To: Board Members
From: Jessica Sieferman
Telephone: (916) 575-7170

Date: April 21, 2017

Subject: Agenda Item 13 – Discussion and Possible Action Regarding Emerging Technologies and the Impact to Consumers and the Profession

Emerging technologies, such as online refractions and kiosk refractions have been closely monitored by the Board since early 2015. The Board has also discussed the topic in multiple public meetings. For reference, staff compiled a hyperlinked list to prior materials and available Webcasts (Attachment 1).

Overall Consumer Protection Concern
The overall concern is patients do not fully understand the difference between a refraction test and a comprehensive eye exam. To the patient, he/she experiences a symptom (difficulty seeing near or far away), and the symptom is “fixed” with a quick and convenient refraction test and a pair of glasses. That patient may assume everything is fine and never see the need to have a comprehensive eye exam.

However, refractions (regardless of setting) cannot evaluate the underlying health of the eye or appropriately determine causation of the refractive error. For example, a patient struggling to see far away (symptom) may think they just need a prescription for glasses (perceived solution). So, that patient, believing all he/she needs is a quick prescription, receives a prescription and glasses from an online source. The patient thinks the problem is solved and his/her vision is fine. However, that patient might have an increase in blood sugar due to diabetes, and getting his/her blood pressure under control would not only negate the need for glasses, but also assist the patient it obtaining proper care for diabetes.

In addition, determining the refractive error is a minor portion of a comprehensive eye examination, and it is typically assessed after evaluating the overall health of the eye.

Consumer Protection Concern Discussed During Sunset Hearing
The Joint Oversight Hearing Background Paper identified emerging technologies, included online refractions, as Issue #15. The issue and Board response is attached for reference (Attachment 2). This consumer protection concern was discussed with Board Members, the Executive Officer and the Legislature during the Board’s Sunset Hearing. That portion of the hearing can be viewed here.

During the hearing, several possibilities were discussed in order to address the issue including, but not limited to, the following:

- increasing accountability and liability,
- potentially requiring the corporations offering the services to register with the applicable regulatory board, and
- increasing educational outreach to consumers.
In addition, a representative from Center for Public Interest Law spoke mentioned an “in-person” requirement during public comment.

The Board also provided information regarding its efforts to educate the public on this issue.

**Consumer Protection Concern Discussed During Informational Hearing**

On March 14, 2017, the Board’s Executive Officer (EO), the California State Board of Pharmacy EO, and the Medical Board of California (MBC) Executive Director served on a healing arts panel to provide information during a joint informational hearing entitled *The Regulation of Corporations and the Impact on Professional Licensing*.

During that hearing, Chair Salas requested additional information related to emerging technologies and online refractions. The Board’s EO discussed the Board’s current consumer protection concerns and the jurisdictional issue with licensed ophthalmologists and medical corporations performing the services. The MBC Executive Director testified that the MBC is evaluating this issue on a case by case basis. Simply providing services online is not illegal; however the same industry standard of care must still be followed regardless of practice setting.

**National Level Attention**

Several states have raised similar concerns, and some have taken legislative/regulatory action in an attempt to address the issue. As previously reported at the August 2016 meeting, the Association of Regulatory Boards in Optometry (ARBO) discussed this during their 2016 annual meeting. Attorney and instructor at Lewis and Clark Law School provided an overview of issues regulatory boards are facing when it comes to new and innovative technology (Attachment 3). While it does not provide any legal advice, it offers some information and questions to consider when considering policy decisions.

Most recently, Delaware Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers attempted to add regulatory provisions providing safeguards to ensure that telemedicine meets an in-person standard of care. Upon review, however, the Federal Trade Commission (FTC) concluded the following:

> *Well-intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition. Thus, we suggest that regulators consider whether a restriction that could limit entry or access is narrowly tailored to the legitimate goals of the restriction, such as health and safety, and whether other provisions in the law or regulations already achieve, or could achieve, such goals through less competitively restrictive means [emphasis added]*

> The proposed Delaware regulation could promote the use of telepractice and enhance competition in the provision of hearing and speech care services, likely increasing access, improving quality of care, and bringing other benefits, by allowing licensees to determine whether telepractice is an appropriate level of care. The proposed regulation may, however, unnecessarily limit those benefits by requiring that all initial evaluations be carried out in person, rather than by telepractice."

The full FTC letter is attached for reference (Attachment 4).

**Action Requested**

Please consider and fully discuss the Board’s consumer protection mandate and its role in regulating a profession with emerging technologies. In discussing potential ways to address the consumer protection concerns raised, please keep in mind the FTC guidance provided.

**Attachments**

1. Prior Board Discussions Related to Emerging Technology
2. Issue #15 Board Response
3. Reasonable Regulation in an Electronic Era
4. FTC November 29, 2016 Letter
Prior Board Discussions Related to Emerging Technology

- April 23-24, 2015 Board Meeting
  - Materials (pgs. 188-203)
  - Webcast (starting 3:22:11)

- November 20, 2015
  - Materials (pgs. 79-134)

- December 16, 2015 Public Relations and Outreach Committee (PROC) Meeting
  - Materials

- February 19, 2016 Board Meeting
  - Materials (pgs. 166-119)
  - Webcast (starting 4:44:44)

- April 21, 2016 PROC Meeting
  - Materials
ISSUE #15: New and Emerging Technologies.

**Background:** Currently, the traditional business model for a consumer to receive optometric services is by visiting an optometric practice at a brick and mortar establishment. At a traditional site, a comprehensive eye examination is typically provided. Recent technological advances are beginning to reshape consumers' access to eye care services. An online refractive test is a service provided through a website. It is a vision test which can be used as a tool by eye care practitioners to determine an individual's needs for an eyeglass or contact lens prescription. Consumers take the test online, pay a fee for services and can then receive a prescription for eyeglasses or contact lenses from a licensed eye care practitioner (either an Optometrist or an Ophthalmologist). These online examinations require consumers to utilize a computer or a smartphone and the examination can be conducted in the privacy of an individual's home.

A quick Google search demonstrates a variety of options for persons interested in acquiring a prescription through online service providers. According to one company's website (Opternative), the way it works is that a consumer registers online and answers questions to ensure eligibility, once approved, the consumer then utilizes a smartphone and a computer for the test (for free), after the examination, the consumer pays a $40 fee for an Ophthalmologist to review and approve a prescription, which then a consumer can take and fill accordingly. This type of service is not considered to be a "comprehensive examination" as it only measures the need for a person's prescription for eyeglasses or contact lenses. As noted by Opternative on its website,

"Opternative is not a replacement for a comprehensive eye health examination. Our licensed Ophthalmologists use Opternative online technology to evaluate a patient's visual acuity and a portion of the ocular health profile, diagnose refractive error, and issue a prescription for corrective eyewear, where clinically appropriate. Our services are limited to patients between the ages of 18 and 50 who are in good health. All tests are conducted and all prescriptions are issued based on the independent clinical judgement of an ophthalmologist. Because our services are not a replacement for an eye health examination, we encourage everyone to obtain a comprehensive eye health exam at least once every 2 years. We prohibit patients from taking an Opternative test more than 4 consecutive years without certifying that they have received a comprehensive eye health exam first. If you need help finding an eye care professional near you, please contact us at info@opternative.com."

According to the Optometric Association, "vision screening programs can't substitute for regular professional vision care. Children or adults who pass a vision screening could still have an eye health or vision problem."

While these services are not purported to offer a full service eye health screening to detect more serious eye conditions, there is concern that consumers may not be aware and mistake a vision screening online program as a replacement for a more comprehensive service. It may be beneficial for the Board to ensure consumers are aware of the differences in services offered including information about where and to whom consumers can raise concerns with quality of care issues.

**Staff Recommendation:** The Board should advise the Committees on whether or not there is a method to verify that the online examinations are valid for what they purport to be. Further the Board should advise the Committees on what, if anything, the Board is doing to provide consumers with information regarding online vision service providers. Lastly, the Board should advise about the current relationship between online examinations and Optometric telehealth.
Board Response: The Board welcomes emerging technologies that better serve California consumers. The Board will continue to take the necessary steps to ensure the same standard of care is followed regardless of practice setting. The Board is taking a two-pronged approach to the issue of online refractions and refractions performed in kiosks within mercantile settings. First, it is refining its outreach message to specifically target consumers (and potential consumers) of online services to provide them with the most accurate information as to what these services can provide and what they can’t – most notably, the inability to effectively and appropriately examine the overall health of the eye as well as the inability to determine whether a change in a patient’s prescription is due to a normal refractive shift or if the change was caused by an ocular health issue.

The Board will increase its social media presence and utilize available technology to reach the technologically savvy consumer. Second, the Board is investigating complaints filed regarding online services. Using a variety of methods, and during these investigations, Board staff will work closely with the Division of Investigation and the Office of the Attorney General to verify that the applicable laws and regulations are being followed. The Board is also reviewing how these services mesh with existing telehealth statutes.
ISSUES FOR REGULATORY/LICENSING AUTHORITIES

1-How to reconcile the utilization of virtual, “boundary-less” health modalities with geographically-bounded legal restrictions?

- potential (and often, actual) benefits from innovative technology—
  expand access, geographically and for routine care
  gain efficiencies, by reducing time/costs to patients
  promote monitoring and adherence
  increase data collection and analysis
  trigger patient awareness of need for more comprehensive care

- problems with current state-based regulation—
  varying legal definitions- telehealth or telemedicine
  some state have no definitions for these modalities
  other states require dual licensure (remote and resident state)
  differing authority and coverage for providers and patients
  varying payments by governmental and commercial insurers
  perils of exceeding the scope of practice in the remote state
  potential conflicts for liability coverage, documentation, etc.

- professional ethical provisions, and state regulations—
  - traditionally based on the essential nature of in-person, face-to-face contact; given technology, is this still valid?
  - bundled all profession-related services into the exclusive domain of a profession; with new kinds of providers and technological advances, will the trends of “un-bundling” and de-regulation continue?
2- Who regulates the development of new technologies and their utilization by whom, and based on what?

- federal -- development and assessment of product, licensing of product, patent and copyright protections, and marketing
- state legislature or agency – authorized providers; payment for services

3- How to assure compliance with:

- federal antitrust laws when regulations are developed and promulgated by market participants?

- constitutional requirements of due process and equal protection?
  - do restrictions address a real, as opposed to a hypothetical, need for public health and safety?
  - are restrictions tailored to the substantiated problem, and do they assess the effects on patients’ access and costs, as well as quality?

4- What is the role of regulatory boards in protecting patient health and safety?
  - the best/highest level of services? Or appropriate services? Or acceptable services? And who decides what those mean?
RESOURCES:

*The Promise of Telehealth For Hospitals, Health Systems and Their Communities*, American Hospital Association, January 2015  
http://www.aha.org/research/reports/tw/15jan-tw-telehealth.pdf

*Realizing the Promise of Telehealth: Understanding the Legal and Regulatory Challenges*, American Hospital Association, May 2015  
http://www.aha.org/research/reports/tw/15may-tw-telehealth.pdf


*Iowa Board of Medicine votes to establish standards for physicians who use telemedicine*  

*New rule establishes standards for physicians who use telemedicine*  
Iowa Board of Medicine Final Rule effective, June 3, 2015

*Telehealth Policy Trends and Considerations*  
National Conference of State Legislatures (2015)  
American Telehealth Association (2015)
50 State Telehealth Gaps Analysis- Coverage and Reimbursement


North Carolina State Board of Medical Examiners v. Federal Trade Commission, U.S. Supreme Court, 2015

FTC Staff Comment to the Alaska State Legislature Regarding Telehealth Provisions In Senate Bill 74, Which Would Allow Licensed Alaska Physicians Located Out-of-State To Provide Telehealth Services
Delaware Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers
Cannon Building
861 Silver Lake Blvd.
Dover, DE 19904

The staffs of the Federal Trade Commission’s (“FTC”) Office of Policy Planning, Bureau of Economics, and Bureau of Competition1 (collectively, “FTC staff”) appreciate the opportunity to respond to the Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers’ (“Board”) notice requesting comments on its proposed revisions to its telecommunication and telehealth regulations. The Board proposes to eliminate an existing restriction on evaluation and treatment by correspondence, including telecommunication at 24 Del. Admin. Code § 3700-9.2.1.4, and replace it with a new § 3700-10, on “Telepractice.”2 The new regulation would promote the use of telepractice by allowing licensed Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers (collectively, “licensees”)3 to determine whether telepractice is an appropriate level of care for a patient. However, before licensees could provide telepractice services, the proposed regulation would require an in-person initial evaluation.4

The Board takes a significant and, we believe, positive step by proposing to remove existing restrictions on service by telecommunication and allow licensees to determine whether telepractice is an appropriate level of care. The proposed regulatory changes could enhance consumer choice by providing an alternative to in-person care, potentially reducing travel expenditures, increasing access to care, and increasing competition. The Board might boost these benefits, however, by allowing licensees to determine on a case-by-case basis whether telepractice is appropriate for an initial evaluation, rather than requiring that all initial evaluations be carried out in person. Accordingly, we encourage the Board to consider the potential effects on competition and access of the proposed prohibition on initial evaluations delivered by telepractice, in conjunction with any potential health and safety consequences of the proposed regulation.

I. Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.5 Competition is at the core of
America’s economy, and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and increased innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement, research, and advocacy. In particular, many of our recent state advocacy comments have addressed scope of practice and supervision provisions that may unnecessarily limit the range of procedures or services a practitioner may provide, or unnecessarily restrict a particular type of practitioner from competing in the market.

Telehealth is an area of particular interest to the FTC because of its potential to increase practitioner supply, encourage competition, and improve access to affordable, quality health care. In a 2004 report, the federal antitrust agencies considered the competitive effects of state restrictions on the interstate practice of telemedicine, and the central finding of that analysis remains applicable today: “When used properly, telemedicine has considerable promise as a mechanism to broaden access, lower costs, and improve health care quality.” More recently, FTC staff submitted a comment to the Alaska legislature supporting proposed legislation that would allow Alaska-licensed physicians located out-of-state to provide telehealth services in the same manner as in-state physicians. FTC staff also recently commented on telehealth regulations proposed by the Delaware Boards of Occupational Therapy Practice and Dietetics/Nutrition. The conclusions of the agencies’ 2004 report and the prior FTC staff comments, which support reduction of barriers to telemedicine, underpin this comment.

II. Delaware’s Proposed Telepractice Regulation for Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers

As a prerequisite to its proposed telepractice regulation covering the provision of speech/language pathology, audiology and hearing aid dispensing professional services, the Board proposes to eliminate an existing regulation, 24 Del. Admin. Code § 3700-9.2.1.4, that does not allow licensees to “evaluate or treat a client with speech, language, or hearing disorders solely by correspondence. Correspondence includes telecommunication.” A telepractice regulation would be added at § 3700-10.

The proposed regulation defines telepractice as “the application of telecommunications technology to the delivery of speech/language pathology, audiology and hearing aid dispensing professional services at a distance by linking clinician to client or clinician to clinician for intervention and/or consultation . . . “ The regulation would have several provisions to ensure that “interventions” are appropriately delivered by telepractice and meet in-person standards of care:

“The licensee shall comply with the Board’s law and rules and regulations and all current standards of care requirements applicable to onsite care.”

“The licensee shall limit the practice of telepractice to the area of competence in which proficiency has been gained through education, training and experience.”
“Licensees who deliver telepractice services must possess specialized knowledge and skills in selecting interventions that are appropriate to the technology and that take into consideration client and disorder variables.”

These provisions provide safeguards to ensure that telepractice meets an in-person standard of care. The proposed regulation, however, also would create a requirement that all “[i]nitial evaluations shall be performed face to face and not through telepractice.” The proposed regulation would allow a licensee to “be responsible for determining and documenting that telepractice is an appropriate level of care for the client only after an initial face to face evaluation.” Accordingly, while the proposed regulation would rely on the judgment of licensees to determine whether to provide telepractice interventions and consultations, it prohibits initial evaluations by telepractice, potentially prohibiting some telepractice diagnostic services and discouraging practitioners and consumers from using telepractice for post-evaluation treatment or intervention.

III. Likely Competitive Impact of Delaware’s Proposed Telepractice Regulation

A. Telepractice Has the Potential to Increase Competition and Access to Speech and Hearing Care Services

Generally, competition in health care markets benefits consumers by containing health care prices, expanding access and choice, and promoting innovation. Telehealth can potentially increase the supply of practitioners and thereby enhance price and non-price competition, reduce transportation expenditures, and improve access to quality care. Many health care professionals and expert bodies support the use of telehealth to address access to health care challenges arising from an aging population, health care workforce shortages, and geographic and other maldistributions of providers that can lead to shortages in urban as well as rural areas.

Telepractice as a delivery model for audiology and speech/language pathology services offers the same potential to enhance competition among providers and improve access to quality care. Practitioners and expert bodies such as the National Academies of Sciences, Engineering, and Medicine have recognized the potential for telepractice to address geographic and economic barriers to hearing and speech care, especially in underserved communities.

The Delaware Division of Public Health has acknowledged the potential for telehealth to mitigate the state’s healthcare access challenges caused by shortages in critical healthcare specialties and underserved geographic locations. While Delaware is a small state, many of its health resources are unevenly distributed. For example, there are few audiologists in Sussex and Kent counties relative to New Castle, suggesting that telehealth would allow New Castle practitioners to serve Sussex and Kent patients. Experts have found that many audiology and speech/language pathology rehabilitation services can be effectively provided through telepractice, potentially improving access to care arising from shortages, economic disparities, and/or poor mobility. As the Delaware State Plan on Aging points out, the elderly and individuals with disabilities could especially benefit from telehealth because it would allow them to “receive some medical care at home, or in other more convenient settings.”
The potential for improved health outcomes and access to cost-effective medical care motivated the Delaware Medicaid Program’s 2012 decision to reimburse services delivered by telemedicine. Telepractice delivery of speech/language pathology and audiology services could help reduce Delaware’s Medicaid transportation expenditures as well as individuals’ pecuniary and time costs.

B. A Range of Services May Safely and Effectively be Provided by Telepractice

The literature indicates that a number of speech and hearing care services can be provided safely and effectively through telepractice. In speech/language pathology, schools are the most common setting in which telepractice is used. For both adults and children, telepractice, often conducted via interactive audio-videoconferencing, may be used for screening, treatment, and consultation. In schools, telepractice is used to evaluate and treat a number of impairments, including language, articulation, and fluency disorders. Typically, a student receiving telepractice speech/language pathology services at school is assisted by a telepractice assistant, such as a teacher’s aide, nursing assistant, or other type of support personnel to help students and other patients focus on the task and provide technology support. The use of speech/language pathology telepractice could help alleviate chronic shortages of speech/language pathologists in Delaware schools.

A number of audiology services, such as the diagnostic hearing assessment of adults and infants, cochlear implant programming, and hearing aid fitting and programming, can also be provided remotely. For example, the U.S. Department of Veterans Affairs (“VA”) has a tele-audiology program that provided more than 15,000 tele-audiology encounters in FY 2014, making tele-audiology one of its top 15 telehealth programs. The program provides services such as hearing aid fitting and programming, and cochlear implant programming. Telepractice encounters typically link a practitioner at a VA medical center with a patient at a community outpatient clinic, where a trained assistant is available to set up specialized equipment that the practitioner operates remotely.

Similarly, the diagnostic evaluation of infants who failed a newborn hearing screening test at a birth hospital can be performed via telepractice by connecting a pediatric audiologist at a major medical center with an infant brought to a community hospital or clinic. A facilitator sets up the equipment for use on the infant, and a remote audiologist conducts a comprehensive diagnostic evaluation, including video-otoscopy, auditory brainstem response, and other tests.

Allowing the telepractice diagnostic evaluation of infants who failed a newborn hearing screening test may improve follow-up and enhance quality of care, yielding significant long-term benefits for children with hearing loss. The Joint Committee on Infant Hearing recommends that diagnostic hearing evaluation of infants who fail newborn hearing screening occur by three months of age. However, because of shortages of pediatric audiologists and the difficulties of travel for some parents, due to lack of transportation, the need for childcare, lost wages, or a combination of these factors, many infants appear to be missing timely evaluation. According to the Centers for Disease Control and Prevention (“CDC”), 58.7% of Delaware infants who failed the newborn hearing screen were not confirmed as having received the recommended audiological evaluation needed to diagnose a hearing loss in 2014. Teleaudiology has been
found to be an effective way to address barriers to obtaining diagnostic hearing evaluation and to reduce or eliminate the number of infants not receiving an audiological evaluation.43

Such a program could enable Delaware-licensed audiologists located in New Castle County or out-of-state to provide diagnostic evaluations to infants in Sussex and Kent counties, addressing the shortages in those counties and potentially reducing the number of infants who did not receive an audiological evaluation.44 Importantly, improved follow-up may enable children found to have a hearing loss to receive treatment without delay, likely allowing them to acquire language skills comparable to hearing children.45 Such early identification and intervention not only improves a child’s quality of life, but also helps avoid substantial educational and societal costs arising from delayed treatment.46

C. The Proposed Restriction on Telepractice Initial Evaluations Could Unnecessarily Discourage the Use of Telepractice

In important respects, the proposed regulation likely would encourage the delivery of speech/language and audiology services by telepractice, thereby increasing competition, consumer choice, and access to care.47 The proposed elimination of § 3700-9.2.1.4 would remove the existing restriction on providing speech/language and audiology services by telecommunications, setting the stage for the provision of telepractice services.48 Proposed §§ 3700-10.2.4.3-10.2.4.5 would hold licensees to existing in-person standards of care, and with the exception of initial evaluations, § 3700-10.2.4.1 would entrust the decision whether to use telepractice to the practitioners best positioned to make that determination.49

The proposed regulation would, however, limit telepractice delivery to “interventions and consultations,” and would require that all initial evaluations be performed in person.50 Across-the-board restrictions not required by legitimate health and safety concerns may unnecessarily discourage the use of telepractice and limit its potential benefits. For example, the proposed rule appears to restrict some types of telepractice services, such as speech/language hearing services and newborn hearing screening follow-up, that may include an initial evaluation.51

The American Speech-Language-Hearing Association’s (“ASHA”) guidelines and model regulations include no provisions that would categorically restrict telepractice initial evaluations. Indeed, they define telepractice to include “assessment” as well as intervention and consultation, without distinguishing between initial and subsequent assessments.52 To ensure appropriate care, ASHA supports holding practitioners to an in-person standard of care and making practitioners responsible for determining whether assessments and interventions should be provided by telepractice, given the nature of the patient’s condition.53

ASHA’s endorsement of telepractice assessment is consistent with positions taken by other professional organizations. For example, several physicians’ organizations have recognized the need for flexibility with regard to the initial evaluation of a patient and have adopted telehealth policies permitting remote examination of a patient during an initial encounter, so long as the practitioner is held to an in-person standard of care.54
Requiring initial in-person examination or evaluation requirements in the health professions may restrict entry of qualified telehealth practitioners, potentially decreasing competition, innovation, and health care quality, while increasing price.\(^5\) Thus, several state legislatures and health care regulatory boards, including Delaware’s Board of Occupational Therapy Practice, have recently eliminated or declined to adopt provisions requiring an initial in-person evaluation.\(^5\)

Similarly, of the 19 states and the District of Columbia with laws, regulations, or policies on speech/language pathology or audiology telepractice, only three—Kentucky,\(^7\) Montana,\(^8\) and Texas\(^9\)—require an in-person initial evaluation or contact.\(^6\) Moreover, neither Kentucky nor Montana requires the distant telepractice provider to make an in-person evaluation if a qualified, in-person practitioner evaluates the client prior to the provision of telepractice services.\(^6\)

The Board could avoid a blanket restriction in the proposed regulation by allowing licensed practitioners to determine whether telepractice is appropriate for an initial evaluation, just as they are permitted to do for subsequent visits, consistent with the in-person standard of care and related health and safety concerns. Allowing the licensed practitioner to determine whether to use telepractice for an initial evaluation would put the decision in the hands of the practitioner in the best position to weigh access, health, and safety considerations on a case-by-case basis. In addition, because the nature of many speech/language pathology and audiology services requires a facilitator to assist with the patient and/or specialized equipment,\(^6\) licensees often will have a proxy for an in-person encounter. In any event, the Board’s proposed rules already would require telepractice providers to ensure that their services are appropriate for the client’s condition, and would hold providers to an in-person standard of care.\(^6\)

For these reasons, we encourage the Board to consider whether the proposed regulation could provide potentially greater access, quality of care, and other benefits to patients by broadening the proposed definition of telepractice to include evaluations and eliminating the apparent prohibition of initial evaluations conducted by telepractice.\(^6\)

**IV. Conclusion**

Well-intentioned laws and regulations may impose unnecessary, unintended, or overbroad restrictions on competition, thereby depriving health care consumers of the benefits of vigorous competition.\(^6\) Thus, we suggest that regulators consider whether a restriction that could limit entry or access is narrowly tailored to the legitimate goals of the restriction, such as health and safety, and whether other provisions in the law or regulations already achieve, or could achieve, such goals through less competitively restrictive means.

The proposed Delaware regulation could promote the use of telepractice and enhance competition in the provision of hearing and speech care services, likely increasing access, improving quality of care, and bringing other benefits, by allowing licensees to determine whether telepractice is an appropriate level of care. The proposed regulation may, however, unnecessarily limit those benefits by requiring that all initial evaluations be carried out in person, rather than by telepractice.
We commend the Board and support the proposed regulation’s flexibility in generally allowing licensees to determine whether to use telepractice. At the same time, we urge the Board to consider whether allowing licensees to decide whether and when to use telepractice delivery, including on initial evaluations, would better promote competition and access to safe and affordable care.

We appreciate your consideration.

Respectfully submitted,

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1 This letter expresses the views of the Federal Trade Commission’s Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. The Commission, however, has voted to authorize staff to submit this comment.

2 3700 State Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers, 20 Del. Reg. Regs. 107 (proposed August 1, 2016) (Telepractice regulation to be codified at 24 DEL. ADMIN. CODE § 3700-10) [hereinafter Proposed Regulation]. For a discussion of § 3700-9.2.1.4 and § 3700-10, see infra Section II. The Board uses the term “telepractice” rather than telehealth or telemedicine, consistent with the American-Speech-Language-Hearing Association’s decision to use the term “to avoid the misperception that these services are used only in health care settings.” AMERICAN-SPEECH-LANGUAGE-HEARING ASS’N, TELEPRACTICE (Practice Portal), Overview, http://www.asha.org/PRPPrintTemplate.aspx?folderid=8589934956 (last visited Oct. 19, 2016) [hereinafter ASHA, TELEPRACTICE]. ASHA’s Practice Portals are “developed through a comprehensive process that includes multiple rounds of subject matter expert input and review.” See ASHA, Telepractice Content Development, http://www.asha.org/Practice-Portal/Professional-Issues/Telepractice/Telepractice-Content-Development/ (last visited Nov. 1, 2016).

3 This advocacy comment focuses on speech/language pathology and audiology because most of the available academic literature and other information sources discuss those services. We note, however, that the proposed regulation would cover hearing aid dispensers as well as speech/language pathologists and audiologists. To the
extent that hearing aid dispensers provide services remotely, we see no reason why an analysis of the likely competitive impact of the proposed regulation would differ for those providers.

4 See Proposed Regulation, supra note 2, §§ 3700-10.2.4.1, 10.2.4.2.


6 Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) (“The heart of our national economic policy long has been faith in the value of competition.”).

7 See generally FTC STAFF, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2016),

8 See, e.g., FTC & U.S. DEP’T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004),

9 FTC and staff advocacy can include letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. See, e.g., Comment from FTC Staff to Valencia Seay, Senator, Ga. State Senate (Jan. 29, 2016),

10 Many of these competition advocacy comments have focused on proposed state-level changes to statutes and rules governing the scope of practice and supervision of advanced practice registered nurses. The FTC staff report, Policy Perspective: Competition and the Regulation of Advanced Practice Nurses, presents an overview of these comments and an in depth analysis of the competitive effects of such statutes and rules. See FTC STAFF, POLICY PERSPECTIVES, supra note 9.


12 FTC & U.S. DEP’T OF JUSTICE, supra note 8, Executive Summary at 23.

13 See Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature (Mar. 25, 2016),
https://www.ftc.gov/policy/actions/advocacy-filings/2016/03/ftc-staff-comment-alaska-state-legislature-regarding (regarding telehealth provisions in Senate Bill 74, which would allow licensed Alaska physicians located out-of-state to provide telehealth services).

14 See Comment from FTC Staff to the Delaware Board of Occupational Therapy Practice (Aug. 3, 2016),

15 This advocacy also draws on knowledge acquired during the Innovations in Health Care Delivery panel of the 2014 FTC workshop, Examining Health Care Competition, supra note 11.

16 24 DEL. ADMIN. CODE § 3700-9.2.1.4. Although the scope of the conduct prohibited by § 3700-9.2.1.4 is unclear, it is the only state with such a provision and its effects may be far-reaching. See, e.g., Jana Cason & Janice A.
Brannon, *Telehealth Regulatory and Legal Considerations: Frequently Asked Questions*, 3 INT’L J. TELEREHAB. 15, 16-17 (“[T]he Delaware Board, through an unfortunate choice of wording, significantly limits the use of telehealth within their state for speech-language pathologists and audiologists by defining telecommunication in this way.”)


19 Proposed Regulation, *supra* note 2, § 3700-10.2.4.3.

20 Proposed Regulation, *supra* note 2, § 3700-10.2.4.4.

21 Proposed Regulation, *supra* note 2, § 3700-10.2.4.5.

22 Proposed Regulation, *supra* note 2, § 3700-10.2.4.2.

23 Proposed Regulation, *supra* note 2, § 3700-10.2.4.1.

24 See, e.g., Comment from FTC Staff to Steve Thompson, *supra* note 13.

25 See generally Am. Acad. of Pediatrics, *Policy Statement: The Use of Telemedicine to Address Access and Physician Workforce Shortages*, 136 PEDIATRICS 202, 203 (2015) (urban as well as rural children “face significant disparities in access and time-distance barriers, which could be partly alleviated by the use of telehealth”); Hilary Daniel & Lois Snyder Sulmasy, *Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper*, 163 ANN. INT. MED. 787, app. (2015) (“Limited access to care is not an issue specific to rural communities; underserved patients in urban areas have the same risks as rural patients if they lack primary or specialty care . . . .”); Rashid L. Bashshur et al., *The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management*, 20 TELEMED. & E-HEALTH 769, 770 (2014) (“Differences in access to care reflect economic, geographic, and functional as well as social, cultural, and psychological factors . . . . many residents of the inner city have limited access to medical resources for economic reasons.”).

26 See, e.g., NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY* 124-25, 132 (Dan G. Blazer et al. eds., 2016) [hereinafter NATIONAL ACADEMIES] (discussing the use of teleaudiology to improve access to hearing health care for underserved and vulnerable populations); M.L. Bush et al., *Rural barriers to early diagnosis and treatment of infant hearing loss in Appalachia*, 36 OTOL. NEUROTOL. 93 (2015); D.W. Swanepoel et al., *Telehealth in audiology: The need and potential to reach underserved communities*, 49 INT’L J. AUDOL. 195 (2010); Janice K. Tucker, *Perspectives of Speech-Language Pathologists on the Use of Telepractice in Schools: Quantitative Survey Results*, 4 INT’L J. TELEREHAB. 61 (2012) (“The potential benefits of telepractice are substantial [] and could include: greater access to speech-language pathology services for underserved populations (e.g., rural and inner city students) . . . .”).

27 See, e.g., DEL. DIV. OF PUB. HEALTH, STATE OFFICE OF PRIMARY CARE, *DELAWARE PRIMARY CARE HEALTH NEEDS ASSESSMENT 2015* 60 (Feb. 2016), www.dhss.delaware.gov/dph/hsm/files/dephealthneedsassessment2015.pdf (“Telehealth in Delaware is used to address health care access issues, whether from shortfalls in critical health care specialties or in underserved geographic locations . . . . The use of telehealth in Delaware is supported by state government as an important cost-effective, access improvement tool.”).

28 As explained by an audiologist who testified at the November 2015 public hearing of the Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers, “there is only one audiologist in Kent and Sussex County who is conducting follow-ups for newborns who fail hearing screenings. Due to the shortage, children are not getting subsequent follow-up appointments. There is a need for providing remote services to families who live far from the hospital and lack transportation.” 20 Del. Reg. Regs. 107, 108 (2016) (statement of Liesel Looney of Nemours/ Alfred I. duPont Hospital for Children). The relative scarcity of audiologists in Kent and Sussex counties is consistent with licensing data: Records of active Delaware audiology licenses showed three in Sussex County (1.52/100,000 people; 0.32/100 sq mi); 6 in Kent County (3.7/100,000 people; 1.01/100 sq mi), and 30 in New Castle County (5.57/100,000 people; 6.85/100 sq mi). License records were obtained from State of Delaware, Search for a License, https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx (last visited

29 See, e.g., Michelle von Murrat et al., Telerehabilitation in Audiology, in TELEPRACTICE IN AUDIOLOGY 153 (Emma Rushbrooke & K. Todd Houston, eds. 2016); Farzan Irani & Rodney Gabel, Telerehabilitation: Adult Speech and Swallowing Disorders, in TELEPRACTICE IN SPEECH-LANGUAGE PATHOLOGY (K. Todd Houston, ed. 2014); NATIONAL ACADEMIES, supra note 26, at 124-125 ("Tele-audiology fills a specific need for people who live in rural areas, for those who do not have transportation or are not physically able to travel to obtain audiology services . . . ."); supra note 26 and accompanying text.

30 See DIV. OF SERVS. FOR AGING & ADULTS WITH PHYSICAL DISABILITIES, DEL. HEALTH & SOC. SERVS., DELAWARE STATE PLAN ON AGING: OCTOBER 1, 2012 TO SEPTEMBER 30, 2016 (2012), www.dhss.delaware.gov/dsaapd/files/state_plan_on_aging_12_15.pdf (telehealth services will improve the lives of older persons and persons with disabilities “by allowing persons to receive some medical care at home, or in other more convenient settings”).

31 See Press Release, Delaware Health and Social Services & Office of Governor Markell, Delaware Medicaid Program to Reimburse for Telemedicine-Delivered Services Beginning July 1 (June 27, 2012), http://news.delaware.gov/2012/06/27/delaware-medicaid-program/ (“Telemedicine will improve access to information and medical care,” and lead “to better health outcomes for patients and reduced costs for hospitalizations and transportation.” (quoting Gov. Jack Markell)).

32 States that receive federal Medicaid funds are required to ensure transportation for Medicaid beneficiaries to and from medical appointments. See 42 C.F.R. § 431.53. The Delaware Medicaid & Medical Assistance Program pays for nonemergency transportation to covered services, which include any services that would be reimbursed when provided face to face. See Medical Transportation, STATE OF DEL., http://www.dhss.delaware.gov/dhss/dmma/medical.html (last updated June 2, 2016); Del. Div. of Pub. Health, supra note 27, at 61 (“Delaware Medicaid reimburses health care providers for telehealth services if the services are also covered when provided face-to-face.”). By providing access to care that would otherwise be unavailable, telepractice could also reduce medical costs for some types of patients, potentially resulting in long-term savings for Medicaid. See Michael P. Towey, Speech Therapy Telepractice for Vocal Cord Dysfunction (VCD): MaineCare (Medicaid) Cost Savings, 4 INT’L J. TELEREHAB. 33 (Spring 2012).

33 See ASHA, TELEPRACTICE, supra note 2, School Setting Considerations (“The effectiveness of telepractice as a service delivery model in the schools is well documented.”); Tucker, supra note 26, at 61 (1.8% of speech/language pathologists report using telepractice).

34 See ASHA, TELEPRACTICE, supra note 2, Telepractice Technology; Michael P. Towey, Speech Telepractice: Installing a Speech Therapy Upgrade for the 21st Century, 4 INT’L J. TELEREHAB. 73 (2012) (“The implementation of speech therapy telepractice . . . is steadily evolving from the use of expensive dedicated video conferencing systems to significantly less expensive hardware and web-based systems.”).

35 See Tucker, supra note 26, at 63. ASHA’s list of speech/language impairments that can be addressed by telepractice (including non-school settings) includes articulation disorders, autism, dysarthria, fluency disorders, language and cognitive disorders, dysphagia, voice disorders. See ASHA, TELEPRACTICE, supra note 2, section on Practice Areas in Speech-Language Pathology.

36 See, e.g., Tucker, supra note 26, at 63 (discussing the locations of students receiving telepractice and the use of telepractice assistants); ASHA, TELEPRACTICE, supra note 2, Facilitators in Telepractice for Audiology and Speech-Language Services.


ASHA’s list of audiologic services that can be provided by telepractice includes aural rehabilitation, cochlear implant fitting, hearing aid fitting, infant and pediatric hearing screenings, pure tone audiometry, speech in noise testing, and videotoscopy. See ASHA, Telepractice, supra note 2, Practice Areas in Audiology.

See Gladden et al., supra note 38, at 793, 795. See also NATIONAL ACADEMIES, supra note 26, at 125 (“One of the leading users of tele-audiology services is the VA, which serves a large number of patients who live outside urban areas and far from VA medical centers[].”). The VA is also exploring “home hearing tests, the scanning and transmission of ear canal images, and the programming of hearing aids in the home through smartphones or tablet computers.”


See CDC, 2014 Annual Data Early Hearing Detection and Intervention (EHDI) Program, Summary of Loss to Follow-up/Loss to Documentation in 2014, http://www.cdc.gov/ncbddd/hearingloss/2014-data/2014_lfu_summary_web_3.pdf (reporting a total of 81 infants who were not confirmed as receiving a follow-up audiological evaluation (lost to follow-up or documentation) out of the 138 who did not pass the newborn screen). Infants not confirmed as having received an audiological evaluation may include some who have had one, as well as those who were not evaluated. See Suhana Alam et al., Improved Newborn Hearing Screening Follow-up Results in More Infants Identified, 20 J. Pub. Health Manag. Pract. 220, 221 (2014) (explaining that EHDI programs are not usually able to determine whether infants not confirmed as having an audiological evaluation did not receive the testing, or received it but the results were not reported to the EHDI program).

See Dharmar, supra note 38; NCHAM, supra note 40 (program at Utah State University).

See supra note 28 and accompanying text.

See, e.g., Dharmar, supra note 38, at 1.

Id. ("It is estimated that when children with hearing loss are not identified early and do not receive early intervention, the additional costs for education is nearly $420,000 with a life-time societal cost of $1 million per child.”).

In addition to concerns about the proposed regulation’s restriction on telepractice initial evaluations, we have concerns about proposed § 3700-10.2.1.2, which provides that “During the telepractice treatment session, the client shall be located within the borders of the State of Delaware.” In the context of practitioners licensed only in Delaware, this restriction would follow general licensing restrictions. However, if a practitioner is licensed and/or authorized by an additional state (or states), it appears that such a practitioner could appropriately provide telepractice services to a client located outside of Delaware, restricted to the additional state or states in which she or he was licensed. Accordingly, we suggest that the Board modify the wording of § 3700-10.2.1.2 to take such situations into account.

See supra note 16 and accompanying text.

See supra notes 19-21, 23 and accompanying text.
See supra notes 18, 22 and accompanying text.

See supra notes 33-36, 40-43 and accompanying text.

ASHA defines “Telepractice” as “the application of telecommunications technology to the delivery of speech language pathology and audiology professional services at a distance by linking clinician to client/patient or clinician to clinician for assessment, intervention, and/or consultation.” See ASHA, TELEPRACTICE, supra note 2, Overview. See also ASHA, MODEL TELEPRACTICE SERVICE DELIVERY REGULATIONS § .01, http://www.asha.org/uploadedFiles/ModRegTelepractice.pdf (“Telepractice Service’ means the application of telecommunication technology to deliver speech-language pathology and/or audiology services at a distance for assessment, intervention and/or consultation.”).

See, e.g., ASHA, MODEL TELEPRACTICE SERVICE DELIVERY REGULATIONS § .02(A) (“Services delivered via telecommunication technology must be equivalent to the quality of services delivered face-to-face, i.e. in-person.”), § .02(C, D) (“Telepractitioners must have the knowledge and skills to competently deliver services via telecommunication technology by virtue of education, training and experience. . . . The use of technology, e.g. equipment, connectivity, software, hardware and network compatibility, must be appropriate for the service being delivered and be able to address the unique needs of each client.”). See also ASHA, TELEPRACTICE, Roles and Responsibilities (audiologists and SLPs are responsible for “selecting and using assessments and interventions that are appropriate to the technology being used and take into consideration client patient and disorder variables”).

Although we take no position on the telemedicine policies of the Federation of State Medical Boards (“FSMB”) and the American College of Physicians (“ACP”), we note that under both policies, a physician-patient relationship can be established during a telemedicine encounter. See FED’N OF STATE MED. BDS., MODEL POLICY FOR THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE 5 (2014), https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf (the physician-patient relationship to “be established using telemedicine technologies so long as the standard of care is met.”); Daniel & Sulmasy, supra note 25, at 787-88, App. (ACP takes the position that “a telemedicine encounter itself can establish a patient-physician relationship,” so long as the physician meets “the standard of care required for an in-person visit”). Occupational therapy organizations and practitioners have taken similar positions, concluding that telehealth may be used throughout the course of care – including for evaluation, intervention, and monitoring – when practitioners are held to existing professional standards of care. See Comment from FTC Staff to the Delaware Board of Occupational Therapy Practice, supra note 14, at note 38.

See Comment from FTC Staff to Steve Thompson, supra note 13.

See, e.g., id. (describing the 2014 adoption by the Alaska State Legislature of a law allowing in-state Alaska licensed physicians to provide telehealth services without an in-person physical examination, and advocating the adoption of provisions in Senate Bill 74 that would allow out-of-state physicians to provide telehealth services in the same manner ); Bill History/Action for 29th Legislature: SB 74, ALASKA STATE LEGISLATURE, http://www.akleg.gov/basis/get_bill.asp?session=29&bill=sb+74 (last updated July 15, 2016) (noting adoption of Alaska SB 74, which eliminated an in-person physical examination requirement for Alaska licensed physicians located out of state); FTC Staff Comment to the Delaware Board of Occupational Therapy Practice, supra note 14, at note 22 (in-person evaluation requirement in the 2015 version of a proposed regulation was eliminated); Ala. State Bd. of Med. Examiners, Certification of Emergency Rules: Emergency Repeal of Chapter 540-X-15 (Aug. 25, 2015), http://www.albme.org/Documents/Rules/Temp/540-X-15ER%20repealed.pdf (repeal of telemedicine rules requiring an in-person physical examination or a telehealth evaluation with the patient at an established medical site in light of their potential antitrust implications).

See 201 KY. ADMIN. REGS. 17:110 § 2 (2016) (“Telehealth and telepractice . . . (2) Client Requirements. A practitioner-patient relationship shall not commence via telehealth. An initial, in-person meeting for the practitioner and patient who prospectively utilize telehealth shall occur. A licensed health care practitioner may represent the licensee at the initial, in-person meeting. . . .”).

See MONT. ADMIN. R. 24.222.916 § 1 (2016) (“Establishing the practitioner-patient relationship (1) A practitioner-patient relationship may commence via telepractice following a practitioner’s in-person evaluation of the prospective patient to assess the patient’s: (a) need for services, and (b) candidacy for telepractice, including...
behavioral, physical, and cognitive abilities to participate in telepractice services. Telepractice services may be provided by the patient’s evaluator or another qualified speech-language pathologist or audiologist by the board.

59 See 16 TEX. ADMIN. CODE § 111.212(h) (2016) (“The initial contact between a licensed speech-language pathologist and client shall be at the same physical location to assess the client’s candidacy for telehealth, including behavioral, physical, and cognitive abilities to participate in services provided via telecommunications prior to the client receiving telehealth services.”). Texas has a Board for speech-language pathologists and audiologists, and another Board for hearing aid fitters and dispensers. Each Board adopted “Joint Rules for Fitting and Dispensing of Hearing Instruments for Telepractice,” requiring that “[a] client’s initial professional contact with a provider shall be in person at the same physical location.” 16 TEX. ADMIN. CODE § 111.232(j) (2016) (audiologists); 16 TEX. ADMIN. CODE § 112.150 (l) (2016) (hearing aid fitters and dispensers). For audiologists, there are apparently no initial contact requirements for telepractice services other than hearing aid fitting and dispensing.


61 See supra notes 57 and 58.

62 See, e.g., Eikelboom & Swanepoel, supra note 38, at 131 (“The local assistant is key in most aspects of teleaudiology.”); Gladden et al., supra note 38, at 795; supra note 36 and accompanying text.

63 See supra notes 19-21 and accompanying text.

64 We suggest that “evaluations” be included in Proposed Regulation, supra note 2, § 3700-10.2.4.5 as well as § 3700-10.1. In addition, we note that a requirement for the use of a facilitator for telepractice initial evaluations would be less restrictive and more narrowly tailored to the apparent goals of the restriction than the proposed requirement that initial evaluations be performed in-person.

65 See FTC STAFF, POLICY PERSPECTIVES, supra note 9. See also THE WHITE HOUSE, OCCUPATIONAL LICENSING: A FRAMEWORK FOR POLICYMAKERS 30 (2015), https://www.whitehouse.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf (excessively stringent restrictions on the services that a practitioner can provide may limit the supply of labor, restrict competition, restrict access to services, and increase the price of services).