West Virginia
Dental Hygienists' Association

July 14, 2021

Dr. Vince Veltri, President
West Virginia Board of Dentistry
1319 Robert C Byrd Dr
Crab Orchard, WV 25827
(304) 252-8266

Dear Dr. Veltri:

The West Virginia Dental Hygienists' Association (WVDHA) represents the professional interests of dental hygienists across the state and works to ensure access to quality oral health care and promote the highest standards of dental hygiene education, licensure, practice and research.

With the rapid growth of technology, teledentistry is another avenue to use in treating oral diseases and promoting public oral health. WVDHA encourages the West Virginia Board of Dentistry to support the use of teledentistry by licensed dental hygienists, with either a general or public health supervision permit, consistent with existing state scope of practice and supervision requirements and should not preclude teledentistry participation for the dental hygienist under direct supervision in the first two years of practice.

WVDHA recommends the following changes be made to new series of rules 5CSR16, Teledentistry. WVDHA recommends striking 'dentist-patient' and replacing it with practitioner-patient or provider-patient. These changes are congruent with both the Nursing Board and Board of Medicine's emergency rules as shown here.

Sincerely,

Gina Sharps, RDH, MPH, NCTTS, WVDHA Legislative Liaison

cc:
Heather Fogus, RDH, President

4.2. No practitioner shall practice teledentistry unless a bona fide ~~dentist~~ practitioner-patient relationship is established. A bona fide ~~dentist~~ practitioner-patient relationship shall exist if the ~~dentist~~ practitioner has (i) obtained or caused to be obtained a health and dental history of the patient: (ii) performed or caused to be performed an appropriate examination of the patient, either physically, through use of instrumentation and diagnostic equipment by which digital scans, photographs, images, and dental records are able to be transmitted electronically, or through use of face-to-face interactive two-way real-time communications services or store-and-forward technologies; (iii) provided information to the patient about the services to be performed: and (iv) initiated additional diagnostic tests or referrals as needed. In cases in which a dentist is providing teledentistry, the examination required by clause (ii) shall not be required if the patient has been examined in person by a dentist licensed by the board within the ~~six~~ twelve months prior to the initiation of teledentistry and the patient's dental records of such examination have been reviewed by the ~~dentist~~ practitioner prior to providing teledentistry.

West Virginia Board of Examiners for Registered Professional Nurses' Emergency Telehealth Rule

http://apps.sos.wv.gov/adlaw/csr/readfile.aspx?DocId=54407&Format=PDF

4.2. If an existing practitioner-patient relationship is not present prior to the utilization of telehealth technologies, or if services are rendered solely through telehealth technologies, a practitioner-patient relationship may only be established through the use of telehealth technologies which incorporate interactive audio using store and forward technology, real-time videoconferencing or similar secure video services during the initial patient evaluation. The standard of care with respect to the established patient, the patient shall visit an in-person health care practitioner within 12 months of an initial telehealth service, or the telehealth service shall no longer be available to the patient until an in-person visit is obtained. This requirement may be suspended, in the discretion of the health care practitioner, on a case-by-case basis, and it does not pertain to the following services: acute inpatient care, post-operative follow-up checks, behavioral medicine, addiction medicine, or palliative care.

West Virginia Board of Medicine's Emergency Telehealth Rule

http://apps.sos.wv.gov/adlaw/csr/readfile.aspx?DocId=54351&Format=PDF

§ 11-15-6. Establishment of the Provider-Patient Relationship.

6.1. Among other ways, a provider-patient relationship is formed when a provider serves a patient's medical needs, examines, diagnoses or treats a patient, or agrees to examine, diagnose or treat a patient.

6.2. A provider-patient relationship may be established through:

6.2.1. An in-person patient encounter;

6.2.2 Store and forward telemedicine or other similar technologies for the practice of pathology and radiology;

6.2.3. Telemedicine technologies which incorporate interactive audio using store and forward technology, real-time videoconferencing, or similar secure video services during the initial provider-patient encounter; or

6.2.4. Audio-only calls or conversations that occur in real time.

American
TeleDentistry
Association

Marc Bernard Ackerman
DMD, MBA
Executive Director

June 21, 2021
West Virginia Board of Dentistry
PO Box 1447
Crab Orchard, WV 25827

RE: Proposed Teledentistry Rules dated June 17, 2021

Dear Doctors:

My name is Dr. Marc Ackerman and I am the Executive Director of the American Teledentistry Association (ATDA), I am also a licensed and practicing dentist, work and lecture at an internationally recognized teaching hospital, and have a deep passion for helping others and making sure that everyone receives the oral healthcare that they deserve. That is why I founded the American Teledentistry Association whose mission to increase access to quality, affordable dental care and that is why I write to you today on the critical regulatory matter pending before the Board.

While much of the proposed rule is consistent with the ATDA's policy principles (such as the use of synchronous and asynchronous technologies, consent requirements, privacy requirements, and other patient protections), the proposed language unfortunately includes an anti-competitive and arbitrary provision which the ATDA has seen unsuccessfully pushed by active market participants in other states. Specifically, this provision in Section 5-16-4.10.c would prohibit a dentist from using teledentistry to "diagnose or initiate correction of malpositions of the human teeth or jaws, or initiate the use of orthodontic appliance or aligners, prior to reviewing the patient's most recent diagnostic digital or conventional radiographs or other equivalent bone imaging suitable for orthodontia." This provision is ill-advised, inconsistent with both the intent and plain language of the recently enacted statute through House Bill 2024, and dangerous to patients who may seek dental care through teledentistry.

This language creates a troubling mandate that all patients be unnecessarily exposed to cancer-causing radiographs[1] even if their treating dentist deems that radiographs are unnecessary and would not be helpful for his or her diagnosis and treatment planning. Furthermore, this language is in direct conflict with the current standard of care for orthodontics. There is no clinical evidence to support the assertion that patients would be safer or better treated if their treating dentist's expertise, education, and discretion was supplanted for a universal mandate for radiographic review of the patient; however, there is a myriad of peer-reviewed clinical studies and guidelines which prove that radiographs are not necessary for every patient and that **teledentistry is just as effective at treating mild-to-moderate malocclusions as traditional dentistry, regardless of review of radiographs.** Indeed, the current standard of care as posited

[1] Do x-rays and gamma rays cause cancer? American Cancer Society. cancer.org/cancer/cancer-causes/radiation-exposure/x-rays-gamma-rays/do-xrays-and-gammarays-cause-cancer.html

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in the dental radiography guidelines produced by the FDA and the American Dental Association states that "radiographs should be taken **only when there is an expectation that the diagnostic yield will affect patient care.**"[2] Similarly, studies have found that "it is **unethical to take radiographs for medico-legal, administrative reasons** or 'just in case' if there is no clinical need"[3] and that "clinicians must perform radiographic imaging on patients **only** when they expect that the information provided by the radiographic examination **will provide additional diagnostic information and meaningfully contribute to the treatment plan.**"[4] Yet even with these well-established guidelines, "routine dental X-rays are among the most common sources of ionizing radiation exposure for healthy individuals globally" and particularly "in the United States, an increased use of dental radiography is evident."[5] Even with an understanding of the underlying dangers posed by ionizing radiation, in a 2021 survey study of dentists and orthodontists, "the authors were surprised at the number of orthodontists who reported "*Routinely*" making radiographic examinations..."[6] (with "financial incentives [having] a substantial impact on dental x-raying" decisions[7]) given that a studies have found that dental X-rays increased the risk of developing a meningioma,[8] thyroid cancer,[9] laryngeal cancer,[10] and leukemia.[11]

Simply put, by requiring that radiographs be taken and/or reviewed before each diagnosis, West Virginia would be in direct conflict with the standard of care and likely putting patients at serious risk by exacerbating a pre-existing issue in the dental industry of overprescribing oral radiographs. I have attached a document that highlights several of these studies and international guidelines for your review.

In fact, this language appears to be in direct conflict with West Virginia's own regulations and radiographic standard of care. WV CSR §18-5-5.1.5 states that it is considered unprofessional conduct to depart "from or failure to conform to applicable federal, state or local governmental rules and regulations regarding medical imaging or radiation therapy technology practice; or, if no rule or regulation exists, to the minimal standards of acceptable and prevailing medical imaging or radiation therapy technology practice" as well as "any medical imaging or radiation therapy technology practice that may create unnecessary danger to a patient's life, health or safety." With the context of the FDA/ADA guidelines for dental radiographs coupled with the peer-reviewed clinical studies and international standards stating that radiographs should <u>never</u> be taken unless deemed necessary for the purpose of diagnosis or treatment planning, it is clear that the proposed rules conflict with the current standards found in the Administrative Code of West Virginia.

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[2] FDA/ADA,DENTAL RADIOGRAPHIC EXAMINATIONS:RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE(2012)
[3] Isaacson KG, (2015), "Guidelines for the Use of Radiographs in Clinical Orthodontics," *British Orthodontic Society.*
[4] A. (2019) Dental Radiography. In: Ferneini E., Goupil M. (eds) Evidence-Based Oral Surgery. Springer, Cham
[5] Vinita Chauhan & Ruth C. Wilkins (2019) A comprehensive review of the literature on the biological effects from dental X-ray exposures, International Journal of Radiation Biology, 95:2, 107-119
[6] Douglas K. Benn, Peter S. Vig, Estimation of X-ray Radiation Related Cancers in U.S. Dental Offices: Is It Worth the Risk?, *Oral Surg Oral Med Oral Pathol Oral Radiol* (2021)
[7] Martin Chalkley, First do no harm – The impact of financial incentives on dental x-rays, Journal of Health Economics, Volume 58, March 2018.
[8] Claus EB, Calvocoressi L, Bondy ML, Schildkraut JM, Wiemels JL, Wrensch M. Dental x-rays and risk of meningioma. Cancer 2012, 118:4530-7.
[9] Memon A, Godward S, Williams D, Siddique I, Al-Saleh K. Dental x-rays and the risk of thyroid cancer: a case-control study. *Acta Oncol.* 2010;49(4):447-453.
[10] Su-Yeon Hwang, Health effects from exposure to dental diagnostic X-ray, Environ Health Toxicol. 2018 Dec; 33(4).
[11] Id.

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Furthermore, while this regulation clearly states in Section 5-16-4.4 that "teledentistry encounters shall be held to the same standard of care as a traditional in-person patient encounter," the language in Section 5-16-4.10.c directly conflicts with this by creating a new and different standard of care unique to dentists treating patients using teledentistry technology for one particular procedure. The current standard of care does not require x-rays in all cases for diagnosis and treatment of mild or moderate malocclusions in a traditional in-person encounter, yet the proposed language attempts to set a separate standard that would supersede evidenced-based clinical guidelines and mandates that patients be exposed to unnecessary radiation. To my knowledge, the Board does not have any rules nor are there any governing statutes that create a separate standard of care within the practice of dentistry for any single procedure; yet, that is exactly what this rule would do for the treatment of malocclusions via teledentistry. Public policy that codifies any medical standard of care that changes over time, varies even within different sections of a state, and is patient specific is dangerous to public health as legislative and regulatory deliberations tends to move at a much slower pace than the quickly advancing medicine.

Additionally, it appears that the proposed rules have only included the "established patient" definition from House Bill 2024 while leaving out the "virtual telehealth" patient definition. While the term "established patient" is not actually used in the proposed rule, the ATDA is concerned that this may create a false impression of the legislation's intent regarding the use of telehealth technologies in patient care and perhaps conclude that all patients have an in-person examination before being able to use teledentistry. This certainly would go against the established legislative intent of HB2024. The ATDA suggests either removing the "established patient" definition from the rules entirely or, alternatively, including the "virtual telehealth" patient definition as well.

From the perspective of the American Teledentistry Association, the proposed language, particularly the language mandating radiographic examination of every patient, lacks clinical justification and is anti-competitive so as to disadvantage innovative providers of dental care through teledentistry. Every dentist, regardless of delivery method used, should be held to the same standard of care and subject to the same requirements and discipline of the West Virginia Board of Dentistry. To that end, we urge you and your Board to carefully review the proposed language and ensure that the proponents provide evidenced-based, peer reviewed clinical data to support positions that such a standard of care exists as set out in the Section 5-16-4.10.c of the proposed rules. The serious potential cost to patients is too great to do otherwise.

Thank you for your consideration of my comments. I am available to discuss any of this with you or the Board at your convenience.

Respectfully,

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SmileDirectClub is an oral care company and creator of the first medtech platform for teeth straightening. Through cutting-edge telehealth technology and a vertically integrated model, SmileDirectClub offers consumers the ability to get clinically safe and effective treatment by state-licensed dentists and orthodontists in all fifty states, including in West Virginia. SmileDirectClub has a keen interest in the West Virginia Board of Dentistry proposed Teledentistry Regulations and serious concerns that some of the provisions would adversely affect the ability of SmileDirectClub contractually-affiliated, West Virginia-licensed, dentists and orthodontists to effectively diagnose and treat West Virginia patients using remote telehealth technology.

The West Virginia legislature has consistently supported the efficacy of the effective use of remote telehealth technology to provide high quality, accessible and affordable health care to West Virginians, including remote dental care. The legislature during 2021 legislative session passed House Bill 2024 that was recently enacted and effective April 9, 2021. That legislation further expanded telehealth in West Virginia, drawing in part from the valuable telehealth lessons learned through the state's response to the recent COVID-19 pandemic when traditional health care offices and facilities were closed or patient access to them was very limited. The new law affirmed that remote patient care can be rendered by state licensed dentists and orthodontists through "the use of synchronous or asynchronous technology or audio only telephone calls" as well as "remote patient monitoring." Further, it is clear that the use of telehealth technology does not alter a provider's scope of practice or create a standard of care that is different from that governing traditional in-person health care. Proponents of the legislation also created a statutory regime to ensure that West Virginia patients with chronic conditions could get access to remote health care but not have to rely on remote technology as the only source of that health care. Accordingly, the new law defines a patient for purposes of telehealth either as an "established patient" who has first received health care services from a health care provider in an in-person setting or a "virtual telehealth" patient who has first received acute care through telehealth technologies (or follow-up) that does not require chronic management or scheduled medications. An "established patient" is then required to "check in" at least every 12 months with the health care provider through an in-person visit (unless superseded by professional discretion on a case by case basis). No such requirement is placed on a "virtual telehealth" patient.

Further, the new law creates an "interstate telehealth service" as the provision of telehealth services to a patient in West Virginia by a licensed health care provider located in any state and "registered" in West Virginia for the limited purpose of providing interstate telehealth services within the registrant's scope of practice. SmileDirectClub fully supports these provisions and others contained in the legislation.

The new statute then directs relevant health care boards to propose "an emergency rule for legislative approval...to regulate telehealth practice by a telehealth provider" and then sets out eight provisions that shall be included in such emergency rule. SmleDirectClub is in general support of the approach

taken by the West Virginia Board of Dentistry with one major exception where the Board has departed from the clear intent of the West Virginia Legislature to ensure the same standard of care applies to patient encounters in telehealth (teledentistry) and in-person encounters.

SmileDirectClub first takes issue with the language in §5-16-4.3(iv) "any other requirements set forth by the board." This language is more appropriate for statutory direction rather than administrative rule. It is the role of administrative rules to set out the clear requirements not such vague generalities for regulated entities to follow. Accordingly, SmileDirectClub recommends that §5-16-4.3(iv) be deleted from the proposed rule.

SmileDirectClub also believes that the proposed language in §5-16-4.10.c as "[d]iagnose or initiate correction of malposition of the human teeth or jaws, or initiate the use of orthodontic appliances or aligners, prior to reviewing the patient's most recent diagnostic digital or conventional radiographs or other equivalent bone imaging suitable for orthodontia. New radiographs or other equivalent bone imaging shall be ordered if deemed appropriate by the treating dentist" attempts to establish a separate standard of care for diagnosis and treatment of malposition of human teeth through teledentistry that does not exist for an in-person encounter. No such standard of care is set out for in-person care in the West Virginia Dental Practice Act. This language is both arbitrary and capricious as it lacks any solid clinical justification or support from peer-reviewed clinical studies and, as such, only serves as an artificial anti-competitive barrier to affordable remote health care. This proposed provision is also nonsensical and dangerous in that it mandates "reviewing the patient's most recent digital or conventional radiographs" but does not give any indication as to whether or not such review would be useful in the diagnosis or treatment. There are five types of dental radiographs, bitewing, periapical, full mouth, panoramic, and occlusal. The proposed rule does not indicate which x-ray is appropriate to meet the standard of care. Apparently the standard of care would be met if the treating dentist reviewed the most recent radiograph that happened to be a periapical even though it was taken of a tooth not among those to be corrected or totally unnecessary for the diagnosis? Alternatively, there are numerous peer-reviewed clinical studies that argue against such radiograph mandates in dentistry. The American Dental Association and the FDA in 2012 released joint guidelines for dental radiography which clearly state that "radiographs should be taken only when there is an expectation that the diagnostic yield will affect patient care" with the ADA further clarifying in 2013 that radiographs must "be justified on individual need, that the perceived or actual benefits to the patient must outweigh the radiation risks, and that exposure of patients to ionizing radiation must never be considered routine." Indeed, in 2020, upon the review of several studies that examined the efficacy of radiography, "researchers [with the Faculty of General Dental Practice] reported the limited effect radiography has on changing orthodontic diagnosis or treatment plans... questions whether the present use of radiography may be excessive" while other research in 2020 has shown that Diagnostic value of orthodontic radiographs and indications for their use are still debatable... the minimum set of records required for orthodontic diagnosis and treatment planning has never been solidly established... [and radiographs] must always be justified." Simply put, "each radiograph must be clinically justified" and "it is unethical to take radiographs for medico-legal, administrative reasons or 'just in case' if there is no clinical need" as noted by the British Orthodontist Society.

§5-16-4.4 appropriately affirms that "[t]eledentistry encounters shall be held to the same standard of care as a traditional in-person encounter." The proposed language in §5-16-4.10.c is clearly contradictory to parity for the standard of care between teledentistry and in-person encounters as it attempts to carve out a separate standard of care for a particular specialty in dentistry. Either the standard of care is the same for teledentistry encounters as in-person encounters or it is not. This is yet

another indication that the arbitrary and capricious provision in §5-16-4.10.c serves no legitimate patient safety purpose; rather it serves to protect the economic interests of licensees regulated by the Board who face market challenges presented by new efficacious ways to treat patients through telehealth technologies.

For all of the reasons discussed, SmileDirectClub strongly urges the Board to delete both §5-16-4.3(iv) and §5-16-4.10.c from the proposed teledentistry rules.

Professionally,

Peter Horkan
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