

2009 DRAFTING REQUEST

Bill

Received: **09/18/2009**

Received By: **tkuczens**

Wanted: **As time permits**

Identical to LRB:

For: **Donna Seidel (608) 266-0654**

By/Representing: **Natalie Verette**

This file may be shown to any legislator: **NO**

Drafter: **tkuczens**

May Contact:

Addl. Drafters:

Subject: **Occupational Reg. - prof lic**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Seidel@legis.wisconsin.gov**

Carbon copy (CC:) to: **tracy.kuczenski@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

Authorize optometrists to dispense medicated contact lenses

Instructions:

See attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?							
/P1	tkuczens 10/08/2009	jdyer 10/09/2009	jfrantze 10/09/2009	_____	cduerst 10/09/2009		
	tkuczens 10/15/2009	jdyer 10/15/2009		_____			
/P2	tkuczens 10/19/2009	jdyer 10/19/2009	rschluet 10/15/2009	_____	cduerst 10/15/2009		
/1			phenry	_____	mbarman	mbarman	

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
			10/19/2009 _____		10/19/2009	11/09/2009	

FE Sent For:

None

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/P2		<u>10</u> <u>19</u> <u>jd</u>	rschluet 10/15/2009	<u>10</u> <u>19</u> <u>ph</u>	cduerst 10/15/2009		

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/? /P1	tkuczens 10/08/2009	P2 10/14 JLD jdyer 10/09/2009	jfrantze 10/09/2009	MD PH	cduerst 10/09/2009		

FE Sent For:

10/15
<END> ST

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/?	tkuczens	PI 10/9 jw	J 10/9	Km JJ	10/9		

FE Sent For:

<END>

Kuczenski, Tracy

From: Verette, Natalie
Sent: Friday, September 18, 2009 2:50 PM
To: Kuczenski, Tracy
Subject: Dispensing Medicated Contact Lenses

Attachments: Dispensing Medicated Contact Lenses.pdf

Hi Tracy,

The info we received from the Optometric Association is attached. You have our permission to talk directly with Peter Theo if you have questions during the drafting process.

Thank you,
Natalie



Dispensing
Medicated Contact L.

Natalie Verette
Legislative Assistant
Office of State Representative Donna Seidel
Assistant Majority Leader
85th Assembly District

State Capitol, 218 North
P.O. Box 8953
Madison, WI 53708

608.266.0654
888.534.0085 (toll-free)
natalie.verette@legis.wisconsin.gov

Dispensing Medicated Contact Lenses by Licensed Doctors of Optometry
Proposal by the Wisconsin Optometric Association

Topic:

New optometric technology is constantly being developed to more effectively meet the ocular therapeutic needs of health care patients. It is widely understood by the ophthalmic industry and eye health professionals there will soon be a contact lens available for treating medical conditions of the eyes. This product is scheduled to receive final FDA approval this year. The medication will be contained in the contact lens and introduced into the eye over a period of time.

It is very clear that Wisconsin doctors of optometry are permitted by law to prescribe both contact lenses and ophthalmic therapeutic pharmaceutical agents. Additionally, licensed optometrists may also instill pharmaceuticals within their offices and provide a complimentary sample of the therapeutic agent to a patient to whom the optometrist has rendered care. These facts are not disputed by organized medicine, ophthalmology or pharmacy. The question now becomes whether medicated contact lenses can also be **dispensed** by appropriately qualified Wisconsin-licensed optometrists.

↳ what

Proposal:

In order to clarify this in law, the Wisconsin Optometric Association (WOA) would like to introduce legislation to expressly authorize optometrists to dispense medicated contact lenses. This simply requires inserting the word "Dispensing" within Chapter 449, Optometry's Practice Act, relating to medicated contact lenses only.

No opposition to this proposal:

Over the past several months, the WOA has worked diligently with the Pharmacy Society of Wisconsin, Wisconsin Medical Society and the Wisconsin Academy of Ophthalmology in order to gain support (or lack of opposition) for this proposal. I am pleased to report we have achieved this objective. With no known opposition to this proposal, we would hope this initiative will receive broad support and swift action by the Wisconsin Legislature.

Peter Theo
Executive Vice President
Wisconsin Optometric Association
6510 Grand Teton Plaza Suite 312
Madison, WI 53719
Phone: 608-824-2200 X 24
Cell: 608-332-6828
Fax: 608-824-2205

2009 Wisconsin Bill Draft

An Act to amend 449.01 (1) (a) 2. c. and to renumber and amend 449.18 (6) relating to:
authorizing certain optometrists to dispense contact lenses that contain therapeutic
pharmaceutical agents.

(Proposed) Analysis by the Legislative Reference Bureau

Under current law, an optometrist who is licensed by the Optometry Examining Board (board) may generally prescribe and administer a therapeutic pharmaceutical agent only if the optometrist was first licensed on or after August 1, 2006, or if the optometrist holds a certificate issued by the board. The Secretary of the Department of Regulation and Licensing (secretary) is required to promulgate rules specifying the therapeutic pharmaceutical agents that such optometrists may prescribe and administer.

This bill permits an optometrist who is authorized to prescribe and administer a therapeutic pharmaceutical agent to prescribe, administer, and dispense contact lenses that contain therapeutic pharmaceutical agents.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

BILL

SECTION 1. 449.01(1)(a) 2. c. is amended to read:

449.01 Definitions. (1) OPTOMETRY. (a) The practice of the profession of optometry is defined as:

1. The employment of any optometric means, including topical ocular diagnostic pharmaceutical agents under s. 449.17, to determine the visual efficiency of the human visual system, including refractive and functional abilities, or to diagnose the presence of ocular disease or ocular manifestations of systemic disease and other departures from normal.

— this is not a contact lens, but a liquid or gel?

2. The diagnosis and treatment of the refractive and functional

ability of the visual system and enhancement of visual performance

by any of the following:

a. Prescribing, furnishing, fitting or employing ophthalmic lenses, contact lenses, frames, aids or prosthetic materials.

b. Administering visual training, orthoptics, visual therapy or any other optometric means.

c. Prescribing, ~~or administering~~ or dispensing drugs for ocular therapeutic purposes or removing superficial foreign bodies from the eye or an appendage to the eye under s. 449.18.

*or agents?
or "ocular diagnostic pharmaceutical agents"
↓
is this/shall this be a defined term?*

SECTION 2. 449.18 (6) (am) 2. of the statutes is renumbered 449.18 (6) (am) 2. (intro.)

and amended to read:

449.18 (6) (am) 2. (intro.) Dispense, as defined in s. 450.01 (7), other than by prescribing or administering. ^{Plan} ~~This, except that this~~ subdivision does not prohibit the optometrist from providing doing any of the following:

a. Providing a complimentary sample of a therapeutic pharmaceutical agent to a patient to whom the optometrist has rendered therapeutic care.

SECTION 3. 449.18 (6) (am) 2. b. of the statutes is created to read:

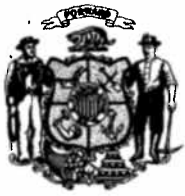
449.18 (6) (am) 2. b. Dispensing a contact lens that also delivers a therapeutic pharmaceutical agent, if the optometrist is authorized to prescribe or administer the therapeutic pharmaceutical agent under the rules promulgated under par. (cm).

(End)

- are "topical ocular [diagnostic] pharmaceutical agents" medicated contact lenses?
- are medicated contact lenses drugs?
- Are there other drugs (other than medicated contact lenses) that an optometrist would dispense?

X-ref 961.37

450.11(3) - sec 450.11 (3)



State of Wisconsin
2009 - 2010 LEGISLATURE

PI
LRB-3569/2
TKK: JLD
d-note
RMFuj

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

10/8/09
by 10/14/09

✓

Gen

1 AN ACT ...; relating to: authorizing certain optometrists to dispense contact
2 lenses that deliver a drug for ocular therapeutic purposes. ✓

Analysis by the Legislative Reference Bureau

* Under current law, a person licensed to practice the profession of optometry by the Optometry Examining Board (board) in the Department of Regulation and Licensing may, among other practices, prescribe contact lenses. ✓ If the person was first licensed after August 1, 2006, or holds a certificate issued by the board, the person may also prescribe or administer drugs for ocular therapeutic purposes. ✓ However, the person may not dispense drugs for ocular therapeutic purposes. ✓

This bill permits a person licensed to practice the profession of optometry who is authorized to prescribe or administer drugs for ocular therapeutic purposes to dispense contact lenses that deliver a drug for ocular therapeutic purposes. ✓

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

3 SECTION 1. 449.01 (1) (a) 2. c. of the statutes is amended to read:
4 449.01 (1) (a) 2. c. Prescribing or administering drugs for ocular therapeutic
5 purposes, dispensing contact lenses that deliver a drug for ocular therapeutic

1 purposes under s. 449.18 (6) (am) 2. b. or removing superficial foreign bodies from
 2 the eye or an appendage to the eye under s. 449.18.

History: 1977 c. 83, 280; 1979 c. 32; 1989 a. 31; 1999 a. 85.

3 **SECTION 2.** 449.18 (6) (am) 2. of the statutes is renumbered 449.18 (6) (am) 2.
 4 (intro.) and amended to read:

5 449.18 (6) (am) 2. Dispense, as defined in s. 450.01 (7), other than by
 6 prescribing or administering. This subdivision does not prohibit the optometrist
 7 from providing doing any of the following:

8 a. Providing a complimentary sample of a therapeutic pharmaceutical agent
 9 to a patient to whom the optometrist has rendered therapeutic care.

History: 1989 a. 31; 1991 a. 39; 2005 a. 297; 2007 a. 97.

10 **SECTION 3.** 449.18 (6) (am) 2. b. of the statutes is created to read:

11 449.18 (6) (am) 2. b. Dispensing a contact lens that also delivers a drug for
 12 ocular therapeutic purposes, if the optometrist is authorized to prescribe or
 13 administer the drug for ocular therapeutic purposes under the rules promulgated
 14 under par. (cm).

15 **SECTION 4.** 961.39 (intro.), (1), (2) and (4) of the statutes are amended to read:

16 **961.39 Limitations on optometrists.** (intro.) An optometrist who is allowed
 17 under s. 449.18 (1) to use therapeutic pharmaceutical agents and under s. 449.18 (6)
 18 (am) to dispense a contact lens that delivers a drug for ocular therapeutic purposes:

19 (1) May not prescribe, dispense, or administer a controlled substance included
 20 in schedule I or II.

21 (2) May prescribe, dispense, or administer only those controlled substances
 22 included in schedules III, IV, and V that are permitted for prescription or
 23 administration under the rules promulgated under s. 449.18 (6) (cm).

1 (4) May not dispense other than by ~~prescribing or administering~~ as provided

2

under s. 449.18 (6) (am) ~~and this section~~.

2.b ← score

← plain period

History: 1989 a. 31; 1995 a. 448 s. 241; Stats. 1995 s. 961.39; 2005 a. 297.

3

this section
and

(END)

d-note
↓

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

PI
LRB-3569/7dn
TKK:.....

date

Jld

Rep. Seidel: ✓

This bill authorizes a person who is licensed to practice the profession of optometry and is authorized to prescribe or administer drugs for ocular therapeutic purposes to dispense contact lenses that deliver a drug for ocular therapeutic purposes. ✓

* As I discussed, briefly, with Peter Theo of the Wisconsin Optometric Association, this bill draft uses a specific term, "drugs for ocular therapeutic purposes," to describe the substances that may be included on contact lenses dispensed by an optometrist under the bill. This term occurs in the current statutes in the provision governing the scope of practice of optometry, s. 449.01 (1) (a) 2. c., stats. In addition, this term is, in my opinion, the most accurate term to use given the definitions for administer (s. 450.01 (1), stats.), dispense (s. 450.01 (7), stats.), drug (s. 450.01 (10), stats.), and prescription (s. 450.01 (19), stats.). ✓

* However, this term is not used consistently in chapter 449; two additional terms, "topical ocular diagnostic pharmaceutical agents" and "therapeutic pharmaceutical agents" are also used (see, for example ss. 449.01 (1) (a) 1., 449.17, and 449.18). Although it is implied by the use of the word "pharmaceutical" in both terms that these substances are drugs, the statutes do not define either "topical ocular diagnostic pharmaceutical agents" or "therapeutic pharmaceutical agents." ✓

stats.

To avoid confusion, I recommend that whatever term is preferred for drugs prescribed, administered, and now dispensed by optometrists be used consistently in chapter 449. If more than one term is to be used, each term should have a corresponding definition. So, if the terms selected are "topical ocular diagnostic pharmaceutical agents" and "therapeutic pharmaceutical agent," I recommend that definitions be provided for these terms, even if the definitions simply clarify that these "pharmaceutical agents" are in fact within a subset of "drug" as that term is defined in s. 450.01 (10), stats. Further, I recommend that the definition for drug found in chapter 450 be referenced in this chapter governing optometrists. ✓

Please let me know if you have any questions or wish to make any changes to the bill or to the terms used in current law. ✓

Tracy K. Kuczenski
Legislative Attorney
Phone: (608) 266-9867
E-mail: tracy.kuczenski@legis.wisconsin.gov

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3569/P1dn
TKK:jld:jf

October 9, 2009

Rep. Seidel:

This bill authorizes a person who is licensed to practice the profession of optometry and is authorized to prescribe or administer drugs for ocular therapeutic purposes to dispense contact lenses that deliver a drug for ocular therapeutic purposes.

As I discussed, briefly, with Peter Theo of the Wisconsin Optometric Association, this bill uses a specific term, "drugs for ocular therapeutic purposes," to describe the substances that may be included on contact lenses dispensed by an optometrist under the bill. This term occurs in the current statutes in the provision governing the scope of practice of optometry, s. 449.01 (1) (a) 2. c., stats. In addition, this term is, in my opinion, the most accurate term to use given the definitions for administer (s. 450.01 (1), stats.), dispense (s. 450.01 (7), stats.), drug (s. 450.01 (10), stats.), and prescription (s. 450.01 (19), stats.).

However, this term is not used consistently in chapter 449; two additional terms, "topical ocular diagnostic pharmaceutical agents" and "therapeutic pharmaceutical agents" are also used (see, for example ss. 449.01 (1) (a) 1., 449.17, and 449.18, stats.). Although it is implied by the use of the word "pharmaceutical" in both terms that these substances are drugs, the statutes do not define either "topical ocular diagnostic pharmaceutical agents" or "therapeutic pharmaceutical agents."

To avoid confusion, I recommend that whatever term is preferred for drugs prescribed, administered, and now dispensed by optometrists be used consistently in chapter 449. If more than one term is to be used, each term should have a corresponding definition. So, if the terms selected are "topical ocular diagnostic pharmaceutical agents" and "therapeutic pharmaceutical agent," I recommend that definitions be provided for these terms, even if the definitions simply clarify that these "pharmaceutical agents" are in fact within a subset of "drug" as that term is defined in s. 450.01 (10), stats. Further, I recommend that the definition for drug found in chapter 450 be referenced in this chapter governing optometrists.

Please let me know if you have any questions or wish to make any changes to the bill or to the terms used in current law.

Tracy K. Kuczenski
Legislative Attorney
Phone: (608) 266-9867
E-mail: tracy.kuczenski@legis.wisconsin.gov

Kuczenski, Tracy

From: Verette, Natalie

Sent: Wednesday, October 14, 2009 10:01 AM

To: Kuczenski, Tracy

Subject: RE: Draft review: LRB 09-3569/P1 Topic: Authorize optometrists to dispense medicated contact lenses

Hi Tracy,

Thanks so much for working on this draft. After going over the Drafter's Note with Rep. Seidel & Peter Theo, there are a few changes Rep. Seidel would like made to the draft.

There are references in current Wisconsin Administrative Rule that address the definition and use of both diagnostic and therapeutic pharmaceutical agents. For example, Chapter Opt. 6 includes language regarding diagnostic and therapeutic agents as well as the Department of Regulation and Licensing Chapter RL 10 which defines the use of pharmaceutical agents by licensed optometrists. RL 10.01 (8) specifically defines diagnostic pharmaceutical agent and RL 10.01 (10) defines a "therapeutic pharmaceutical agent".

Because these administrative rules have worked well for many years, we are hesitant to change the statutes at this time because they serve as the foundation for these administrative rules. Please note that Chapter 449.17 relating to Diagnostics Pharmaceutical Agents was adopted by the Legislature over 30 years ago and Therapeutics Pharmaceutical Agents 20 years ago.

We agree that it would be ideal if the existing DPA statute, the current TAP statute and the bill draft regarding medicated contact lenses, matched up perfectly to the related definitions in the Pharmacy Examining Board law (Chapter 450). However, for the purposes of these relatively modest changes to Chapter 449, the preference would be not to undertake the larger approach you suggest. The timeline for the remainder of session is short and these changes would require conversations with the other entities impacted. We may explore the possibility of separate legislation to clarify these definitions once a consensus can be reached among everyone affected by the changes, which I am hopeful we could achieve with more time.

Therefore, we would like to return back to the original draft language that we sent you initially. Both the Wisconsin Academy of Ophthalmology and the Wisconsin Optometric Association have agreed to this language and the bill is being drafted at the request of Rep. Seidel's constituent that belongs to the association.

Additionally, your P1 draft includes a Section 4 regarding s.961.39. There is no problem with this as it is simply applying the dispensing of medicated contact lenses to the limitations under controlled substances. Finally, we recognize the Optometry Examining Board has the discretion to issue an administrative rule to provide greater specificity, if they believe it is necessary.

Please let me know if you have questions and you can feel free to talk directly with Peter Theo as well.

Thank you again for all of your help!

10/14/2009

Natalie

From: Duerst, Christina

Sent: Friday, October 09, 2009 2:56 PM

To: Rep.Seidel

Subject: Draft review: LRB 09-3569/P1 Topic: Authorize optometrists to dispense medicated contact lenses

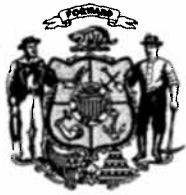
Following is the PDF version of draft LRB 09-3569/P1 and drafter's note.

T. conference w/ Peter Theo 824-2200 10/14/09

Section 1, 2, & 4 are done

Section 3 - change "drug for ocular therapeutic purposes" 2x to
"therapeutic pharmaceutical agent"

10/14/2009



PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

10/15/09
soon

✓
Regen

1 AN ACT to renumber and amend 449.18 (6) (am) 2.; to amend 449.01 (1) (a) 2.

2 c. and 961.39 (intro.), (1), (2) and (4); and to create 449.18 (6) (am) 2. b. of the

3 statutes; relating to: ✓ authorizing certain optometrists to dispense contact

4 (4) lenses that deliver a drug for ocular therapeutic purposes. pharmaceutical agent

Analysis by the Legislative Reference Bureau

Under current law, a person licensed to practice the profession of optometry by the Optometry Examining Board (board) in the Department of Regulation and Licensing may, among other practices, prescribe contact lenses. If the person was first licensed on or after August 1, 2006, or holds a certificate issued by the board, the person may also prescribe or administer drugs for ocular therapeutic purposes. However, the person may not dispense drugs for ocular therapeutic purposes.

This bill permits a person licensed to practice the profession of optometry who is authorized to prescribe or administer drugs for ocular therapeutic purposes to dispense contact lenses that deliver a drug for ocular therapeutic purposes.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows: the therapeutic pharmaceutical agent ✓ a therapeutic pharmaceutical agent ✓

5 SECTION 1. 449.01 (1) (a) 2. c. of the statutes is amended to read:

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 3 purposes under s. 449.18 (6) (am) 2. b., or removing superficial foreign bodies from
 4 the eye or an appendage to the eye under s. 449.18.
 e pharmaceutical agent ✓

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 6 (intro.) and amended to read:

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 9 from providing doing any of the following: ✓

10 a. Providing ✓ a complimentary sample of a therapeutic pharmaceutical agent
 11 to a patient to whom the optometrist has rendered therapeutic care.

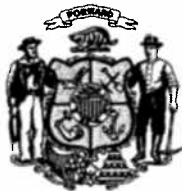
12 SECTION 3. 449.18 (6) (am) 2. b. of the statutes is created to read:

13 449.18 (6) (am) 2. b. Dispensing a contact lens that also delivers a drug for
 14 ocular therapeutic purposes, if the optometrist is authorized to prescribe or
 15 administer the drug for ocular therapeutic purposes under the rules promulgated
 16 under par. (cm).
 e pharmaceutical agent ✓

17 SECTION 4. 961.39 (intro.), (1), (2) and (4) of the statutes are amended to read:

18 **961.39 Limitations on optometrists.** (intro.) An optometrist who is allowed
 19 under s. 449.18 (1) to use therapeutic pharmaceutical agents and under s. 449.18 (6)
 20 (am) 2. b. to dispense a contact lens that delivers a drug for ocular therapeutic
 21 purposes: pharmaceutical agent ✓
 e

22 (1) May not prescribe, dispense, or administer a controlled substance included
 23 in schedule I or II.



~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

10/18/09

soon

✓
Regen

- 1 AN ACT *to renumber and amend* 449.18 (6) (am) 2.; *to amend* 449.01 (1) (a) 2.
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1 449.01 (1) (a) 2. c. Prescribing or administering drugs for ocular therapeutic
2 purposes, dispensing contact lenses that deliver a therapeutic pharmaceutical agent
3 under s. 449.18 (6) (am) 2. b., or removing superficial foreign bodies from the eye or
4 an appendage to the eye under s. 449.18.

5 **SECTION 2.** 449.18 (6) (am) 2. of the statutes is renumbered 449.18 (6) (am) 2.
6 (intro.) and amended to read:

7 449.18 (6) (am) 2. (intro.) Dispense, as defined in s. 450.01 (7), other than by
8 prescribing or administering. This subdivision does not prohibit the optometrist
9 from ~~providing~~ doing any of the following:

10 a. Providing a complimentary sample of a therapeutic pharmaceutical agent
11 to a patient to whom the optometrist has rendered therapeutic care.

12 **SECTION 3.** 449.18 (6) (am) 2. b. of the statutes is created to read:

13 449.18 (6) (am) 2. b. Dispensing a contact lens that also delivers a therapeutic
14 pharmaceutical agent, if the optometrist is authorized to prescribe or administer the
15 therapeutic pharmaceutical agent under the rules promulgated under par. (cm).

16 **SECTION 4.** 961.39 (intro.), (1), (2) and (4) of the statutes are amended to read:

17 **961.39 Limitations on optometrists.** (intro.) An optometrist who is allowed
18 under s. 449.18 (1) to use therapeutic pharmaceutical agents and under s. 449.18 (6)
19 (am) 2. b. to dispense a contact lens that delivers a therapeutic pharmaceutical
20 agent:

21 (1) May not prescribe, dispense, or administer a controlled substance included
22 in schedule I or II.

23 (2) May prescribe, dispense, or administer only those controlled substances
24 included in schedules III, IV, and V that are permitted for prescription or
25 administration under the rules promulgated under s. 449.18 (6) (cm).

1 (4) May not dispense other than ~~by prescribing or administering as provided~~

2 under this section and s. 449.18 (6) (am) 2. b. ✓

3

(END)

Duerst, Christina

From: Verette, Natalie
Sent: Friday, November 06, 2009 3:34 PM
To: LRB.Legal
Subject: Draft Review: LRB 09-3569/1 Topic: Authorize optometrists to dispense medicated contact lenses

Please Jacket LRB 09-3569/1 for the ASSEMBLY.