Charles M. Ludwig, DDS
7645 Patterson Drive
Harrisburg, PA 17112

2720

September 24, 2008

Christopher P. Grovich, Counsel
Pennsylvania State Board of Dentistry
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: 16A-4617 - State Board of Dentistry's Proposed Regulation: Dental Hygiene Scope of Practice; Local Anesthesia **(IRRC No. 2720)**

Dear Mr. Grovich:

From May 1994 to December 1999, I served the Commonwealth as the Department of Health's Public Health Dentist, the first dentist to be so appointed pursuant to Act 87-1996 of the General Assembly. In this capacity I was a member of the State Board, serving as the designee for the Secretary of Health.

I would like to offer the following commentary and recommendations on the above referenced proposed regulation.

In the late eighties and early nineties, the Board performed a general revision of its regulations. IRRC issued its Report on these regulations on May 12, 1993, **EXHIBIT A**. The May 12, 1993 IRRC Report has relevance to the Board's 2008 proposed regulations, IRRC No.2720, and where applicable I will reference it in my comments.

The dental Board's major concerns in IRRC No.2720 are local anesthesia administration for dental hygienists and the newly created "public health dental hygiene practitioner." Other issues are lowering the standard of dental hygiene education in the Commonwealth, and issues that are not in the public interest.

Local Anesthesia.

My assessment: **The Pennsylvania Dental Law does not contain a statutory provision authorizing dentists to allow dental hygienists to administer local anesthesia.**

Referencing IRRC's May 12, 1993 Report (beginning on page 11 with the fourth paragraph starting with the word "Finally,..... and continuing on page 12 with the first paragraph starting with the word "Again....."), IRRC stated unequivocally:

"Although we agree with commentators that properly educated and tested dental hygienists should be capable of administering local anesthesia and nitrous oxide/oxygen conscious sedation, Section 11.2 of the Dental Law (63 P.S. § 130c) requires the Board to establish minimum training and education or certification for the issuance of permits to dentists to administer anesthesia..... Nowhere in this section or in other provisions of the Dental Law are dental hygienists statutorily authorized to administer any type of anesthesia. Nor does the Dental Law confer power upon the Board to permit dental hygienists to administer anesthesia. Therefore, we believe that to allow dental hygienists to administer anesthesia, an amendment to the Dental Law is required.

Again, we believe that the issue of whether dental hygienists should be authorized to administer local anesthesia represents a policy decision of a substantial nature that requires legislative review. We therefore strongly recommend that the Board work with the General Assembly to develop language to amend the Dental Law to authorize dental hygienists to administer local anesthesia and to esrablish consistent training requirements and a permitting process." (Emphasis added by this writer).

In the intervening 15 years, 1993 to 2008, **no** language has appeared in Section 11.2 of the Dental Law which would provide the statutory authority for dental hygienists to administer local anesthesia. The regulations proposed in IRRC No.2720 for dental hygienists to administer local anesthesia are devoid of the statutory authority recommended by IRRC in 1993.

As a consequence of the Board's inaction to follow through on IRRC's 1993 statutory recommendation, the proposed local anesthesia regulations in IRRC No.2720 are moot and deprived of practical significance at this time.

Nitrous oxide analgesia does not appear in IRRC No. 2720.

Practice as a public health dental hygiene practitioner.

My assessment: **Act 51-2007, which created the "public health dental hygiene practitioner (PHDHP)" is unconstitutional. Act 51 contains conflicting provisions, to be described as follows:**

The Dental Law, in its definition of a Dental Hygienist, **EXHIBIT B**, states, inter alia: "The foregoing (*beginning words in the definition*) shall not be construed as authorizing the assignment of diagnosing, [and] treatment planning....."

The Dental Law's definition of the Practice of Dentistry, **EXHIBIT C**, states, inter alia "A person engages in the 'Practice of Dentistry,' within the meaning of this act, who diagnoses, treats, operates on or prescribes for any disease.....'

These definitions grant oral diagnosis and treatment selection decisions to licensed dentists and prohibit dental hygienists from performing oral diagnosis. Dental treatment selections are based on oral diagnosis, and by extension these selections are prohibited.

Act 51 created a category of dental hygienists called "public health dental hygiene practitioners (PHDHPs)," **EXHIBIT D**, with permission to provide their legally designated services, **EXHIBIT E**, only in pubic and private institutions. Their services would be provided without a dentist's authorization and without dentist supervision.

To illustrate how PHDHPs would in fact be performing oral diagnostic and treatment decisions in public and private institutions, let's consider two examples, i.e., (1) providing dental prophylaxes ("cleanings") in a nursing home, and (2) providing dental sealants (see Footnote) to children in school.

(School employment would have its problems. PHDHPs would require Bachelor's degrees and teaching certification from the Department of Education).

In a nursing home, in the process of authorizing themselves, i.e. "self-authorization," to provide dental prophylaxes, PHDHPs would evaluate the prophylaxis requirement of a resident, and **decide** whether **or not** a prophylaxis is required. It may be safe to say that a high percentage of severely medically compromised residents can be found in nursing homes. What is the resident's ASA health status? The American Society of Anesthesiology, **EXHIBIT F**, has developed a classification system grading the health status of patients requiring surgery and/or general anesthesia. The healthier a patient is, the safer the anesthesia administration will be; the sicker a patient is, more risk is involved for the patient.

In my view, the public interest is ill served in the nursing home. Has the resident been told that there is no dentist responsibility for the treatment that he/she will receive? Does the resident have an expectation that a dentist or physician or nurse will be present in case of an emergency? Will a resident feel comfortable knowing that their health concerns are being carefully considered? Should there be a physician consult? Will the resident need pre-medication? PHDHPs cannot prescribe medications. Will the nursing home have liability exposure? Have family members been consulted and given informed consent for treatment? What are the nursing home's dental care procedures as required by Federal law? Will medical,

---

Footnote. Simply stated, sealants are plastic coatings placed on children's back teeth to prevent tooth decay.

dental hygiene and drug costs be incurred by the resident? What equipment and instruments will be available for optimal delivery of care? Can the PHDHP use local anesthesia? If ever it is allowed in Pennsylvania, the answer is no, because of the lack of direct supervision.

In a school setting, in the process of authorizing themselves, i.e. "self-authorization," to provide dental sealants to school children, PHDHPs would evaluate the sealant requirements of a school child, and **decide** whether **or not** a sealant is required. (See Footnote). Have the child's parents/guardians been told that there is no dentist responsibility for the treatment that the child will receive? Do the parents have an expectation that a dentist will be present in case of an emergency? What factors are involved in deciding if sealants are indicated? What is the tooth decay history of the child? What conditions exist to make a child prone to decay on the chewing surfaces of the back teeth? Has chewing surface decay penetrated into the enamel of the tooth? How would this be determined? Is there a dental x-ray unit at the school? Will costs be incurred by child's family? Informed consent? What equipment and instruments will be available for optimal delivery of care? Will dental sealants be required or not required? The current standard of care for sealant applications is that not all children require this procedure.

At last count, 69 Pennsylvania school districts have dental hygiene programs served by dental hygienist(s), and supervised by dental consultant(s). These programs are required to file annual or biannual dental hygiene program objectives with the Department of Health.

As per the nursing home and school examples above, the delivery of dental services by PHDHPs is all about decision making. All dental care, wherever provided, requires strict adherence to a sacred principle of patient care, to wit: patient examinations, dental histories, and diagnostic modalities. All are mandated in the public interest in order to make **"decisions,"** or **diagnoses,** if you will. **Diagnoses** will determine which dental procedures are to be performed, or not to be performed. **Diagnosis and treatment decisions and non-treatment decisions are inextricably joined.**

The Dental Law in its definition of the Practice of Dentistry states that diagnosis and treatment planning are the exclusive prerogative of licensed dentists. The same Dental law creates a dental hygiene provider (the PHDHP) who can self-authorize his or her procedures. I have demonstrated that "public health dental hygiene practitioners" in fact have to diagnose and treatment plan in order to decide which of their legally designated procedures they will perform or not perform in public and private institutions. In doing so, they engage in the illegal practice of dentistry.

The issues of diagnosis and treatment planning are the practice of dentistry. The performance of diagnosis and diagnostically selected treatment by any dental hygienist violates the Dental Law. One part of the Dental Law states that dentists have exclusivity over diagnosis and treatment planning. Act 51 takes away this exclusivity by creating the "public health dental hygiene practitioner" **Conflicting provisions are unconstitutional**.

If my view of unconstitutionality is supported, then the Board's proposed regulations emanating from Act 51 are moot and deprived of practical significance at this time.

Other Board proposed regulations that impact the oral health of patients.

- The Board proposes to accept a dental hygiene diploma from a dental hygiene school accredited by an approved United States Department of Education-recognized regional accrediting agency. This proposal could detriment the public because USDOE accreditation is institutional only and not programmatic. With only an institutional accreditation, a hygiene school can develop its own program with no review of its content by an independent agency. Curricula could span from good to bad. Graduates of schools with only USDOE accreditation will be unable to take the Northeast Regional Board of Dental Examiners (NERB) dental hygiene licensing examination. Passage of the NERB examination can qualify a dental hygiene graduate for licensure in up to16 states. In lieu of this, the Board may have to develop its own licensing examination. The other accreditation factor that has been constant in the Dental Law is the American Dental Associations' Commission on Dental Accreditation (CODA). CODA provides programmatic guidance to over 250 dental hygiene school in the United States, providing standards for quality dental hygiene education. A similar commission exists in Canada under the same circumstances as CODA.

  The USDOE approach could lower the standard of dental hygiene education in the Commonwealth. Lowering of educational standards in any endeavor is not in the public interest.

  Recommendation. Delete the USDOE reference.

- The Board has revised its general supervision requirement for dental hygienists by allowing the dental hygienist up to one year to provide their legally designated procedures after the dentist has examined the patient, developed a treatment plan and authorized the one year

extension for the hygienist. The hygienist can schedule his/her services as he/she sees fit whether or not the dentist is physically present in the office. In the case of a dental prophylaxis the public is ill served. Patients usually expect a dental prophylaxis soon after they have made a commitment to seek dental care. Dental prophylaxis is an important preventive procedure to combat oral disease, along with vital home care instruction. Why would the Board opt to delay a dental prophylaxis up to a year to eliminate bacterial toxins that are harmful to oral health? The former 90-day wait period, and now the 1 year wait, in my view, is for the convenience of the hygienist and not the oral health care of the public. Additionally, when the dentist is out of the office, dental hygiene appointments will not be available for patients who must be seen under direct supervision, a condition based on the patient's general health.

We now have two standards of dental hygiene care: in the private dental office the dentist is present (direct supervision) when medically compromised patients receive a dental prophylaxis from a dental hygienist, but in a nursing home no dentist is present when medically compromised patients receive a dental prophylaxis from a "public health dental hygiene practitioner." Clearly a double standard of care.

Recommendation: In the public interest, delete the up to the one year time delay for a patient to receive a valuable oral health service.

Recommendation: Eliminate the double standard in dental hygiene care in the private sector and the public/private institutional sector. But how?

May I boldly recommend the revocation of Act 51-2007. The Dental Law cannot be manipulated to allow dental hygienists to practice without supervision of some kind. The public deserves dentist responsibility for their care, wherever provided. Supervision provides the "equal treatment playing filed" which is in the best oral health interest of all Pennsylvanians. There should be no double standards of care. The Dental Law clearly delineates between the practice of dentistry and the practice of dental hygiene. Hygienists who have desired to practice dentistry have enrolled in dental schools to acquire the necessary education and training to become dentists.

Thank you.

Sincerely,

Charles M. Ludwig, DDS

cc: IRRC
Encls.

EXHIBIT A

COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

STATE BOARD OF DENTISTRY REGULATION #16A-321

GENERAL REVISIONS

MAY 12, 1993

We have reviewed the above-captioned regulation proposed by the State Board of Dentistry (Board) and submit for your consideration the following comments, objections and recommendations. Subsections 5(d) and (e) of the Regulatory Review Act (71 P.S. §§ 745.5(d) and (e)) delineate the criteria we must employ to determine whether a regulation is in the public interest. To this end, our comments address issues that relate to the statutory authority of the Board, the legislative intent of the General Assembly and the clarity, feasibility and reasonableness of the regulation. We strongly recommend that these comments be considered as the Board prepares the final-form version of the regulation.

1. Section 33.1. Definitions. "General supervision."

A major concern we have with the proposed rulemaking deals with the supervision of dental hygienists. The Dental Law (63 P.S. § 121 *et seq.*), through the definition of "dental hygienist" contemplates that there are some functions that a dental hygienist must perform under the direct supervision of a dentist, but other functions a dental hygienist may perform under general supervision of a dentist. Specifically, the definition provides:

> A "dental hygienist" is one legally licensed as such by the said dental council and examining board to perform those educational, preventive and therapeutic services and procedures that licensed dental hygienists are educated to perform. Licensed dentist may assign to their employed dental hygienist intra-oral procedures which the hygienist have been educated to perform and which require their professional competence and skill but which do not require the professional competence and skill of the employer dentist. Such assignments shall be under the supervision of a licensed dentist. . . . The Board shall issue rules setting forth the necessary education and defining the procedures that may be performed by dental hygienists licensed under this act including those procedures that may be performed under direct and general supervision. (63 P.S. § 121)

Currently, the dental regulations allow a dental hygienist to practice under the general supervision of a licensed and registered dentist. While there is no definition of "general supervision" in the current regulation, the Board has proposed to interpret the Dental Law to require that a dentist be physically present in the dental office while the dental hygienist performs his or her services.

In order to provide clarification on this issue, the Board has added definitions for "direct supervision" and "general supervision." The proposed regulation defines "direct supervision" as the following:

> Supervision by a dentist who examines the patient, authorizes the procedure to be performed, is physically present in the dental facility and available during the performance of the procedure, and examines and takes full responsibility for the completed procedure.

The proposal defines "general supervision" as the following:

> Supervision by a dentist who is physically present in the dental facility when the presence is required under Section 33.205(b) (relating to practice as a dental hygienist), authorizes the performance of dental hygiene services and takes full professional responsibility for their performance.

The intent of the new definition for "general supervision" is to clarify that a dental hygienist may only perform his or her duties when the dentist is in the dental office. Both definitions require on-site presence of a dentist in a dental office. The reason for the required physical presence of a dentist in the dental office is clear in the definition of direct supervision since certain functions are beyond the scope of practice of a dental hygienist and therefore require the presence of a dentist. The rationale for the on-site requirement in a dental office is not clear in the definition of "general supervision" since this provision authorizes a dental hygienist to perform the same functions in other health care settings independent of a dentist.

In drafting the language of the Dental Law, the Legislature indicated that there are to be two distinct levels of supervision provided to a dental hygienist: direct supervision and general supervision. The words "direct" and "general" are not synonymous. The Statutory Construction Act requires effect be given to all provisions of a statute (1 Pa. C.S. §1942(a)). It is clear that the General Assembly did not mandate that dental hygienists perform all functions only under the on-site presence of a dentist. Therefore, we believe the requirement that a dentist always be present when dental hygienists perform their duties is contrary to the legislative intent of the Dental Law.

The Board has based its proposal to require dentists to be present in the dental office on its belief that it is in the patient's best interest to have a dentist physically present. The Board believes that the dentist needs to be present in case an emergency occurs or the patient is in need

of immediate attention by the dentist. Therefore, the Board believes the physical presence of a dentist is needed for the safety and welfare of the dental patient.

However, the Board, in Section 33.205(b) of the proposed regulation, has contradicted its doctrine that a dentist needs to be physically present for the safety and welfare of dental patients. In this section, the Board authorizes dental hygienists to perform their duties in a public or private school, public health care agencies and nursing homes without a dentist physically present. Therefore, it would appear that the Board's belief that a dentist needs to be physically present for a dental hygienist to practice for the safety of the patient does not apply to situations when a dental hygienist practices in a public facility.

The Board's justification for allowing this double standard is that the Board has a shared jurisdiction over dental hygienists practicing in public facilities with other State agencies as opposed to sole jurisdiction in a dental office. This justification is questionable given the language of the Dental Law. Specifically, Section 121 of the Dental Law provides the following:

> Such performance of intra-oral procedures by licensed dental hygienists shall be in the office of a dentist or public or private institution such as schools, hospitals, orphanages, and sanitoria or State health cars [sic].

We believe that the language of Section 121 clearly provides that the Board is solely responsible for the licensure and practice of dental hygienists regardless of whether the dental hygienist is rendering services in dental offices or public facilities. No other agency or Board is granted the authority to regulate the practice of dentistry or dental hygienists. Therefore, we believe that this language exclusively authorizes the Board to determine the standards of practice in both dental offices and public facilities.

As mentioned, we find the Board's position on requiring a dentist to be physically present in a dental office when a dental hygienist performs their duties to be contrary to the legislative intent of the Dental Law. Additionally, we believe this requirement to be unreasonable and not in the public interest. We take this position for the following reasons:

1. Dental hygienists are licensed professionals. All dental hygienists must complete a two-year accredited educational program, which include courses that are required of dentists, and must pass a licensure examination.

2. The Board has not provided any documentation of how the physical presence of a dentist will increase the welfare of the dental patient while dental hygienists perform their duties.

3. We believe if the Board felt strongly about the need for a dentist to be present while dental hygienists performed their duties, it would require this standard in public facilities as well.

4. Eighteen other states allow a dental hygienist to practice without requiring a dentist to be physically present in the dental office. Other states allow dental hygienists to perform some (but not all) procedures without the dentist being physically present in the office.

5. Requiring the dentists to be present in the dental office while the dental hygienist cleans teeth would limit the access and increase the cost of preventative dental care because the patient will only be able to obtain appointments when the dentist is scheduled to be in the office.

6. A dental hygienist receives similar amounts of training as a registered nurse. A registered nurse is permitted to administer medicine and inject needles without the physical presence of a doctor. These activities have the potential to be more of a risk, if done improperly, than the activities performed by a dental hygienist.

We believe that the dental hygienists' educational training is sufficient to allow them to safely practice without a dentist physically present in the office. We do not believe the Board has documented any possible harm that could occur to a dental patient simply because a dentist would not be present in the office at the same time the dental hygienists' services are rendered. We therefore recommend that the Board modify the definition of "general supervision" to allow the dental hygienist to perform those procedures in which they have been specifically educated and trained to do and are not procedures which require the expertise of a licensed dentist, without the required presence of a dentist in the dental office.

2. Section 33.102 Professional Education

The Board is proposing that candidates for licensure as dental hygienists show compliance with Section 3(d) of the Dental Law which requires a certificate or diploma from an approved institution or college. The Board is proposing to delete the current minimum educational requirement found in Section 33.213 which requires a dental hygienist candidate to complete at least 2 years of training, of not fewer than 32 weeks, of not fewer than 30 hours each week, or its equivalent.

The Pennsylvania Dental Hygienists' Association (PDHA) believes that the Board should maintain this language on minimum educational requirements to ensure that dental hygienists receive proper, consistent training. The PDHA believes the practice of dental hygiene has become more complex, with new emphasis on environmental, safety, infection control and complex medical conditions of patients and therefore, minimum educational requirements are needed.

The Board has not offered any reason for the deletion of these educational requirements from the proposed rulemaking. Since the Board is responsible for establishing standards for licensing dental hygienists, we believe it should continue to include language on the minimum educational requirements that a dental hygienist must obtain for licensure. Therefore, we

recommend that the Board maintain the current language of Section 33.213 regarding the educational requirements for dental hygienists.

3. Section 33.103. Examination.

In this section the Board will only accept successful completion of the Northeast Regional Dental Examination (NERB) for up to five years from the date the scores are reported to the Board. The only exception to this would be if the individual had been practicing in another state.

We note that a dentist may, after completion of the NERB, enter the military to begin their dental career. As the regulation is currently proposed, if the individual leaves the military after five years of service and enters private practice, he or she would be required to re-take the NERB examination prior to obtaining licensure in the Commonwealth.

We do not believe that dentists who serve in the United States military forces should be required to re-take the NERB examination if they have already successfully completed the examination. Therefore, we recommend that Subsection 33.103(c) be amended to provide an exemption for those individuals who have successfully completed their NERB and enter the military from having to re-take the NERB before they enter into private practice.

4. Section 33.204. Delegation of duties.

Subsection (1) of this section prohibits a dentist from delegating procedures which require the professional judgment and skill of a dentist. Nondelegable procedures include:

1. Diagnosis and treatment planning;

2. Cutting or otherwise altering of hard or soft tissue, or both;

3. Preparation of a tooth for restorative materials;

4. Restoration or replacement of a tooth, including the placement of endodontic filling materials;

5. An intra-oral procedure that would lead to the fabrication of an appliance which, when worn by the patient, would come in direct contact with hard or soft tissue and which could result in tissue irritation or injury.

We have received a significant amount of comments from members of the General Assembly, dentists, dental auxiliaries and dental patients in opposition to the language of this section which prohibits a dentist from delegating the listed procedures to a dental hygienist or to other auxiliary personnel. The majority of comment letters were from a particular group of dental auxiliaries, the expanded functions dental assistants (EFDAs) and dentists utilizing EFDAs in their practices. Currently, many dentists employ EFDAs to perform restorative

procedures, specifically the placing of amalgam as fillings in teeth. Under the proposed rulemaking, EFDAs would no longer be authorized to perform these duties.

In the Preamble to the regulation, the Board provided its justification for prohibiting the use of EFDAs in the practice of dentistry. The Board states that it has become aware that some dentists delegate restorative procedures, including the placement of restorations, to auxiliaries, apparently in the belief that these procedures do not require a dentist's judgment and skill. The Board, as well as the American Dental Association (ADA), take the position that intra-oral restorative procedures may be performed only by dentists and are not appropriate duties for delegation to auxiliary personnel. The Board supports its position by stating the following

> In the case of restorations, a harmful condition may take years to develop. For example, a restoration that does not have a matrix band properly placed or that is not wedged properly will result in an overhang that will cause, over years, a periodontal condition. Moreover, placing and wedging a matrix band often draws blood and is classified as an invasive procedure; such a procedure should be performed only by a dentist. An improper contact point between two teeth results in a food impaction area, which will create a severe periodontal pocket and dental decay - and, eventually severe periodontal disease. Failure to have appropriate contact points when placing a restoration could lead to shifting of the teeth and ultimately to a malocclusion. If an improper occlusion occurs when a restoration is placed, it could put the entire dentition into a malocclusion and lead to a temporomandibular joint dysfunction. Failure to exclude saliva when placing a restoration causes the restorative material to become weakened and fracture. When the ultimate harmful condition becomes evident, there may well not be a "trail" leading back to the improperly placed restoration.

The Board also cites the support of the three Pennsylvania dental school deans on this issue. According to the Board, the dental educators agree that restorative procedures cannot be isolated from the broad scope of dental practice and taught in a vacuum; rather competence in performing these procedures is attained through 4 years of integrated training as a dental student. The Board points to the fact that in several administrations of the NERB clinical examination, the highest failure rate for dental students was in restorative dentistry.

Opponents of the Board's position, point to the numerous articles and a report from the United States General Accounting Office supporting the use of EFDAs in the practice of dentistry and note that for the past 20 years dentists in the Commonwealth have been utilizing the services of EFDAs with the endorsement of the Board. According to the numerous letters received on this issue, many believe that the delegation of restorative procedures to properly trained and supervised auxiliaries has been unequivocally shown to be safe and cost-effective, while meeting all acceptable standards of care. Controlled double-blind studies have consistently shown that there were equal or better quality restorations from trained auxiliaries than from dentists.

Many of the opponents of the regulation believe that the Board's concern about the use of EFDAs which was stated in the Preamble and set forth above, is misdirected. Commentators point to the fact that EFDAs can only function under the direct supervision of a dentist. The ultimate responsibility remains with the dentist to properly supervise and evaluate the work performed by the EFDA. Additionally, the dentist also has the responsibility to determine whether a particular restoration or function can be delegated to the EFDA or not. Many of the commentators believe that if the Board has a sincere concern about substandard care being rendered by EFDAs, it should be detected and proved by the Board. Then the offending dentist or dentists should be appropriately reprimanded. Commentators argue, however, that there have been no citations and no cases against dentists utilizing EFDAs or EFDAs themselves in the past 20 years.

The Dental Law defines the "Practice of Dentistry" as a person who diagnoses, treats, operates on, or prescribes for any disease, pain or injury, or regulates any deformity or physical condition, of the human teeth, jaws or associated structures, or conducts a physical evaluation, or administers anesthetic agents, or uses ionizing radiation in the course of dental practices, or who fits, constructs, and inserts any artificial appliance, plate or denture for the human teeth or jaws, or who holds himself or herself out as being able or legally authorized to do so. Section 122 of the Dental Law authorizes the Board to establish standards of preliminary and professional education and the training required for licensure to practice dentistry and for dental hygienists.

No provisions exist in the statute which contemplate the licensure of EFDAs or other dental auxiliaries, except for the administration of x-rays. The Dental Law only provides licensure requirements for dentists and dental hygienists. The Board argues that because restorative procedures require the skill and judgment of a licensed dentist, the performance of such procedures by EFDAs constitutes the unlicensed practice of dentistry.

Section 129 of the Dental Law regarding penalties imposes penalties upon any person who holds himself or herself out as a practitioner, or entitled or authorized to practice dentistry or as a dental hygienist unless he or she has been duly licensed, and authorized to engage in such practice under the provisions of the statute. Additionally, Section 122(i) authorizes the Board to suspend, revoke or refuse to grant licenses when a dentist knowingly aids, assists, procures or advises any unlicensed person to practice dentistry or dental hygiene contrary to the Dental Law or regulations. From the language of these sections, the Board believes, and we agree, that the Dental Law prohibits the performance of such duties (in particular restorative procedures) by EFDAs or any other unlicensed auxiliary. In addition, because of the duties being performed by EFDAs require the skill and judgment of a dentist, we believe that the Board may impose sanctions upon dentists utilizing EFDAs in their practices since such duties constitute the unlicensed practice of dentistry.

Furthermore, unlike other similar professional licensing statutes, the Dental Law does not contain a statutory provision authorizing dentists to delegate duties. Section 17 of the Medical Practice Act of 1985 (63 P.S. § 422.17) specifically allows a medical doctor to delegate to a health care practitioner or technician the performance of medical services under certain specified conditions. The Medical Practice Act also provides for the certification of physician assistants as

paraprofessionals. The Dental Law does not contain any similar provisions for delegating duties to auxiliaries other than dental hygienists and for x-ray procedures.

The Dental Law does not lend itself to any interpretation which would authorize the delegation of duties to EFDAs or any other auxiliary personnel other than dental hygienists or certified radiological auxiliary personnel. As was explained above, the Dental Law, read as a whole, provides that the unlicensed practice of dentistry is subject to penalties under the statute. Furthermore, the Dental Law only provides licensure for dentists, dental hygienists and x-ray personnel. Therefore, we believe that the Board is well within its statutory authority to prohibit the delegation of restorative procedures to EFDAs.

However, for the same reasons, the Commission believes that the Dental Law also prohibits the delegation of ***any*** duties to auxiliary personnel other than dental hygienists or x-ray personnel. As proposed, Section 33.204 only prohibits the delegation of duties that require the professional judgment and skill of a dentist. The regulation does not prohibit dentists from delegating procedures which the delegatee is competent to perform and for which the dentist exercises direct supervision and assumes full professional responsibility. According to the Board, such procedures would include the placement of temporary crowns and temporary fillings.

We disagree with the Board's position. We believe that the placing of temporary crowns and fillings is the practice of dentistry. Even though these procedures are only considered to be temporary and the Board argues they require a lesser degree of professional judgment and skill, we see no distinction between these procedures and the performance of reversible restorative procedures prohibited by Section 33.204(1). If such procedures are conducted by EFDAs, performance of these duties continue to constitute the unlicensed practice of dentistry subject to penalties.

While we agree with the commentators who argue that the use of trained and properly supervised EFDAs in the practice of dentistry can be safe, cost effective and in the public interest, we are bound by the criteria of the Regulatory Review Act to first and foremost determine if the regulation is contrary to the statutory authority of the promulgating agency and intention of the General Assembly in the enactment of the statute upon which the proposal is based. Accordingly, based upon our review of the proposal, we believe that the Dental Law, as written, prohibits dentists from delegating any duties to auxiliary personnel, does not allow for the use of EFDAs in the practice of dentistry nor does it contemplate any type of certification program for EFDAs.

Furthermore, we believe that the continued use, the certification or licensing of EFDAs and the establishment of consistent and uniform educational and training requirements for these dental auxiliaries represent policy decisions of such a substantial nature that they require legislative review. We strongly recommend that the Board work closely with the General Assembly to amend the Dental Law to incorporate language allowing a dentist to delegate duties and to allow for the certification of EFDAs after the completion of a rigorous educational and training program before the regulation is submitted in its final-form.

To this end, the Commission will issue a report of its findings with regard to the use of EFDAs in the practice of dentistry and delegation of duties issues to the General Assembly for further action. In order to allow the General Assembly adequate time to review and legislatively address the EFDA issue, we therefore recommend that the Board delete Section 33.204 in its entirety from the proposed regulation before proceeding with the remainder of the rulemaking.

5. Application of Section 33.204 to Orthodontics

One other issue has been brought to our attention in this section. There appears to be uncertainty or inconsistency as to whether the nondelegable duties only apply to EFDAs performing services in general dentistry offices and whether equivalent duties performed by EFDAs in orthodontists offices are also nondelegable. We believe that given the language of the Dental Law the language of Section 33.204 should clarify that it applies to all specialties as well as to the practice of general dentistry.

6. Section 33.205. Practice as a dental hygienist.

Subsection (a)(1) of this section provides that a dental hygienist may do scaling, root planing, polishing or any other procedure required to remove calculus deposits, accretions and stains from the exposed surface of the teeth and beneath the free margin of the gingiva.

The PDHA believes that the language used in this subsection is imprecise because it does not clearly describe how far below the gum line a dental hygienist can go to clean tartar or calculus. The PDHA believes, given the educational training that a dental hygienist receives, the regulation should state that a dental hygienist may work from the free margin of the gingiva to the base of the junctional epithelium. This would allow the dental hygienist to go approximately 3-5 millimeters below the gum line.

We believe that the Board needs to provide specific language indicating how far the dental hygienist may work below the gum line. We believe if the Board does not agree with the recommended language of the PDHA, it needs to show why the dental hygienist does not have the necessary skills to work on this area of the tooth.

The second issue with Subsection (a)(1) involves an apparent conflict with language contained in Subsection 33.204(1). In Section 33.204 the Board is proposing to prohibit dentists from delegating certain procedures which include the cutting or otherwise altering of hard or soft tissue. In Subsection (a)(1), the Board is allowing the dental hygienist to do root planning which involves the alteration of soft and hard tissue. Procedures involving root planning are currently being done by dental hygienists in the Commonwealth and is a permissible procedure for hygienists in all states.

We believe the Board needs to amend Subsection 33.204 to provide for an exemption in the delegation of duties in the area concerning the alteration of soft and hard tissue. Specifically, we believe the Board needs to state that a dentist may not delegate procedures that involve the

alteration of hard or soft tissue except when it is an allowable procedure for a dental hygienist as found in Section 33.214.

Third, Subsection (a) provides that a dental hygienist may offer to perform or perform services that involve "one of the following." We have received numerous comments seeking clarification of this subsection. The Board informed us that when the regulation was published in the *Pennsylvania Bulletin* the Legislative Reference Bureau amended the language to fit into its formatting requirements by adding the phrase "one of the following." The Board, however, intended that the language read as it appears in Annex A of the regulatory analysis form without the added phrase. Therefore, we recommend that the original language in Annex A be incorporated into the final-form regulation so that it is clear that a dental hygienist may perform any of the activities listed.

Fourth, the PDHA has recommended that the Board provide more specific language in this section on the scope of practice for a dental hygienist. They believe that a more definitive outline reflecting the true nature of the broad scope of practice actually provided by a dental hygienist would be more helpful to individual dental hygienists and the dentist who chooses to delegate functions to them. The PDHA, in their comments, has provided specific examples of procedures that a dental hygienist can and cannot perform.

We believe the PDHA recommendation on providing more specific language on the procedures that a dental hygienist can perform has merit. Therefore, we recommend the Board include more specific language on the scope of practice of a dental hygienist.

Finally, both the Commission and the Board have received numerous comments objecting to the lack of language authorizing dental hygienists to administer local anesthesia and nitrous oxide/oxygen conscious sedation as a permitted function for the practice of dental hygiene. Currently, only a dentist may administer anesthesia to a patient or monitor the nitrous oxide/oxygen conscious sedation procedure.

Many of the commentators point to the fact that local anesthesia is currently permitted as a function of dental hygiene practice in 18 states. As late as the 1970s, many hygienists in Pennsylvania administered local anesthesia safely and effectively. Under current practice, however, a dentist must stop his or her procedure with a patient and enter the dental hygiene room to administer anesthesia which may be needed for the dental hygiene patient. Dental hygienists object to this restriction given the educational competence of dental hygienists in Pennsylvania and the absence of any harm to patients who received anesthesia from a dental hygienist.

Although we agree with the commentators that properly educated and tested dental hygienists should be capable of administering local anesthesia and nitrous oxide/oxygen conscious sedation, Section 11.2 of the Dental Law (63 P.S. § 130c) requires the Board to establish minimum training and education or certification for the issuance of permits to *dentists* to administer anesthesia including conscious sedation or nitrous oxide or oxygen analgesia. Nowhere in this section or in other provisions of the Dental Law are dental hygienists statutorily

authorized to administer any type of anesthesia. Nor does the Dental Law confer power upon the Board to permit dental hygienists to administer anesthesia. Therefore, we believe that to allow dental hygienists to administer anesthesia, an amendment to the Dental Law is required.

Again, we believe that the issue of whether dental hygienists should be authorized to administer local anesthesia represents a policy decision of a substantial nature that requires legislative review. We therefore strongly recommend that the Board work with the General Assembly to develop language to amend the Dental Law to authorize dental hygienists to administer local anesthesia and to establish consistent training requirements and a permitting process.

7. Section 33.208. Prescribing, administering and dispensing medications.

This section sets forth the procedures that a dentist must follow in dispensing non-narcotic drugs. Commentators object to the lack of language authorizing a prescription in an emergency situation. Under Section 33.207 (Prescribing, administering and dispensing controlled substances), Subsection (4) authorizes a dentist to telephone to a pharmacy an appropriate short-term prescription in an emergency. However, no similar language is contained in Section 33.208.

According to the comments we received, Section 33.208 would forbid a dentist from starting a patient on antibiotics to treat symptoms of an infection before the patient was physically examined by the dentist. Another example of the need for greater flexibility would be where a two to three-year old child may get a dental cellulitis/abscess late in the evening. The prescription of the proper antibiotic is the treatment of choice and is typically done by phoning in an emergency prescription.

We agree with the commentators and suggest that the Board add a provision to Section 33.208, similar to the provision contained in Section 33.208(4), authorizing the emergency prescription of medications.

8. Section 33.210. Storage of drugs.

This section contains standards and procedures for dentists who administer or dispense drugs to ensure that controlled substances are stored and dispensed in a safe manner. To maintain control over the entry of persons into a drug storage area, Subsection (2) requires that any entry into the area may only be allowed when a dentist or dental hygienist is present and supervising.

The Commission has received comments objecting to the language of this subsection that either a dentist or a dental hygienist must be present and supervise the entry into a drug storage area. According to the comment letters received, the term "dental hygienist" should be deleted from this provision because no federal or state regulations permit anyone without a drug license to supervise controlled substances. Additionally, commentators state that if there were a breach of conduct in this area, the dentist would be held liable.

We agree with the commentators. Because prescribing or administering drugs is beyond the scope of practice of a dental hygienist as defined in the Dental Law or in the corresponding regulation, we recommend that the term "dental hygienist" be deleted from this subsection.

9. Section 33.211 Unprofessional conduct

In Subsection (7), the Board provides that failing to follow current infection control recommendations issued by the Federal Centers for Disease Control (CDC) will be considered to be unprofessional conduct. The Pennsylvania Medical Society noted that one of the provisions established by the CDC was requiring health care workers to reveal that they have the HIV virus and to obtain consent by the patient in order to perform certain invasive procedures. According to the Pennsylvania Medical Society, the CDC has not yet established a list of what procedures it would require health care workers to reveal their health status to the patient.

We note that the Pennsylvania Confidentiality of HIV-Related Information Act (35 P.S. § 7601 *et seq.*) provides strict standards governing the release of information of an individual's HIV status. It would appear that the CDC guideline, on requiring a health care worker to inform a patient that they have the HIV virus, would be in conflict with the HIV Confidentiality Law. Therefore, we recommend that the Board provide for a specific exemption to this disclosure provision in the CDC guidelines.

EXHIBIT B

A. **"Dental Hygienist"** is one who is legally licensed as such by the State Board of Dentistry to perform those educational, preventive, and therapeutic services and procedures that licensed dental hygienists are educated to perform. Licensed dentists may assign to dental hygienists intra-oral procedures which the hygienists have been educated to perform and which require their professional competence and skill but which do not require the professional competence and skill of the dentist. Such assignments shall be under the supervision of a licensed dentist. Such performance of intra-oral procedures by licensed dental hygienists shall be in the private office of a dentist or public or private institution such as prescribed under section 11.9(b). Dental hygienists certified as public health dental hygiene practitioners may perform intra-oral procedures without the assignment of a dentist pursuant to section 11.9. The foregoing shall not be construed as authorizing the assignment of diagnosing, treatment planning and writing prescriptions for drugs or writing authorizations for restorative, prosthetic, or orthodontic appliances. The board shall issue rules setting forth the necessary education and defining the procedures that may be performed by dental hygienists licensed under this act including those procedures that may be performed under direct and general supervision.

(Def. amended July 20, 2007, P.L.327, No.51)

Section 1. Be it enacted, &c., That - Short Title.
This act shall be known, and may be cited, as "The Dental Law."

Section 2. Definitions.
A person engages in the **"Practice of Dentistry,"** within the meaning of this act, who diagnoses, treats, operates on, or prescribes for any disease, pain or injury, or regulates any deformity or physical condition, of the human teeth, jaws, or associated structures, or conducts a physical evaluation, or administers anesthetic agents, or uses ionizing radiation in the course of dental practice, or who fits, constructs, and inserts any artificial appliance, plate, or denture for the human teeth or jaws, or who holds himself or herself out as being able or legally authorized to do so. The term "Practice of Dentistry" does not include:

(a) The practice of any of the healing arts by duly licensed practitioners.

(b) The extracting of teeth or relieving pain by a licensed physician or surgeon in emergencies, or the making of applications for such purposes.

(c) The practice of dentistry by a duly licensed practitioner of dentistry of any other state or country, for the limited purpose of consultation with respect to any case under treatment in this Commonwealth, or of demonstrating before any duly authorized dental society in this Commonwealth.

(d) The practice of dentistry by a duly licensed practitioner of dentistry of any other state or country for the limited purpose of teaching, including clinical teaching, in a dental school or advanced dental education program in the Commonwealth approved by the board after notification to the board and in accordance with board regulations. Appointments shall not exceed four (4) years and may only be extended if the practitioner receives a license from the board.

(e) The practice of dentistry in clinical departments and laboratories of dental schools and their affiliated facilities approved by the board in the Commonwealth, by bona fide students pursuing a course of study leading to the degree of Doctor of Dental Surgery or Doctor of Dental Medicine.

(f) The practice of dentistry in a dental clinic operated not for profit for the duration of an internship, residency or other graduate training program approved by the American Dental Association Commission on Dental Accreditation or a dental anesthesiology training program that meets the standards of an accrediting body acceptable to the board, by persons having acquired the preliminary and professional education required for admission into the program, after notification to the board.

(Def. amended Dec. 16, 1992, P.L.1222, No.160)

EXHIBIT D

"Public Health Dental Hygiene Practitioner" means a licensed dental hygienist who may perform educational, preventative, therapeutic and intra-oral procedures which the hygienist is educated to perform and which requires the hygienist's professional competence and skill but which do not require the professional competence and skill of a dentist without the authorization, assignment or examination of a dentist, and who is certified by the State Board of Dentistry as having satisfied the requirements of section 11.9. Public health dental hygiene practitioners may only engage in professional practice in the practice sites enumerated in section 11.9(b).

(Def. added July 20, 2007, P.L. 327, No. 51)

§ 33.205. Practice as a dental hygienist.

(a) *Scope of professional practice.* A dental hygienist may offer to perform or perform services that involve:

(1) Placement of antimicrobial cord.

(2) Periodontal probing, scaling, root planing, polishing or another procedure required to remove calculus deposits, accretions, excess or flash restorative materials and stains from the exposed surfaces of the teeth and beneath the free margin of the gingiva to the base of the junctional epithelium.

(3) Evaluation of the patient to collect data to identify dental hygiene care needs.

(4) The application of fluorides and other recognized topical agents for the prevention of oral diseases.

(5) Conditioning of teeth for and application of sealants.

(6) Taking of impressions of the teeth for athletic appliances.

EXHIBIT F

Cleveland Clinic

ASA Physical Classification System

The American Society of Anesthesiologists (ASA) Physical Status classification system was initially created in 1941 by the American Society of Anesthetists, an organization that later became the ASA.

The purpose of the grading system is simply to assess the degree of a patient's "sickness" or "physical state" prior to selecting the anesthetic or prior to performing surgery. Describing patients' preoperative physical status is used for recordkeeping, for communicating between colleagues, and to create a uniform system for statistical analysis. The grading system is *not* intended for use as a measure to predict operative risk.

The modern classification system consists of six categories, as described below.

ASA Physical Status (PS) Classification System*:

ASA PS Category	Preoperative Health Status	Comments, Examples
ASA PS 1	Normal healthy patient	No organic, physiologic, or psychiatric disturbance; excludes the very young and very old; healthy with good exercise tolerance
ASA PS 2	Patients with mild systemic disease	No functional limitations; has a well-controlled disease of one body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without chronic obstructive pulmonary disease (COPD); mild obesity, pregnancy
ASA PS 3	Patients with severe systemic disease	Some functional limitation; has a controlled disease of more than one body system or one major system; no immediate danger of death; controlled congestive heart failure (CHF), stable angina, old heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms
ASA PS 4	Patients with severe systemic disease that is a constant threat to life	Has at least one severe disease that is poorly controlled or at end stage; possible risk of death; unstable angina, symptomatic COPD, symptomatic CHF, hepatorenal failure
ASA PS 5	Moribund patients who are not expected to survive without the operation	Not expected to survive > 24 hours without surgery; imminent risk of death; multiorgan failure, sepsis syndrome with hemodynamic instability, hypothermia, poorly controlled coagulopathy
ASA PS 6	A declared brain-dead patient who organs are being removed for donor purposes	

*ASA PS classifications from the American Society of Anesthesiologists