STATE OF WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES	**:**	**REPORT TO THE LEGISLATURE CR 19-028**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The Department is amending ch. SPS 10 in order to fully enact 2005 Wisconsin Act 297. The definitions for "adverse drug reaction," "adverse drug reaction referral plan," "approved institution," "classroom hour," and "course of study in pharmacology" have been removed from ch. SPS 10 and inserted into the proposed order for ch. Opt 6, CR 19-027.

In order to conform the chapter to drafting standards, the definitions for "diagnostic pharmaceutical agent" and "therapeutic pharmaceutical agent" were repealed and recreated as substantive provisions. The specific continuing education provisions, formerly included in s. SPS 10.02 (1) (a), have been repealed. Continuing education requirements have been consolidated into ch. Opt 8.

The content formerly included in ss. SPS 10.02 (1) (b) and (2) has been inserted in the proposed order for ch. Opt 6. The requirements of s. SPS 10.03 are addressed in the proposed order for ch. Opt 6. Since the authority for issuing DPA certificates has shifted from the Department to the Optometry Examining Board, s. SPS 10.04 has been repealed.

The Optometry Examining Board and the Department have opened chs. Opt 6 and SPS 10, respectively, concurrently to accurately and consistently implement this legislative shift. This order will become effective on the same date as the proposed order for ch. Opt 6, CR 19-027. Revisions were reviewed by the Optometry Examining Board and Department staff to ensure accuracy.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Department held a public hearing on May 30, 2019. The following people either testified at the hearing, or submitted written comments:

- In favor: Dr. Ann Meier Carli, Chairperson, Optometry Examining Board
- In favor: Peter Theo, Executive Vice President, Wisconsin Optometric Association

The Department made no modifications to its rule-making proposal prompted by public comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: 2. f.

Response: The Department consulted with the delegated liaison of the Optometry Examining Board on whether this change would be beneficial or useful for licensees. The recommendation was to reject the recommendation to avoid unnecessary confusion for licensees and that the change is unnecessary from a scientific perspective. The Department accepted the recommendation of the liaison.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

N/A

STATE OF WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES	:	PROPOSED ORDER OF THE DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES ADOPTING RULES (CLEARINGHOUSE RULE 19-028)

PROPOSED ORDER

An order of the Department of Safety and Professional Services to repeal and recreate ch. SPS 10, relating to use of pharmaceutical agents by licensed optometrists.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Sections 449.17, 449.18, and 961.39, Stats.

Statutory authority:

Sections 449.17 (5) and 449.18 (6) (cm), Stats.

Explanation of agency authority:

Section 448.17 (5), Stats., provides that the department, "shall, after consultation with the examining board, the medical examining board and the pharmacy examining board, promulgate rules specifying the topical ocular diagnostic pharmaceutical agents which optometrists may utilize in this state."

Section 449.18 (6) (cm), Stats., provides that the department, "shall, after consultation with the examining board, the medical examining board and the pharmacy examining board, promulgate rules specifying those therapeutic pharmaceutical agents that may or may not be prescribed or administered."

Related statute or rule:

Chapter Opt 6, relating to use of diagnostic and therapeutic pharmaceutical agents and removal of superficial foreign bodies from eye or from an appendage to the eye

Plain language analysis:

The definitions for "adverse drug reaction," "adverse drug reaction referral plan," "approved institution," "classroom hour," and "course of study in pharmacology" have been removed from ch. SPS 10 and inserted into the proposed order for ch. Opt 6.

In order to conform the chapter to drafting standards, the definitions for "diagnostic pharmaceutical agent" and "therapeutic pharmaceutical agent" were repealed and recreated as substantive provisions.

The specific continuing education provisions, formerly included in s. SPS 10.02 (1) (a), have been repealed. Continuing education requirements have been consolidated into ch. Opt 8.

The content formerly included in ss. SPS 10.02 (1) (b) and SPS 10.02 (2) has been inserted in the proposed order for ch. Opt 6. The requirements of s. SPS 10.03 are addressed in the proposed order for ch. Opt 6. Since the authority for issuing DPA certificates has shifted from the Department to the Optometry Examining Board, s. SPS 10.04 has been repealed.

Summary of, and comparison with, existing or proposed federal regulation:

The federal government schedules therapeutic pharmaceutical agents through the Controlled Substances Act, which categorizes optometrists as mid-level practitioners under Title 21, Code of Federal Regulations, Section 1300.01.

Comparison with rules in adjacent states:

Illinois:

Under Illinois law, optometrists may prescribe Schedule II (hydrocodone products only), III, IV, and V controlled substances and ocular pharmaceutical agents to patients without consulting a physician unless the patient is under 5 years of age. Ocular pharmaceutical agents include topical anesthetics, topical mydriatics, topical cycloplegics, topical miotics and mydriatic reversing agents, anti-infective agents, anti-allergy agents, anti-glaucoma agents (except oral carbonic anhydrase inhibitors, which may be prescribed only in a quantity sufficient to provide treatment for up to 30 days), anti-inflammatory agents (except oral steroids, which may be prescribed only in a quantity sufficient to provide treatment for up to 7 days), over-the-counter agents, analgesic agents, anti-dry eye agents, and agents for the treatment of hypotrichosis. The authority to prescribe a Schedule III, IV, or V controlled substance shall include analgesic agents only in a quantity sufficient to provide treatment for up to 72 hours. The prescription of a Schedule II controlled substance is prohibited, except for Dihydrocodeinone (Hydrocodone) with one or more active, non-narcotic ingredients only in a quantity sufficient to provide treatment for up to 72 hours, and only if such formulations of Dihydrocodeinone are reclassified as Schedule II by federal regulation.

The Illinois Optometric Licensing and Disciplinary Board may recommend additional pharmaceutical agents approved by the FDA to the Department of Financial and Professional Regulation, and the Department shall promulgate rules to allow for the prescribing or administering pharmaceutical agents. See 225 ILCS 80/15.1.

Illinois designates Optometrists to meet specific requirements to prescribe or distribute each type of pharmaceutical agents, depending on when they graduated from an approved school, including Diagnostic Ocular Pharmaceuticals (TN-D-OPT), Topical Therapeutics (TN-T-OPT) and Oral Therapeutic Medications (TN-T-OPT Oral Therapeutics). Illinois also requires a separate Controlled Substance license to prescribe controlled substances, and it must be renewed annually. Illinois's administrative rules relating to the practice are found in Title 68: Professions and Occupations, Chapter VII: Department of Financial and Professional Regulation Part 1320, Optometric Practice Act of 1987.

Iowa:

Under Iowa law, the Board of Optometry Examiners is part of the Department of Public Health. An optometrist licensed by the Board of Optometry Examiners may employ all diagnostic and therapeutic pharmaceutical agents for the purpose of diagnosis and treatment of conditions of the human eye and adnexa, excluding the use of injections other than to counteract an anaphylactic reaction, and may without charge supply any of the above pharmaceuticals to commence a course of therapy. Iowa Code § 154.1 3. and 4. Optometrists can prescribe oral medications including antibiotics, antivirals, and DMARDs, prescribe Schedule II, III, IV, and V drugs, and prescribe oral steroids (for a maximum of 14 days without consultation of a physician). The Board of Pharmacy reviews requests for additions to the controlled substances schedules, and the Board's decision will amend Iowa Code section 124.201, subs. 4. 657-10.37, Iowa Admin. Code.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Iowa are substantially similar to the requirements in Wisconsin. Both Iowa and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Iowa and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Iowa requires optometrists who are not certified to use therapeutic pharmaceutical agents to complete 30 hours of continuing education, and optometrists who are certified to use therapeutic pharmaceutical agents to complete 50 hours of continuing education. Iowa's administrative rules relating to the practice of optometry are found in their chapters 179 to 183.

Michigan:

In Michigan, the Board of Optometry requires optometrists to be certified to administer topical ocular diagnostic pharmaceutical agents and to prescribe therapeutic pharmaceutical agents. R 338.315 and R 338.317. The requirements are very similar to those in Wisconsin. The authority to prescribe or administer pharmaceutical agents

includes Schedule III, IV, and V drugs and dihydrocodeinone combination drugs. See 333.17401 (f), Michigan Stats. A controlled substances license is required to prescribe controlled substances. A management and emergency plan is also required. See Article 7 of Public Act 3.68 of 1978, as amended.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Michigan are substantially equivalent to the requirements in Wisconsin. In addition, both Michigan and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Michigan and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Wisconsin requires 30 hours of continuing education. Michigan requires 40 hours of continuing education. Michigan's administrative rules relating to the practice of Optometry are found in their sections R. 338.211 to 338.279 (General Rules) and R 338.291 (Ethical and Unprofessional Conduct).

Minnesota:

Optometrists may prescribe or administer FDA approved drugs to aid in the diagnosis, cure, mitigation, prevention, treatment, or management of disease, deficiency, deformity, or abnormality of the human eye and adnexa included in the curricula of accredited schools or colleges of optometry, and as limited by Minnesota statute and adopted rules by the Board of Optometry. § 148.56 (a), Minn. Stats. Optometrists may not prescribe or administer Schedule II and III oral FDA approved drugs and oral steroids; oral antivirals to be prescribed for more than ten days; or oral carbonic anhydrase inhibitors to be prescribed or administered for more than seven days. § 148.56 (b), Minn. Stats. The Board of Pharmacy schedules substances. § 152.02, Minn. Stats.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Minnesota are substantially equivalent to the requirements in Wisconsin. Both states require applicants to be a graduate of an accredited college of optometry and to pass a qualifying examination in order to obtain a license. Both states allow for applicants holding equivalent licensure from another jurisdiction to apply for licensure. In addition, both Minnesota and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to experience required in order to obtain a certification to use therapeutic pharmaceutical agents, Minnesota requires 2 years of supervised clinical experience in differential diagnosis of eye disease or disorders as part of optometric training or one year of that experience and ten years of actual clinical experience as a licensed optometrist. Other than experience or training required in conjunction with an initial optometry degree program, Wisconsin does not require an applicant to complete experience in order to obtain a certificate to use therapeutic pharmaceutical agents. In reference to continuing education, Minnesota and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Wisconsin requires 30 hours of continuing education. Minnesota

requires 40 hours of continuing education. Minnesota's administrative rules relating to the practice of optometry are under their Chapter 6500.

Summary of factual data and analytical methodologies:

Opt 6, relating to the Use of Diagnostic and Therapeutic Pharmaceutical Agents and Removal of Superficial Foreign Bodies From an Eye or From an Appendage to the Eye, was amended in 2007 to implement 2005 Wisconsin Act 297. The legislation shifted to the Optometry Examining Board from the Department of Safety and Professional Services the authority to determine which licensed optometrists may use pharmaceutical agents. The Department is amending SPS 10 in order to fully enact 2005 Wisconsin Act 297. The Optometry Examining Board and the Department have opened Opt 6 and SPS 10, respectively, concurrently to accurately and consistently implement this legislative shift. Revisions were reviewed by the Optometry Examining Board and Department staff to ensure accuracy. The Pharmacy Examining Board and Medical Examining Board were informed of the rule project.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Helen Leong, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-266-0797; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Helen Leong, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to

DSPSAdminRules@wisconsin.gov. Comments must be received before 8:45am on May 30, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter SPS 10 is repealed and recreated to read:

CHAPTER SPS 10

USE OF PHARMACEUTICAL AGENTS BY LICENSED OPTOMETRISTS

SPS 10.01 Authority. The rules in ch. SPS 10 are adopted under the authority in ss. 449.17 (1), 449.18 (6) (cm), and 961.39, Stats., to authorize the pharmaceutical agents for use by licensed optometrists in Wisconsin.

Note: To determine whether a licensed optometrist is eligible to use pharmaceutical agents under this chapter, refer to ch. Opt 6, relating to diagnostic and therapeutic pharmaceutical agents and removal of superficial foreign bodies from any eye or from an appendage to the eye.

SPS 10.02 Diagnostic pharmaceutical agents. (1) A licensed optometrist, authorized in accordance with ch. Opt 6, may use topical ocular diagnostic pharmaceutical agents 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 system disease and other departures from normal.

(2) Diagnostic pharmaceutical agents include:

(a) *Mydriatics.*

1. Phenylephrine 2.5%.
2. Hydroxyamphetamine 1%.

(b) *Cycloplegics.*

1. Tropicamide 1%.
2. Cyclopentolate 1%.

(c) *Topical anesthetics.*

1. Benoxinate 0.4%.
2. Proparacaine 0.5%.
3. Tetracaine 0.5%.
4. Benoxinate 0.4% - Fluorescein 0.25% Combination.

(d) *Dyes.*

1. Fluorescein 0.25% - Benoxinate 0.4% Combination.
2. Rose Bengal.

(e) *Miotics.*

1. Dapiprazole HCl.
2. Pilocarpine .125%.

(f) Any drug or device that is used for an ophthalmic diagnostic purpose and that is the subject of a new drug application approved by the food and drug administration under section 505 (c) (1) of the federal food, drug and cosmetic act, 21 USC 355, as amended.

(g) Any drug or device that is used for an ophthalmic diagnostic purpose and that is generally exempt from the new drug application approval requirement contained in section 505 of the federal food, drug and cosmetic act, 21 USC 355, as amended.

SPS 10.03 Therapeutic pharmaceutical agents. (1) A licensed optometrist, authorized in accordance with ch. Opt 6, may prescribe or administer a drug, as specified in sub. (2), for ocular therapeutic purposes.

(2) For the purposes of this chapter, therapeutic pharmaceutical agents are limited to:

(a) *Oral analgesics.*

1. Acetaminophen.
2. Aspirin.
3. Salicylates.
4. Schedule III, IV and V narcotic analgesics.

(b) Controlled substances in schedule II with limitations, as specified in s. 961.39 (2m), Stats.

(c) *Topical decongestant agents and decongestant combinations.*

1. Epinephrine HCl.
2. Hydroxyamphetamine HBr.
3. Naphazoline HCl.
4. Oxymetazoline HCl.
5. Phenylephrine HCl.
6. Tetrahydrozoline HCl.
7. Combinations of the above agents with antihistamines or zinc sulfate.

(d) *Antiallergy agents.*

1. Topical and oral antihistamine agents in the following drug categories:
   a. Alkyamines.
   b. Ethanolamines
   c. Ethylenediamines.
   d. Phenothiazines.
   e. Piperazines.
   f. Piperidines.
   g. Terfenadines.
2. Cromolyn sodium, a mast cell stabilizing agent.

(e) Artificial tear solutions, ophthalmic irrigants and ocular lubricants.

(f) Hypertonic sodium chloride, a topical hyperosmotic agent.

(g) Yellow mercuric oxide, a miscellaneous preparation and product.

(h) *Topical anesthetics.*

1. Benoxinate HCl.
2. Benoxinate HCl and sodium fluorescein.
3. Proparacaine HCl.
4. Tetracaine HCl.

(i) *Antibiotics.*

1. Topical antibiotics.
    a. Aminoglycosides.
    b. Bacitracin.
    c. Cephalosporins.
    d. Ciprofloxacin HCl.
    e. Erythromycin.
    f. Gramicidin.
    g. Norfloxacin
    h. Penicillins.
    i. Polymyxin B.
    j. Sulfonamides.
    k. Tetracyclines.
    L. Trimethoprim.
    m. Zinc sulfate.
2. Oral antibiotics.
    a. Erythromycin.
    b. Tetracycline.
3. Topical antiviral agents.
    a. Acyclovir.
    b. Idoxuridine.
    c. Trifluridine.
    d. Vidarabine.
4. Acyclovir, an oral antiviral agent.

(j) *Anti-inflammatory agents.*

1. Oral non-steroidal anti-inflammatory agents.
    a. Fenoprofen.
    b. Ibuprofen.
    c. Ketoprofen.
    d. Naproxen.
2. Topical corticosteroid agents.
    a. Dexamethasone.
    b. Fluoromethalone.
    c. Medrysone.
    d. Prednisolone.
    e. Prednisolone and atropine combinations.
    f. Topical corticosteroid and antibiotic combinations.
    g. Topical corticosteroid and mydriatic combinations.
3. Topical non-steroidal agent, diclofenac sodium.

(k) *Topical anticholinergic agents.*

1. Atropine.
2. Atropine sulfate.
3. Cyclopentolate.
4. Homatropine.
5. Homatropine hydrogen bromide.
6. Scopolamine.

7. Tropicamide.

(L) *Antiglaucomatous agents.*

1. Sympathomimetics.
   a. Dipivefrin.
   b. Epinephrine.
2. Miotics, direct acting.
   a. Acetylcholine.
   b. Carbachol.
   c. Pilocarpine.
3. Miotics, cholinesterase inhibitors.
   a. Demecarium bromide.
   b. Echothiophate.
   c. Isoflurophate.
   d. Physostigmine.
4. Topical beta-adrenergic blocking agents.
   a. Betaxolol.
   b. Carteolol HCl.
   c. Levobunolol.
   d. Metipranolol HCl.
   e. Timolol.
5. Oral carbonic anhydrase inhibitors.
   a. Acetazolamide.
   b. Dichlorphenamide.
   c. Methazolamide.

(m) Any drug or device that is used for an ophthalmic therapeutic purpose and that is the subject of a new drug application approved by the food and drug administration under section 505 (c) (1) of the federal food, drug and cosmetic act, 21 USC 355, as amended.

(n) Any drug or device that is used for an ophthalmic therapeutic purpose and that is generally exempt from the new drug application approval requirement contained in section 505 of the federal food, drug and cosmetic act, 21 USC 355, as amended.

(o) Any drug or device that is used for an ophthalmic therapeutic purpose and that is certified by the food and drug administration pursuant to section 507 (a) of the federal food, drug and cosmetic act, 21 USC 357, or is exempt from certification under section 507 (c) of the act, as amended.

(3) A licensed optometrist authorized to use therapeutic pharmaceutical agents may dispense a contact lens that delivers therapeutic pharmaceutical agents that are permitted under sub. (2).

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats., of CR 19-027, Opt 6, relating to diagnostic and therapeutic pharmaceutical agents.

(END OF TEXT OF RULE)

This Proposed Order of the Department of Safety and Professional Services is approved for submission to the Governor and Legislature.

Dated June 6, 2019 Agency Dawn B. Crim

Secretary
Department of Safety and Professional Services

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
SPS 10

3. Subject
Use of pharmaceutical agents by licensed optometrists

4. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
2005 Wisconsin Act 297 restricted the Department of Safety and Professional Services authority relating to pharmaceutical use by optometrists to promulgation of rules specifying the topical ocular diagnostic pharmaceutical agents which an optometrist may utilize and therapeutic pharmaceutical agents which may be administered or prescribed. In addition, 2005 Act 297 transferred all other authority relating to the use of pharmaceutical agents to the Optometry Examining Board.

This rule will update the SPS 10 chapter to remove obsolete provisions relating to the change in statutory authority.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.
The proposed rule was posted on the Department of Safety and Professional Services' website for 14 days in order to solicit comments from businesses, representative associations, local governmental units, and individuals that may be affected by the rule. No comments were received.

11. Identify the local governmental units that participated in the development of this EIA.
None.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This proposed rule will not have a significant impact on specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The primary benefit of updating SPS 10 is to ensure consistency with statutes and the pending updates to Opt 6 in order to provide clarity to licensees applying for DPA or TPA certificates, or both.

If the rule is not implemented, then licensees will have uncertainty and potential confusion if applying for a

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

DPA or TPA certificate.

14. Long Range Implications of Implementing the Rule

The long-range implication of the rule is providing transparency and consistency with the process of approving DPA and TPA certificates, consistent with statutory requirements, for licensees.

15. Compare With Approaches Being Used by Federal Government

The federal government schedules therapeutic pharmaceutical agents through the Controlled Substances Act, which categorizes optometrists as mid-level practitioners under Title 21, Code of Federal Regulations, Section 1300.01.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois:

Under Illinois law, optometrists may prescribe Schedule II (hydrocodone products only), III, IV, and V controlled substances and ocular pharmaceutical agents to patients without consulting a physician unless the patient is under 5 years of age. Ocular pharmaceutical agents include topical anesthetics, topical mydriatics, topical cycloplegics, topical miotics and mydriatic reversing agents, anti-infective agents, anti-allergy agents, anti-glaucoma agents (except oral carbonic anhydrase inhibitors, which may be prescribed only in a quantity sufficient to provide treatment for up to 30 days), anti-inflammatory agents (except oral steroids, which may be prescribed only in a quantity sufficient to provide treatment for up to 7 days), over-the-counter agents, analgesic agents, anti-dry eye agents, and agents for the treatment of hypotrichosis. The authority to prescribe a Schedule III, IV, or V controlled substance shall include analgesic agents only in a quantity sufficient to provide treatment for up to 72 hours. The prescription of a Schedule II controlled substance is prohibited, except for Dihydrocodeinone (Hydrocodone) with one or more active, non-narcotic ingredients only in a quantity sufficient to provide treatment for up to 72 hours, and only if such formulations of Dihydrocodeinone are reclassified as Schedule II by federal regulation. The Illinois Optometric Licensing and Disciplinary Board may recommend additional pharmaceutical agents approved by the FDA to the Department of Financial and Professional Regulation, and the Department shall promulgate rules to allow for the prescribing or administering pharmaceutical agents. See 225 ILCS 80/15.1.

Illinois designates Optometrists to meet specific requirements to prescribe or distribute each type of pharmaceutical agents, depending on when they graduated from an approved school, including Diagnostic Ocular Pharmaceuticals (TN-D-OPT), Topical Therapeutics (TN-T-OPT) and Oral Therapeutic Medications (TN-T-OPT Oral Therapeutics). Illinois also requires a separate Controlled Substance license to prescribe controlled substances, and it must be renewed annually. Illinois's administrative rules relating to the practice are found in Title 68: Professions and Occupations, Chapter VII: Department of Financial and Professional Regulation Part 1320, Optometric Practice Act of 1987.

Iowa:

Under Iowa law, the Board of Optometry Examiners is part of the Department of Public Health. An optometrist licensed by the Board of Optometry Examiners may employ all diagnostic and therapeutic pharmaceutical agents for the purpose of diagnosis and treatment of conditions of the human eye and adnexa, excluding the use of injections other than to counteract an anaphylactic reaction, and may without charge supply any of the above pharmaceuticals to commence a course of therapy. Iowa Code § 154.1 3. and 4. Optometrists can prescribe oral medications including antibiotics, antivirals, and DMARDs, prescribe Schedule II, III, IV, and V drugs, and prescribe oral steroids (for a maximum of 14 days without consultation

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

of a physician). The Board of Pharmacy reviews requests for additions to the controlled substances schedules, and the Board's decision will amend Iowa Code section 124.201, subs. 4. 657-10.37, Iowa Admin. Code.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Iowa are substantially similar to the requirements in Wisconsin. Both Iowa and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Iowa and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Iowa requires optometrists who are not certified to use therapeutic pharmaceutical agents to complete 30 hours of continuing education, and optometrists who are certified to use therapeutic pharmaceutical agents to complete 50 hours of continuing education. Iowa's administrative rules relating to the practice of optometry are found in their chapters 179 to 183.

Michigan:
In Michigan, the Board of Optometry requires optometrists to be certified to administer topical ocular diagnostic pharmaceutical agents and to prescribe therapeutic pharmaceutical agents. R 338.315 and R 338.317. The requirements are very similar to those in Wisconsin. The authority to prescribe or administer pharmaceutical agents includes Schedule III, IV, and V drugs and dihydrocodeinone combination drugs. See 333.17401 (f), Michigan Stats. A controlled substances license is required to prescribe controlled substances. A management and emergency plan is also required. See Article 7 of Public Act 3.68 of 1978, as amended.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Michigan are substantially equivalent to the requirements in Wisconsin. In addition, both Michigan and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to continuing education, Michigan and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Wisconsin requires 30 hours of continuing education. Michigan requires 40 hours of continuing education. Michigan's administrative rules relating to the practice of Optometry are found in their sections R. 338.211 to 338.279 (General Rules) and R 338.291 (Ethical and Unprofessional Conduct).

Minnesota:
Optometrists may prescribe or administer FDA approved drugs to aid in the diagnosis, cure, mitigation, prevention, treatment, or management of disease, deficiency, deformity, or abnormality of the human eye and adnexa included in the curricula of accredited schools or colleges of optometry, and as limited by Minnesota statute and adopted rules by the Board of Optometry. § 148.56 (a), Minn. Stats. Optometrists may not prescribe or administer Schedule II and III oral FDA approved drugs and oral steroids; oral antivirals to be prescribed for more than ten days; or oral carbonic anhydrase inhibitors to be prescribed or administered for more than seven days. § 148.56 (b), Minn. Stats. The Board of Pharmacy schedules substances. § 152.02, Minn. Stats.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Minnesota are substantially equivalent to the requirements in Wisconsin. Both states require applicants to be a graduate of an accredited college of optometry and to pass a qualifying examination in order to obtain a

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

license. Both states allow for applicants holding equivalent licensure from another jurisdiction to apply for licensure. In addition, both Minnesota and Wisconsin require applicants to complete specialized course work relating to the use of diagnostic and therapeutic pharmaceutical agents and to pass a qualifying examination. In reference to experience required in order to obtain a certification to use therapeutic pharmaceutical agents, Minnesota requires 2 years of supervised clinical experience in differential diagnosis of eye disease or disorders as part of optometric training or one year of that experience and ten years of actual clinical experience as a licensed optometrist. Other than experience or training required in conjunction with an initial optometry degree program, Wisconsin does not require an applicant to complete experience in order to obtain a certificate to use therapeutic pharmaceutical agents. In reference to continuing education, Minnesota and Wisconsin require licensees to complete course work every two years in order to renew their credentials. Wisconsin requires 30 hours of continuing education. Minnesota requires 40 hours of continuing education. Minnesota's administrative rules relating to the practice of optometry are under their Chapter 6500.

17. Contact Name	18. Contact Phone Number
Helen Leong, Administrative Rules Coordinators	608 – 266 – 0797

This document can be made available in alternate formats to individuals with disabilities upon request.