

June 5, 2019

Dr. Paul Levy  
Chair  
Massachusetts Board of Registration in Dentistry  
239 Causeway Street, Suite 500  
Boston, MA 02114

Dear Dr. Levy:

I write on behalf of the Massachusetts Dental Society (MDS), which represents 80% of dentists in Massachusetts, to express the growing concerns of MDS member dentists regarding the risks to patient safety posed by certain retail and virtual orthodontic providers—specifically, providers of do-it-yourself (DIY) orthodontic clear aligner therapy. Many licensed dentists in Massachusetts are seeing firsthand the damage caused to patients by these DIY orthodontic products, including the diminished ability to bite and chew properly, pain, and loose teeth.

Last year, the MDS shared with the Board of Registration in Dentistry our concerns that one such company's ecommerce model of diagnosing, prescribing, and supplying devices for orthodontic treatments constituted the unauthorized practice of dentistry, presenting significant risks to the health and wellbeing of citizens of Massachusetts. Since then, a federal court has dismissed a claim brought by this same company against the Georgia Board of Dentistry seeking a declaratory judgment that its practice of taking digital images of patients' teeth in retail locations without an onsite dentist does not constitute the "practice of dentistry or dental hygiene." The court called the argument "incorrect," stating that the company's "acts of taking digital scans of a patient's mouth for the purpose of having a dentist or orthodontist approve a treatment plan for correcting a malposition of the patient's teeth falls squarely within the definition of the practice of dentistry" in that state.<sup>1</sup>

On April 25, a large retail pharmacy corporation based in New England announced a new partnership with this same provider of direct-to-consumer orthodontic devices to open "hundreds" of shops in its stores in 2019, with the "potential to expand to over a thousand locations over the next several years." The expansion of retail locations for this teledentistry platform—which promises to straighten teeth "on average, three times faster," without any in-person visits with a licensed orthodontist or the prescriber of the clear aligner products—has raised serious concerns among our membership that it will promote a standard of care that, as these services are described in the announcement, appears to lack appropriate safeguards to ensure patient safety.

The standard of care for determining the suitability of a person to receive orthodontic treatment requires the performance of a clinical examination by a licensed dentist and the review of X-rays. Dentists take X-rays in these instances to identify cavities that cannot be seen by simply reviewing a 3-D scan, as well as to determine if there is sufficient supporting bone of adequate density. Without an in-person evaluation or X-rays that could identify undiagnosed dental disease or underlying issues that would make a patient an unsuitable candidate for clear aligner orthodontic therapy, a patient may be exposed to irreversible harm, including potential bone loss and receding gums, changed bites, and other issues. Absent direct oversight and monitoring of a licensed practitioner, increased access to DIY "dentistry" will place members of the public on a path toward unnecessary risk and possible adverse consequences based on marketing promises of easy fixes to complex oral health issues.

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<sup>1</sup> <https://www1.aaoinfo.org/wp-content/uploads/2019/05/SDC-v-GA-Board-of-Dentistry-Doc-51-Order-on-Defendants-Motion-to-Dismiss.pdf>

The MDS and its member dentists are not alone in expressing concerns over DIY services. There have been many reports of unsatisfactory outcomes for patients utilizing these DIY services. For example, the April 29 edition of the *New York Post* reported that DIY orthodontics often “require additional, costly procedures” due to unintended consequences. As one provider stated, DIY dental services “can cause problems long term with the health and function and life span of a tooth.” And, as you may know, the American Dental Association recently petitioned the U.S. Food and Drug Administration to issue consumer warnings regarding the risks presented by DIY orthodontics, citing concerns about patient safety; transparency in diagnosis and treatment planning; and patient recourse when results are not positive.

With increased access and marketing of these teledentistry platforms at retail locations throughout New England, licensed dentists in Massachusetts expect to encounter more patients whose oral health has been jeopardized by DIY orthodontic devices and the lack of adequate supervision by licensed practitioners.

Accordingly, MDS believes that it is appropriate and urgent for BORID to consider whether the services offered by these retail and virtual orthodontic providers constitutes the practice of dentistry in Massachusetts, and, if so, how these companies should be regulated and monitored under Massachusetts law. Additionally, when a patient presents to a licensed dentist seeking care for oral health problems caused by DIY orthodontic devices, what is the responsibility of the dentist in reporting such negative outcomes to BORID? And what recourse do patients have in reporting and resolving instances of sub-standard care provided by representatives of a teledentistry platform and its “digital network” of state licensed dentists and orthodontists whom the patient has never seen?

On behalf of 5,000 licensed dentists in Massachusetts and the millions of patients they serve, the MDS appreciates your guidance on how to address the risks posed by DIY orthodontic dental services, how to best advise patients when adverse results occur, and what recourse patients have in Massachusetts when these results occur.

Sincerely,

Dr. Howard M. Zolot  
President  
Massachusetts Dental Society