C1801
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Final Order No. DOH-14-1563-DS -MQA
FILED DATE - SEP 16 2014
Department of Health
By [signature] Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BOARD OF OPTOMETRY

IN RE: PETITION FOR DECLARATORY
STATEMENT OF KIMBERLY REED, O.D.
F.A.A.O.
_____/

FINAL ORDER ON PETITION FOR DECLARATORY STATEMENT

This matter came before the Florida Board of Optometry (hereinafter the "Board") for a July 23, 2014 public hearing, in Boca Raton, Florida, for consideration of the Petition for Declaratory Statement (attached hereto as exhibit A) filed May 13, 2014 by KIMBERLY REED, O.D., F.A.A.O. (hereinafter the "Petitioner"). The Notice of Petition for Declaratory Statement was republished on June 25, 2014, in Volume 40, No. 123, of the Florida Administrative Register.

The Petition seeks the Board's determination that the use of a specific biological contact lens bandage, marketed under the name PROKERA® is authorized under Florida law "because it does not fall within the definition of surgery found in subsection 463.002(6), Florida Statutes" ("F.S."), and that its use falls within the definition of "optometry" as found in subsection 463.002(7), F.S. At the public hearing, the Board considered the written comments on the Petition received from the Florida Society of Ophthalmology and the American Academy of Ophthalmology, as well as oral comments from D. Bruce May, Jr., Esq., representing the Florida Society of Ophthalmology.

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FINDINGS OF FACTS

1. The facts set forth in the Petition are hereby adopted and incorporated herein by reference as the findings of fact by the Board.

CONCLUSIONS OF LAW

1. The Board of Optometry has authority to issue this Final Order pursuant to Section 120.565, F.S., and Rule 28-105, Florida Administrative Code ("F.A.C.").

2. The Petition filed in this cause is in substantial compliance with the provisions of Section 120.565, F.S., and Rule 28-105.002, F.A.C.

3. For purposes of determining standing in this matter, the Petitioner, a Certified Optometrist currently licensed to practice in Florida pursuant to Chapter 463 F.S., is a substantially affected person due to the fact that Petitioner wishes to use the PROKERA® biological contact lens bandage in her optometry practice.

4. As set forth in the Petition, the Petitioner asserts that PROKERA® is a type of biological contact lens bandage, composed of amniotic membrane in a thermoplastic ring set, which is placed onto the surface of the eye in the same manner as a bandage soft contact lens. The PROKERA® biological contact lens bandage is a treatment option for ocular surface and corneal healing, and is FDA approved as a class II medical device. Petitioner asserts the PROKERA® biological contact lens bandage "would be beneficial in serving my patients suffering from a badly damaged corneal surface."

5. Petitioner specifically requests "that the Board determine that, as a Florida Certified Optometrist, my use of this type of biological contact lens bandage in my Florida practice is authorized by subsection 463.002(7), F.S." Petitioner also requests that the Board determine that the use of the PROKERA® type biological contact lens bandage is authorized "because it does not involve surgery as defined in subsection 463.002(6), F.S., because it is not a procedure using an instrument . . . and because the procedure does not use an instrument which requires the closure of human tissue by suture, clamp, or other such device." Petitioner specifically notes that she is "not requesting to suture or glue the amniotic membrane to the corneal surface or in any way create a wound that would then require 'closure' via the use of amniotic membrane."

6. Based on the foregoing, the Board finds that the use of the PROKERA® biological contact lens bandage in the manner specified in the Petition does not constitute the transplantation of human tissue as defined in section 381.004(1), F.S. The Board finds that optometrists currently use bandage contact lenses in their practice. The Board further finds that the application of the PROKERA® biological contact lens bandage in the manner and for the purposes described in the Petition would not constitute surgery as that term is used in subsections 463.002(6) and 463.014(4), F.S.

7. The Board finds the use of the PROKERA® type biological contact lens bandage, in the manner identified and described in the Petition, is within the scope of the practice of optometry as used in Section 463.002(7), F.S.

8. The Board's response to this Petition addresses the determinations requested by the Petitioner and only addresses issues regarding the practice of optometry, and not the practice of medicine or any other profession. The Board's conclusion is based solely on the Board's application of the factual circumstances outlined in the Petition to the pertinent statutory and rule provisions set forth above.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 11th day of September, 2014.

BOARD OF OPTOMETRY

Adrienne Rodgers, Executive Director
For Timothy Underhill, O.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: **Kimberly Reed**, O.D., 2780 S.W. 116th Avenue, Davie, Florida 33330; and by interoffice mail to Lawrence Harris, Assistant Attorney General, Department of Legal Affairs, PL-01 The Capitol, Tallahassee, Florida 3239-1050 and Board of Optometry, 4052

Bald Cypress Way, Bin #C-05, Tallahassee, Florida 32399-1703, ON Sept. 16, 2014.

Angel Sanders

Deputy Agency Clerk

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Bridget Coates
DATE: MAY 13 2014

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MAY 13 2014

To: The Florida Board of Optometry
4052 Bald Cypress Way, Bin # C07
Tallahassee, FL 32399-3257
May 8, 2014

From: Kimberly Reed, O.D., FAAO
2780 SW 116th Avenue, Davie, FL 33330
FL OPC 2454
(954) 262-4227

RE: Petition for Declaratory Statement before Florida Board of Optometry

I am Dr. Kimberly Reed, a Florida certified optometrist (License No. OPC 2454) currently practicing optometry in Florida. I wish to use in my Florida optometric practice a type of biological contact lens bandage composed of amniotic membrane in a thermoplastic ring set. The bandage is a treatment option for ocular surface and corneal healing. The bandage is a FDA approved as a class II medical device and is marketed under the name PROKERA®.

The bandage is composed of cryopreserved amniotic membrane tissue clipped into a PMMA (rigid contact lens-type plastic) thermoplastic ring set that is placed onto the surface of the eye, after the application of topical proparacaine, in the same manner as a bandage soft contact lens. The use of topical proparacaine is authorized by Florida certified optometrists because it is currently listed on the TOPA Formulary in Rule 64B13-18.002(2)(b), F.A.C. The bandage has been found to promote accelerated healing, reduced inflammation, reduced neovascularization and reduced pain in patients that have suffered significant corneal surface injury from trauma, severe infection or severe auto-immune disease. The bandage offers healing technology that exceeds "pressure patching" and would be beneficial in serving my patients suffering from a badly damaged corneal surface.

I am currently treating patients in my practice in Florida who would benefit from this type of ocular bandage. It has been suggested to me by some health care practitioners that a Florida certified optometrist is not authorized to use of this type of ocular bandage. While I do not agree with those opinions, I have delayed any use of the bandage on my patients so that I might be certain that its use by Florida certified optometrists is authorized by chapter 463, Florida Statutes. I hereby request that the Florida Board of Optometry determine that, as a Florida certified optometrist, my use of this type of biological contact lens bandage in my Florida practice is authorized by because it falls within the definition of optometry found in subsection 463.002 (7), Florida Statutes. Specifically, I am requesting that the Board determine that, as a Florida optometrist, my use of this type of biological contact lens bandage is authorized by the following language of subsection 463.002 (7);

> "...the employment of lenses ... contact lenses, ... and any other means or methods, including ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages".

I hereby request that the Florida Board of Optometry also determine that, as a Florida certified optometrist, my use of this type of biological contact lens bandage in my Florida practice is authorized because it does not fall within the definition of surgery found in subsection 463.002 (6), Florida Statutes. Specifically, I am requesting that the Board determine that, as a Florida certified optometrist, my use of use of this type of biological contact lens bandage, including its placement on the ocular surface, does not involve surgery as defined in subsection 463.002 (6) because it is

not a procedure using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped or vaporized by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation, and because the procedure does not use an instrument which requires the closure of human tissue by suture, clamp, or other such device.

I would summarize the following in support of my petition:

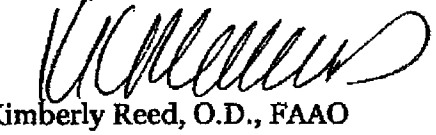
1. The application and use of this type of biological contact lens bandage (CPT code 65778) on the human eye is no different than my use and handling of a contact lens. Specifically, the bandage is applied to the cornea in a straightforward manner with a technique no different from that required in the application of a non-biological bandage contact lens (CPT 92071) or a scleral shell rigid gas permeable contact lens as used in the fitting of a keratoconic cornea (CPT 92072). Both of these services are routinely and successfully performed in my office for the management of both trauma and degenerative external eye diseases. Thus for patients with severe corneal damage or other severe ocular surface disease not responsive to traditional measures, the use of this biological contact lens bandage serves as a logical extension of "contact lens" applied corneal rehabilitative therapy.

2. The Board may wish to review the following summary excerpt regarding PROKERA® taken from the Federal Register:

"A recent consideration by CMS of the use of amniotic membranes for ocular surface disease which appeared in the PFS 2013 Final Rule as appears **Federal Register** /Vol. 77, No. 221 /Thursday, November 15, 2012 /Rules and Regulations **68339-68341** from which I quote: *In addition, our medical advisors indicated that the procedure described by CPT code 65778 is not significantly different than placing a bandage contact lens on the surface of the eye to cover a corneal epithelial defect. CPT code 65778 describes the simple placement of a special type of bandage (a self-retaining amniotic membrane device) on the surface of the eye, which would most commonly be used to cover the surface of the eye after a procedure that results in a corneal epithelial defect."*

Please note, I am not requesting to suture or glue the amniotic membrane to the corneal surface or in any way create a wound that would then require "closure" via the use of amniotic membrane. I am simply requesting to place the "PMMA clipped amniotic membrane" on to the surface of a significantly damaged eye in a manner exactly like the fitting of a bandage or scleral fit contact lens. I humbly await your formal consideration in this matter.

Sincerely,



Kimberly Reed, O.D., FAAO

Cc: John E. Griffin
Carson & Adkins
2930 Wellington Circle, Suite 201
Tallahassee, FL 32309