House
Legislative
Analysis
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LET OPTOMETRISTS USE THERAPEUTIC DRUGS

House Bill 4331 as enrolled
Public Act 384 of 1994
Second Analysis (1-3-95)

Sponsor: Rep. Michael J. Bennane
House Committee: Public Health
Senate Committee: Health Policy

THE APPARENT PROBLEM:

The Public Health Code allows optometrists to use only two specific drugs: Proparacaine HCL 0.5 percent and Tropicamide in strength not greater than one percent. Both of these drugs are topically applied to (that is, applied to the surface of) the eye and both are used for diagnosis only. Proparacaine is an anesthetic used in detecting glaucoma, while Tropicamide is a commercially prepared pupil-dilating drug used in evaluating the structure and function of the eye. Optometrists are prohibited from using any diagnostic drugs other than the two specified in the health code and are prohibited from using any therapeutic drugs (that is, drugs used to treat disease) at all.

Optometrists, non-physicians who are best known for examining eyes to see if corrective lenses are needed, say that allowing them limited use of certain therapeutic drugs would greatly benefit the public without any additional risks. Ophthalmologists, physicians who specialize in eye surgery, remain opposed to optometrists using drugs as part of optometric practice, arguing that optometrists are not adequately trained to deal with adverse reactions that can arise when prescription drugs are used.

As happened in 1984, in the case of legislation that authorized optometrists to use diagnostic drugs, and as is common in "scope of practice" disputes between licensed health professionals, the legislature has been called upon to referee.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code (MCL 333.17401 et al.) to allow properly certified optometrists to prescribe and administer certain therapeutic drugs, to set certification fees for these optometrists, and to allow pharmacists to dispense therapeutic drugs to such optometrists. In effect, ten years after the bill took effect, optometrists who sought certification to administer diagnostic drugs would have to become certified to administer and prescribe therapeutic drugs as well.

Scope of practice. Under existing law, the practice of optometry basically is limited to the examination of the human eye for "defects" and "abnormal conditions" and to the prescription of glasses ("lenses, prisms, or mechanical devices," including contact lenses) to correct any such defects or abnormalities. Within this scope of practice, optometrists are allowed to use two "topical [that is, applied to the surface] ocular diagnostic pharmaceutical agents" specified in the health code: a commercially prepared anesthetic used in detecting glaucoma and a pupil-dilating drug. The practice of optometry does not include the use of any other diagnostic drugs and does not include the use of any therapeutic drugs at all. If, in the course of an eye examination, an optometrist "determines" that the patient may have an eye disease (that is, optometrists are not allowed to diagnose disease), he or she is required to advise the patient to see a physician and is prohibited from attempting to treat the suspected disease. The health code also explicitly prohibits optometrists from accepting third-party (that is, insurance) payment for using the drugs currently allowed them.

The bill would expand the practice of optometry to allow optometrists to use not only "diagnostic pharmaceutical agents" (DPAs) but also "therapeutic pharmaceutical agents" (TPAs). The bill would remove the word "topical" from the definition of the diagnostic drugs optometrists could use, but would otherwise keep the existing list of two allowable diagnostic drugs.

The definition of "therapeutic pharmaceutical agent" basically would be restricted to topically applied

drugs used to "correct, remedy, or relieve" a defect or abnormal condition (or the effects of a defect or an abnormal condition) of the front part of the eye. (The bill's definition of "TPA," specifically, would be "a topically administered prescription drug or other topically administered drug used for the purpose of correcting, remedying, or relieving a defect or abnormal condition of the anterior segment of the human eye or for the purpose of correcting, remedying, or relieving the effects of a defect or abnormal condition of the anterior segment of the human eye.")

The bill would specifically prohibit optometrists from performing "invasive procedures," defined in the bill to include administering medication by injection and the use of lasers ("other than for observation"), ionizing radiation, and ultrasound.

Certification requirements. Currently, in order to administer either of the two allowable diagnostic drugs, optometrists must be certified by the Board of Optometry and meet certain specified qualifications. Before the board may certify an optometrist to use diagnostic drugs, the optometrist must have done the following: (1) Completed 60 classroom hours of board-approved study in general and clinical pharmacology as it relates to optometry from a fully accredited school or college of optometry. At least 30 of these hours must be in "ocular pharmacology" and must emphasize the systemic effects of and reactions to diagnostic drugs, including the emergency management and referral of any possible adverse reactions to the drugs; (2) passed a board-approved examination on general and ocular pharmacology, with a particular emphasis on the use of diagnostic drugs (including emergency management and referral of possible adverse reactions); (3) successfully completed a course in cardiopulmonary resuscitation offered or approved by the Red Cross, the American Heart Association, an accredited hospital, or a comparable organization or institution; and (4) established a board-approved emergency plan for the management and appropriate medical referral of patients who experience adverse drug reactions. Emergency referral plans must, further, require optometrists to do at least four things: (1) Refer patients who notify the optometrist of adverse drugs reactions to "appropriate" medical specialists or facilities; (2) routinely advise each patient to immediately contact the optometrist if the patient experiences an adverse drug reaction; (3) record adverse drug reactions in the patient's permanent record, along with the date and time of any referrals; and (4) list the names of at least three physicians, clinics, or hospitals to whom the optometrist will refer patients with adverse drug reactions, at least one of which must be skilled or specialize in the diagnosis and treatment of eye diseases.

The bill would allow optometrists to administer and prescribe therapeutic drugs if they were certified by their board to do so, and the board could certify optometrists to administer and prescribe therapeutic drugs if the optometrist did the following: (1) met the certification requirements to administer diagnostic drugs; (2) had successfully completed a certain amount of study in the didactic and clinical use of therapeutic drugs from a school or college of optometry that was recognized by the board as fully accredited; and (3) established a management plan that met the requirements of the emergency plan for diagnostic drug reactions. The management plan would apply to patients who either (a) had an eye condition or disease that might "be related to a non-localized or systemic condition or disease" or to an adverse drug reaction or (b) didn't "demonstrate adequate clinical progress as a result of treatment."

The bill also would allow optometrists to substitute a patient's primary care physician for one of the non-specialist physicians required to be named in the diagnostic drug emergency plan.

Optometrists who were licensed after the bill took effect and who intended to obtain certification to use both diagnostic drugs and therapeutic drugs would be required to get that certification when they obtained their optometric license for the first time. (Licensed optometrists from other states who applied for a license in Michigan would be exempted from this requirement.)

The bill would delete the current requirement in the health code that the Board of Optometry approve the required course of study, examination, and emergency plans only after consulting with the Boards of Medicine, Osteopathy, and Pharmacy.

Treatment restrictions. Currently, whenever an optometrist determines that a patient might have a disease, the optometrist must not attempt to treat the condition and must "promptly advise that patient to seek evaluation by an appropriate physician for diagnosis and possible treatment."

The bill would specify that these same requirements would apply to disease that optometrists weren't authorized to treat under the bill. The bill also would require that optometrists consult appropriate physicians whenever the optometrist treated a patient for a condition or disease that might be related to a nonlocalized or systemic condition or disease or didn't respond adequately to treatment.

Fees. The bill would establish a $55 certification fee to administer diagnostic pharmaceutical agents for ten years after the bill took effect, and a $55 certification fee to administer both diagnostic and therapeutic drugs.

Pharmacists. The bill would authorize pharmacists to dispense diagnostic pharmaceutical agents and therapeutic pharmaceutical agents (TPAs) to qualified optometrists, and to dispense prescriptions for TPAs issued by qualified optometrists.

Repeal. The bill would repeal the section of the health code that prohibits optometrists from accepting third-party payment for using diagnostic drugs.

Tie-bar. House Bill 4331 is tie-barred to a set of bills (House Bills 4569 through 4573) that would allow restrictions on certain third-party reimbursements for optometric and chiropractic services.

FISCAL IMPLICATIONS:

According to a Senate Fiscal Agency analysis of the bill, the fees proposed in the bill should be sufficient to cover administrative costs incurred by the Board of Optometry in implementing the bill. Whether or not the bill would increase state Medicaid costs would depend on whether or not the proposed administration and prescription of therapeutic drugs by optometrists were "separately billable events rather than an integral part of an office visit." (12-1-94)

ARGUMENTS:

For:

The bill is an attempt to work out a compromise between optometrists, non-physicians who favor expanding their scope of practice to include the prescription of therapeutic drugs to treat such conditions as "pink eye," and ophthalmologists, physicians who oppose what they see as further encroachments on medical practice by non-physicians. Currently, optometrists, who may not diagnose diseases, must refer all of their patients to physicians for diagnosis and treatment -- even such common and easily treatable diseases such as "pink eye." This not only is inconvenient to optometric patients, it unnecessarily increases health care costs by requiring patients (or their medical insurers) to pay for medical consultations even in cases where their condition could be safely and easily treated by the optometrist. The bill still would not allow optometrists to diagnose disease, but it would allow qualified optometrists to prescribe and use therapeutic drugs to treat certain conditions (such as "pink eye"), which would benefit optometric patients while also reducing health care costs. Optometrists would continue to have to refer patients to ophthalmologists whenever the optometrist detected signs of other than localized eye disease.

Optometrist proponents of the bill point to studies suggesting that optometric care is more accessible to health care consumers (in terms of shorter waiting times for appointments, more evening and weekend appointments, and greater geographic distribution of optometrists, who, for example, tend to be proportionally more represented in rural areas than ophthalmologists) and less expensive to both consumers and third-party payers than is primary eye care provided by ophthalmologists. Optometrists emphasize their cost savings to consumers and health insurers based on optometrists' generally lower office overhead costs (including lower malpractice insurance rates than ophthalmologists by more than a factor of ten) and lower educational costs. Optometrists also argue that allowing them to use therapeutic pharmaceutical agents ("TPAs") can further lower health care costs by reducing second provider fees (currently, optometrists must refer patients with even minor eye diseases, such as "pink eye," to physicians) and by saving patients the costs of additional travel time and lost work time in order to see these "second providers." Optometrists point out that optometrists in the military, the federal Indian Health Service, the federal Veterans' Administration, and 26 other states already are allowed to use therapeutic drugs and non-invasive procedures to treat common eye diseases, and argue that Michigan should allow this also. Finally, optometrists point out that the dire predictions of public harm that were used to argue against the 1984 legislation that allowed optometrists to use

"diagnostic pharmaceutical agents" ("DPAs") simply failed to come true. In fact, there have been no complaints to the Michigan Board of Examiners in Optometry concerning optometrists' misuse or abuse of these diagnostic drugs, and there is evidence from other states that allow optometrists to administer therapeutic drugs that there has been no increase either in public complaints or in malpractice insurance rates.

For:

Modern optometric education and clinical training provide the necessary background to allow optometrists to use therapeutic drugs safely and effectively, and the bill would further ensure that all optometrists who used such drugs complete a certification process to guarantee competency (the bill does not include so-called "grandfathering" provisions). While it is understandable that physicians would oppose further inroads by limited license practitioners on physicians' once virtual monopoly on primary care, the fact remains that other limited license practitioners (including dentists and podiatrists) have increased their scope of practice as their education and training has improved. As one study (by an M.D. with a master's degree in public health) notes, "Laws regulating the practice of optometry were written as we entered this century. While they subsequently served as a useful beginning point, they are no longer up-to-date with respect to the education and clinical training of the modern-day optometrist. In a pattern similar to the evolution of medicine, the apprentice optometrist of the 1890s has become a university graduate with a doctorate in a distinct health care discipline. Advances in education through basic and applied research have placed the graduate optometrist alongside the physician and dentist as the third largest independent health care discipline." This same study points out that decades of experience with dentists and podiatrists prescribing drugs (with potentially general physiological impact on the patient's body) without imminent or remote supervision by physicians has not resulted in a single state repealing its laws granting this privilege due to negative outcome. As the author of the study says, "Accordingly, today's legislator is less likely from now on to accept uncritically the claim by physicians that prudence demands that physicians alone should be allowed to write prescriptions."

Against:

Ophthalmologists argue that optometrists do not have the training and education to diagnose and treat eye diseases, nor to treat adverse drugs reactions. Although the bill does not, technically, allow optometrists to diagnose disease -- traditionally the exclusive province of physicians -- it in effect does so by allowing optometrists to prescribe and administer therapeutic drugs. Yet the education and training of optometrists is far less extensive than that of physicians who specialize in the diagnosis and treatment of diseases of the eyes, and which could result in harm to patients if optometrists inappropriately used therapeutic drugs due to their less extensive education and training. Further, ophthalmologists argue that while the bill appears to protect patients by restricting optometrists' use of therapeutic drugs to only those drugs that are topically applied (that is, applied to the surface of the eye), it in fact dangerously extends optometrists' scope of practice to include the prescription and use of drugs that they may not have the education and training to use safely. Just because a drug is absorbed into the body through surface application does not mean that it necessarily is less powerful -- or could have fewer potential adverse reactions than -- drugs that are injected or swallowed. What is more, the bill nowhere otherwise limits which therapeutic drugs optometrists can use, which effectively means that there is no medical oversight of the prescription and administration of these drugs by non-physicians (other than the vague requirement that optometrists consult physicians if the patient doesn't respond "adequately" to treatment or if the "condition or disease may be related to a nonlocalized or systemic condition or disease").

Ophthalmologists further deny that the economic benefits to the public and to health insurers will be as great as the optometrists claim, pointing out that historically an increase in the number of primary eye care practitioners drives up health costs (partly, for example, because the federal government pays most professions the same fee for the same services), rather than decreasing them. With regard to the issue of access to care, the Department of Social Services (DSS) said in 1991 that were 450 ophthalmologists (virtually all of the ophthalmologists in the state) and 574 active optometrists (out of approximately 1,400 in the

state) accepting Medicaid patients. The department's Medicaid staff reports that clients generally do not have problems with access to vision care providers and that there is no significant problem with unmet needs for vision treatment. Medicaid payment levels are the same for both types of providers, and the department assumes that the bill would not result in an increase in Medicaid utilization since clients seem to be receiving needed treatment.

Ophthalmologists also argue that the eye cannot be treated as an organ isolated from the rest of the body, and that diagnosis and treatment of eye disease should be done only by those who are trained in medicine dealing with the whole person. For example, not only can certain systemic diseases, such as diabetes and tuberculosis, be detected by looking at the eye (provided that the examiner has the requisite medical training), but medications applied to the eye can affect the whole body. While optometrists do have some classroom study in pharmacology, their clinical training and experience nowhere matches that of even general physicians, much less ophthalmologists. As one ophthalmologist put it, optometrists are trying to enter the practice of medicine through legislation rather than medical school.

Response:

While it is indeed true that the eye is an integral part of the body, so, too, for example, are one's feet and teeth and gums. Podiatrists and dentists have been, like optometrists, categorized as limited license practitioners, yet both professions are allowed to write prescriptions for drugs with the potential to affect the entire body. The fact is, as the education and training of health professions deemed "auxiliary" to that of medicine have grown and changed over the years, there has been a continuous expansion of scope of practice and licensure of the "limited license" health professionals. The once exclusive domain of medicine has been successfully challenged, both through legislation and by incremental changes in the traditional practice of the "auxiliary" health professions. Partly, this has stemmed from the public recognition that it is in the public interest to utilize each health professional in a way that maximizes the highest levels of that professional's skills and that levels of health care should be assigned to the most appropriate providers (that is, primary care to providers trained in primary care, secondary and tertiary care to providers trained in these levels of care). But there also has been a growing recognition that health competition among qualified health professionals will benefit both consumers and third-party payers. The bottom line is that optometrists do not want to practice medicine, but they do want to practice primary eye care at a level commensurate with their education and training.