

State AGs See Eye to Eye on Recent Telehealth Settlement

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Enforcement in the telehealth space continues – this time with a bipartisan settlement between 11 State AGs and Visibly (f.k.a. Opternative), a vision telehealth company. Unlike recent telehealth settlements where enforcers focused on consumer privacy, the State AGs focused on whether the company's claims about its products and services, including its online vision tests, were properly substantiated.

State AGs began a multistate investigation after the Federal Drug Administration (FDA) warned the company about marketing its online vision tests without appropriate approval. The State AGs claim that their investigation revealed that Visibly deceived consumers, including by: (1) marketing and selling a device without the required clearance or approval from the FDA; (2) marketing unsubstantiated safety and effectiveness claims about its online vision test; and (3) falsely claiming to offer a 100% satisfaction or money back guarantee. Note that while the State AGs' investigation was pending, Visibly began the process of seeking FDA approval, but they did not have this prior to the investigation.

To resolve these allegations, Visibly agreed to pay \$500,000 combined to the participating states. Visibly must among other requirements do the following:

- Comply with consumer protection statutes, the Federal Food, Drug, & Cosmetics Act (FDCA), and FDA authority;
- Align all representations that its products can diagnose, cure, mitigate, treat, or prevent any disease or condition with the FDCA and FDA authority;
- Possess competent and reliable scientific evidence substantiating any claims that its products
 are comparable to the safety and effectiveness of products offered by doctors' offices or other
 FDA approved devices;
- Clearly and conspicuously disclose any terms or conditions for eligibility for a satisfaction guarantee, money back guarantee or other offer of refund to consumers;
- Ensure all optometrists and ophthalmologists who contract with the company are in good standing with applicable states;
- Clearly disclose that providers in any "find a doctor" feature do not endorse its products (unless specifically obtained), and agree to remove doctors upon their request; and
- Provide a disclosure that Visibly's online vision test is not a substitute for an in-person comprehensive eye examination and urge consumers to seek such exams to determine overall eye health.

Takeaway: Claims on telehealth platforms attract enforcers' attention due to the sensitive nature of the services and the relative novelty of the technology involved. From the FTC, to the FDA, to State AGs, governmental entities are interested not only in protecting the privacy of telehealth consumers (as shown in the BetterHelp settlement), but also the substantiation of advertising claims. Companies should:

- Substantiate telehealth-related claims.
- Clearly describe any relationships with providers, and ensure providers comply with state licensing laws.
- Make appropriate disclosures regarding limitations of products and services where a failure to disclose may materially affect a consumer's decision.