

Regulatory Analysis Form

(Completed by Promulgating Agency)

INDEPENDENT REGULATORY
REVIEW
REVISION
IRRC

2011 NOV - 9 A 10:54

IRRC Number: 2795

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency:

Department of State, Bureau of Professional and
Occupational Affairs, State Board of Dentistry

(2) Agency Number: 16A

Identification Number: 16A-4616

(3) PA Code Cite: 49 Pa. Code §§ 33.1, 33.3, 33.102 and 33.117

(4) Short Title: EFDA Program Approval

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Cynthia K. Montgomery, Regulatory Counsel, State Board of Dentistry, phone: 717-783-7200; fax: 787-0251; email: cymontgome@pa.gov.

Secondary Contact: Sabina Howell, Counsel, State Board of Dentistry, phone: 717-783-7200; fax: 787-0251; email: showell@pa.gov.

(6) Type of Rulemaking (check applicable box):

PROPOSED REGULATION
 Final Regulation
 Final Omitted Regulation

Emergency Certification Regulation;
 Certification by the Governor
 Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The rulemaking establishes standards for the education of expanded function dental assistants (EFDAs). It would require EFDA programs to be approved by the Board and establishes criteria for Board approval relating to accreditation, faculty and staff, facilities, curriculum and objective measurement of competencies. Finally, the rulemaking establishes a procedure for denying approval or removing an EFDA program from the approved list.

(8) State the statutory authority for the regulation. Include specific statutory citation.

Sections 3(a) and (b) of the Dental Law, 63 P.S. § 122(a) and (b), authorize the Board to "establish and alter, from time to time, the standards of preliminary education and training required for...certification for expanded function dental assistants" and to "investigate and determine the acceptability and to approve and disapprove institutions and colleges of this State and of other states and countries for the education of students desiring to be...certified as expanded function dental assistants, and to revoke approvals where such institutions and colleges no longer are deemed proper." Section 3(d.1)(1) establishes the general authority of the Board to regulate the certification of expanded function dental assistants; and section 3(o) provides the general authority of the Board "to adopt, promulgate and enforce such rules and regulations as may be deemed necessary by the Board."

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The regulation is not mandated by any federal or state law or court order or federal regulation.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

In spite of its best efforts, the Board was unable to establish an affordable clinical examination for EFDAAs to demonstrate their clinical competence prior to licensure, therefore, in an effort to ensure the public's health, safety and welfare, the Board determined that it is necessary to enforce minimum standards for EFDA education, to include clinical competence. Under the proposed rulemaking, EFDA education programs must apply to the Board for approval and submit evidence of meeting the various criteria for EFDA education established by the Board.

(11) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No scientific data, studies or references are the basis for this regulation.

(12) Describe who and how many people will be adversely affected by the regulation. How are they affected?

Only those EFDA programs that are unable to meet the minimum standards set by the Board would be adversely affected because the Board would not grant certificates to graduates of an EFDA program that is not approved. There are currently nine EFDA programs established in this Commonwealth. The Board had previously established non-binding guidelines for EFDA education programs. Each of the nine programs worked with the Board in establishing their EFDA education programs to assure they meet the criteria established by these regulations and previously espoused by the guidelines.

- (13) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

All EFDA education programs must comply with the regulation. There are currently nine EFDA education programs established within the Commonwealth: All-State Career School, 50 West Powhattan Avenue, Essington, PA 19029; Allied Medical and Technical Careers, 517 Ash Street, Scranton, PA 18509; Bradford School, 125 West Station Square Drive, Pittsburgh, PA 15219; Career Training Academy, 950 Fifth Avenue, New Kensington, PA 15068-6308; Harcum College, 750 Montgomery Avenue, Bryn Mawr, PA 19010-3476; Harrisburg Area Community College, One HACC Drive, Harrisburg, PA 17110-2999; Keystone Technical Institute, 2301 Academy Drive, Harrisburg, PA 17112; Luzerne Community College, 1333 S. Prospect Street, Nanticoke, PA 18634; and Manor College, 700 Fox Chase Road, Jenkintown, PA 19040. In addition, the Board has issued EFDA certificates to graduates of two EFDA programs located in Ohio: Jefferson Community College, 4000 Sunset Blvd, Steubenville, OH 43952; and Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH 44106-4905.

- (14) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to dentists, dental hygienists and EFDAAs because the regulation is directed at institutions that offer EFDA educational programs. Each EFDA program must submit an application for approval and pay an application fee of \$200, and renew that approval every 2-years at a cost of \$100. There will also be indirect costs of compiling all of the information/documentation required to apply for approval. The Board anticipates applications from 12 EFDA programs during the first year after implementation of the final rulemaking. Subsequently, the Board estimates no more than four new applications each year.

- (15) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with this proposed rulemaking.

- (16) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Costs associated with processing applications for EFDA program approval will be borne by the applicants, therefore there will be no direct costs associated with the proposed rulemaking. Any costs associated with the legal process for denying approval or removing an EFDA education program from the approved list will be borne by the Board as part of its legal office expenses. However, those costs are too speculative to estimate at this time.

(17) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2011-2012	FY +1 2012-13	FY +2 2013-14	FY +3 2014-15	FY +4 2015-16	FY +5 2015-17
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings	N/A	N/A	N/A	N/A	N/A	N/A
COSTS:						
Regulated Community	\$2400	\$2000	\$800	\$2800	\$800	\$3600
Local Government						
State Government						
Total Costs	\$2400	\$2000	\$800	\$2800	\$800	\$3600
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	N/A	N/A	N/A	N/A	N/A	N/A

(17a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
State Board of Dentistry	\$1,545,511,80	\$1,582,000.00	\$1,645,000.00	\$1,711,000.00

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The minimal costs to EFDA programs to apply for Board approval are outweighed by the benefit of standardized EFDA education that produces competent EFDAAs.

- (19) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Board held a public hearing on the EFDA exam and education requirements at its July 20, 2001, Board meeting. At that time, it was determined that EFDA education guidelines would be developed. Five drafts of the EFDA education guidelines were developed between 2001 and 2005. In 2006, the Board determined that the guidelines should be promulgated as regulations in order to have the full force and effect of law. An exposure draft was sent out to interested parties and stakeholders in September of 2006, including all nine of the currently operating EFDA programs in this Commonwealth. Comments received were considered in drafting the proposed rulemaking. In addition, the Board meets in public session eight times a year at which time its regulatory proposals are discussed. Comments from the public are always welcomed. The comments received on the proposed rulemaking and possible responses/amendments were discussed at Board meetings on the following dates: January 8, 2010; April 16, 2010; June 4, 2010; July 30, 2010; and April 29, 2011.

- (20) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered. However, the Board did consider adding a “site visit” requirement, but decided to move forward with the regulation as drafted and consider the financial implications to the Board and the EFDA programs before moving forward with site visits. The Board does not believe the proposed regulatory scheme imposes an unacceptable burden on EFDA education programs.

- (21) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no applicable federal standards.

- (22) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

Of the surrounding states, only Maryland, New York, New Jersey and Ohio currently certify dental assistants to perform expanded functions. Maryland does not regulate EFDA education, but permits dental assistants certified by the Dental Assisting National Board as “qualified in general duties” to perform expanded functions. Ohio’s regulations establish accreditation and curriculum requirements for EFDA education programs and required EFDA applicants to pass a clinical examination in expanded functions. In New Jersey, a “registered dental assistant” may engage in expanded functions if they have graduated from a board-approved program of education and have passed the New Jersey Expanded Functions examination. In New York, the Education department regulates the curriculum of dental assisting programs. The proposed rulemaking would not place Pennsylvania at a competitive disadvantage.

(23) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(24) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The Board will develop necessary EFDA Program Approval application forms during the final rulemaking process which will incorporate those items listed in § 33.117(b) (relating to application for EFDA program approval). Some slight changes may be needed to the application for certification as an EFDA, specifically with regard to the certificate of expanded function dental assistant education completed by the EFDA education program. EFDA education programs will have additional reporting, recordkeeping and paperwork requirements because they will be required to renew their board approval biennially.

(25) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

No particular needs of any affected group have been identified.

(26) Include a schedule for review of the regulation including:

A. The date by which the agency must have received public comments: **November 9, 2009**

B. The date or dates on which public meetings or hearings will be held: **The Board considered comments on the proposed rulemaking at regularly scheduled board meetings after publication as proposed on the following dates: January 8, 2010; April 16, 2010; June 4, 2010; July 30, 2010; and April 29, 2011. The Board's public meeting schedules are available on the Bureau's website at www.dos.state.pa.us/bpoa.**

C. The expected date of promulgation of the proposed regulation as a final-form regulation: **Anticipated January 2012.**

D. The expected effective date of the final-form regulation: **Upon publication of the final form rulemaking in the Pennsylvania Bulletin – Anticipated January of 2012.**

E. The date by which compliance with the final-form regulation will be required: **Upon publication of the final form rulemaking in the Pennsylvania Bulletin – Anticipated January of 2012.**

F. The date by which required permits, licenses or other approvals must be obtained: **Applications will be made available upon publication of the final form rulemaking in the Pennsylvania Bulletin – Anticipated January/February of 2012.**

(27) Provide the schedule for continual review of the regulation.

In general, the Board continually monitors the effectiveness of its regulations on at least an annual basis under Executive Order 1996-1. However, The Board will review the effectiveness of these specific regulations with each biennial renewal of EFDA program approvals in spring of each odd-numbered year.

FEE REPORT FORM

Agency: State - BPOA

Date: June 8, 2011

Contact: Katie True

Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application Fee: Approval for EFDA Programs: \$200.00

Estimated Revenue first year: \$2400.00 (12 applications x \$200.00)

Fee Description:

The fee will be charged to every applicant for approval of an Expanded Function Dental Assisting Program.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Dentistry to review and process an application for approval of an Expanded Function Dental Assisting Program and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Board administrator: application preparation	(1.00 hr.)	\$ 48.52
Board committee review - avg. time to review and present to full board for approval	(3.00 hr.)	\$ 112.50
Administrative Overhead:		<u>\$ 33.66</u>
	Total Estimated Cost:	\$ 194.68
	Proposed Fee:	\$ 200.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$200.00 be established to process an application for approval of a Expanded Function Dental Assisting Program.

Application for Approval of a Expanded Function Dental Assisting Program:

Board Staff: Reviews application for approval to establish a new state-approved Expanded Function Dental Assisting Program. Review Committee for the State Board of Dentistry reviews program goals and objectives including curriculum, faculty, admission and administrative policies, establishment, philosophy, organization and plan for evaluation of program. The review Committee on the State Board of Dentistry submits summary and recommendations for approval to the full board when the program provider is in compliance with all regulations. When required, any discrepancy letters will be written by the Board Administrator and sent to the program provider as directed by the review committee.

Because expenses vary widely due to the possibility of multiple revisions, the fee proposed here covers only minimal staff time and the administrative overhead charge.

FEE REPORT FORM

Agency: State - BPOA

Date: June 7, 2011

Contact: Katie True

Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Biennial Renewal Fee: EFDA Programs: \$100.00

Estimated Revenue first year: \$1200.00 (12 applications x \$100.00)

Estimated Biennial Revenue after initial licensing: \$400.00 (4 applications x \$100.00)

Fee Description:

The fee will be charged to every applicant for the biennial renewal fee for an Expanded Function Dental Assisting Program.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Dentistry to review and process an application for renewal of an Expanded Function Dental Assisting Program and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Board administrator: application preparation	(1.00 hr.)	\$ 48.52
Board committee review - avg. time to review and present to full board for approval	(1.00 hr.)	\$ 37.50
Administrative Overhead:		<u>\$ 12.34</u>
	Total Estimated Cost:	\$ 98.36
	Proposed Fee:	\$ 100.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$100.00 be established to process a renewal application for an Expanded Function Dental Assisting Program.

Application for Renewal of an Expanded Function Dental Assisting Program:

Board Staff: Reviews renewal application for continued approval of an Expanded Function Dental Assisting Program. Review Committee for the State Board of Dentistry reviews program goals and objectives including curriculum, faculty, admission and administrative policies, establishment, philosophy, organization and plan for evaluation of program. The review Committee on the State Board of Dentistry submits summary and recommendations for renewal approval to the full board when the program provider is in compliance with all regulations. When required, any discrepancy letters will be written by the Board Administrator and sent to the program provider as directed by the review committee.

Because expenses vary widely due to the possibility of multiple revisions, the fee proposed here covers only minimal staff time and the administrative overhead charge.

**FACE SHEET
FOR FILING DOCUMENTS
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(Pursuant to Commonwealth Documents Law)

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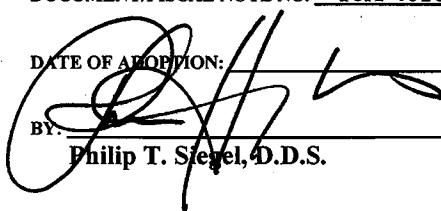
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Executive or Independent Agencies.

BY: _____
(DEPUTY ATTORNEY GENERAL)

State Board of Dentistry
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4616

DATE OF ADOPTION: _____

BY: 
Philip T. Siegel, D.D.S.

INDV 8 2011

DATE OF APPROVAL

Deputy General Counsel,
Chief Counsel,
Independent Agency
(Strike inapplicable title)

DATE OF APPROVAL

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

- Check if applicable
Copy not approved.
Objections attached.
- Check if applicable.
No Attorney General approval
or objection within 30 day
after submission.

**FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF DENTISTRY
49 PA. CODE, CHAPTER 33**

EFDA PROGRAM APPROVAL

The State Board of Dentistry (Board) hereby amends §§ 33.1, 33.3, 33.102 (relating to definitions; fees; and professional education) and adds § 33.117 (relating to EFDA program approval), to read as set forth in Annex A.

Effective Date

The amendments will be effective upon publication of the final-form rulemaking in the Pennsylvania Bulletin.

Statutory Authority

The rulemaking is authorized by section 3(a) and (b), (d.1)(1) and (o) of the Dental Law, 63 P.S. § 122(a), (d.1)(1) and (o). Section 3(a) authorizes the Board to “establish and alter, from time to time, the standards of preliminary and professional education and training required for . . . certification for expanded function dental assistants.” Section 3(b) authorizes the Board to “investigate and determine the acceptability and to approve and disapprove institutions and colleges of this State and of other states and countries for the education of students desiring to be . . . certified as expanded function dental assistants, and to revoke approvals where such institutions and colleges are no longer deemed proper.” Section 3(d.1)(1) provides the general authority for the Board to provide for and to regulate the certification of expanded function dental assistants. Section 3(o) provides the general authority of the Board “to adopt, promulgate and enforce such rules and regulations as may be deemed necessary by the Board.”

Background and Purpose

The act of December 27, 1994, (P.L. 1361, No. 160) (Act 160) amended the Dental Law to require the certification and regulation of expanded function dental assistants (EFDAs). Act 160 required dental assistants who desired to be certified as EFDAs to complete an education program and pass an examination approved by the Board. The Board, through regulations published on May 13, 2000, determined that the examination would include both a written component and a clinical component to ensure that certificateholders possess the requisite knowledge and skills to properly and safely perform their job functions. At the time, many interested parties and stakeholders, including dentists, dental hygienists, dental assistants and their professional associations participated in the development of the rulemaking. A major impetus for including the clinical component came from the dental assisting community itself, who felt that a clinical exam was necessary.

Ultimately, after years of attempts at obtaining a suitable examination through "requests for proposals" as well as through sole-source contracting, the Board was unable to identify a vendor who could provide a valid, reliable and defensible clinical exam that was also affordable to candidates. Because there is no widely available regional or national examination for EFDA's, the costs of developing and administering a Pennsylvania-specific examination for EFDA's would have to be borne by a rather small pool of candidates. Due in part to the projected costs of the clinical component of the examination, temporary permit holders and members of the legislature asked the Board to take another look at the clinical component requirement. As a result, the Board held a public hearing on July 21, 2001. Based upon the testimony received, as well as written comments, the Board was persuaded that the clinical component could be eliminated while still meeting its goals of public protection by placing more emphasis on standardizing EFDA education. Thereafter, the Board initiated proposed rulemaking to eliminate the clinical component of the examination and developed non-binding "guidelines" for EFDA education programs.

In the intervening years, the Board developed five drafts of the "EFDA curriculum guidelines" by working with members of the dental community as well as dental educators. Eventually, the Board determined that the guidelines should be promulgated as regulations in order to assure that all EFDA education programs meet minimum requirements and that all candidates for EFDA certification must demonstrate competence in performing each of the dental procedures permitted under the Dental Law prior to graduation from an EFDA program.

Summary of Comments and the Board's Response

Notice of proposed rulemaking was published on October 10, 2009, at 39 Pa.B.5916, followed by thirty days of public comment. During the public comment period, the Board received public comments from the Pennsylvania Academy of General Dentistry (PAGD) and the Pennsylvania Association of Private School Administrators (PAPSA). In addition, as part of their review under the Regulatory Review Act, on October 21, 2009, the House Professional Licensure Committee (HPLC) and on December 9, 2009, the Independent Regulatory Review Commission (IRRC) submitted comments. The Senate Consumer Protection and Professional Licensure Committee did not comment. The following represents a summary of the comments received and the Board's response.

Pennsylvania Academy of General Dentistry (PAGD)

The Pennsylvania Academy of General Dentistry recommended that the Board require that EFDA programs only admit individuals to an EFDA training program who either worked as a dental assistant for 2 years, or who has 1 year of experience and is certified by the Dental Assisting National Board (DANB) as a certified dental assistant (CDA). The PAGD observed that EFDA's are expected

to perform at a higher level within the dental team and their job duties require a greater sense of professional understanding. However, it is possible for an individual to complete their general dental assisting training and EFDA training “back-to-back” without any intervening experience working in a dental office. The PAGD observed that “some EFDAAs that have gone for back-to-back training cannot even properly suction let alone place complex restorations.”

The Board understands and shares PAGD’s concerns that EFDAAs must enter the dental office with a basic understanding of how the dental team interacts and proper knowledge of procedures and materials. This is precisely why the Board initially planned to offer a clinical examination, and ultimately designed these regulations to assure that EFDA education would include a clinical component and would require a licensed dentist evaluator to “sign off” regarding the clinical competence of the candidate. Unfortunately, the Board does not believe it has the statutory authority to impose an experience requirement on EFDA applicants, nor can it impose one indirectly by setting an admission standard for EFDA education programs. It is up to the educators to assure that they are properly preparing EFDA candidates to function in a dental office, regardless of the amount of practical experience the candidate has upon entering the EFDA training program.

Additionally, as set forth in section 2 of the Dental Law (63 P.S. § 121), all EFDAAs must work under the direct supervision of a dentist, meaning that “a dentist is in the dental office or treatment facility, personally diagnoses the condition to be treated, personally authorizes the procedure and remains in the dental office or treatment facility while the procedure is being performed and, before dismissal of the patient, personally evaluates the work performed.” Further, it is considered unprofessional conduct for an EFDA to practice without the direct supervision of a dentist, or to perform a service that the EFDA is not competent to perform. See § 33.211(c)(1) and (2) (relating to unprofessional conduct). Likewise, it is considered unprofessional conduct for a dentist to fail to properly supervise the EFDA, or to delegate duties to the EFDA that the dentist knows, or has reason to know, the EFDA is not competent to perform. See § 33.211(a)(2) and (3). Therefore, the supervising dentist is another layer of patient safety protection. For these reasons, the Board made no changes to the final rulemaking in response to the PAGD’s comment.

Pennsylvania Association of Private School Administrators (PAPSA)

PAPSA, which represents nine Pennsylvania schools with EFDA programs, offered five comments. First, PAPSA asked if existing programs that were previously “approved” by the Board under the prior curriculum guidelines would need to apply for approval based on these regulations or would they be “grandfathered.” All EFDA programs will need to apply for approval under these regulations, and as amended, renew those approvals on a biennial basis.

PAPSA also asked whether the EFDA program must be an associate degree program or the school must offer an associate degree in some of its programs. An EFDA program does not need to be an associate degree program. There are three alternative educational paths provided in section

3(d.1) of the act (63 P.S. §122(d.1)): 1) an EFDA program at an accredited 2-year college or other accredited institution which offers an associate degree; 2) an accredited dental hygiene program which requires the successful completion of at least 75 hours of clinical and didactic instruction in restorative functions; or 3) an EFDA certification program of at least 200 hours clinical and didactic instructions from an accredited dental assisting program. The Board has always interpreted the first pathway as a 2-year or associate degree EFDA program. The third pathway is for all other EFDA programs that are less than a 2-year or associate degree program.

PAPSA also asked if each program must be accredited or if institutional accreditation is acceptable. The Board believes that programmatic accreditation is necessary to fulfill its goals of assuring that the educational standards for EFDAs are high enough to assure public protection by standardizing EFDA education to overcome the lack of a clinical examination. The Board understands that CODA does not currently accredit EFDA programs. For that reason, the Board will approve an EFDA program that is either: offered by a school whose dental assisting program is accredited by CODA, or that is accredited by any accrediting agency approved by the United States Department of Education Council on Postsecondary Accreditation whose educational standards are approved by the Board. PAPSA goes on to ask if other allied medical program accrediting agencies such as the Accrediting Bureau of Health Education Schools (ABHES) would be included as an accrediting option to CODA. The Board notes that ABHES offers both institutional and programmatic accreditation. Because ABHES currently only offers programmatic accreditation for three types of programs: medical assisting, medical laboratory technology and surgical technology, programmatic accreditation by ABHES would not be possible at this time. If an EFDA program applies for approval and is accredited by another accrediting body, the Board will review the educational standards of that particular accrediting body to determine if Board approval is warranted as provided in § 33.102(c)(1)(iii)(B).

PAPSA also asked for clarification of the clinical instruction component of an approved EFDA education program. PAPSA felt it was unclear whether clinical instruction can be done on the school premises, including laboratory or preclinical instruction. The clinical component of the EFDA curriculum may be done on school premises, for example where a school has its own clinic, or through an internship or externship at a dental facility that has contracted with the school. PAPSA also asked if a student is doing an internship or externship at a separate dental facility, whether the instructor must be present at all times. The student must be directly supervised by a licensed dentist at anytime they are performing expanded functions on patients. That licensed dentist may be the instructor or may be a licensed dentist overseeing the internship or externship experience. It is anticipated that the licensed dentist must "sign off" regarding the clinical competence of the student before they graduate, and documentation of clinical competence must be maintained by the school and included with the EFDA applicant's application materials.

Finally, PAPSA questioned why certification as a certified dental assistant (CDA) by the Dental Assisting National Board (DANB) was the only alternative for EFDA faculty and suggested

that the Board consider those individuals who hold the registered dental assistant (RDA) credential from the American Medical Technologists (AMT). In considering this comment, the Board compared the requirements of these two credentials.

To be eligible for the CDA certification from DANB, one must either 1) be a graduate of a dental assisting program accredited by the Commission on Dental Accreditation (CODA); 2) complete a minimum of 3,500 hours of work experience as a dental assistant over a period of 2 to 4 years; or 3) be a former DANB CDA, a graduate of a CODA-accredited DDS or DMD program, or be a graduate from a foreign dental degree program. The candidate must have CPR certification and pass all three components of the CDA exam (General Chairside Assisting; Radiation Health and Safety; and Infection Control) within a 5-year period. The three components consist of a total of 320 multiple-choice items, and candidates have a total of 4 hours to complete the exams. To maintain the CDA credential, which is renewable annually, the dental assistant must earn 12 continuing dental education credits; maintain current CPR certification; apply and respond to background information questions; and pay a fee.

To be eligible for the RDA credential from AMT, one must have either 1) graduated from a dental assisting program accredited by an organization approved by the U.S. Department of Education (which would include CODA); 2) graduated from a dental assisting program in an institution accredited by a Regional Accrediting Commission or by a National accrediting organization approved by the U.S. Department of Education; 3) completed a dental assisting training program offered and approved by the Armed Forces AND have completed a minimum of 1 year of full-time (or equivalent) experience in the dental assisting profession; or 4) been employed in the occupation of dental assisting for a minimum of 3 years full time (5,250 hours of experience) AND present a recommendation from an employer of the applicant who is a dentist. The applicant must also be of good moral character, hold current CPR certification, and pass the AMT Certification Exam for Registered Dental Assistant. The RDA exam consists of 200-210 multiple choice items covering the following four topics: Office assisting skills (office procedures, patient management and communication, ethics and professional conduct), dental sciences (dental anatomy and terminology, patient education, local anesthesia, medical emergencies, sterilization, and dental materials), clinical procedures (instruments and equipment, chairside procedures and laboratory) and radiography. The exam must be completed in 3 hours. To maintain the RDA credential, which is renewable every 3 years, the dental assistant must accrue a combination of employment experience, continuing education, professional leadership experience, experience in presenting educational instruction, or experience in the authorship of written works; complete a compliance evaluation worksheet and attestation; and pay the required fee.

While the two certifications might look similar, there are significant differences. First, DANB is an organization that is dedicated solely to the dental assisting profession, whereas AMT primarily offers medical certifications including: medical technologist, medical lab technician, medical assistant, phlebotomist, medical administrative specialist, allied health instructor and clinical

lab consultant. The only dental related certification offered by AMT is the registered dental assistant. In addition, to qualify for the CDA credential based on education, the dental assistant must have graduated from a dental assisting program accredited by the American Dental Association's Commission on Dental Accreditation (CODA). To qualify for the RDA credential based on education, a dental assistant only needs to graduate from an institution accredited by an accrediting organization approved by the U.S. Department of Education; programmatic accreditation by CODA is not required, although would be accepted. The Board notes that there are currently eight Pennsylvania Schools that have dental assisting programs accredited by CODA. Further, to maintain the CDA credential, which is renewable annually, a certified dental assistant must complete 12 hours of continuing dental education each year. To maintain the RDA credential, which is renewable every 3 years, a registered dental assistant must participate in AMT's continued certification program (CCP) and must obtain 30 points for approved activities during the 3-year renewal cycle. Although continuing dental education is one of the approved activities for the purpose of earning CCP points, employment as a dental assistant also qualifies. Simply being employed as a dental assistant for the 3-year renewal cycle could earn all 30 required points, with no need for any continuing dental education. For all of these reasons, the Board finds that the CDA credential should remain the requirement for EFDA educators in Pennsylvania.

House Professional Licensure Committee

The House Professional Licensure Committee (HPLC) submitted two comments for the Board's consideration. First, the HPLC questioned whether there should be a renewal process for an EFDA program after initial approval of its application. The Board considered this comment and agreed that approval of EFDA education programs should be renewed every 2 years, to allow approved EFDA programs to report any changes to their program that may have occurred since initial approval. The final rulemaking has been amended to provide for the renewal of EFDA program approval every 2 years and to include the fees for renewal. With the input from the Bureau's revenue office, it was determined that the biennial fee for renewing the approval of an EFDA program would be initially set at \$100 until we have enough historical data to determine if the fee is adequate. This fee should be enough to evaluate any changes in a program, such as changes to curriculum, faculty, and so forth.

The discussion regarding renewal lead the Board to consider the possibility of conducting a site visit to confirm the information submitted by the EFDA program applying for approval. After much discussion, the Board determined that it would go forward with the rulemaking as drafted and evaluate the need of a site visit by the Board, or an agent of the Board, and if the Board determines that a site visit is necessary, to adopt such a requirement by regulation at some point in the future. At that time, the fees would be reevaluated.

The HPLC also asked if § 33.117(c)(7) (relating to EFDA program approval) should be amended to provide that a student is required to attain a passing grade on written and oral

examinations, rather than “written or oral examinations.” The HPLC is concerned that the language could be interpreted in such a way as to permit a student, for example, to pass written examinations, but fail oral examinations. In response, the Board has amended the language to require the student to attain a passing grade on examinations. This change was made in recognition of the fact that not all schools offer both written and oral examinations. So whether the examinations are written or oral, or some other method such as computer-based or even practical examinations, the student must attain a passing grade to demonstrate competency.

Independent Regulatory Review Commission

The Independent Regulatory Review Committee (IRRC) reiterated the HPLC’s comment regarding renewal. IRRC believes that a renewal process would be a reasonable requirement that would ensure these programs continue to provide the education and training needed for EFDAs. As previously discussed, the Board has amended the final regulation to provide for renewal of program approval biennially. IRRC also questioned the \$80 EFDA program approval application fee, which is based on a 2-hour review of an application. IRRC asked the Board to explain how a 2-hour review of an application for approval, which requires review of several dozen requirements, adequately protects the public health and safety. The Board, in consultation with the Bureau’s Revenue Office, reviewed the proposed fee and agrees with IRRC that the fee, and the 2-hour review that is contemplated by the fee, is inadequate. A revised fee has been calculated to be \$200 based on review by the Board’s administrative and legal staff, and presentation to the Board at a regular Board meeting. In addition, the Board determined that a biennial renewal fee of \$100 should be adopted so that these approved programs will continue to be reviewed by the Board on a regular basis.

IRRC also questioned the use of the phrases “Board-approved EFDA program” and “Board-approved certification program” in § 33.102(c)(1)(i) and (iii). As noted previously, there are three educational pathways to becoming an EFDA. One is to take a CODA-accredited dental hygiene program that meets certain requirements. The other two require an individual to participate in a Board-approved EFDA program. The difference is that under paragraph (i) the program is one that confers an associate degree. Paragraph (iii) contemplates those EFDA programs that offer a diploma or certificate. This type of program is generally used by those individuals who are already trained as dental assistants and who would only need additional training in the expanded functions. The review process is the same for either associate degree or certificate/diploma programs. The Board has amended these sections in the final rulemaking to aid clarity. IRRC also asked how a person would know if an EFDA program had been approved by the Board and suggested that the Board publish a list of approved EFDA programs on its website. In response, the Board has amended § 33.102(c)(2) to state that the approved list will be maintained on the Board’s website. In addition, each approved EFDA program will be provided an approval number, which will be searchable on the Department’s LicensePA website (www.license.state.pa.us). Therefore, any prospective student will be able to verify online whether a program has been approved, and whether its approval has been renewed as required.

With regard to § 33.117 (relating to EFDA program approval), IRRC suggested that the requirement for applicants to provide “other information requested by the Board” is overly broad and should be limited to information related to the EFDA program. The Board understands this concern and has amended the final rulemaking to clarify its intent. IRRC also commented that subsection (c)(3)(viii), which requires the applicant to identify a program director who is involved in the maintenance of records related to the EFDA program is also vague because it does not list all of the records that must be kept and it does not specify how long the records must be maintained. The intent of the Board in this section was merely to have the EFDA program identify the individual who is involved in and responsible for the enumerated tasks. The Board did not intend to mandate a specific list of documents that must be maintained, nor dictate how long the EFDA program must maintain those records. For that reason, the Board did not amend the final-rulemaking in response to this comment.

IRRC also commented that the requirement that an EFDA instructor have completed or is in the process of completing a course in education methodology is vague because almost anyone could claim to be in the process of completing it, but as written, would never have to complete it. In response, the Board has amended the language in subsection (c)(4)(iv) to require an EFDA educator complete the course in education methodology within 18 months of hire, if they have not already done so.

Additionally, IRRC questioned the use of the phrase “adequate physical facilities and equipment” as vague and asked for more detail. In considering this comment, the Board reviewed the regulations of the Department of Education to determine what existing requirements might apply to EFDA education programs. The Board notes that the State Board of Private Licensed Schools addresses equipment and facilities at 22 Pa. Code §§ 73.91 and 73.92 (relating to equipment; and facilities). Because many of the schools that offer EFDA programs are already required to follow these existing regulations, the Board determined that it should adopt similar language. Therefore, the final regulation has been amended to be consistent with the regulations of the Department of Education, State Board of Private Licensed Schools.

IRRC also questioned whether the phrase “all restorative materials” was overly broad. The Board reviewed this comment and has amended the final rulemaking to clarify that the Board intended EFDAs to demonstrate competency in using all restorative materials commonly used in direct restorations such as amalgam and composite resin; not those materials used in indirect restorations or fabricated in a laboratory, such as the metals, metal alloys, gold or porcelain used in crowns, inlays, onlays or veneers.

Finally, IRRC noted that EFDA program directors are required to provide “documentation” of the student’s competency attainment to the Board as part of the student’s application for certification and asked that the final-form regulation specify what type of documentation will be

required. The Board intends to have the program director certify on a form provided by the Board that the student has demonstrated each of the competencies listed in § 33.117(c)(7)(i) –(iii) as part of the application process, and to maintain supporting documentation for 5 years after the student graduates from the EFDA program. Supporting documentation could consist of the source records of the school, such as the exams themselves, instructor's grade reports, evaluations of the student's clinical competence by the licensed dentist evaluator, and any other record that the school uses to document competency that is used by the program director as a basis for the certification provided to the Board. The Board has amended the final rulemaking to clarify its intent.

In addition to these comments received during the regulatory review process, while discussing the draft final rulemaking with stakeholders and interested parties at a regularly scheduled meeting of the Board on April 29, 2011, it was pointed out that the act of April 29, 2010 (P.L. 176, No. 19) (Act 19 of 2010) amended the Dental Law to expand the scope of practice of expanded function dental assistants to include performing coronal polishing, performing fluoride treatments and taking impressions of teeth for limited purposes. It was suggested that these functions be added to § 33.117 with regard to content of approved EFDA program curriculum, and with regard to demonstration of required competencies. The Board agreed and has added these functions to the final rulemaking, noting that a separate rulemaking will address other aspects of the implementation of Act 19 of 2010.

Description of Amendments to the Final Rulemaking

Section 33.3 (relating to fees) is amended to change the EFDA program approval application fee to \$200, and to add a biennial renewal fee of \$100. Section 33.102(c)(1)(iii) (relating to professional education) has been amended to clarify that the Board requires all EFDA programs, both associate degree programs, as well as those that offer a certificate or diploma, to go through the approval process. Subsection (c)(2) has been amended to provide that the list of approved EFDA programs will be available on the Board's website.

Section 33.117(b)(9) (relating to EFDA program approval) is amended to clarify the requirement for applicants for Board approval to provide other information related to the EFDA program requested by the Board. Section 33.117(c)(4)(iii) is amended to clarify that EFDA faculty shall have completed a course in education methodology no later than 18 months after employment as a faculty member. Section 33.117(c)(5) has been amended to conform the facilities and equipment requirements to those of the Department of Education, Board of Private Licensed Schools.

Section 33.117(c)(6)(ii) is amended to add coronal polishing, fluoride treatments and the taking of impressions of the teeth to the curriculum requirements. Section 33.117(c)(7)(i) is amended to provide that students shall demonstrate competence in general education subjects by

attaining passing grades on examinations, rather than “written or oral examinations” to allow the EFDA programs the flexibility to use either type of examination, or other types of examinations such as computer-based examinations or practical examinations. Section 33.117(c)(7)(ii) has been amended to clarify that EFDA students must demonstrate competency using all restorative materials commonly used in direct restorations, such as amalgam and composite resin, and to include the requirement that EFDA students demonstrate competency in performing coronal polishing, fluoride treatments, and taking impressions of teeth for study models, diagnostic casts and athletic appliances. Section 33.117(c)(7)(iv)(C) and (D) have been amended to clarify that the EFDA program director shall certify as to the EFDA student’s competence and maintain supporting documentation for a minimum of 5 years. Finally, a new subsection (e) has been added to § 33.117 to address the topic of biennial renewal of EFDA program approval.

Fiscal Impact and Paperwork Requirements

The proposed amendments should have no fiscal impact on the Commonwealth or its political subdivisions because the costs associated with processing EFDA program approval applications will be borne by applicants, who will pay a \$200 initial fee and a biennial renewal fee of \$100. The Board anticipates that 10-12 schools will apply for approval and renew their approvals biennially.

The proposed amendments will require the Board to develop an application for EFDA program approval, but should not result in any additional legal, accounting or reporting requirements for the Commonwealth. The regulated community will have the additional legal and paperwork requirements of applying for approval and renewing that approval biennially.

Sunset Date

The Board continuously monitors the cost effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Board submitted a copy of the notice of proposed rulemaking, published at 40 Pa.B. 5916, on October 10, 2009, to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC) for review and comment.

In compliance with section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), the Board also provided IRRC, SCP/PLC, and HPLC with copies of comments received as well as other documents when requested. In preparing the final-form regulation, the Board has considered the comments received from IRRC, the HPLC, and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), this final-form regulation was approved by the HPLC on _____, 2011, and deemed approved by SCP/PLC on _____, 2011. Under section 5.1(e) of the Regulatory Review Act (71 P.S. § 745.5a(e)), IRRC met on _____, 2011 and approved the final-form regulation.

Contact Person

Further information may be obtained by contacting Cynthia Montgomery, Regulatory Counsel, State Board of Dentistry, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Dentistry finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to the final form rulemaking do not enlarge the purpose of proposed rulemaking published at 40 Pa.B. 5916.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act identified this Preamble.

Order

The State Board of Dentistry, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 33, are amended by amending §§ 33.1, 33.3 and 33.102, and by adding § 33.117, to read as set forth in Annex A.

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Final Preamble
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(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

Philip T. Siegel, D.D.S.
Chairperson
State Board of Dentistry

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS
CHAPTER 33. STATE BOARD OF DENTISTRY

Subchapter A. GENERAL PROVISIONS

§ 33.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

EFDA Program – An expanded function dental assisting training program.

* * * * *

§ 33.3. Fees.

(a) Following is a schedule of fees charged by the Board:

* * * * *

EFDA program approval application fee.....\$ 80 200

* * * * *

BIENNIAL RENEWAL FEE – EFDA PROGRAM APPROVAL.....\$100

* * * * *

Subchapter B. LICENSURE OF DENTISTS AND DENTAL HYGIENISTS AND
CERTIFICATION OF EXPANDED FUNCTION DENTAL ASSISTANTS

* * * * *

§ 33.102. Professional education.

* * * * *

(c) *Expanded function dental assistants.*

(1) Candidates for certification as expanded function dental assistants shall show compliance with section 3(d.1) of the act by submitting verification of one of the following:

(i) Graduation from [an expanded function dental assisting program] a Board-approved EFDA program at a 2-year college or other institution accredited or provisionally accredited by an accrediting agency approved by the United States Department of Education Council on Postsecondary Accreditation which offers an Associate Degree.

(ii) Graduation from a dental hygiene school which required the successful completion of at least 75 hours of clinical and didactic instruction in restorative functions accredited or provisionally accredited by the Commission on Dental Accreditation (CODA) of the American Dental Association.

(iii) Completion of a Board-approved certification program in expanded function dental assisting EFDA PROGRAM, WHICH OFFERS A CERTIFICATE OR DIPLOMA, CONSISTING of at least 200 hours of clinical and didactic instruction from a dental assisting program accredited by one of the following:

(A) The Commission on Dental Accreditation (CODA) of the American Dental Association.

(B) An accrediting agency approved by the United States Department of Education Council on Postsecondary Accreditation

whose expanded function educational standards are approved by the Board.

(2) The Board will approve EFDA programs that meet the criteria in § 33.117 (relating to EFDA program approval). A LIST OF BOARD-APPROVED EFDA PROGRAMS WILL BE MAINTAINED ON THE BOARD'S WEBSITE.

(3) Candidates for certification who receive their professional education outside the United States or from a nonaccredited program may satisfy the education requirement by submitting their credentials to a program listed in paragraph (1) and obtaining additional training that will lead to the awarding of a degree by that school.

[(3)] (4) This subsection does not apply to persons who are not required to meet the educational requirements under section (3)(d.1)(2) of the act.

* * * * *

§ 33.117. EFDA program approval.

(a) Definitions. The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Clinical setting –

(i) A setting in which expanded function dental assisting procedures are performed through direct patient care.

(ii) The term does not include any setting where procedures are performed on typodonts, manikins or by other simulation methods.

Clinical evaluation – An evaluation system based on observation of a student's performance of clinical skills in contexts that resemble those the student will be expected to encounter as an expanded function dental assistant in a dental office.

Clinical instruction – A learning experience in a clinical setting where the student performs expanded functions on patients under the supervision of an instructor.

Competencies – Statements describing the necessary requirements to perform each procedure set forth in § 33.205a (relating to practice as an expanded function dental assistant) to the level required to meet the acceptable and prevailing standard of care within the dental community in this Commonwealth.

Competent – Having sufficient knowledge, skill and expertise in performing expanded functions to meet and maintain the acceptable and prevailing standard of care within the dental community in this Commonwealth.

Laboratory or preclinical instruction – A learning experience in which students perform expanded functions using study models, typodonts, manikins or other simulation methods under the supervision of the instructor.

(b) Application. EFDA programs shall apply for Board approval on forms to be provided by the Board and pay the fee set forth in § 33.3 (relating to fees). The application must include the following information:

- (1) EFDA program goals and objectives.
- (2) Criteria for measuring competencies.
- (3) Documentation of accreditation as required by section 3(d.1) of the act (63 P.S. § 122(d.1)).
- (4) The curriculum vitae and job description of the EFDA program director.

(5) The curriculum vitae and job description of each faculty member assigned to the EFDA program.

(6) A description of the physical facilities and equipment used by the EFDA program for laboratory, preclinical and clinical instruction.

(7) A copy of the formal written agreement for the use of off-campus laboratory, preclinical or clinical facilities, if applicable.

(8) Course outlines, course descriptions or syllabi for the EFDA program curriculum.

(9) Other information RELATED TO THE EFDA PROGRAM requested by the Board.

(c) Requirements for approval. The Board will approve EFDA programs that meet the following requirements:

(1) Planning and assessment.

(i) The EFDA program shall delineate its program goals and objectives for preparing individuals in the expanded function dental assisting procedures set forth in § 33.205a to a level consistent with the acceptable and prevailing standard of care within the dental community in this Commonwealth.

(ii) The EFDA program shall develop specific criteria for measuring levels of competency for all procedures set forth in § 33.205a which must reflect the acceptable and prevailing standards and expectations of the dental community. Students shall be evaluated by faculty according to these predetermined criteria.

(iii) The EFDA program shall record and retain all student clinical evaluations as documentation of student competency for a minimum of 5 years from the student's graduation or completion of the EFDA program.

(2) Institutional accreditation. The EFDA program shall comply with the accreditation requirements of section 3(d.1) of the act (63 P.S. § 122(d.1)) and § 33.102(c)(relating to professional education).

(3) Program director. The EFDA program shall identify a program director who is responsible for and involved in the following:

(i) Student selection.

(ii) Curriculum development and implementation.

(iii) Ongoing evaluation of program goals, objectives, content and outcomes assessment.

(iv) Annual evaluations of faculty performance including a discussion of the evaluation with each faculty member.

(v) Evaluation of student performance and maintenance of competency records for 5 years from graduation or completion of the EFDA program.

(vi) Participation in planning for and operation of facilities used in the EFDA program.

(vii) Evaluation of the clinical training and supervision provided in affiliated offices and off-campus facilities, as applicable.

(viii) Maintenance of records related to the EFDA program, including instructional objectives and course outcomes.

(ix) Instruction of all licensed dentists overseeing off-campus clinical procedures performed by EFDA students to ensure that the policies and procedures of the off-campus facility are consistent with the philosophy and objectives of the EFDA program.

(4) Faculty. An EFDA program faculty member shall either be a dentist who holds a current license in good standing from the Board, or shall have or possess the following MEET ALL OF THE FOLLOWING CRITERIA:

- (i) A HOLD A current expanded function dental assistant certificate issued by the Board.
- (ii) A HAVE A minimum of 2 years of practical clinical experience as an expanded function dental assistant.
- (iii) Current HOLD National certification as a certified dental assistant (CDA) issued by the Dental Assisting National Board.
- (iv) Completed, or are in the process of completing, HAVE COMPLETED a course in education methodology of at least 3 credits or 45 hours offered by an accredited institution of postsecondary education, OR SHALL COMPLETE SUCH A COURSE NO LATER THAN 18 MONTHS AFTER EMPLOYMENT AS A FACULTY MEMBER.

(5) Facilities AND EQUIPMENT.

- (i) The EFDA program shall provide adequate physical facilities WHICH PROVIDE SPACE ADEQUATE TO THE SIZE OF ITS STUDENT BODY AND SUFFICIENT TO ENABLE IT TO MEET ITS EDUCATIONAL

OBJECTIVES and equipment for laboratory, preclinical and clinical instruction.

(ii) THE EFDA PROGRAM SHALL PROVIDE EQUIPMENT SUITABLE TO MEET THE TRAINING OBJECTIVES OF THE COURSE OR PROGRAM AND SHALL BE ADEQUATE IN QUANTITY AND VARIETY TO PROVIDE THE TRAINING SPECIFIED IN THE COURSE CURRICULUM OR PROGRAM CONTENT.

(iii) If the EFDA program contracts for off-campus laboratory, preclinical or clinical instruction facilities, the following conditions must be met:

(A) There must be a formal written agreement between the EFDA program and the laboratory, preclinical or clinical facility.

(B) In off-campus clinical facilities, a licensed dentist shall oversee all dental procedures performed on patients by EFDA program students. The licensed dentist shall receive instruction to ensure that the policies and procedures of the off-campus facility are consistent with the philosophy and objectives of the EFDA program.

(iii) (iv) The standards in this paragraph are equally applicable to extramural dental offices or clinic sites used for clinical practice experiences, such as internships or externships.

(6) Curriculum. The curriculum of an EFDA program must consist of the following components:

(i) General education. The EFDA program shall include general education subjects as determined by the educational institution with a goal of preparing the student to work and communicate effectively with patients and other health care professionals.

(ii) Dental sciences. The EFDA program shall include content in general dentistry related to the expanded functions set forth in SECTION 11.10(a) OF THE ACT (63 P.S. § 130k(a)), and as set forth in § 33.205a, including courses covering the following topics:

- (A) Dental anatomy.
- (B) Occlusion.
- (C) Rubber dams.
- (D) Matrix and wedge.
- (E) Cavity classification and preparation design.
- (F) Bases and liners.
- (G) Amalgam restoration.
- (H) Composite restoration.
- (I) Sealants.
- (J) Crown and bridge provisional fabrication.
- (K) Dental law and ethics.
- (L) CORONAL POLISHING.
- (M) FLUORIDE TREATMENTS, INCLUDING FLUORIDE VARNISH.

(N) TAKING IMPRESSIONS OF TEETH FOR STUDY MODELS, DIAGNOSTIC CASTS AND ATHLETIC APPLIANCES.

(iii) *Clinical experience component.* The EFDA program shall include a minimum of 120 hours of clinical experience performing expanded function dental assisting procedures as an integral part of the EFDA program. The clinical experience component shall be designed to achieve a student's clinical competence in each of the expanded function dental assisting procedures set forth in § 33.205a.

(7) *Demonstrating competency.*

(i) *General education.* Students of the EFDA program shall be required to demonstrate competency in general education subjects by attaining a passing grade on written or oral examinations.

(ii) *Laboratory and preclinical instruction.* Students of the EFDA program shall be required to demonstrate competency by attaining a score of at least 80% in all laboratory and preclinical courses. Students shall be required to demonstrate the knowledge and skills required to:

(A) Carve the anatomy of all teeth.

(B) Establish proper contact areas, embrasures, marginal adaptation, as well as facial and lingual heights of contour so as to restore the proper tooth form and function in all restorative materials COMMONLY USED FOR DIRECT RESTORATIONS, SUCH AS AMALGAM AND COMPOSITE RESIN.

- (C) Apply the basic concepts and terms of occlusion and carving concepts in the restoration of proper occlusal relationships.
 - (D) Describe the problems associated with improper contouring of restorations.
 - (E) Identify and differentiate G.V. Black's cavity classifications.
 - (F) Select, prepare, assemble, place and remove a variety of matrices and wedges.
 - (G) Place and finish Class I – VI restorations with correct marginal adaptation contour, contact and occlusion.
 - (H) Assemble, place and remove rubber dams.
 - (I) Place sealants.
 - (J) Crown and bridge provisional fabrication.
 - (K) Understand the Dental Law and this chapter as they apply to an expanded function dental assistant's responsibilities.
 - (L) PERFORM CORONAL POLISHING.
 - (M) PERFORM FLUORIDE TREATMENTS, INCLUDING FLUORIDE VARNISH.
 - (N) TAKE IMPRESSIONS OF TEETH FOR STUDY MODELS, DIAGNOSTIC CASTS AND ATHLETIC APPLIANCES.
- (iii) *Clinical experience.* EFDA program students shall be evaluated and deemed clinically competent by at least one licensed dentist evaluator

in a clinical setting. The EFDA program director shall instruct the dentist clinical evaluators regarding the required competencies to ensure consistency in evaluation. Clinical competency is achieved when the dentist evaluator confirms the student has sufficient knowledge, skill and expertise in performing expanded functions to meet and maintain the acceptable and prevailing standard of care within the dental community in this Commonwealth.

(iv) Documenting competency.

(A) The EFDA program faculty and program director shall document the student's general education, preclinical and laboratory competency attainment.

(B) The licensed dentist evaluator shall document the student's clinical competency attainment prior to graduation from the EFDA program.

(C) The EFDA program director shall provide documentation of SIGN A STATEMENT CERTIFYING the student's competency attainment IN GENERAL EDUCATION, LABORATORY AND PRECLINICAL INSTRUCTION, AND CLINICAL EXPERIENCE to the Board as part of the student's application for certification as an expanded function dental assistant.

(D) The EFDA program shall retain SUPPORTING DOCUMENTATION EVIDENCING the student's competency

documentation ATTAINMENT for a minimum of 5 years from graduation or completion of the EFDA program.

(d) Refusal or Withdrawal of approval. The Board may refuse to approve an EFDA program or may remove an EFDA program from the approved list if it fails to meet and maintain the requirements set forth in this section, in accordance with the following:

- (1) The Board will give an EFDA program notice of its provisional denial of approval or of its intent to remove the program from the approved list.
- (2) The notice will set forth the requirements that are not being met or maintained by the EFDA program.
- (3) A program served with a provisional denial or notice of intent to remove will be given 45 days in which to file a written answer to the notice.
- (4) The EFDA program will be provided an opportunity to appear at a hearing to demonstrate why approval should not be refused or withdrawn.
- (5) The Board will issue a written decision.
- (6) The Board's written decision is a final decision of a governmental agency subject to review under the Administrative Agency Law, 2 Pa. C.S. § 702.

(e) ***BIENNIAL RENEWAL OF EFDA PROGRAM APPROVAL.*** EFDA PROGRAM APPROVALS ARE RENEWABLE FOR A 2-YEAR PERIOD BEGINNING ON APRIL 1 OF EACH ODD-NUMBERED YEAR. AN EFDA PROGRAM SHALL APPLY FOR RENEWAL OF BOARD APPROVAL ON FORMS PROVIDED BY THE BOARD AND PAY THE FEE FOR BIENNIAL RENEWAL SET FORTH IN § 33.3 (RELATING TO FEES). UPON APPLYING FOR RENEWAL, THE EFDA PROGRAM SHALL UPDATE ALL OF THE INFORMATION REQUIRED BY

SUBSECTION (b)(1)-(9) OR CERTIFY THAT THERE HAVE BEEN NO CHANGES
TO THE EFDA PROGRAM.

* * * * *

LIST OF COMMENTATORS
REGULATION 16A-4616

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November 9, 2011

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Dentistry
16A-4616: EFDA PROGRAM APPROVAL

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Dentistry pertaining to EFDA Program Approval.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,



Philip T. Siegel, DDS, Chairperson
State Board of Dentistry

PTS/CKM:rs

Enclosure

cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Sabina I. Howell, Counsel
State Board of Dentistry
State Board of Dentistry

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-4616

SUBJECT: EXPANDED FUNCTION DENTAL ASSISTANTS

AGENCY: DEPARTMENT OF STATE
STATE BOARD OF DENTISTRY

TYPE OF REGULATION

Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation

a. With Revisions

b.

Without Revisions

RECEIVED
IRRC

2011 NOV - 9 A 10:54

FILING OF REGULATION

DATE

SIGNATURE

DESIGNATION

HOUSE COMMITTEE ON PROFESSIONAL LICENSURE

11/9/11 Annie Kelly

MAJORITY CHAIRMAN Julie Harhart

SENATE COMMITTEE ON CONSUMER PROTECTION &
PROFESSIONAL LICENSURE

11/9/11 Mary Walmer

MAJORITY CHAIRMAN Robt. M. Tomlinson

INDEPENDENT REGULATORY REVIEW COMMISSION

ATTORNEY GENERAL (for Final Omitted only)

LEGISLATIVE REFERENCE BUREAU (for Proposed only)