



ONLINE VISION TESTS RAISE NEW POLICY CONCERNS

OVERVIEW

Several companies are aggressively marketing online “vision tests” directly to consumers for the purpose of obtaining a prescription for eyeglasses or contact lenses. The new technology allows patients to self-administer a series of visual tests and pay for an eyeglass prescription signed by an “optometrist” or “ophthalmologist.” The largest of the new companies, Opternative, has partnered with 1-800-Contacts, enabling patients to obtain contact lenses without an in-person exam from an optometrist, ophthalmologist or physician.

The new technology provides consumers with convenience and affordability but also raises patient safety concerns for consumers and policy issues for lawmakers and regulators.

It is important to distinguish this technology from “telemedicine.” Where telemedicine brings eye professionals closer to patients, Opternative and similar platforms do the opposite—pushing patients away from health professionals.

HOW DOES AN ONLINE VISION TEST COMPARE WITH AN EXAM ADMINISTERED BY A DOCTOR OF OPTOMETRY?

INCLUDED

Self-administered refractive test for myopia prescription



NOT INCLUDED

Physical examination of the eye to detect glaucoma, cataracts, and macular degeneration

Ability to distinguish between diabetes-related vision loss and need for an eyeglass prescription

Contact lens fitting specific to a patient’s eye (size, curvature, material)

Detection of adverse symptoms of contact lens wear such as corneal damage

Assessment of patients’ ability to focus on a single object with two eyes (condition that would necessitate a prism prescription)

Assessment for hyperopia, axis for astigmatism, cylinder for astigmatism, or other components of a typical prescription



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HEALTH CONCERNS

ACCURACY

Opternative has been marketed directly to consumers as an online “eye exam” that claims to provide a prescription for eyeglass or contact lenses “as accurate as an in-person refractive eye exam.” However, the FDA has not reviewed the safety or efficacy of the technology or these claims of accuracy. What’s more, because the technology relies on patients to self-administer, including measuring the distance from their computer, there is significant room for prescriptive error.

UNDERLYING HEALTH CONDITIONS

Many conditions that affect eye health can mis-present themselves as refractive errors. Optometrists are concerned that replacing an in-person exam delivered by a licensed professional will mean patients do not get the thorough examinations they need to detect vision or life-threatening conditions such as diabetes, high blood pressure, or cancers.

UNDERSERVED COMMUNITIES

Misuse of technology could exacerbate the already significant health access issues faced by California’s underserved communities. Latino, African-American, low-income families, and other communities who face the biggest hurdles to accessing healthcare are also at greater risk for diabetes, hypertension, and other eye-sight robbing conditions. Self-administered, online eye tests can’t detect these serious conditions and may deter the most at-risk populations from life-saving, comprehensive eye health examinations.

CONTACT LENS DANGERS

Without a fitting by an eye doctor, contact lens wearers are at additional risk for poor fitting lenses, dry eye, and other complications. A poor-fitting lens can cause corneal disease that is not apparent to the patient, but can lead to serious vision loss. The FDA has issued warning letters to manufacturers of unapproved contact lenses that are sold directly to individuals without the order of a licensed physician or optometrist.

POLICY CONCERNS

BUSINESS MODEL

Opternative has raised millions of dollars in venture capital from investors who must be repaid. This structure raises questions about whether patients or investors will be the priority for the company.

TECHNOLOGY LACKS INDEPENDENT CLINICAL TRIALS

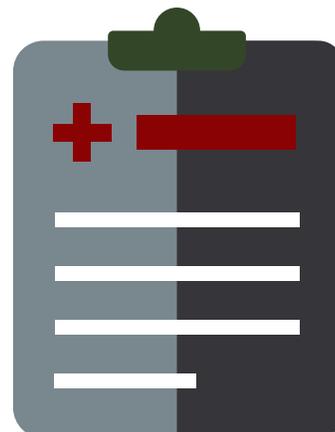
The “clinical trial” the company commissioned was not peer reviewed, lasted only four months and was limited to 30 people. Opternative is currently offered to patients outside the scope of the clinical trial, including those ages 40-55 and those with higher refractive errors.

TECHNOLOGY LACKS FDA APPROVAL

The FDA is currently investigating the American Optometric Association’s complaint that Opternative technology should be considered a medical device and required to meet safety and efficacy tests.

CALIFORNIA LAW IS CLEAR

Current California law says only an optometrist or physician and surgeon can examine human vision (B&P Section 2540). An optometrist or ophthalmologist may not delegate the subjective refraction part of the exam to an unlicensed individual (B&P Code Section 2544 (a)(8)).

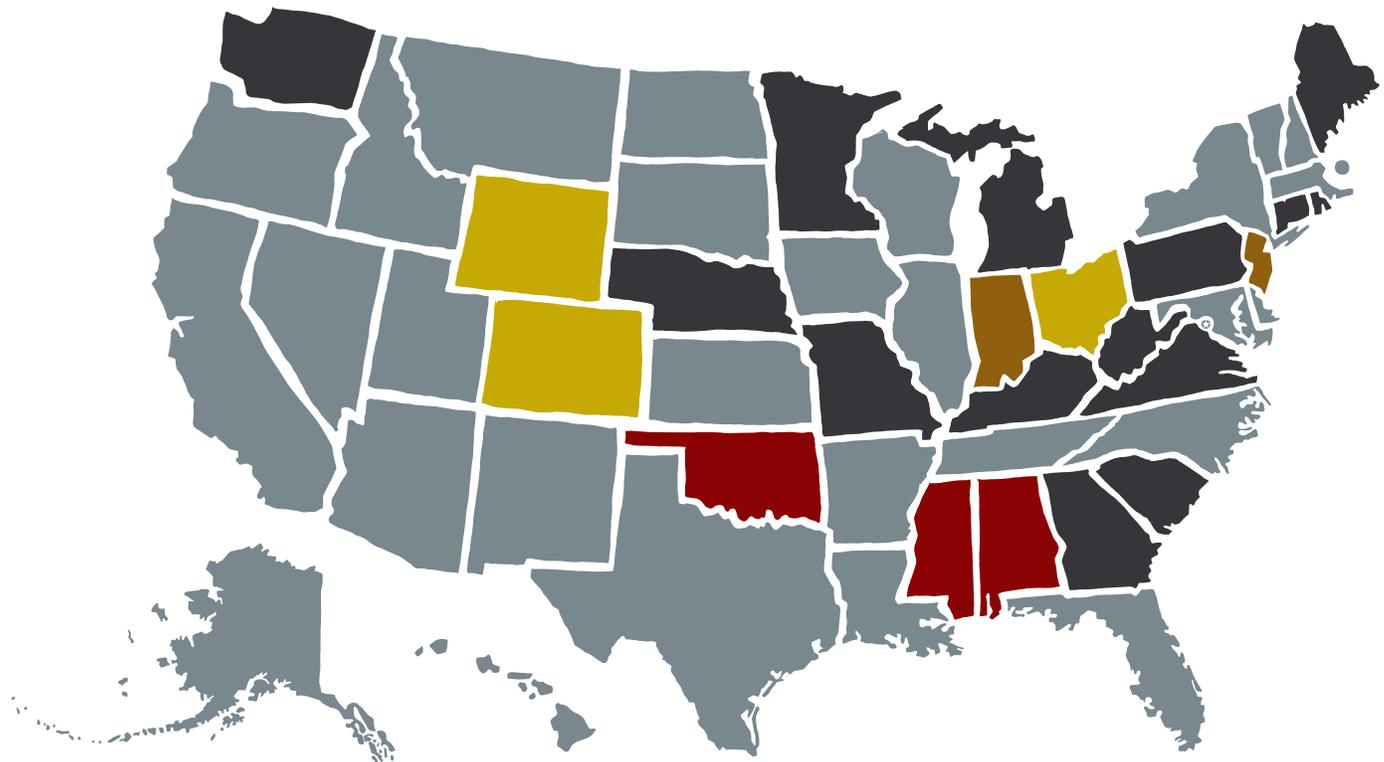




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STATES' RESPONSE TO POLICY ISSUES

SEVENTEEN STATES CURRENTLY LIMIT ONLINE VISION TESTS OR HAVE LEGISLATION PENDING TO LIMIT THIS TECHNOLOGY:



● CONSUMER PROTECTION LAW

● TELEMEDICINE AMENDMENT

● STATE BOARD OF OPTOMETRY POLICY OR REGULATION

● OTHER STATE LAW

Michigan issued a cease and desist order against Opternative for violating provisions of the state's Eye Care Consumer Protection Law. The state's Department of Licensing and Regulatory Affairs found Opternative's "prescriptions" are invalid because the "vision test" consists solely of objective refractive data generated from an automated device, and does not provide a complete ocular health assessment.

In 2016, both Indiana and South Carolina passed laws that prohibit prescriptions based solely on online vision tests.