Chapter SPS 10

USE OF PHARMACEUTICAL AGENTS BY LICENSED OPTOMETRISTS

Note: Chapter RL 10 was renumbered chapter SPS 10 under s. 13.92 (4) (b) 1., Stats., Register November 2011 No. 671.

SPS 10.01 Definitions. As used in the rules in this chapter:

(1) "Adverse drug reaction" means an adverse, physical or psychological reaction experienced by a person resulting from diagnostic or therapeutic pharmaceutical agents administered by an optometrist which occurs within 24 hours after the drug is administered. An adverse drug reaction may be indicated by symptoms which include, but are not limited to, the following: red eye, painful eye, decrease in vision, pale or red swelling of the periocular or periorbital tissues, nausea, vomiting, fainting, mental confusion or cessation of respiration.

(2) "Adverse drug reaction referral plan" means a plan submitted to the department on an approved form in which the optometrist agrees to: a) refer patients who notify the optometrist of an adverse drug reaction to appropriate medical specialists or facilities; b) routinely advise the patient to immediately contact the optometrist if the patient experiences adverse reactions; and c) place in a patient's permanent record information describing any adverse drug reactions experienced by the patient and the date and time that any referral was made. Such plan shall include the names of at least 3 physicians, physician clinics or hospitals to whom the optometrist agrees to refer patients who experience an adverse drug reaction. At least one of these physicians shall be skilled in the diagnosis and treatment of diseases of the eye.

(3) "Approved institution" means a college of optometry accredited by the American council on optometric education approved by the optometry examining board which offers a course of study in general and ocular pharmacology meeting the requirements of s. 449.17 (1m) (b), Stats., or a course of study relating to the use of therapeutic pharmaceutical agents and the removal of superficial foreign bodies from an eye or from an appendage to the eye meeting the requirements of s. 449.18 (2), Stats.

Note: The optometry examining board annually reviews for approval the colleges of optometry accredited by the council on optometry education of the American optometric association or other accrediting bodies. A list of board approved colleges of optometry is available from the board upon request.

(4) "Classroom hour": For the purpose of determining whether a course of study meets the requirements of s. 449.17 (1m) (b), Stats., "classroom hour" means a 50–60 minute period of lecture, group discussion or laboratory directly associated with a course in pharmacology; time spent working in a clinic other than as part of a laboratory directly associated with a course in pharmacology does not qualify as a "classroom hour".

(5) "Course of study in pharmacology" means a course of study completed in an approved institution after 1973 in general and clinical pharmacology as it relates to optometry with the characteristics described in s. 449.17 (1m) (b), Stats. For courses, such as continuing education courses, which do not lead to a degree in optometry to qualify as part of a course of study in pharmacology, the courses must include at least one examination on course content.

(6) "DPA certificate" means a certificate issued by the department to an optometrist approving an adverse reaction referral plan submitted by the optometrist and as evidence that the optometrist has completed all requirements in s. SPS 10.03 and is entitled to use diagnostic pharmaceutical agents in accordance with ss. 449.17 and 449.19, Stats.

(8) "Diagnostic pharmaceutical agent" means any topical ocular diagnostic pharmaceutical agent which is an optometric means used 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. "Diagnostic pharmaceutical agents" include but are not limited to:

(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 which is used for an ophthalmic diagnostic purpose and which 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 which is used for an ophthalmic diagnostic purpose and which 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.

(9) "TPA certificate" means a certificate granted by the optometry examining board to an optometrist as evidence that the optometrist is certified to use therapeutic pharmaceutical agents in accordance with s. 449.18, Stats.

(10) "Therapeutic pharmaceutical agent" means a drug which is prescribed or administered for ocular therapeutic purposes. Except as provided in par. (am), therapeutic pharmaceutical agents include all of the following:

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

(am) Controlled substances in schedule II, limited to either of the following:

1. Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four–fold or greater quantity of an isoquinoline alkaloid of opium.

2. Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(b) 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.

(c) *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.

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

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

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

(g) Topical anesthetics.

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

(h) Antibiotics.

1. Topical antibiotics.

a. Aminoglycosides.
b. Bacitracin.
c. Cephalosporins.
cm. Ciprofloxacin HCl.
d. Erythromycin.
e. Gramicidin.
em. Norfloxacin
f. Penicillins.
g. Polymyxin B.
h. Sulfonamides.
i. Tetracyclines.
j. Trimethoprim.
k. 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.

(i) *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.

(j) *Topical anticholinergic agents.*

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

(k) *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.
am. Carteolol HCl.
b. Levobunolol.
bm. Metipranolol HCl.
c. Timolol.

5. Oral carbonic anhydrase inhibitors.

a. Acetazolamide.
b. Dichlorphenamide.
c. Methazolamide.

(L) Any drug which is used for an ophthalmic therapeutic purpose and which 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.

(m) Any drug which is used for an ophthalmic therapeutic purpose and which 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.

(n) Any drug which is used for an ophthalmic therapeutic purpose and which is certified by the food and drug administration pursuant to s. 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.

Note: Section 961.39, Stats., contains certain limitations relating to the prescribing and administering of controlled substances by optometrists certified under section 449.18, Stats.

History: Cr. Register, January, 1979, No. 277, eff. 2−1−79; am. (2) and (5), r. (9) (d) 2., Register, April, 1979, No. 280, eff. 5−1−79; r. (7), renum. (8) and (9) to be (7) and (8), Register, November, 1986, No. 371, eff. 12−1−86; r. (7), Register, August, 1990, No. 416, eff. 9−1−90; am. (intro.), (1) and (8), cr. (9) and (10), Register, November, 1990, No. 419, eff. 12−1−90; cr. (8) (d) 2., (e), (10) (h) 1. cm. and em., (i) 3., (k)

4. am. and bm., Register, June, 1993, No. 450, eff. 7−1−93; am. (3), r. and recr. (8) (intro.) and (10) (intro.), cr. (8) (f), (g), (10) (L) to (n), Register, April, 1994, No. 460, eff. 5−1−94; corrections in (3), (4) and (5) made under s. 13.93 (2m) (b) 7., Stats., Register November 2007 No. 623; correction in (6) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671; **EmR1605: emerg. cr. (10) (am), eff. 1−16−16; CR 15−100: am. (10) (intro.), cr. (10) (am) Register July 2016 No. 727, eff. 8−1−16.**

SPS 10.02 Restrictions and reports. (1) RESTRICTIONS. (a) *Certification and education.* Therapeutic pharmaceutical agents may be prescribed or administered by an optometrist who holds a current TPA certificate and who satisfies the continuing education requirements specified in s. Opt 6.04. Diagnostic pharmaceutical agents may be administered by an optometrist who holds a current DPA certificate and who successfully completes biennially a minimum of 1 hour of continuing education approved by the optometry examining board relating to new drugs which are used for ophthalmic diagnostic purposes and which are approved by the food and drug administration, or other topics as designated by the optometry examining board.

Note: Completion of the continuing education required in s. Opt 6.04 for TPA certification satisfies the continuing education requirement under this section for an optometrist who holds both a DPA and a TPA certificate.

(b) *Prescribing.* Therapeutic pharmaceutical agents may be prescribed or administered by an optometrist only for the ocular therapeutic purposes for which the drugs are intended. These drugs shall be prescribed or administered in accordance with minimum standards and procedures established in the optometric profession. An optometrist shall not prescribe or administer a therapeutic pharmaceutical agent which is not allowed under s. SPS 10.01 (10). Approved agents may be used in combination only with other approved agents when appropriate. Prior to prescribing beta blockers or carbonic anhydrase inhibitors for the treatment of glaucoma, or any oral antiviral, or any other therapeutic pharmaceutical agent, as may be identified and designated in the future by the optometry examining board, which might prove to have significant systemic adverse reactions, the optometrist shall inform the patient's primary physician of his/her treatment plans and document that contact on the patient's chart. If the patient does not identify a primary physician, the patient shall be referred to a physician to determine the presence or absence of any systemic contraindications to the intended therapeutic agent. Following that assessment, and prior to prescribing, the prescribing optometrist shall contact the examining physician, documenting that contact on the patient's chart. Closed−angle glaucoma shall be considered an emergency in which the treating optometrist shall make immediate referral directly to a physician who specializes in the treatment of diseases of the eye and shall institute such emergency procedures as are directed by that physician.

(2) REPORTING REQUIRED. (a) Any optometrist certified to use therapeutic pharmaceutical agents shall file with the department within 10 working days of its occurrence a report on any adverse reaction resulting from the optometrist's administration of such agents. This report shall include the optometrist's name, address and license number, the patient's name, address and age, the patient's presenting problem, the diagnosis, the agent administered and the method of administration, the reaction and the subsequent action taken.

(b) Any optometrist certified to use diagnostic or therapeutic pharmaceutical agents shall file a revised adverse drug reaction plan with the department within 10 working days after the optometrist designates a new physician, physician clinic or hospital to which he or she agrees to refer patients who experience adverse drug reactions.

History: Cr. Register, November, 1990, No. 419, eff. 12−1−90; renum. (1) and (2) to be (1) (b) and (2) (a) and am. (1) (b), cr. (1) (a) and (2) (b), r. (3), Register, April, 1994, No. 460, eff. 5−1−94; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

SPS 10.03 Statement of approval required. A licensed optometrist may not use diagnostic pharmaceutical agents in the practice of optometry unless the optometrist has completed an application form and received a DPA certificate from the department. A licensed optometrist may not use therapeutic pharmaceutical agents in the practice of optometry unless the optometrist has completed an application form, met the requirements under s. 449.18, Stats., and received a TPA certificate from the optometry examining board.

History: Cr. Register, January, 1979, No. 277, eff. 2−1−79; am. Register, November, 1986, No. 371, eff. 12−1−86; renum. from RL 10.02 and am. Register, November, 1990, No. 419, eff. 12−1−90; CR 01−068: am. Register January 2002 No. 553, eff. 2−1−02.

SPS 10.04 Application for certificate. To obtain a DPA certificate, an optometrist must submit evidence to the department showing that the optometrist has:

(1) Completed a course of study in pharmacology.

(2) Successfully completed one of the following examination requirements:

(a) Obtained a score of not less than 75 on the pharmacology section of the examination administered prior to 1994 by the national board of examiners in optometry.

(b) Obtained passing scores on parts I and II of the examination administered after 1986 by the national board of examiners in optometry.

(c) Obtained a passing score on an examination approved by the department of safety and professional services and the optometry examining board.

(3) Established an adverse reaction referral plan.

Note: The required score of "not less than 75" relates only to the pharmacology section of the national examination. Therefore, if all sections of the national examination were taken at once, the 75 score minimum applies only to the pharmacology section and not to the other sections of the examination.

History: Cr. Register, January, 1979, No. 277, eff. 2−1−79; r. and recr. (2), Register, August, 1990, No. 416, 9−1−90; renum. from RL 10.03, Register, November, 1990, No. 419, eff. 12−1−90; am. (2), Register, April, 1994, No. 460, eff. 5−1−94; am. (1), r. and recr. (2), Register, May, 1996, No. 485, eff. 6−1−96; CR 01−068: am. (2) (a), r. (2) (b) (intro.), renum. (2) (b) 1. and 2. to be (2) (b) and (c) and am. (2) (b), Register January 2002 No. 553, eff. 2−1−02; correction in (2) (c) made under s. 13.92 (4) (b) 6., Stats., Register November 2011 No. 671.