



**House
Legislative
Analysis
Section**

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CONTACT LENS PRESCRIPTIONS

**House Bill 5376 as passed by the House
Sponsor: Rep. Gilda Z. Jacobs**

**House Bill 5377 as passed by the House
Sponsor: Rep. Gary Woronchak**

**House Bill 5378 as passed by the House
Sponsor: Rep. Stephen Ehardt**

**House Bill 5379 as passed by the House
Sponsor: Rep. Artina Tinsley Hardman**

**Second Analysis (2-19-02)
Committee: Health Policy**

THE APPARENT PROBLEM:

Under the ophthalmic practice rules of the Federal Trade Commission (16 CFR 456), it is “an unfair act or practice for an ophthalmologist or an optometrist to . . . [f]ail to provide to the patient one copy of the patient’s *prescription* immediately after the eye examination is completed” (emphasis added). A “prescription” is defined as “the written specifications for *lenses for eyeglasses* which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses” (emphasis added). According to the FTC, the “Eyeglass Prescription Release Rule” was designed to protect the patient’s right to shop for the best deal from doctors who performed eye exams with the understanding that patients would have to buy their eyeglasses directly from them. The rule does not address the issue of whether an ophthalmologist or optometrist may refuse to give a patient a copy of a contact lens prescription.

It has been suggested that the distinction between prescriptions for eyeglasses and prescriptions for contact lenses made sense when the FTC first issued the rule in 1973, since at that time most lenses were hard lenses that needed to be ground and fitted to each eye. The FTC, while desiring to promote fair trade practices, acknowledged that eye doctors, like all doctors, have a duty to ensure the well-being of their patients and that the ocular health of their patients’ could be compromised if eye doctors did not closely monitor their patients’ use of contact lenses. Unlike eye glasses, contact lenses sit directly on the cornea, and eye doctors argue that the improper use

of contact lenses can lead to serious and even irreversible eye damage before the wearer even notices any severe problems. Corneal microbial infections, due to improper or infrequent cleansing, and corneal neovascularization, due to oxygen deprivation, are two examples of severe complications that may arise from the improper use of contact lenses. Most eye doctors believe it is important that patients appear for a follow-up consultation whenever they begin wearing contact lenses under a new prescription, and they suggest that even contact lens wearers whose prescriptions have not changed should see their doctors on a regular basis. Holding onto the prescription gives eye doctors some leverage to ensure that their patients return for necessary check-ups. Nevertheless, critics believe that such “leverage” gives eye doctors an unfair competitive edge, leaving both consumers and nonprescribing contact lens providers with greatly restricted access to the marketplace. Arguing that contact lens technology has evolved significantly since the FTC first issued the Eyeglass Prescription Release Rule, they suggest that there is little, if any, empirical data to support the purported dangers of most types of contact lenses (with the possible exception of extended-wear lenses) when they are used properly.

In response to perceived inaction at the federal level, 26 states have passed legislation requiring the release of contact lens prescriptions to patients, according to committee testimony. (See “Background Information” for a brief discussion of federal initiatives.) A consumer alert published by the

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Consumer Protection Division of the Attorney General's office explains that contact lens prescriptions typically include a "K-reading," a measurement of the cornea's curvature and thus refractive power. According to the consumer alert, state law requires that doctors release "K-readings"; specifically the alert states, "As long as K-readings are part of a patient's medical records, then the patient has a legal right to receive them." The alert recommends that anyone who experiences difficulty in acquiring a *complete* contact lens prescription from his or her doctor ask for a copy of his or her complete medical records. While this provides a roundabout way of obtaining the relevant information, some people believe that patients should be able to get the prescription itself from their ophthalmologists and optometrists.

THE CONTENT OF THE BILLS:

Article 15 of the Public Health Code regulates health care professions, charging the Department of Consumer and Industry Services with powers and duties related to licensing and registering health care professionals. House Bills 5376-5379 would add a part to the code—Part 186—establishing a system of registration for contact lens providers within the Department of Consumer and Industry Services (CIS). House Bill 5376 would require ophthalmologists and optometrists to release a contact lens prescription to a patient or as directed by the patient, upon the patient's request, with some specific exceptions. The bills would set forth various other requirements, as well as sanctions for violations of the requirements, for "contact lens providers"—i.e., persons who dispense, sell, or provide contact lenses—and for prescribing physicians (i.e., ophthalmologists) and optometrists. The bills are tie-barred. More specifically, the bills would do the following:

House Bill 5377 would amend the code (MCL 333.18601) to require all "contact lens providers" to register with CIS. A "contact lens provider" would be defined as "a person, whether located within or outside of Michigan, who dispenses, sells, or provides contact lenses to a Michigan resident." CIS would prescribe the form of the registration form, which would have to include the contact lens provider's name and telephone number, as well as the provider's principal address and the addresses of all other offices in the state. If the provider did not maintain a principal office in the state, the registration form would have to contain the name and address of the person having custody of the provider's records and the name of a resident agent in

the state for acceptance of service of process. The form would also have to contain a declaration that the provider would comply with all applicable laws and regulations in the conduct of its business in the state. The department would register a contact lens provider upon proper application and payment of a \$20 application processing fee and a \$30 license fee, and the provider would have to apply for a renewal and pay a \$30 renewal fee every two years. The application processing fees and license fees collected would be deposited in the "Health Professions Regulatory Fund." A licensed ophthalmologist or optometrist would be required to register but not until his or her next license renewal date after the bill's effective date.

House Bill 5378 would amend the code (MCL 333.18605 and 333.18607) to prohibit a contact lens provider from dispensing, selling, or providing contact lenses to a state resident without an (unexpired) contact lens prescription that contained the following information: the dioptric power; the base curve or inside radius of curvature; the diameter; the color or tint; the lens wearing schedule; the date of issuance; the patient's name; the prescription expiration date; the typed or commercially printed name, office address, and telephone number of the prescribing physician or optometrist; and the signature of the prescribing physician or optometrist. A prescription for soft hydrophilic contact lenses would also have to specify the manufacturer's name and the product's brand name, (which could not be satisfied by providing a house brand, co-brand, or private label name alone,) the quantity of lenses to be dispensed, and the number of allowable refills. A prescription for rigid gas permeable contact lenses would have to specify, in addition to the general information required, the peripheral curve or curves, including curvature and width, the optical zone diameter, the center thickness, the lens material, and any special features.

The bill would also specify that a contact lens prescription could not expire less than one year from the date of issuance unless the patient's history or current circumstances established a reasonable probability of changes in the patient's vision of sufficient magnitude to require reexamination earlier than one year. The prescription would have to be based upon a comprehensive vision and eye health examination, a diagnostic trial contact lens evaluation, and a follow-up evaluation of the contact lens on the patient's eye by the prescriber. The evaluation would be presumed complete if there was no contact lens related appointment scheduled within thirty days after the patient's most recent visit to the

prescribing physician or optometrist. A provider could not refill a contact lens prescription that was within 60 days of its expiration date with more than the quantity of replacement lenses needed through the expiration date based on the prescribed wearing schedule. If the original written contact lens prescription or a facsimile or other electronic transmission of the original prescription was not available to a provider, the provider would have to confirm the specifics of the prescription with the prescriber (or his or her agent), prior to providing the contact lenses and would have to maintain a written record of that communication. The prescriber would have to confirm the specifics of the prescription with the provider no more than ten *of the prescriber's* business hours after the request was made, and a provider could not require a prescriber to confirm the specifics any sooner. The prescriber would also have to mail, fax or electronically transmit a copy of the original written prescription to the provider. Finally, the bill would specify that the patient's health record does not constitute a contact lens prescription.

House Bill 5376 would amend the Public Health Code (MCL 333.18609 and 333.18611) to require an ophthalmologist or optometrist to release a contact lens prescription upon request to a patient, or as directed by the patient. This requirement would not apply if the prescription had expired, if the patient had not paid the physician or optometrist for goods or services previously rendered, or if the physician or optometrist made a good faith determination that giving the patient the prescription could jeopardize the patient's ocular health. If the ophthalmologist or optometrist denied a request because he or she perceived a possible danger to the patient's ocular health, he or she would have to explain the reason for denial to the patient or the patient's representative, record the reason in the patient's record, and provide the patient with a written statement of the reason. If a physician or optometrist gave a patient a prescription, and the patient had the prescription filled by a person other than the physician or optometrist (or a person employed or contracted by him or her), the physician or optometrist would not be liable in a civil action for damages for an injury to the patient caused directly or indirectly by the manufacturing, packaging, or dispensing of the contact lenses.

House Bill 5379 would amend the code (333.18613) to impose several additional requirements on contact lens providers. First, contact lens providers would have to fill all contact lens prescriptions accurately and according to the specific orders of the written prescription. Second, a provider would have to

maintain records for contact lenses shipped, mailed, or otherwise delivered or provided to state residents for five years and make them available to CIS upon request. Third, a provider would have to provide a telephone number, to be included with each supply of contact lenses, for responding to questions and complaints. Fourth, a provider would have to disclose in any price advertisement any required membership fees, enrollment fees, and any shipping fees. Finally, a provider would have to provide with each supply of contact lenses a written notice that substantially conformed to the following:

“WARNING: IF YOU EXPERIENCE ANY UNEXPLAINED EYE DISCOMFORT, WATERING, VISION CHANGES, OR REDNESS, REMOVE YOUR CONTACT LENSES IMMEDIATELY AND CONSULT YOUR EYE CARE PRACTITIONER BEFORE WEARING YOUR CONTACT LENSES AGAIN.”

The bill would also amend the code (MCL 333.16221 and 333.16226) to specify sanctions for violations of the proposed requirements for contact lens providers, and prescribing ophthalmologists and optometrists. Article 15 of the code authorizes CIS to investigate activities related to the practice of a health professional by a licensee, a registrant, or an applicant for licensure or registration. The department may hold hearings and order testimony and must report its findings to the “appropriate disciplinary subcommittee.” The chair of each professional board or task force—e.g., the board of nursing or the board of pharmacy—appoints one or more disciplinary subcommittees to impose sanctions on licensees, registrants, or applicants under its jurisdiction for one or more violations enumerated in the general provisions of Article 15.

House Bill 5379 would specify that the disciplinary subcommittee would impose one or more of the following sanctions for violations of the bills' various requirements: restitution, probation, a reprimand, a fine, or the denial, revocation, suspension, or limitation of a license, registration, or application for registration. Moreover, a disciplinary subcommittee, or CIS if there was no disciplinary subcommittee with jurisdiction, could impose an administrative fine of not more than \$10,000 for such violations.

The bill would also amend a general provision that is not specific to the bills' requirements for contact lens providers and prescribing ophthalmologists and optometrists. The code directs the appropriate disciplinary subcommittee to punish proven violations of general duty, consisting of negligence or

failure to exercise due care, whether or not injury results, or any conduct, practice, or condition which impairs, or may impair, the ability to safely and skillfully practice the health profession. The code also directs the subcommittee to sanction one or more instances of eleven different types of personal disqualification. Currently the code states that a disciplinary subcommittee may impose a fine of up to, but not exceeding, \$250,000 for proven violations of general duty or personal disqualification. The bill would specify that a disciplinary subcommittee could impose an *administrative* fine of not more than \$250,000. Although this change would apply to contact lens providers, ophthalmologists, and optometrists who were found guilty of violations of general duty or personal disqualification, it would also apply to all other health care professionals regulated under Article 15.

BACKGROUND INFORMATION:

The FTC reviewed the Eyeglass Prescription Release Rule from 1985 to 1989 and decided not to extend the release requirement to contact lens prescriptions, finding that there was insufficient evidence that the refusal to provide prescriptions was a prevalent practice and maintaining that it may be necessary “to verify the fit of the lens because there is some danger that lenses may not conform to the eye as expected”. Various attempts have been made to change the federal law—e.g., the proposed “Contact Lens Prescription Release Act of 2001.” Moreover, the FTC was scheduled to conclude a four-year review of the rule by the end of last year but has not yet acted; the commission could revise, repeal, or retain the rule. According to a spokesperson for the FTC, the questions surrounding the issue have largely remained the same throughout the years: are large numbers of ophthalmologists and optometrists refusing to provide prescriptions to their patients? Is the price differential between prescribers and other dispensers significant? Are there legitimate health reasons for refusing to provide contact lens prescriptions to patients, and if so, under what conditions? The FTC does inform consumers that a doctor may release the prescription and suggests that consumers who wish to retain the option of buying contact lenses from a dispenser other than the doctor who performs the eye exam inquire about the doctor’s release policy prior to making an exam appointment.

FISCAL IMPLICATIONS:

Fiscal information is not available.

ARGUMENTS:

For:

The bills strike an appropriate balance between the patient’s right to shop around, doctors’ obligation to protect their patients’ health, and other, nonprescribing dispensers’ right to participate in a competitive market. The AMA’s code of ethics clearly states that “A patient is entitled to a copy of the physician’s prescription for drugs, eyeglasses, contact lenses, or other devices as required by the Principles of Medical Ethics and as required by law. The patient has the right to have the prescription filled wherever the patient wishes.” Despite the AMA’s code of ethics, under current law it is legal for an optometrist or ophthalmologist to diagnose a patient and then refuse to allow the patient to have the prescription filled by a contact lens provider of his or her choice. This is odd, considering that other prescribing doctors, with the exception of prescribing dispensers, provide patients with prescriptions up front.

While the doctor’s primary concern ought to be the patient’s health, this is fully consistent with the right of the consumer to obtain a contact lens prescription from his or her doctor. In refusing to extend the Eyeglass Prescription Release Rule to contact lens prescriptions, the FTC has cited empirical data, such as the relatively low numbers of consumer complaints about providers’ refusal to provide prescriptions and the negligible price differential between prescribers who dispense contact lenses and other dispensers, to suggest that the potential risk to health outweighs the benefits of extending the rule. The FTC has, however, consistently supported the consumer’s right to shop around.

House Bill 5376 would allow a patient to request a copy of a valid contact lens prescription and thus to purchase lenses from another provider, and the doctor would have to honor the request unless there was a legitimate health reason for not doing so. It is significant that the doctor would not be required to offer the prescription to the patient up front. This presumption in favor of the doctor recognizes the trust inherent in a solid doctor-patient relationship and the importance of the doctor in the proper monitoring of the patient’s health. A prescription would have to be based on a comprehensive vision and eye health examination, a diagnostic contact lens evaluation, and, very importantly, a follow-up evaluation of the contact lens on the patient’s eye. The patient would have the responsibility of making and keeping a follow-up appointment, regardless of

where he or she purchased the lenses, and a prescribing doctor would not be liable for injuries due to problems stemming from improper dispensing, if the contact lenses were dispensed by someone other than the prescriber. Some alternative dispensers have earned notoriety for failing to verify that their customers' contact lens prescriptions are valid, and many eye doctors believe that it would be wrong to encourage customers to buy their contact lenses from such dispensers. This arrangement leaves it to the providers to prove that they are concerned with their patients' health and not simply focused on making a quick sale. Finally, contact lens providers would have to register with the Department of Consumer and Industry Services and comply with regulations designed to help ensure that as the consumer gains more options, the patient's health is not compromised.

Response:

Although the bills would take steps in the right direction, they would essentially safeguard the profits of ophthalmologists and optometrists at the expense of both patients' rights and the right of alternative contact lens providers to a fair marketplace. The FTC's suggestions that the refusal to release prescriptions is not a prevalent practice and that there is no significant price differential between contact lenses purchased for eye doctors and those purchased from other dispensers are difficult to maintain. According to a December 1998 article in the Detroit Free Press, "[o]f 50 optometry offices surveyed in Wayne, Oakland and Macomb counties, only one would release a contact-lens prescription. Nearly all the rest require patients to purchase lenses from them—for an average price that was almost triple the best price available elsewhere".

House Bill 5376 would require a patient to request a copy of a prescription from his or her doctor, which is problematic for two basic reasons. First, it would create a distinction between those patients who knew that they had the right to request their contact lens prescriptions and those who did not. Those patients who knew the law would be able to shop around for their contact lenses elsewhere, and those who did not know their rights would simply assume that they had to buy their lenses from the prescribing doctor. Considering the findings reported by the Detroit Free Press, such a situation amounts to "perfect price discrimination"—i.e., the practice of charging different prices for different units of the same good—at the systemic level: since optometrists are charging significantly more than other contact lens prescribers, consumers who did not know that they could get a copy of their prescription would be forced to pay significantly more for what is essentially the same

product than those who knew their rights. Second, even among those patients who know their rights, there would still be patients who feel that it would be rude and confrontational to request the prescription from their doctors, thereby suggesting that they are considering shopping elsewhere to avoid inflated prices.

The very nature of the doctor-patient relationship tilts the marketplace in favor of doctors who provide contact lenses. The very convenience of one-stop shopping is enough to convince many patients that it is not worth their time to look for better deals. The fact that *some* unscrupulous contact lens providers reportedly bend or even break the rules should not be used as a reason to perpetuate the imbalance between doctors and legitimately nonprescribing providers. Doctors roles as ocular health care providers and suppliers of eyewear should be strictly separated, especially since it is not even clear that there are significant health risks involved in wearing contact lenses. Comments submitted to the FTC by the attorneys general of 17 states, including Michigan, point out that "a disposable contact lens is subject to the same standards of FDA review as a toothbrush". As they argue, "[o]ur multistate investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels." In short, the bills do not go far enough to allow consumers to decide what is best for themselves or to allow alternative contact lens providers access to the marketplace.

Reply:

The bills are perfectly consistent with the AMA's code of ethics, which states that the patient has the right to obtain his or her prescription. No knowledgeable medical professional disputes the claim that contact lenses have significant potential to cause eye damage, and thus require some degree of medical supervision. Although the *consumer* may know best in many cases, doctors are reluctant to merely let their *patients* beware.

As for the charge of perfect price discrimination, many eye doctors who dispense contact lenses provide a superior level of service to that of other providers, by allowing their patients to try out different types or brands of lenses. If this is the case, the charge rests on an equivocation involving the concept of an economic "good". If "good" is defined as the contact lens only—i.e., "good" in the strict economic sense, where it is opposed to service—then the optometrist may claim that he or she is providing better service in addition to a different unit of the same good, and the better service justifies the price

differential. If “good” is defined more loosely, as including both the contact lens and an expanded range of service options, then it is simply not true that optometrists who provide superior service are charging different prices for different units of the same *good*. Either way, the accusation of perfect price discrimination must ultimately be supported by solid evidence that prescribing contact lens providers and nonprescribing contact lens providers are providing the same goods and services for different prices.

Against:

The requirement that a prescribing doctor verify a prescription with a contact lens provider within ten of the prescriber’s business hours leaves too much power to the doctor. Consider the case of a prescriber whose office is open from 9 to 5 on weekdays. Conceivably, a patient could go to purchase her lenses on a Friday afternoon at 4:30, at which point the lens provider would call to verify the prescription. The doctor would not have to get back to the provider before 9:30 Tuesday morning, which means that the patient would not be able to get the lenses until Tuesday at a retail dispenser, or Wednesday if the lenses had to be sent by mail. This clearly leaves the prescribing doctor with considerable leverage in determining how satisfactory her patient’s experience of purchasing contact lenses from someone other than her doctor will be. Even more troubling, doctors in other states that require the prescribing doctor to verify the prescription do not always return providers’ calls. The bills should allow contact lens providers to assume that the prescriptions are correct and dispense lenses to their customers, unless the doctor calls back within a reasonable amount of time—preferably less than ten business hours.

Response:

Contact lens providers should not be allowed to assume that a prescription is valid. Originally, House Bill 5378 would have given a physician two business days to return a contact lens provider’s call and verify the prescription. Ten business hours is a significant compromise, allowing the doctor a reasonable amount of time to respond while acknowledging that an express verification of the prescription is desirable for ensuring the patient’s health. While doctors in other states may not comply with similar verification requirements, CIS would investigate any such complaints and would be required to punish prescribers for non-compliance.

Against:

House Bill 5378 would require that a contact lens prescription be written for a minimum of one year from the date of its issuance. Some people believe that a contact lens prescription should standardly be valid for two years from the date that it is written. According to the American Optometric Association’s (AOA) “Recommendations for Regular Optometric Care,” individuals between 6 and 60 years old who are asymptomatic and who are “risk-free” should have their eyes examined approximately every two years. Moreover, many people have vision plans that only cover one visit to an eye doctor every two years. However well-intentioned, the bills could lead individuals to try to extend the life of their contact lenses beyond their expiration dates, making a one-year supply last two years, which could in turn lead to precisely the sorts of ocular health problems that eye doctors are presumably trying to prevent.

Response:

If anything, a one-year minimum for a contact lens prescription leaves too much to the discretion of the individual contact lens prescriber. The AOA’s “Recommendations for Regular Optometric Care” are general guidelines that do not distinguish between individuals who wear contact lenses, those who wear glasses, and those who do not wear either. In fact, the “Recommendations” make no mention whatsoever of contact lenses. In addition to its “Recommendations,” however, the AOA publishes a clinical practice guideline for optometrists’ care of patients who wear contact lenses. These guidelines set forth the standard for care. Regarding progress evaluations, the AOA guideline states: “Followup visits are important for proper management of the patient with CLs [contact lenses]. Planned evaluation should occur during the initial weeks and months of CL wear to allow any necessary mechanical or optical refinements in lens prescription(s), to monitor adaptation and minimize ocular complications, and to reinforce appropriate CL care. Subsequent evaluations are usually indicated at 6-to-12 month intervals for health patients wearing cosmetic CLs. It is advisable to see patients who may be at additional risk for ocular compromise during CL wear more often than every 6 months, perhaps ever 3 or 4 months or even more frequently.” An optometrist who writes a prescription for longer than one year may be opening him- or herself up to a lawsuit by not adhering to the guideline. Still, the prescription release and one-year minimum reflects some balance between a consumer’s rights to choose a contact lens provider and to take responsibility for his or her own health, on the one hand, and the doctor’s responsibility for the patient’s ocular health and right

to practice according to his or her own judgment, on the other.

Although some vision plans only cover one visit every two years, prescription standards must be based on what is, generally speaking, in the patient's best health. If this is a common feature of vision plans, it may be appropriate to examine the issue separately.

Against:

CIS and some contact lens providers have expressed concerns that multiple entities would be responsible for disciplining violations of the bills' provisions. Professional boards would ultimately be responsible for disciplining their members, while CIS would be responsible for disciplining other contact lens providers. Such a system would not guarantee that justice was meted out even-handedly and would thus open up the door for accusations that different types of providers are being treated differently. Perhaps CIS should be responsible for all disciplinary proceedings.

POSITIONS:

The Michigan Optometric Association supports the bills. (2-14-02)

The Michigan Ophthalmological Society supports the bills. (2-14-02)

The Department of Consumer and Industry Services supports the bills "in concept" but has concerns about the possibility of inconsistent disciplinary action. (2-14-02)

1800Contacts, Cole Vision and seven other retail contact lens dispensers operating in the state oppose the bills. (2-14-02)

Analyst: J. Caver

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.