



Physicians Caring for Texans



April 2, 2015

Mr. Chris Kloeris  
Executive Director  
Texas Optometry Board  
333 Guadalupe Street, Suite 2-420  
Austin, Texas 78701-3942

Re: Comments on Proposed Rule 22 TAC §280.6, Procedures Authorized for Therapeutic Optometrists as published in the March 20, 2015 edition of the Texas Register at 40 TexReg 1628.

Dear Mr. Kloeris,

The Texas Medical Association (TMA) is a private, voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: “Physicians Caring for Texans.” TMA’s diverse physician members practice in all fields of medical specialization.

The Texas Ophthalmological Association (TOA) is a private, voluntary, nonprofit association of over 850 ophthalmologists and ophthalmologists in training in Texas. TOA’s purpose is to promote and advance the science and art of medicine appertaining to the eye.

We are writing today on behalf of the TMA and the TOA and its combined membership of over 48,000 physicians to state our position that the utilization of an ocular medical device such as PROKERA®, is beyond the scope of practice for optometrists in Texas.

Texas’ optometric scope of practice statute does authorize optometrists to prescribe lenses, contact lenses, and ocular pharmaceutical agents. PROKERA® would not fall under any of those classifications. Inaccurately classifying PROKERA® within one of those categories minimizes both the significance of the device, and more concerning, for safety, the severity of the patient’s condition requiring use of the device. PROKERA® is a medical device intended for use in the closure of human tissue, which is specifically prohibited by Texas statute.

The PROKERA® device consists of human donor tissue—specifically, amniotic membrane—attached to a large plastic ring, which is used for the treatment of moderate and severe corneal conditions. It is often used in conjunction with corneal surgery or significant anterior ocular diseases, and therefore is employed by ophthalmologists (medical eye physicians and surgeons), frequently those specializing in corneal surgery. There are times when the amniotic membrane

donor tissue is used to stabilize an eye to allow a more controlled surgical treatment later or even obviate the need for surgery. When applying the device, the transplanted tissue is intended to close the tissue, meaning that the procedure is defined as “surgery” within Texas statute, and therefore is not within the optometric scope of practice authority.

The PROKERA® device is intended for use in significant anterior segment diseases, such as Stevens-Johnson syndrome or chemical burns, and can actually cause trauma. Therefore, the medical device is typically used by ophthalmologists, who are trained in the medical and surgical treatment of these complicated cases.

Additionally, for those who are not appropriately trained, they may not readily recognize when a more substantial application of amniotic tissue is necessary or an alternative surgical approach is more appropriate. As such, the use of this device is outside the scope of practice for optometry. It is a misrepresentation to equate the PROKERA® medical device to the placement of a bandage contact lens given the complexity of the situations in which it is used and the potential complications that can occur.

The more common corneal problems such as abrasions and recurrent erosions can be treated, if needed, with an inexpensive bandage contact lens that is within the scope of practice for optometry. Furthermore, the difference in pricing between the bandage contact lens and PROKERA® is substantial, and its use when not medically necessary could bear significant financial burden for both payers and the patient.

For these reasons, it is our position that Texas statutes do not authorize optometrists to use the PROKERA® ophthalmic device or similar devices from other manufacturers in their practice.

TMA and TOA appreciate the board’s efforts in its rulemaking on this issue, and the opportunity to provide comment on the proposed rules. If you have any questions or comments, please feel free to contact Jeffrey S. Gdula, JD, TMA Staff Attorney at TMA’s main number 512-370-1300 or Sam V. Stone, JD at 512-478-2885.

Sincerely,

A handwritten signature in cursive script that reads "Austin King MD".

Austin King, MD  
President  
Texas Medical Association

A handwritten signature in cursive script that reads "Sidney K. Gicheru, MD".

Sidney K. Gicheru, MD  
President  
Texas Ophthalmological Association