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US states and the ocular care battle: Technology innovation versus in-person eye care

The development of telehealth has led to numerous legislative and court battles in the US, typically pitting traditional care interests on one side against the telehealth industries on the other. A facet of this battle has involved access to ocular care via telehealth, which has been the subject of numerous laws and proposed bills at state level, several of which have sought to prohibit or restrict ocular telehealth on the grounds that eye care provided in this way is not adequately comprehensive; the telehealth industries meanwhile have argued that such technology expands access to care. Michele Satterlund, SVP Government Relations - State at McGuireWoods Consulting LLC and Partner at McGuireWoods LLP, provides an overview of action at state level in this area, the arguments for and against ocular telehealth, and the recent involvement of the US Federal Trade Commission.

As more states have sought to identify opportunities to expand access to care and reduce healthcare costs, an increasing number are creating policies that address healthcare delivery via telecommunications technology, commonly known as virtual care services or 'telehealth.' And as the use of these virtual care services has grown, so have state policymaking battles, pitting telehealth industries against long standing traditional care interests and forcing policymakers to weigh traditional patient safety notions against the benefits of expanded access to care and cost effectiveness.

These battles have been particularly brutal in the specialty care segment of ocular telehealth, where a smartphone app can now be used to complete an online eye test that measures for refractive errors¹. In some instances, patients who complete the online eye test can obtain electronic prescriptions for glasses or contact lenses from an online provider without ever visiting a traditional brick-and-mortar store.

As more technology stakeholders have entered the ocular care market, the arguments for and against the technology have gotten more heated. Proponents contend that the technology expands access to care

while opponents counter that the technology is not comprehensive and may miss other healthcare conditions.

Similar to the telemedicine battles that have played out over the past five years, where the primary care telemedicine industry fought against in-person exam requirements for prescribing Schedule VI medications, ocular technology interests are fighting against statutory or regulatory requirements that mandate an in-person examination take place before a prescription for glasses or contact lenses can be written.

Among the first states to weigh in on the issue was South Carolina, which passed the Eye Care Consumer Protection Law ('ECCPL') in 2016. The ECCPL prohibits the use of refractive-only testing, and clarifies that vision assessments cannot 'be based solely on objective refractive data or information generated by an automated testing device, including an autorefractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination².'

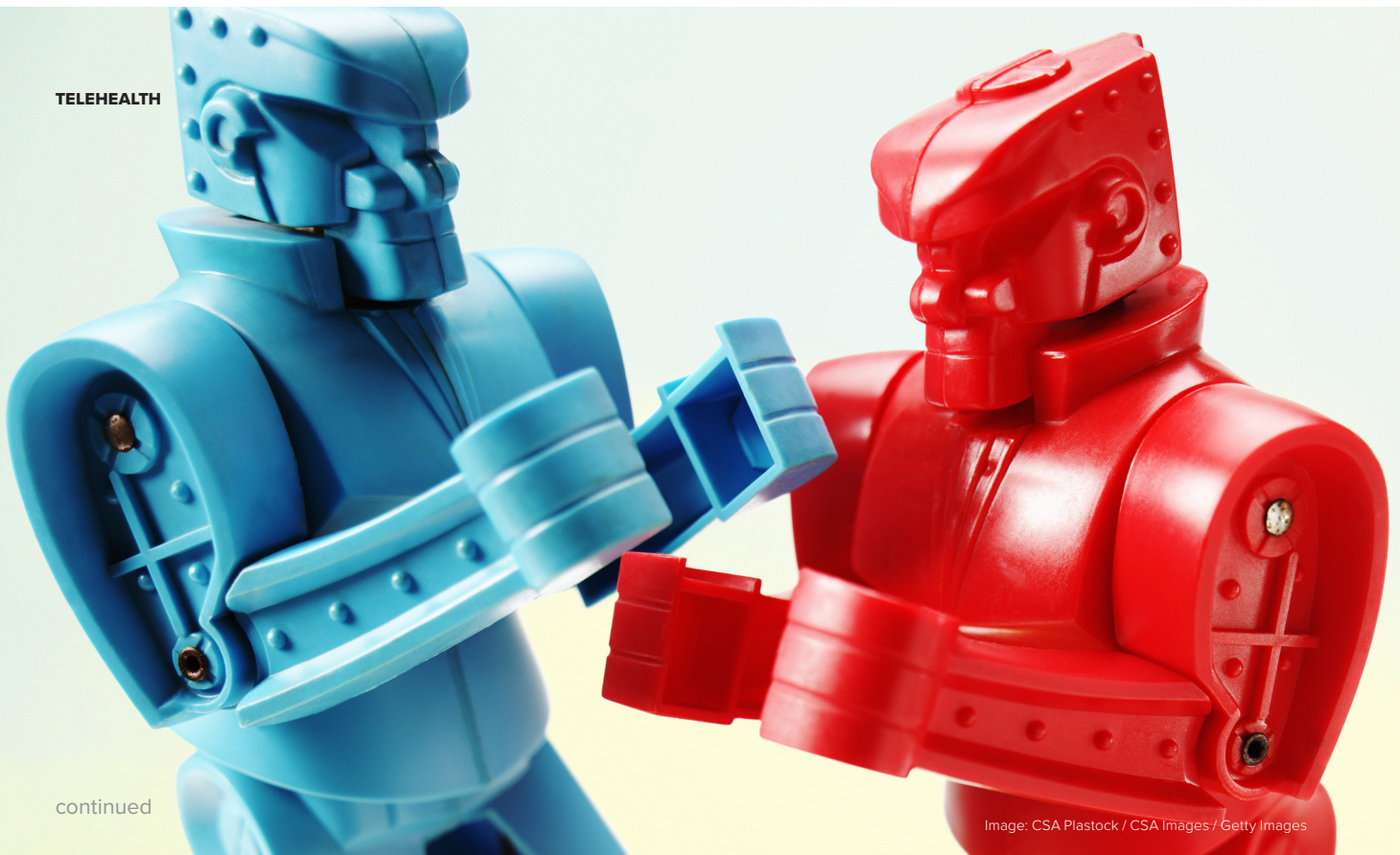
The South Carolina Optometric Physicians Association ('SCOPA') and The American Optometric Association ('AOA') supported the ECCPL, arguing

that "apps cannot assess a patient's overall medical condition and can give patients a false sense of security, potentially causing them to forego eye- and life-saving treatment³."

Others disagreed, including then-Governor Nikki Haley, who vetoed the bill and criticised it for using "health practice mandates to stifle competition for the benefit of a single industry [...]." Others who opposed the ECCPL included app developer Opternative, which called the legislation protectionist, saying it sought to protect the economic interest of one group over the interests of the citizens of South Carolina⁴.

Haley's veto was ultimately overridden and the ECCPL took effect in May 2016. Opternative and The Institute for Justice sued the South Carolina Board of Medical Examiners and the State Department of Labor, Licensing & Regulation, arguing, among other things, that South Carolina's regulatory regime (specifically the ECCPL) "does not further any valid public health or safety purpose and therefore violates Opternative's right to pursue an honest living free from arbitrary, irrational, and protectionist regulation⁵."

In January 2018 US District Court Judge DeAndrea Gist Benjamin dismissed Opternative's lawsuit on



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the basis that the company lacked proper standing because the law had not caused injury to Opternative⁶.

In Indiana, a similar battle ensued when HB1263 was introduced in the 2016 legislative session. As introduced, HB1263 expanded providers' ability to issue prescriptions to patients through telemedicine and allowed glasses, contact lenses and low-vision devices to be prescribed via telemedicine. The Indiana Optometric Association ('IOA') opposed the Bill, arguing that online technology could not duplicate the benefits of an in-person eye care visit. The IOA argued that in-person eye screenings, despite being more expensive, provided more patient benefit by minimising the risk that other health conditions, such as diabetes, would not be discovered by online app technology.

The Bill was amended to prohibit prescriptions of ophthalmic devices via telemedicine. Opponents of the amended Bill, including Opternative and 1-800 Contacts, argued that it limited access to eye care, noting that many rural residents had limited or no access to basic eye care, and without access to the technology, these individuals might forego any vision care. Despite opponents' arguments, then-Governor Mike Pence signed HB1263 as amended and it became law on 1 July 2016.

Indiana legislators revisited the issue last year, when they introduced

HB1331, which sought to remove the restrictions placed on the prescribing of ophthalmic devices through telemedicine. It failed, and Indiana law continues to prohibit prescribing of ophthalmic devices via telemedicine.

In contrast to Indiana and South Carolina, Virginia took a different approach by proactively allowing ocular telehealth, but only if certain patient care standards are met. Senate Bill 1321 and HB1497, introduced in the 2017 Virginia legislative session, were originally advanced at the request of the Virginia Optometric Association ('VOA') and sought to limit the use of technology and prohibit ophthalmic prescriptions outside a bona fide patient-provider relationship.

The stakeholders in Virginia, which included the VOA and the Virginia Society of Eye Physicians and Surgeons ('VSEPS'), as well as app developers and contact lens retailers, successfully crafted compromise language that mirrored Virginia's existing law governing the prescription of controlled substances via telemedicine.

The final Bill, which became effective on 1 July 2017, clarified that an examination is required prior to a prescription being issued for glasses or contact lenses, but permits the use of technology for purposes of the examination, provided the technology allows for face-to-face interactive, two way, real time communication or store-and-forward

technology⁷. The Law also requires that, regardless of the technology used, the ocular care provider must conform to the same standard of care expected of an in-person examination, and must consider the patient's age, presenting condition and whether the standard of care requires diagnostic testing or a physical examination.

To date, Virginia is the only state to pass legislation that affirmatively allows the use of technology to perform an eye examination for the purposes of prescribing, although other states allow eyeglass and contact lens prescriptions under general telemedicine rules. For instance under Washington law, telemedicine is defined as 'the delivery of health care services through the use of interactive audio and video technology.' The definition does not differentiate between the types of healthcare services delivered and would encompass ocular care:

'(13) "Telemedicine" means the delivery of health care services through the use of interactive audio and video technology, permitting real-time communication between the patient at the originating site and the provider, for the purpose of diagnosis, consultation, or treatment. "Telemedicine" does not include the use of audio-only telephone, facsimile, or email⁸.'

In January 2018, SB5411/HB1473 were reintroduced in the Washington Legislature. The legislation sought to

1. A refractive error means the shape of the eye does not bend light correctly, resulting in a blurred image. The main types of refractive errors are myopia (near-sightedness), hyperopia (far-sightedness), presbyopia (loss of near vision with age), and astigmatism. See <https://nei.nih.gov/health/errors/errors>
2. South Carolina Code Ann. §40-24-10.
3. Press release: <https://www.aoa.org/newsroom/patient-victory-in-south-carolina-x20251>
4. <https://dc.statelibrary.sc.gov/handle/10827/21260> / https://dc.statelibrary.sc.gov/bitstream/handle/10827/21260/GOV_Veto_S_1016_2016-05-16.pdf?sequence=1&isAllowed=y
5. *Opternative v. South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing and Regulation*, 2016-CP-40- (5th Judicial Cir., Oct., 2016); http://ij.org/wp-content/uploads/2016/10/Opternative-Complaint_Final-10192016-Version.pdf
6. *Opternative v. South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing and Regulation*, 2016-CP-40-06276 (5th Judicial Cir., Jan. 26, 2018).
7. Store and forward technologies allow for the electronic transmission of healthcare information, such as digital images, documents and videos through a secure transmission, from an originating site, which is then forwarded to a provider at a distant site.
8. Washington RCW 48.43.735.
9. <http://apps2.leg.wa.gov/bills/summary?Year=2017&BillNumber=5411&Year=2017&BillNumber=5411>
10. <http://2o9ub0417chl2lg6m43em6psi2i.wpengine.netdna-cdn.com/wp-content/uploads/2018/01/AFVCI-KY-Letter.pdf>
11. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-washington-state-rep-paul-graves-regarding-ssb-5411/hb-1473/proposed_advocacy_comment_-_wa_eye_care_final_2-9-18.pdf
12. https://www.ftc.gov/system/files/documents/amicus_briefs/teladoc-incorporated-et-al-v-texas-medical-board-et-al/teladoc_doj-ftc_amicus_brief.pdf
13. <https://www.aoa.org/documents/advocacy/AOA-Opternative-Complaint-April04.pdf>
14. <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm600029.htm>

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limit the use of virtual care technology specific to ocular care by requiring that an optometrist or ophthalmologist conduct an in-person eye exam before prescribing contact lenses or glasses:

‘Comprehensive eye examination does not include any form of examination or evaluation that consists solely of objective refractive data or information obtained through the use of remote technology without the involvement or supervision of a qualified vision care provider⁹.’

Americans for Vision Care Innovation, a coalition whose members include the Center for Freedom Prosperity, the National Hispanic Medical Association and the League of United Latin America Citizens, as well as 1-800 Contacts and Opternative, opposed the legislation, arguing that online app technology is designed to help renew prescriptions and not to replace comprehensive eye exams¹⁰. The bills died.

Interestingly, before the 2018 Washington Legislature adjourned, the Federal Trade Commission (‘FTC’) weighed in on SB5411. Through written comments dated the 9 February 2018¹¹, the FTC raised concerns that the legislation might stifle competition, decrease access to ocular care, limit consumer choice in eye care, and raise care costs for consumers:

‘[...] the bill’s requirements would restrict the use of telehealth eye care by qualified vision care providers, which

would deny consumers the benefits of innovative eye care telehealth technologies. Second, the bill might require unnecessary services by mandating a comprehensive examination before prescribing corrective lenses, regardless of the patient’s visual health status, examination history, or other circumstances. This requirement could override the judgment of a vision care provider who otherwise would have concluded that the standard of care could be met with more limited services, either in-person, or if allowed, by telehealth.’

This is not the first time the FTC has weighed in on state telehealth policy. In one of the nation’s biggest telemedicine battles, online telemedicine provider Teladoc brought an antitrust lawsuit against the Texas Medical Board for requiring an in-person examination before a provider writes a prescription. The FTC submitted a 44 page letter to the US 5th Circuit Court of Appeals that criticised the Texas Medical Board for attempting to impose restrictions on telehealth¹². Teladoc ultimately dropped the lawsuit after the state finalised new laws allowing physicians to treat patients virtually without a prior face-to-face interaction.

Because some states may view the FTC’s involvement in a state health matter as an intrusion and a states’ rights issue, it’s not clear how the FTC might shape state level telehealth policies, or whether the FTC’s comments may help or hinder

the efforts of ocular care technology proponents. But the FTC’s involvement does seem to reflect an interest by the eye care industry for federal input on the issue. The American Optometric Association (‘AOA’) filed a complaint in April 2016 with the Food and Drug Administration’s Center for Devices and Radiological Health (‘FDA’)¹³.

In the complaint, the AOA states that the “FDA should not permit the continued marketing of the Opternative device until CDRH has reviewed the safety and efficacy issues raised by the device.” The FDA recently made public a letter dated the 30 October 2017, in which it responds to the complaint and orders Opternative to “cease activities that result in the misbranding or adulteration of the On-line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website¹⁴.”

While at least 12 states have laws that limit ocular telehealth (whether through an in-person exam requirement or a ban on the technology) it’s not yet clear how this battle will end and whether the demand for telehealth by today’s consumers and patients will outweigh traditional ocular care interests. But what is clear is that technology is developing at a speed that is disrupting every aspect of healthcare and policymakers are being forced to rethink how they develop and apply a legal framework in today’s ever changing environment.