

February 25, 2021

The Honorable Bill Devlin
Chairman, Assembly Administrative Rules Committee
North Dakota State Capitol
600 E Boulevard Ave
Bismarck, ND 58505



Re: *Public Comment and Request to Void on Board of Dental Examiners Proposed Rules*

Dear Chairman Devlin:

This letter serves as formal public comment from SmileDirectClub (“SDC”) on the North Dakota State Board of Dental Examiners (“Board”) proposed rule changes to *NDAC 20-01-02-01 through 20-05-01-01 non-seq.* SDC is an oral care company and creator of the first medtech platform for teeth straightening, now also offered directly via dentist and orthodontists’ offices. SDC contracts with North Dakota-licensed dentists and orthodontists who use the SDC platform to treat North Dakota patients. Hence, SDC’s interest in this rule.

While the SDC medtech platform is largely virtual, SDC also operates through retail locations across the country. This platform, and our business model, could be profoundly affected by the proposed rule. We believe that this proposed rule violates NDCC § 28-32-18(1) due to its lack of statutory authority, its arbitrary nature, and the Board’s failure to comply with express legislative intent. Due to these statutory violations, these rules should be voided.

SDC strongly opposes the Board’s definition of “final impression for digital capture” in *NDAC 20-01-02-01(18)* and believes that there is no statutory authority for the Board to promulgate these specific regulations. This language creates – without any statutory basis – a new dental fiction “final impression for digital capture.” The plain language meaning of a “dental impression” is a negative imprint of hard and soft tissues in the mouth from which a positive reproduction (cast or model) can be formed. The new proposed definition turns this traditional, plain language definition on its head in a nonsensical and capricious manner. Simply put, the Board seeks to regulate the taking of photographs of the mouth as a negative “impression.” There is no language in the ND Dental Practice Act which would give the Board reason to believe that this regulation is statutorily appropriate. In fact, the term “impression” cannot be found in the Dental Practice Act and only appears in the rules for Dental Assistants and Hygienists – rules which clearly intend to regulate the plain-language meaning of an impression.

While the Board has authority to promulgate regulations to protect the health, safety, and welfare of North Dakota patients, it does not have the authority to arbitrarily promulgate anti-competitive and clinically-unsound regulations which pose zero-risk to North Dakotans. For clinical context, traditional impressions consist of a putty that the patient must have placed and held in their mouth which could create a potential choking hazard and requires some clinical training to safely apply to a patient; meanwhile, digital scans/photographs pose no risk to the patient and there is no clinical knowledge nor training required to take a digital photograph. The digital scanning technologies used today are light emitting cameras usually on the tip of a plastic “wand” that are safe and simple to use. Moreover, the taking of a digital photograph is neither a dental therapeutic nor a procedure – it is more similar to a portraiture than a dental procedure. Accordingly, any requirement for licensure to accomplish this simple task is regulatory overreach absent a public safety protection imperative – of which there is

none. Plainly said, the proposed rules would require an individual doing these activities to hold a license, which is arbitrary and beyond the scope of authority provided by the state's dental practice act.

Furthermore, the proposed rules allow an unlicensed dental assistant to take an intraoral photograph – a task that poses zero risk to a patient and is more akin to the taking of a portraiture than a dental procedure but now would require the “direct supervision” of a dentist. What was once, correctly, an unregulated activity now requires that a dentist must actually be physically present at the location the photos are taken. On its face, this requirement creates an anti-competitive barrier for dentists using telehealth technology, is without any clinical justification as there is no clinical basis for having a dentist on-site for the taking of simple digital photographs, lacks any public safety imperative to regulate as it poses no risk whatsoever to the patient nor operator, and would only decrease access to oral healthcare to the detriment of North Dakotans. Neighboring South Dakota allows an unregistered dental assistant to take these photos under general supervision.

Lastly, while we acknowledge that pending legislation isn't binding on the Board, the Administrative Rules Committee should be aware that House Bill 1151, sponsored by you and dealing specifically with teledentistry standards, has unanimously passed the North Dakota House of Representatives. The bill simply seeks to codify modern, science-based teledentistry standards of care that mirror the standards adopted by the legislature for modern, science-based telemedicine—something entirely at odds with the board's proposed rules. We respectfully request the committee consider this pending legislative action as informative and persuasive in its own deliberation regarding the overreach of the proposed rules.

Thank you for this opportunity to comment on the proposed rule changes. It is our hope that the Administrative Rules Committee will void these rules as they lack statutory authority, are clinically unsupported and arbitrary, and do not reflect the legislative intent of the current dental practice act nor pending legislation. These same issues were appropriately raised with the Board during the rulemaking public comment period and summarily ignored. If you have any questions or would like to talk further on this issue or on teledentistry more broadly, please do not hesitate to contact me at 615-647-8656 or Peter.Horkan@smiledirectclub.com.

Respectfully,

A handwritten signature in black ink, appearing to read 'Peter Horkan', with a long horizontal flourish extending to the right.

Peter Horkan
Vice President, Government Affairs
SmileDirectClub