

Prescription Digital Therapeutics Don't Need a Physician

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm in the Health Care & Life Sciences practice at Epstein Becker Green authored an article in *MobiHealthNews*, titled "Prescription Digital Therapeutics Don't Need a Physician."

Following is an excerpt:

Prescription digital therapeutic products can improve health for the underserved, especially in the area of mental health. Apart from addressing the severe shortage of mental health professionals by increasing access to care, recent science would suggest the digital therapeutic modality can be particularly effective at treating widespread conditions, including those made worse by the pandemic.

But there's a regulatory problem, and it's not FDA's fault: The problem is with the industry.

The root of the problem is, I think, a misunderstanding. I suspect there are many in the industry who believe that a prescription digital therapeutic product can only be made available to patients through physicians, dentists and veterinarians who have prescribing authority under state law.

But that's wrong. More healthcare professionals than just those three have the ability to order the use of prescription medical devices.

Background on federal law

The misunderstanding probably arose because people tend to be more familiar with the prescribing process for pharmaceuticals that includes authorized prescribers under state law and authorized dispensers such as pharmacies. But the law for

People



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prescription medical devices is quite different.

I don't normally like to quote a law in a post, but I think it's important to be very clear here what the law actually says. The FDA's regulation creating the prescription device category (21 CFR Sec. 801.109(a)(2)) provides in part that a prescription device must be "sold only to or on the prescription *or other order of such practitioner* for use in the course of his professional practice." The required labeling must include "The symbol statement 'Rx only' or ' *only*' or *the statement 'Caution: Federal law restricts this device to sale by or on the order of a __,'* the blank to be filled with the word 'physician,' 'dentist,' 'veterinarian,' or *with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.*" (Emphasis added.)

The flexibility is pretty obvious. The FDA regulation allows for an order rather than a prescription. Further, instead of "prescription-only" labeling, the regulation allows the use of labeling restrictions that identifies a broader category of healthcare professionals that can order the device beyond only those who have prescribing authority under state law.