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
Opt 6

3. Subject
Diagnostic and therapeutic pharmaceutical agents

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
The Department of Safety and Professional Services has the authority to promulgate rules specifying the topical ocular diagnostic pharmaceutical agents which an optometrist may utilize and therapeutic pharmaceutical agents which may be administered or prescribed. 2005 Act 297 transferred all other authority relating to the use of pharmaceutical agents to the Optometry Examining Board. The Department of Safety and Professional Services is updating SPS 10 chapter to remove obsolete provisions relating to the application, examination, continuing education and reporting requirements. The Optometry Examining Board promulgated rules to implement 2005 Act 297, however, there are references to portions of SPS 10 which will be repealed as part of the Department of Safety and Professional Services' rule-making project.

The Optometry Examining Board is updating Opt 6 to ensure conformity with statutes and that there are no gaps created by the changes to SPS 10.

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

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The primary benefit of updating Opt 6 is to ensure consistency with statutes and the pending updates to SPS 10 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 DPA or TPA certificate.

14. Long Range Implications of Implementing the Rule

The long-range implications of implementing 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.

The requirements for licensure and certification to use diagnostic and therapeutic pharmaceutical agents in Illinois are substantially equivalent to the requirements in Wisconsin. Both Illinois 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, Illinois requires licensees to complete 24 hours of continuing education. Optometrists who are certified to use therapeutic ocular pharmaceuticals are required to complete an additional 6 hours of continuing education in the treatment of ocular disease. 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

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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 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. 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. 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; prescribe oral antivirals for more than ten days; or prescribe or administer oral carbonic anhydrase inhibitors for more than seven days. § 148.56 (b), Minn. Stats. The Board of Pharmacy schedules substances. § 152.02, Minn. Stats.

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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. 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.

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☐ No