clarify which hormonal contraceptives would be included.

There was discussion related to the fact that Standing Orders may be a viable middle-ground approach.

ACTION ITEM- Patricia Tilley will research which entity would be the best to discuss Standing Orders and Statutory Protection for prescribers and present information to the Commission.

Melissa Martina-Adorno described a patient-centric vision for the ultimate goal of expanding affordable access to hormonal contraception.

> **ACTION ITEM- Melissa Martina-Adorno will develop a written statement that describes a patient-centric vision for increased access to affordable hormonal contraception and share it with the Commission for their consideration.**

Old Business

Rep Mariellen MacKay followed through with the request of the Commission from September 14, 2017 to explore if recording equipment can be used to electronically record Commission meetings.

Because recording meetings is not the standing protocol of Legislative Commissions and because of the potentially chilling effect it may have on discussion, she has determined that meetings will not be recorded.

Agenda for Next Meeting

Adjournment

Meeting was adjourned at Noon by Representative Mariellen MacKay. The next general meeting will be at 10:00AM-Noon on October 12, 2017, in the Legislative Office Building, Room 205, Concord.

Minutes submitted by: Patricia Tilley

Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
October 12, 2017

Opening

The third meeting of the Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order at 10AM on October 12, 2017 in Room 205, Legislative Office Building by Representative Mariellen MacKay.

Present

Rep Mariellen MacKay; Rep William Marsh; Robert Stout; Michael Bullek; Gary Sobelson; Christopher Lopez; Brenden Rock; Jennifer Frizzell; Sara Kellogg Meade;; Patricia Tilley; Melissa Martinez-Adorno; Joyce Cappiello; Amy Schneider; Diane Trowbridge; Sen Donna Soucy; Rep Peter Schmidt.

Approval of minutes

Rep William Marsh motioned to accept the minutes from September 28, 2017. Christopher Lopez seconded the motion. Minutes approved.

Presentations

Standing Orders and Statutory Protection for Prescribers, Patricia Tilley

Patricia Tilley presented language from SB 222 (2017) and the Controlled Drug Act section RSA 318-B:15 that describes legal protections for prescribers working directly or by standing order.

SB 222 (2017), lines 26- 1 state:

III. No health care professional who, acting in good faith and with reasonable care, prescribes, dispenses, or distributes an antimicrobial medication for the treatment or prevention of a communicable disease as described in paragraph I, shall be subject to any criminal or civil liability, or any professional disciplinary action, for any action authorized by this section or any outcome resulting from an action authorized by this section.

RSA 318-B:15 states:

III (c) No health care professional who, acting in good faith and with reasonable care, prescribes, dispenses, or distributes an opioid antagonist directly or by standing order and no person who, acting in good faith and with reasonable care, stores, dispenses, or distributes an opioid antagonist or administers an opioid antagonist to another person who the person believes is suffering an opioid-related drug overdose shall be subject to any criminal or civil liability, or any professional disciplinary action, for any action authorized by this paragraph or any outcome resulting from an action authorized by this paragraph.

Questions/Comments:

Representative Marsh asked: *Do we want to add similar protections to the current draft LSR?*

Jennifer Frizzell responded that *she wasn't sure yet.*

Rep Mariellen MacKay suggested that *we hold off on discussing until we learn more have a better sense and consensus for the general direction of the recommendations.*

Massachusetts Senate Bill 499 (2017), Robert Stout

Robert Stout presented recent legislation from Massachusetts, *Senate Bill 499 (2017), An Act advancing contraceptive coverage and economic security in our state.* SB 499 would improve access to preventative health care, including contraception, by eliminating co-pays for that care by commercial insurance carriers.

Mr. Stout described that while this may be outside the scope of this Commission, it is important for the Commission to be aware of and consider related legislative policy activity among other states.

Questions/Comments:

Jennifer Frizzell commented: *States like Vermont and Maine are taking preemptive steps to ensure continued, affordable access to contraception in light of uncertainties with the Affordable Care Act.*

Rep Peter Schmidt asked: *Were the bills in Maine and Vermont widely supported?*

Jennifer Frizzell responded: *The bills passed with bipartisan support to ensure continued protection of benefits as a "belt and suspenders" approach.*

Robert Stout commented that insurers are at the table in Massachusetts discussing SB499. The commercial carriers just wanted to ensure that if there were generic equivalents to name brand contraceptives, that they could maintain the generics at no cost to member but charge for a name brand.

Report of the Commission to Study the Standards for Collaborative Practice,

Rep James MacKay

Representative James MacKay described the process by which the Commission to Study the Standards for Collaborative Practice developed recommendations for current RSA 318:16-a. In part, the RSA now states:

> *Any practitioner with prescriptive authority who holds an active, unrestricted license in the state of New Hampshire may enter into a collaborative pharmacy practice agreement. A service authorized by a practitioner to be performed by a pharmacist under a collaborative pharmacy practice agreement must be within the practitioner's current scope of practice.*

Rep MacKay described how his experience shadowing clinicians and pharmacists at Dartmouth Hitchcock Medical Center as instrumental in furthering his understanding of the importance of collaborative practice. He was pleased that within the Commission the NH Medical Society made the motion to accept these recommendations to promote this more sophisticated role for pharmacists.

Collaborative Practice, Michael Bullek

Michael Bullek provided a brief summary of the current laws and Administrative Rules for Collaborative Practice. He noted that more detail cannot be provided at this time because updated Administrative Rules are still in draft form. However, the new Rules will give authority to the medical provider to describe in more detail what extra standards or training the pharmacists must have to work within a specific collaborative practice agreement.

Mr. Bullek described that collaborative practice is a more detailed plan between a specific medical provider and a pharmacist while standing orders are more broad and generalized in nature. He stated that he believed that the easiest way for increased access to contraception to flow would be through a standing order. However, it he anticipated that it would not be easy "to sell" this idea to retail, chain pharmacies. Insurance payments also remain a significant hurdle.

Questions/Comments:

Dr Sorbelson asked: *How does reimbursement occur under collaborative practice?*

There may be specific agreements with carriers, but the reimbursement does not typically flow directly to the pharmacists in a clinical setting.

Dr Sorbelson asked: *Why would a chain pharmacy reject the idea of standing orders for contraceptives?*

Mr Bullek responded that: *There is a big difference in reimbursement. Contraceptives are typically are "cash in/cash out" as opposed to flu shots where there is room for profit. There is little incentive to spend the amount of time that will be needed with little to no profit margin on the product.*

Robert Stout noted that: *Dispensing fees range from as much as $2.50 to nothing from current insurers. In another model, Colorado created the infrastructure for the Colorado Boards of Pharmacy, Medicine, and Nursing to work collaboratively with the Colorado Department of Public Health and Environment to create statewide protocols to increase access to contraception. This protocol reduces liability issues for both the pharmacists and the medical providers.*

Joyce Capiello asked: *Are there small margins for all hormonal contraception?*

Mr Bullek responded: *There is a class effect. Contraception is a loss leader in the retail environment.*

Sara Meade asked: *Is naloxone being sold in retail?*

Yes, it is sold in retail. Commercial insurers cover the cost. However, it is not widely sold in the retail market.

Patricia Tilley noted that: *Many people, especially those that are low income or do no not have commercial insurance, are receiving naloxone free of charge through other sources such as community health centers and Public Health Networks.*

Dr Martinez-Adorno asked: *Are we going down a slippery slope if we consider profit margins? I worry about this being part of our considerations.*

Dr Sobelson responded: *There is a great deal of profit somewhere. Retail pharmacies such as CVS caremark provide medications at a low cost, but profit is made in the rest of the store. We may need to worry about independent pharmacies, but not the retail chains.*

Robert Stout commented: *Independent pharmacists will continue to provide services for women seeking contraception.*

Jennifer Frizzell noted that: *When NH policy makers discussed its Contraception Equity Law it was noted that women purchasing contraception at pharmacies typically spent another $28 in other retail purchases.*

Rep Marsh stated: *We need to consider how women get the right product for them. That may not occur unless the pharmacists are compensated for their time.*

Dr Martinez-Adorno stated: *Women are educating themselves about their contraceptive options. ACOG and other medical provider have suggested that through their own self screening, women most often they know what they want and need.*

Rep Mariellen MacKay asked: *But who will women call if their contraceptive choice is not meeting their needs or if they need advice?*

Dr Martinez-Adorno responded: *Like other issues with their health, women call their physician when they need medical advice.*

Dr Sobelson asked: *How do pharmacists deal with these sorts of questions now?*

Christopher Lopez stated: *Pharmacists are accessible and patients often come with questions; treating symptoms related to medication is well within their scope of practice.*

Hormonal Contraceptives and Related Devices, Chris Lopez

Christopher Lopez presented a comprehensive list of the types of hormonal contraceptives available on the market today. Some devices such as IUDs would likely not fall within the category of hormonal contraception that this Commission is considering.

There could be as many as 84 products available for just oral contraception. In addition, the ring and patches could also be included within the scope of this Commission. Further discussion would need to occur to talk about intradermal implants and injectables.

Questions/Comments:

Sen Soucy asked: *Would additional instruction be needed for the ring?*

Dr Martinez-Adorno responded: *Little instruction is needed for the ring. It just requires simple insertion by the woman.*

Patricia Tilley asked: *So how do we simplify a woman's choices?*

Dr Martinez-Adorno responded: *Perhaps pharmacies would take the "Wal-Mart" approach. Describe the basic types of contraceptives available and provide or suggest limited choices within each of these groups.*

Dr Sobeloson noted: *The public health benefit of increased access to contraception may outweigh some of the inherent risks. Physicians will always be available to help their patients with more complicated questions and needs.*

Rep Schmidt commented: *The expertise in this room is impressive, but have other states gone down this path and what can we learn from them?*

Patient-Centric Access to Affordable Hormonal Contraception,

Dr Melissa Martinez-Adorno

Dr Martinez-Adorno presented a patient screening algorithm for contraception. These recommendations could be used by providers and pharmacists to help determine the safe use of contraceptive methods among women with various characteristics and medical conditions. This algorithm is based on the 2016 U.S. Medical Eligibility Criteria for Contraceptive Use from Centers for Disease Control and Prevention.

Rep Marsh commented: *The idea of a statewide protocol is appealing. But is there enough time to develop that idea for legislation that will need to be filed? Do we reinvent the wheel or tweak the wheel?*

Dr Martinez-Adorno responded: *A statewide protocol based on CDC recommendations could be developed in the time we have.*

Old Business

LSR 2018-2207 has been re-written to reflect standing orders as the mechanism to enable pharmacists to dispense contraception. The definition currently includes all hormonal contraception. Legally, the physician is responsible for the content of the standing order and the pharmacist is responsible for implementing those orders.

Questions/Comments:

Dr Sobeloson asked: *Have we made a decision about injectables?*

In this model, it would be under the purview of the physician authorizing the standing orders to determine that.

Rep Mariellen MacKay remarked: *It may be putting the cart before the horse to discuss the draft in detail.*

Rep Marsh noted that a draft needs to be filed ASAP.

Jennifer Frizzell commented: *Please do not forget about the need to require pharmacist education and a fact sheet about publicly available healthcare.*

Christopher Lopez asked: *We need further discussion about keeping the injectables within the scope. And can the language explicitly state that IUDs are not included?*

Joyce Capiello stated: *We also need further discussion about pros and cons of a tailored standing orders or a statewide protocol.*

There was further discussion about the process of filing the LSR and the appropriate way to stop and start the clock for draft language.

Mariellen MacKay stated: *The process should not constrain the Commission. Whatever the recommendations of the Commission are will be what is finally presented in the bill.*

There was continued conversation about the concept of standing orders vs statewide protocol.

Robert Stout stated: *If the Commission wants uniform implementation, then a statewide protocol is the way to go.*

Rep Marsh asked: *Could we do both? Could we do standing order or statewide protocol?*

Sen Soucy asked: *Could there be standing orders until such a time as statewide orders could be put in place?*

Christopher Lopez asked: *Would a statewide protocol be subject to the Administrative Rules process?*

ACTION ITEM- Attorneys from DHHS should be invited to the next meeting to discuss statewide protocol and the Administrative Rules Process.

New Business:

Representative Mariellen MacKay noted that in the upcoming meeting we will need to prioritize what direction we should go, determine educational components of the bill, and have DHHS attorneys weigh in on statewide protocols.

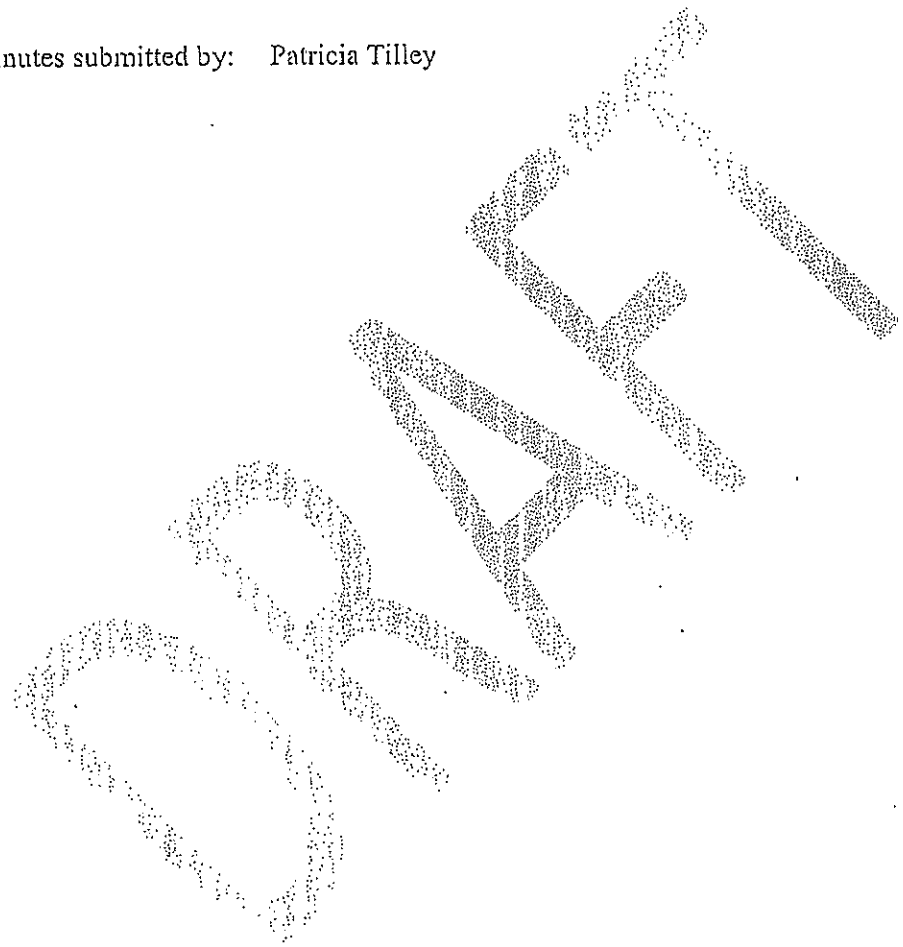
There was a question if additional language needs to be added to the bill about personal financial benefit, but it was determined that this is already covered under ethics rules.

Adjournment

Meeting was adjourned at 11:50 by Representative Mariellen MacKay. The next general meeting will need to be rescheduled due to conflicts.

The meeting was rescheduled to October 24, 2017 at 1:00 in Room 205, Legislative office building.

Minutes submitted by: Patricia Tilley



Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
October 24, 2017

Opening

The fourth meeting of the Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order at 1:00PM on October 24, 2017 in Room 205, Legislative Office Building by Representative Mariellen MacKay.

Present

Rep Mariellen MacKay; Rep William Marsh; Robert Stout; Michael Bullek; Gary Sobelson; Christopher Lopez;; Jennifer Frizzell; Sara Kellogg Meade; Patricia Tilley; Amy Schneider; Rep Peter Schmidt.

Approval of minutes

Christopher Lopez motioned to accept the minutes from October 12, 2017. Rep William Marsh seconded the motion. Minutes approved.

Agenda/Presentations

Rep MacKay opened the meeting by requesting that the Commission focus on draft LSR language. In doing so, it was clarified that the Commission can submit late legislation.

Rep MacKay requested that even though the Commission has a little more time to come to consensus on strategy, the meeting should focus on the language of Rep Marsh's proposed LSR. If time allows the Commission may consider working in small workgroups to further discuss details.

Rep Marsh reviewed the current draft. He noted that this version does not include a statewide protocol and instead utilizes language regarding Standing Orders.

John Williams, attorney for NH DHHS, addressed the Commission to discuss concerns and questions about potential legislation. Attorney Williams agreed with Reps Marsh and MacKay that there was still time available to work on a potential bill.

It was discussed that there is a need for the Commission to engage with Nancy Smith from the Attorney General's Office to seek ensure that potential language and direction of any bill is in alignment with NH law.

Previous bills about Naloxone distribution and Emergency Partner Therapy can provide a model for how to address issues such as prescriber protections and issues such as standing orders. The Boards of Medicine and Pharmacy should also weigh in heavily as they have through their representatives on the Commission.

Attorney Williams also suggested that NH DHHS may not be the most appropriate agency to implement potential Statewide Protocols for hormonal contraception. In situations such as distribution of Naloxone, the Public Health Agency was acting in response to a Public Health Emergency.

Questions/Comments:

Bob Stout commented that in Colorado the State Health Department worked with the Boards of Pharmacy and Medicine to develop statewide protocols that were acceptable.

Attorney Williams suggested that Nancy Smith would be better prepared to provide additional guidance as to if or how to propose similar authority and protections within NH for pharmacists and prescribers.

> ACTION ITEM: Nancy Smith should be invited to the next Commission meeting. The meeting should be set for the week of October 30.

Gary Sobelson asked Attorney Williams to talk a little more about DHHS's role with statewide protocols for vaccines and/or Naloxone. John Williams described that DHHS has not been involved with vaccine protocols for pharmacists but that with Naloxone, DHHS did provide standing orders for retail pharmacists that wished to participate. Again, Naloxone was seen as a needed response to a public health emergency. Typically DHHS does not bypass the doctor/patient relationship.

The State could potentially provide protocols or orders for contraception, but it is a gray area if that the appropriate role for DHHS.

Representative Marsh then discussed potential opportunities for pharmacist remuneration using MTM codes.

Commission members then debated the utility of breaking up into small workgroups to further discuss the models of:

- Collaborative Practice
- Statewide Protocols
- Standing Orders

Bob Stout and Christopher Lopez commented that Statewide Protocols continue to be the most intriguing idea, but that there were a number of details that needed to be pursued and questions that would need to be answered by the Attorney General's Office.

Bob Stout noted that he believed that the agencies - the Boards of Medicine, Pharmacy and NH DHHS- could be empowered to create the Statewide Protocol.

Christopher Lopez noted that since other states have made this work, we could learn from their example.

Representative Mariellen MacKay asked if a small group could come together and develop a set of questions for the Attorney General's Office. She named the following members onto the group:

- Bob Stout
- Gary Sobelson
- Chris Lopez
- Jennifer Frizzell
- Michael Bullek

Gary Sobelson noted that the Medical Society is concerned about scope creep. As described in earlier meetings, the Commission needs to be cautious about the maintaining the relationship and differences between medical prescribers and pharmacists.

Christopher Lopez responded by stating that diagnosis is not within the scope of pharmacy. It's not realistic to say that pharmacists want to take on the role of primary care provider.

Sara Kellogg Meade stated that if we indeed want to expand access to hormonal contraception then we need to seek the guidance of the Attorney General's Office to see how to strike a balance that both improves access and maintains the doctor/patient relationship.

Jennifer Frizzell stated that she would benefit from learning more from the Attorney General's Office. Liability is only a small slice of the total set of issues. She would also

like to discuss the resources that are needed for full implementation. Other states have invested funds when they've gone down this path.

Representative MacKay t called for a recess from the general meeting so that the workgroup that she appointed could convene.

The meeting reconvened at 2:30 PM.

Bob Stout spoke on behalf of the workgroup. The Medical Society wants to be sure that there is a medical provider involved in the process. A potential bill could direct and empower the NH Medical Society to adopt a statewide model for increasing access to hormonal contraception. Any Bill should also include language provided by Jennifer Frizzell to improve education and training requirements.

In contrast to the challenges in providing pharmacist training regarding emergency contraception years ago, there is now readily available, national, web-based training for pharmacists about hormonal contraception.

There was a question as to whether or not a bill should have language that would compel commercial and public insurers to support these efforts. Protections should also be put in place for the uninsured.

Representative MacKay stated that the Commission will schedule a meeting for the next week. And while the Commission has a little extra time to come to consensus on a direction for any such legislation, ultimately the Commission may choose to not put forward a Bill. As the Commission consolidates its thoughts, a report will be made to document where the Commission came to agreement and any areas for which there remained questions or a lack of consensus.

The meeting on November 9th will develop the draft recommendations and report and the report will be voted upon on November 16th.

Adjournment
Meeting was adjourned at 3:00 by Representative Mariellen MacKay.

The next meeting was scheduled for 10/31/17 at 1:00 in the Legislative Office Building, Room 205.

Minutes submitted by: Patricia Tilley

Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
October 31, 2017

Opening

The meeting of the Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order at 1:00PM on October 31, 2017 in Room 205, Legislative Office Building by Representative Mariellen MacKay.

Present

Rep Mariellen MacKay; Rep William Marsh; Robert Stout; Michael Bullek; Gary Sobelson; Jennifer Frizzell; Sara Kellogg Meade; Patricia Tilley; Amy Schneider; Sen Donna Soucy; Rep Peter Schmidt; Lyndsay Schommer.

Approval of minutes

Representative William Marsh moved to approve the minutes from October 24, 2017. The motion was seconded by Michael Bullek. The minutes were approved.

Presentations

The primary purpose of this meeting was to hear from Attorney Nancy Smith with regard to questions about proposed legal immunities and options for structuring standing orders.

Nancy Smith opened the conversation by re-stating her understanding of the Commission's questions. It was her understanding that the CDC has not made the same efforts to expand access to contraception as they had done with naloxone. While there is significant public health benefit to increased access to contraception, there does not appear to be the same urgent need that would suggest that government would need to bypass the doctor patient relationship. Exceptions to this doctor patient relationship construct were made for the recent bill to promote expedited partner therapy for treatment of sexually transmitted disease. Similar to naloxone, this was considered to address an urgent public health threat.

Attorney Smith described that there are inherent risks to standing orders and legal immunities. They can possibly be challenged. Both would have to meet the clinical standard of care. If there is consensus that it meets the standard of care, then the prescriber or those working under the umbrella of the standing order would have general protection. National standards or guidelines also reduce the risk. If there is no consensus about the standard of care, it could be challenged.

The Court is not likely "to close the courtroom door" for a potential challenge, but the key is to ensure that you are working under this consensus of the standard of care. There have been other occasions where the government has demonstrated that there can be limits on liability for for functions considered to urgently needed to protect public health health, such as naloxone administration.

It was noted by Commission members that CDC has a standard of care regarding contraception guidelines and this would likely be used to structure any standing order. It was also noted that the Medical Society wishes to see increased access to contraception, but is still interestested in understanding how to protect its members from potential liability.

Commission members noted that there is a balancing test between increasing access to contraception and the right for an individual to pursue remedies if there was a perceived wrong or injury.

There was additional conversation from the Commission about who decides if increasing access to contraception constitutes a public health emergency?

Nancy Smith stated that the issue of increasing access to contraception is a policy issue, but the standard of care is based upon the science.

The Commission asked clarifying questions about potentially imposing age limits to address concerns of parental rights. Commission members discussed that minors already have access to over the counter contraception such as condoms and have the right to seek confidential medical care for reproductive health issues. Minors are empowered to make these decisions and providers have the right to provide care to a mature minor.

There were additional questions about what could potentially happen if a women misrepresents her medical history and a negative health outcome occurred. Nancy Smith stated that she assumed that you would have to rely on the customer's representation. The Commission agreed that this is why there should be standard patient education with acknowledgement from the customer that she understood the risks.

The Commission also discussed the concern for vulnerable populations of women, those who have low literacy or who are not English speakers- many of whom would likely benefit from increased access. How do we provide protections for these groups?

Nancy Smith noted that again, this is a policy question.

New Business

Representative Marsh suggested that if we pursued language that includes working with the Boards of Medicine and Pharmacy, we can establish a standard of care and then we may not need further immunity.

Senator Soucy noted that the situation between contraception and and more urgent public health matters such as expedited partner therapy is different. While there is consensus on the benefit of increasing access to contraception, there is not the same level of urgency nor the same need for urgency in extending additional protections for liability. She also urged the Commission to consider whether this bill would in fact expand access to those that most need access or just making it easier for a population that already has access to medical care.

Commission members discussed that contraception available within pharmacies would, in fact, expand access for additional populations. The legislature has historically been supportive of public health efforts especially when these efforts are supported by the Boards of Medicine and Pharmacy. Rulemaking authority would also provide another check and balance and ultimately provide more protections. If we only think about liability, we would not do anything.

It was noted that we could agree to a standard of care on this issue.

Jennifer Frizzell suggested that we should include language that specifically requires public insurers to support this model of care. The women most likely to benefit from expanded access are low income. It was noted that if Medicaid supports this model, commercial insurers are likely to follow.

Representative MacKay reminded the Commission that there are only two meetings left for the Commission to come to consensus (or not); write a report; and determine whether or not to support legislation.

The report will document whether the Commission recommended legislation and/or document where the Commission came to consensus and where they may have been continued disagreements. When the Commission meets on November 9th members should be prepared to discuss the actual language of a bill. We should be able to list where we agree and disagree.

Representative MacKay requested that members submit in writing their concerns and forward them to Reps Marsh and MacKay and DC Bates.

Adjournment

Meeting was adjourned by Representative Mariellen MacKay. The next general meeting will be November 9, 2017, Room 205 of the Legislative Office Building.

Minutes submitted by: Patricia Tilley

Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications

Meeting Minutes
November 9, 2017

Opening

The Commission to Study Allowing Pharmacists to Prescribe or Make Available via Protocol Oral Contraceptives and Certain Related Medications was called to order at 10AM on November 6, 2017 in Room 205, Legislative Office Building by Representative Mariellen MacKay.

Present

Rep Mariellen MacKay; Rep William Marsh; Michael Bullek; Gary Sobelson; Christopher Lopez; Jennifer Frizzell; Sara Kellogg Meade; Patricia Tilley; Joyce Cappiello; Amy Schneider; Diane Trowbridge; Sen Donna Soucy; Rep Peter Schmidt; April Kvetkosky; Lindsay Schommer.

Approval of minutes

Rep William Marsh motioned to accept the minutes from October 31, 2017. Senator Soucy seconded the motion. Minutes approved.

New Business

Representative MacKay opened the meeting by thanking the Commission for their full participation and dedication to coming to consensus. She named the following people to a working group to collaborate with David Bates to produce the report of final recommendations for the November 16th meeting:

> Patricia Tilley; John Williams; Jennifer Frizzell; Robert Stout; Gary Sobelson; Michael Bullek; and Rep Marsh.

Representative MacKay asked Patricia Tilley to describe the Department of Health and Human Services' recommendations regarding standing orders and protocols. DHHS has determined that at this time it does not recommend statewide orders issued by DHHS

and/or signed by a DHHS physician. In addition to lingering concerns about whether it is appropriate to use a DHHS physician to issue standing orders for a non-emergent need such as contraception, there are other pragmatic reasons to not pursue this option. In order to receive Medicaid reimbursement, prescriptions must be ordered by a Medicaid enrolled provider. There is no physician in DHHS that meets this qualification. DHHS recommends that the Boards of Medicine and Pharmacy work with DHHS to develop a model set of standing orders that can be signed at the community level. The participation of the Boards of Medicine and Pharmacy with DHHS will ensure that a standard of care will be implemented within the template of model orders.

The Commission then reviewed Representative Marsh's bill *making hormonal contraceptives available directly from pharmacists by means of a standing order.*

A straw poll vote was taken regarding the inclusion of "shots" within the definition of hormonal contraceptives. The vote was 9-3 to remove "shots" from the definition.

Although there was discussion about the exact nature of the training referenced in line 30 on page 2, Commission members agreed that it is essential.

The Commission discussed that resources are needed for DHHS to help produce patient educational materials. In addition to information about the specific products, information must be made available to help direct individuals to where they can receive low or no cost reproductive health care. The Anyone, Anytime materials are a good example of a previous public education campaign.

Commission members reviewed the Centers for Medicare & Medicaid Services Informational Bulletin regarding *State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols* (Jan 17, 2017). This bulletin described opportunities for using innovative approaches such as standing orders for pharmacy dispensing as an appropriate option for states. Select members of the Commission will follow up with NH Medicaid to answer any remaining questions.

The next step for the Commission will be for the small working group to coordinate with David Bates to complete the final report based upon the Commission recommendations. The report will be reviewed and approved at the November 16th meeting.

Before the close of the meeting, Senator Soucy informed the Commission of legislation that she is sponsoring that would encourage the dispensing of 12 months of contraception at one time. While the Commission is very supportive of this idea, there was consensus

that this was a separate issue from the legislation the Commission is recommending. The two bills are complementary, but will remain separate.

Adjournment

Meeting was adjourned at 11:30 by Representative Mariellen MacKay. The last meeting of the Commission is scheduled for November 16, 2017

Minutes submitted by: Patricia Tilley