Regulatory Analysis For	1 INDEPENDENT REGULATORY REVIEW COMMISSION					
(Completed by Promulgating Agency)	8					
(All Comments submitted on this regulation will appear on IRR						
(1) Agency: Department of State, Bureau of Professional and	29					
Occupational Affairs, State Board of Osteopathic	Medicine					
(2) Agency Number: 16A	Ģ					
Identification Number: 5321	IRRC Number: 2941.					
(3) PA Code Cite: 49 Pa. Code §§ 25.141, 25.142, 2 25.201, 25.215, 25.231, 25.501-25.510	5.161, 25.163, 25.164, 25.176, 25.191, 25.192,					
(4) Short Title: Physician Assistant and Respirator	y Therapist					
(5) Agency Contacts (List Telephone Number and En	nail Address):					
Primary Contact: Teresa Lazo, Board Counsel, State Board of Osteopathic Medicine, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251); tlazo@pa.gov.						
Secondary Contact: Cynthia K. Montgomery, Regu Medicine P.O. Box 2649, Harrisburg, PA 17105- llboyle@pa.gov.	•					
(6) Type of Rulemaking (check applicable box):						
Proposed Regulation	Emergency Certification Regulation;					
X Final Regulation Final Omitted Regulation	Certification by the Governor Certification by the Attorney General					
(7) Briefly explain the regulation in clear and nontech	nical language. (100 words or less)					
The act of July 4, 2008 (P.L. 589, No. 46) (Act 46) amended the Osteopathic Medical Practice Act (the act) (63 P.S. §§ 271.1 – 271.18) to specify additional authorized acts of practice for physician assistants and to require physician assistants to complete continuing education as a condition of license renewal and have malpractice insurance. Additionally, the act of July 2, 2004 (P.L. 486, No. 56) (Act 56) amended section 10(f) of the act (63 P.S. § 271.10(f)) to provide that the Board shall grant licensure, rather than certification, to physician assistants. Act 46 also amended the act to provide for licensure of respiratory therapists, rather than certification of respiratory care practitioners, and to increase the required amount of continuing education for respiratory therapists from 20 to 30 hours during a biennial period.						
(8) State the statutory authority for the regulation. Inc	lude specific statutory citation.					
The amendments are authorized under section Osteopathic Medical Practice Act (act) (63 P.S. §	ons 10(f), 10(h), 10.1(c), 10.2(f) and 16 of the § 271.10(h), 271.10a(c), 271.10b(f), and 271.16).					

(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.

Yes, the State Board of Osteopathic Medicine (Board) makes these changes to conform the Board's regulations to the amendments made to the act by Act 46 of 2008 and Act 56 of 2004.

(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.

The rulemaking is required to implement the Act 46 and Act 56 amendments to the act.

(11) 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 federal licensure standards for physician assistants or respiratory therapists.

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

This rulemaking implements the statutorily-mandated revisions to licensure. For physician assistants, according to the Pennsylvania Society for Physician Assistants (PSPA), the National Commission on Certification of Physician Assistants (NCCPA) requires all physician assistants in all states to obtain 100 hours of continuing medical education. According to the American Academy of Physician Assistants (AAPA) data taken from the 2008 and 2007 AAPA Physician Assistant Census Surveys, physician assistants carry professional liability insurance. Therefore, the requirements in this regulation, as mandated by Act 46, would not put Pennsylvania at a competitive disadvantage for physician assistants.

For respiratory therapists, the American Association for Respiratory Care (AARC) maintains a website at http://www.aarc.org/advocacy/state/2000 licensure matrix.html#matrix, which lists the continuing education requirements in other states. Pennsylvania and four other states (GA, NY, SC and WA) require 30 hours of continuing education in a biennial period. Of the remaining states, 12 states require 24 hours biennially, while 14 require 20 hours biennially. Because Pennsylvania is among the 5 states that require the most continuing education, it does not necessarily mean that Pennsylvania is at a competitive disadvantage. Requiring a greater number of continuing education hours biennially protects public health and safety for those who rely on the skills and education of respiratory therapists. Therefore, this regulation, by implementing the statutory mandate of Act 46, would not put Pennsylvania at a competitive disadvantage for respiratory therapists.

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

The regulation will not affect other regulations of the Board or other state agencies.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

Because much of this proposed rulemaking is statutorily mandated, the Board did not send an exposure draft of the proposed rulemaking to interested parties. However, after the Pennsylvania Society for Respiratory Care, Inc. (PSRC) filed public comments on June 7, 2012, the Board's assistant regulatory counsel and Board staff communicated with PSRC to address its public comments, as further detailed in the Preamble. Furthermore, the Board discussed the proposed rulemaking at public meetings of the Board, which are routinely attended by members of the regulated community and their professional associations.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

There are currently approximately 965 physician assistants licensed by the Board in Pennsylvania. According to the Pennsylvania Department of Labor and Industry in 2010, the majority of physician assistants work in offices of physicians (58.4%), while a minority of physician assistants are employed in general medical and surgical hospitals (23.0%), work in outpatient care centers (5.1%), or work for the federal government (1.6%). Other physician assistants work in dentist offices, psychiatric and substance abuse hospitals, and other health practitioner offices.

There are currently approximately 488 respiratory therapists licensed by the Board in Pennsylvania. According to the Pennsylvania Department of Labor and Industry in 2010, the majority of respiratory therapists work in general medical and surgical hospitals (70.0%), while a minority of respiratory therapists work in retail health and personal care stores (1.5%), work for commercial goods wholesalers (1.5%), or are employed in physician offices (1.4%). Other respiratory therapists are employed in nursing care facilities, other hospitals, and durable medical equipment firms.

According to the Small Business Administration (SBA), there are approximately 982,692 businesses in Pennsylvania; of which 978,831 are small businesses. Of the 978,831 small businesses, 236,775 are small employers (those with fewer than 500 employees) and the remaining 772,056 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses.

For the business entities listed above for physician assistants and respiratory therapists, small businesses are defined in Section 3 of Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's (SBA) Small Business Size Regulations under 13 CFR Ch. 1 Part 121. Specifically, the SBA has established these size standards at 13 CFR 121.201 for types of businesses under the North American Industry Classification System (NAICS).

In applying the NAICS standards to the types of businesses where physician assistants work, a small business in offices of physicians is one with \$10.0 million or less in average annual receipts. A small business in general medical and surgical hospitals is one with \$35.5 million or less in average annual receipts. According to the NAICS, small businesses in outpatient care centers have \$19.0 million or less in average annual receipts. For other businesses where physician assistants work, these businesses are considered small businesses if they have less than the following average annual receipts: dentist offices with \$7.0 million; psychiatric and substance abuse hospitals with \$35.5 million; and other health practitioner offices with \$7.0 million. Therefore, most physician assistants probably work in small businesses in this Commonwealth.

In applying the NAICS standards to the types of businesses where respiratory therapists work, as noted above, a small business in general medical and surgical hospitals is one with \$35.5 million or less in average annual receipts, while a small business in offices of physicians is one with \$10.0 million or less in average annual receipts.. A small business in retail health and personal care stores is one with \$7.0 million in average annual receipts, while a business in commercial goods wholesalers has at least 100 employees. For other businesses where respiratory therapists work, these businesses are considered small businesses if they have less than the following average annual receipts: nursing care facilities with \$25.5 million; other hospitals with \$35.5 million and consumer goods rental shops with \$7.0 million. Therefore, most respiratory therapists probably work in small businesses in this Commonwealth.

Although many licensed respiratory therapists either are or work in small businesses, whether or not the small businesses that employ respiratory therapists will be adversely affected by the increased amount of continuing education (CE) hours from 20 to 30 during a biennial period, and to what extent, is subject to many factors. First, as noted in the answers to questions 17 and 19, not all CE courses require licensees to pay for the continuing education. Second, some licensees working in a variety of small businesses will have their CE costs (if any) paid for by their employers, while other licensees will pay for their continuing education costs themselves. Finally, it is important to note that it was the Pennsylvania General Assembly in enacting Act 46 in 2008 that increased the number of required CE hours from 20 to 30 during a biennial period. Thus, the Board is required to increase the CE for respiratory therapists under § 25.509a(a)(1) due to the statutory mandate at section 10.2(f)(2) of the act, 63 P.S. § 271.10b(f)(2). Therefore, the costs of complying with the increased CE requirement will fall to some extent upon small business, depending on whether those who employ respiratory therapists pay for their CE costs. According to the Pennsylvania Society for Respiratory Care, Inc. (PSRC), approximately 20% of employers reimburse respiratory therapists for their continuing education costs.

Likewise, for physician assistants, due to two requirements of Act 46 of 2008, the small businesses in which they work will incur costs for CE and professional liability insurance. The CE is required by the National Commission on Certification of Physician Assistants (NCCPA) under new § 25.163(c), as required by section 10(f) of the act (63 P.S. § 271.10(f)) for biennial renewal of licensure for physician assistants. (Prior to the enactment of Act 46 in 2008, according to the

Pennsylvania Society for Physician Assistants (PSPA), the NCCPA had required CE, but Act 46 required the CE be completed as a condition of biennial license renewal.) The small businesses that employ physician assistants may also incur costs for professional liability insurance coverage of at least \$1,000,000 per occurrence or claim made, which is required by section 10(g.3) of the act (63 P.S. § 271.10(g)(3)) which is referenced under new § 25.164. (According to the PSPA, physician assistants had always had malpractice insurance coverage prior to the enactment of Act 46, which set a minimum coverage amount of \$1,000,000 per occurrence or claim made.) As with respiratory therapists, whether or not the small businesses that employ physician assistants will have to pay for the costs of the physician assistants' CE and professional liability insurance depends upon whether the small businesses or the physician assistants pay for these costs. According to the American Academy of Physician Assistants (AAPA) data taken from the 2008 and 2007 AAPA Physician Assistant Census Surveys received by clinically practicing physician assistants who work 32 or more hours per week for their primary clinical employer and are not self-employed, 98% of employers of physician assistants pay for 95 to 100% of a physician assistant's professional liability insurance. This insurance is the most commonly reimbursed fringe benefit for physician assistants. The AAPA 2008 and 2007 Surveys also indicated that 90% of physician assistants participating in the surveys receive CE funding from their primary employer. Therefore, most employers of physician assistants who work 32 or more hours per week for their primary clinical employer and are not self-employed pay for the costs of their CE and professional liability insurance.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

There are approximately 965 physician assistants and 488 respiratory therapists licensed by the Board, including those who work for small businesses, who will be required to comply with the rulemaking.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The regulation will have only a minor fiscal impact on respiratory therapists, who must take an additional 10 credit hours of continuing education (CE) during a biennial period due to the requirement of Act 46 of 2008. Because the costs of CE vary from one course provider to another, a precise estimate of the increased costs is not possible. According to the Pennsylvania Society for Respiratory Care, Inc. (PSRC), many courses are offered free of charge. Most hospital respiratory therapy departments also allow companies to provide a lecture at their facility for their staff to attend at no charge as well as offer "grand rounds," which are performed in their Intensive Care Units (ICUs). Print publications (such as Saxe Healthcare Communications at http://www.saxetesting.com) are also offered online at no charge.

Other CE courses for respiratory therapists are offered at no or low cost. The American Association for Respiratory Care (AARC) is the national professional association for respiratory therapists, which has an annual membership fee of \$90; included with the membership is access to

free webinar programs that are recognized as live courses on its website at http://www.aarc.org/education/webcast_central/. If no other benefits of membership are used, the biennial cost to comply with the CE requirement would be \$45. A membership in AARC also includes membership in the PSRC, which offers CE in all major Pennsylvania cities for courses that average no more than \$10 per hour of credit for members. Finally, there are multiple feebased online course providers that charge \$10 to \$15 per course hour, such as Respiratory Associates of Texas (http://www.ganesco.com/index.php?sect=testlist), and RCECS (https://www.reces.com). Therefore, for the increased cost of 10 hours of continuing education during a biennial period, the Board estimates a cost of \$50 per year. For 488 respiratory therapists licensed by the Board, the approximate increased cost is a total of \$19,520 (488 licensees x .8 [percent of licensees not reimbursed] x \$50).

The additional requirement of 10 hours of CE may or may not affect the employers of respiratory therapists depending upon whether the employers reimburse the respiratory therapists for the costs of continuing education. According to the PSRC, approximately 20% of employers reimburse respiratory therapists for their continuing education costs.

Act 46 of 2008 imposed two types of costs upon physician assistants. First, Act 46 required physician assistants to complete continuing education (CE) as required by the National Commission on Certification of Physician Assistants (NCCPA) as a condition of licensure renewal. Second, Act 46 required physician assistants to maintain professional liability insurance.

The NCCPA requires physician assistants to take 100 hours of CE every 2 years and pass a recertification exam every 6 years. As with the cost of CE for respiratory therapists, the costs of CE for physician assistants varies greatly. Several entities provide free continuing education—hospitals, online courses and regional association meetings of the Pennsylvania Society for Physician Assistants (PSPA). Furthermore, at PSPA state and national meetings, low cost CE is offered at a rate of approximately \$15 to \$20 per credit hour. Physician assistants may also attend physician conferences, where the CE costs may be greater. An estimate of the varied costs of CE for physician assistants is approximately \$10 per credit hour. With 100 hours required every two years, that comes to a cost of \$1,000 every 2 years or \$500 per year for each licensed physician assistant. For 965 licensed physician assistants licensed in Pennsylvania, the approximate CE cost is a total of \$482,500 per year.

Act 46 also required physician assistants to maintain professional liability insurance. As with the costs of CE, the costs of insurance for physician assistants vary greatly, depending upon the amount of insurance purchased, the area of specialty, the practice setting, the geographic location and whether the physician assistant works full-time or part-time. For further information on the range of insurance costs, see the link for one such insurance carrier, the American Academy of Physician Assistants, at http://www.aapa.org/your pa career/malpractice insurance.aspx. For example, insurance costs can vary from \$2,760 a year for a part-time physician assistant to \$4,246 a year for a full-time physician assistant, or an average of \$3,503 per year. For the 965 licensed physician assistants in Pennsylvania, the average professional liability insurance cost is approximately \$3,380,395 per year. Therefore, the combined CME and insurance costs for all licensed physician assistants is \$3,862,895 per year. As noted in the answer to question 15, most employers (most of which are probably small businesses) of physician assistants (who work 32 or more hours per week for their primary clinical employer and are not self-employed) reimburse them for the costs of CE and professional liability insurance.

Not all of the financial and economic impact of the regulation will be negative due to the increased amount of 10 hours of continuing education required of respiratory therapists and the continuing education that the NCCPA requires of physician assistants. Those businesses and associations that are course providers for continuing education will benefit from continuing education to these licensees.

The regulation is beneficial to ensure that the Board regulations conform to current statutory changes and do not cause confusion in the regulated communities or in the general population. Furthermore, the regulated communities and the public will benefit from these changes because respiratory therapists will be required to take more continuing education, and physician assistants will be required to take continuing education for biennial renewal and carry professional liability insurance. This will hopefully result in increased public health and safety for the work done by respiratory therapists and physician assistants.

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

The regulated community, the public and those who receive the services of respiratory therapists will benefit from these changes because respiratory therapists will be required to take more continuing education. Likewise, requiring continuing education and professional liability insurance for physician assistants will protect public health and safety as well as the medical professionals who depend upon physician assistants. Finally, the regulation will benefit the regulated communities, those who contract for the services of these licensees and the public by ensuring that board regulations are consistent with the amendments to the act made by Act 46 of 2008 and will not be a source of confusion.

(19) 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.

See the answer to question 17 for information on the varied costs for both respiratory therapists and physician assistants. The estimated annual cost for respiratory therapists is as follows: (488 licensees x .8 (percent of licenses not reimbursed) x \$50 = \$19,520.

Physician assistants are required by Act 46 of 2008 to take continuing medical education (CE) as required by the NCCPA and to maintain professional liability insurance. For 965 licensed physician assistants in Pennsylvania, the approximate CE cost is a total of \$482,500 per year, and the average professional liability insurance cost is approximately \$3,380,395 per year. Therefore, the combined CE and insurance costs for all licensed physician assistants is \$3,862,895 per year, which are usually paid for by the employers of physician assistants who work 32 or more hours per week for their primary clinical employer and are not self-employed.

(20) Provide a specific estimate of the costs and/or savings to the 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 compliance with the rulemaking.
(21) Provide a specific estimate of the costs and/or savings to the 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.
The Department randomly audits licensees for compliance with the continuing education requirements. Increasing the number of CE credits for respiratory therapists and requiring physician assistants to complete CE as a condition of renewal will require Department staff to devote more time to this audit process. However, the Department does not maintain records of the
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
time specifically devoted to the audit process, so an estimate is not available.
(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal,
(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork,
(22) For each of the groups and entities identified in items (19)-(21) above, 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
(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork,
(22) For each of the groups and entities identified in items (19)-(21) above, 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
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to
(22) For each of the groups and entities identified in items (19)-(21) above, 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. Because this regulation is required by Act 46 of 2008, there is no way to minimize any paperwork requirements. Reporting forms must be changed to reflect the change in the required number of continuing education credits that a respiratory therapist must take. Licensees will still need to

(23) 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	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	Year \$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community – Respiratory Therapists	\$0	\$19,520	\$19,520	\$19,520	\$19,520	\$19,520
Regulated Community – Physician Assistants	\$3,380,395	\$3,862,895	\$3,862,895	\$3,862,895	\$3,862,895	\$3,862,895
Local Government		·				
State Government						
Total Costs	\$3,380,395	\$3,882,415	\$3,882,415	\$3,882,415	\$3,882,415	\$3,882,415
REVENUE LOSSES:						
Regulated Community						
Local Government			-			
State Government						
Total Revenue Losses	N/A	N/A	N/A	N/A	N/A	N/A

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
	(FY 2009-10)	(FY 2010-11)	(FY 2011-12)	(Budgeted)
State Board of Osteopathic Medicine	\$843,184.15	\$918,199.50	\$967,480.10	\$1,006,000.00

⁽²⁴⁾ For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.

- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.
- (a) As noted in the answer to question 15, there are 965 licensed physician assistants and 488 licensed respiratory therapists licensed by the Board in Pennsylvania. In considering all of the small business thresholds set by NAICS for the businesses in which these licensees work, it is probable that most of these licensees work in small businesses. However, it is not possible to provide an estimate of the total number of small businesses subject to the regulation.
- (b) As stated in the answers to questions 17 & 19, the additional cost to each respiratory therapist for 10 additional credit hours of continuing education is approximately \$ 50 per year. For each physician assistant, the cost of CE is approximately \$500 per year, and the cost of professional liability is on the average approximately \$3,500 per year. As noted above, these amounts can vary greatly depending on the number and type of different courses that a licensee takes to fulfill the continuing education requirements.
- (c) As discussed in the answer to question 15, while many respiratory therapists and physician assistants are probably employed in small businesses, the probable effect upon small businesses depends upon whether the employers of respiratory therapists pay for their continuing education. Likewise, for physician assistants, the probable effect upon small businesses depends upon whether the employers of physician assistants pay for their continuing education and professional liability insurance.
- (d) There are no less intrusive or less costly alternative methods of achieving the purpose of the final regulation because the increase of 10 additional hours of biennial continuing education for respiratory therapists was mandated by the General Assembly in Act 46 of 2008. Likewise, for physician assistants, Act 46 of 2008 mandated continuing education that is required by the NCCPA as well as professional liability insurance.
- (25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

No special provisions are required to address any particular group because the increase of 10 additional hours of biennial continuing education for respiratory therapists was mandated by the General Assembly in Act 46 of 2008. Likewise, for physician assistants, Act 46 of 2008 mandated continuing education that is required by the NCCPA, as well as professional liability insurance.

(26) 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.

Because this final rulemaking incorporates the statutory language of Act 46 of 2008, which added 10 hours of biennial continuing education for respiratory therapists and mandated for physician assistants continuing education that is required by the NCCPA, as well as professional liability insurance, no alternative regulatory provisions would accomplish the goal of the regulation.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Because this final rulemaking incorporates the statutory language of Act 46 of 2008, which added 10 hours of biennial continuing education for respiratory therapists and mandated for physician assistants continuing education that is required by the NCCPA as well as professional liability insurance, no regulatory methods were considered that will minimize any adverse impact on small businesses. Because most physician assistants and respiratory therapists work for small businesses, exempting small business from any part of the requirements would be inconsistent with the statute and would be contrary to public safety and welfare.

(28) If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> 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.

This rulemaking is not based upon any scientific data, studies or references.

(29) Include a schedule for review of the regulation including	:
A. The date by which the agency must receive public of	comments: <u>N/A</u>
B. The date or dates on which public meetings or hear will be held:	ings <u>N/A</u>
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	<u>Fall 2013</u>
D. The expected effective date of the final-form regula	etion: <u>Fall 2013</u>
E. The date by which compliance with the final-form regulation will be required:	Upon final publication
F. The date by which required permits, licenses or othe approvals must be obtained:	er <u>Upon final publication</u>

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally 4-6 meetings a year. The remaining meeting dates scheduled for 2013 are: June 12, August 14, October 9 and December 11. More information can be found on the Board's website (www.dos.state.pa.us/ost).

RECEIVED IRRC

FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

2013 OCT 29 M 10: 33

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

	<u> </u>		
	below is hereby approved as to and legality. Attorney General	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by	Copy below is approved as to seem and legality. Executive or Independent Agencies.
		State Board of Osteopathic Medicine	Which >1 X
BY:	(DEPUTY ATTORNEY GENERAL)	(AGENCY)	SHAWN E. SMITH
	DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 16A-5321	OCT 0 9 2013
	DATE OF REPROVAL	DATE OF ADOPTION: BY: Samuel I Garloff, D.O.	Deputy General Counsel Chief Counsel, Independent Agency (Strike inapplicable title)
[]	Check if applicable Copy not approved. Objections attached. Check if applicable. No Attorney General approval or objection within 30 day after submission	TITLE: Chairman (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

STATE BOARD OF OSTEOPATHIC MEDICINE

49 Pa. Code Ch. 25, Subchs. C, D and K ACT 46 OF 2008 - PHYSICIAN ASSISTANT AND RESPIRATORY THERAPIST

The State Board of Osteopathic Medicine (Board) hereby amends §§ 25.141, 25.142, 25.161, 25.163, 25.176, 25.191, 25.192, 25.201, 25.215, 25.231, and 25.501 – 25.510; and adds § 25.164 (relating to professional liability insurance coverage for licensed physician assistants) 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 amendments are authorized under sections 10(f) and (h), 10.1(c), 10.2(f) and 16 of the Osteopathic Medical Practice Act (act) (63 P.S. §§ 271.10(f) and (h), 271.10a(c), 271.10b(f) and 271.16).

Background and Need for the Amendment

The act of July 4, 2008 (P.L. 589, No. 46) (Act 46) amended the act to change references to the "certification of respiratory care practitioners" to "licensure of respiratory therapists" and revised the standards for licensure as a respiratory therapist and for receipt of a temporary practice permit. Act 46 also identified additional specific acts of practice for physician assistants and required physician assistants to complete continuing education and maintain professional liability insurance. Additionally, the act of July 2, 2004 (P.L. 486, No. 56) (Act 56) amended section 10(f) of the act (63 P.S. § 271.10(f)) to provide that the Board shall grant licensure, rather than certification, to physician assistants. This final rulemaking amends the Board's regulations to implement these changes.

Summary of Comments to Proposed Rulemaking and the Board's Response

The Board published notice of proposed rulemaking in the *Pennsylvania Bulletin* on May 12, 2012, at 42 Pa. B. 2474, followed by 30 days of public comment. The Board received public comments from the Pennsylvania Society for Respiratory Care, Inc. (PSRC). The Board also received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review under the Regulatory Review Act (71 P.S. §§ 745.1 – 745.14).

Comments from the Pennsylvania Society for Respiratory Care, Inc.

PSRC sent the Board four comments on June 7, 2012. Regarding § 25.507(1)(i) (relating to criteria for licensure as a respiratory therapist), PSRC requested that the Board identify the "credentialing examination" as the examination for entry to practice rather than the "CRTT." IRRC agreed. In addition to making this change, the Board similarly clarified the examination in § 25.506(b) (relating to temporary permits), a necessary amendment noted by the HPLC.

PSRC also recommended that the Board completely eliminate § 25.506 (relating to temporary permits). PSRC opined that temporary permits are unnecessary because graduates may now schedule the entry level examination immediately upon graduation. Act 46 revised qualifications of applicants for a temporary permit, such that section 10.2(b) of the act (63 P.S. § 271.10b(b)) sets forth the criteria for the Board issuing a temporary permit to individuals who have applied for licensure and section 10.2(c) of the act sets forth the duration and effect of temporary permits. These recent amendments indicate that the General Assembly has reaffirmed the viability of temporary permits for respiratory therapists and, accordingly, the Board believes that it lacks statutory authority to eliminate temporary permits.

In addition, the Board believes there is some value to retaining temporary permits. A temporary permit to practice is valid for 12 months, unless the holder fails the entry level credentialing examination. Upon notification to the permit holder that the examination attempt was not successful, the permit becomes null and void. An applicant is not required to obtain a temporary permit, but may apply for a temporary permit to allow practice prior to the time the applicant takes the licensing examination, while the applicant is waiting for the examination results, or while the applicant's application for licensure is being processed. In short, a temporary permit bridges any time gap that may occur between graduation and licensure and allows graduates to become employed without delay.

PSRC also recommended changes to § 25.509a (relating to requirement of continuing education). First, PSRC questioned whether this subsection applied to new graduates. In response, the Board rewrote subsection (b) for clarity to read: "An individual applying for the first time for licensure in this Commonwealth is exempt from completing the continuing education requirements during the initial biennial renewal period in which the license is issued." This language exempts from the continuing education requirement the three types of applicants who may obtain initial Pennsylvania licensure: 1) new graduates from Pennsylvania; 2) new graduates from other states; and 3) licensees in other states who are seeking licensure in Pennsylvania.

Second, PSRC suggested eliminating the exemption for licensees in other states who are seeking licensure in Pennsylvania who are not "new graduates." The Board declines to make this change. Continuing education is required for license renewal in the 48 states where respiratory therapists are licensed. If a practicing respiratory therapist from another state applies for a license in Pennsylvania and has not taken as many hours of continuing education as now required in Pennsylvania, that individual will still have both experience and knowledge gained while practicing in another state. The exemption is applied to only the first biennial renewal period for all of the allied health professionals licensed by the Board. Finally, eliminating the exemption would be time consuming and difficult for the Board to administer because it would require the Board to distinguish between licensees whose initial license was granted in Pennsylvania and licensees whose initial license was granted by another state. For all of these reasons, the Board maintains that the new language it has added to § 25.509a(b) clarifies this subsection and that further changes are not necessary or warranted.

Finally, at § 25.509b(a) (relating to approved educational courses), PSRC had asked the Board to approve advanced life support courses accredited by the American Heart Association

(AHA) or similar groups. AHA advanced life support courses are approved by the American Medical Association (AMA). The Board's current regulation at § 25.509b(a) already provides approval for AMA-approved continuing education programs. Therefore, AHA advanced life support courses are already approved as CE for Respiratory Therapists.

Comments from the House Professional Licensure Committee

On June 13, 2012, HPLC submitted comments. The first comment noted the Board's timing for the submission of these regulations as proposed. The Board respectfully understands the Committee's comments and will work to provide more timely proposed regulations in the future.

Second, as noted previously, HPLC suggested that with the deletion of CRTT in the definitions section of the regulations, § 25.506(b) should be amended to refer to the "credentialing examination." The Board made this change and also amended § 25.507(1)(i) to add "entry level" before "credentialing examination" to accurately identify the required examination.

Comments from the Independent Regulatory Review Commission

On July 11, 2012, IRRC submitted seven comments. First, IRRC pointed out that the "Note" section of Act 46 requires the Board and the State Board of Medicine to jointly promulgate these regulations. The act and the Medical Practice Act of 1985 (63 P.S. §§ 422.1 – 422.51a) authorize each board to license and regulate only those who practice under each act, respectively. The amendments to each act in Acts 45 and 46 do not change which board licenses and regulates the professionals under the jurisdiction of each board. Likewise, the boards do not jointly license or regulate the professionals under the jurisdiction of each board. Each board promulgated similar proposed regulations and now adopts substantially identical final regulations. By promulgating these regulations at the same time, all of the statutorily mandated changes will be effective at the same time, regardless of which board has jurisdiction over an individual practitioner. The board believes this process meets with the statutory intent.

With respect to Subchapter C (relating to physician assistant provisions), IRRC raised two issues. First, IRRC noted that § 25.163(c) (now relating to approval and effect of licensure; biennial renewal of physician assistants; registration of supervising physicians) requires physician assistants to maintain national certification and recommended that the final-form regulation should identify the recertification mechanisms recognized by the Board or identify how a physician assistant can access this information. The Board adds to the first sentence of this subsection a reference to the National Commission on Certification of Physician Assistants (NCCPA) and directs physician assistants to the NCCPA's website (currently www.nccpa.net) to access the information.

Second, IRRC recommended that the Board clarify where it will publish any future recognition of an organization's certification of physician assistants. The Board addressed this request at § 25.163(c), noting that any additional National certification organization will be announced on the Board's website (www.dos.state.pa.us/ost).

IRRC's remaining comments addressed Subchapter K relating to respiratory therapists. IRRC indicated some confusion in § 25.506(a), which refers to an individual "who is recognized as a **credentialed respiratory therapist**..." (Emphasis added by IRRC.) The Board amended this subsection to clarify that an applicant for a temporary permit would not yet be a licensee of the board. The reference to a "credentialed respiratory therapist" is intended to mean an individual who holds one of the credentials issued by the National Board for Respiratory Care (NBRC).

At § 25.506(b), IRRC echoed the suggestion made by HPLC to replace "CRTT" with "credentialing examination" The change has been made. IRRC also agreed with PSRC's comment regarding replacing the term "credentialing examination" with "entry level credentialing examination," changes which were also made at § 25.507(1)(i).

IRRC made two recommendations at § 25.509a (relating to requirement of continuing education). First, IRRC recommended that the Board address in the Regulatory Analysis Form (RAF) any additional costs that the increase in the minimum number of mandatory continuing education hours will impose on the regulated community. The Board has added this analysis in the RAF. Many courses are offered free of charge or at low cost through the American Association for Respiratory Care (AARC). Most hospital respiratory therapy departments sponsor lectures at their facility for their staff to attend at no charge and some offer "grand rounds," in their Intensive Care Units (ICUs). Print publications (such as Saxe Healthcare Communications at www.saxetesting.com) are also offered online at no charge. Because many courses are offered free of charge or at a low price, the Board estimates a cost of \$10 per credit hour, for a total additional cost of \$100 per licensee during a biennial renewal period or \$50 per year. Respiratory therapists may receive free or low cost continuing education by joining the AARC at a cost of \$90 annually. If one assumes that a licensee joins AARC primarily to receive low cost or free continuing education, then the total estimated cost of continuing education and AARC membership is \$140 a year.

Second, IRRC recommended consistency between the Board's proposal that no more than 10 hours of creditable continuing education may be earned through nontraditional sources (prerecorded presentations, Internet-based presentations and journal review programs) and the State Board of Medicine's proposal that there be no restriction on these hours. The Boards have now agreed to identical language requiring at least 10 hours of continuing education be earned in traditional continuing education (classroom lecture, clinical presentation, real-time web-cast or other live sessions where a presenter is involved) to assure consistent standards across the two boards.

IRRC also recommended that the Board define the term "practice building." The Board added a definition in § 25.502 (relating to definitions) as "marketing or any other activity that has as its primary purpose increasing the business volume or revenue of a licensee or the licensee's employer."

IRRC suggested that the Board's description of amendments to the final-form rulemaking address first physician assistant provisions, followed by the respiratory therapist provisions. The

Board has done so.

Finally, IRRC asked the Board to add Purdon's citations to §§ 25.164(c) and (d) and 25.505(b). The Board confirmed with the Legislative Reference Bureau that the proposed rulemaking is correct. Purdon's citations to a cross-referenced statute are to appear only the first time the section of the act is referenced within a particular section of a regulation. The first citation applies to all subsequent references to the same statutory section or any subsection or paragraph of the section. Accordingly, the Board did not make the requested additions.

Description of Amendments to the Final-Form Rulemaking

The Board amended § 25.142 (relating to definitions) to further define NCCPA as the organization recognized by the Board to certify and recertify physician assistants by requiring continuing education and examination. The Board added information to § 25.163 (relating to approval and effect of licensure; biennial renewal of physician assistants; registration of supervising physicians) to direct applicants to NCCPA's website for information regarding maintaining current certification with that organization and clarified that it will publish recognition of additional National organizations on the Board's website.

The remaining changes in the final-form regulations appear at Subchapter K (relating to respiratory therapists). The Board added at a definition of "practice building" at § 25.502 (relating to definitions).

At § 25.506 (relating to temporary permits), the Board clarified that a temporary permit will be issued to an applicant who is not yet a licensee of the Board. Furthermore, as requested by the PSRC, HPLC and IRRC, the Board replaced CRTT with "entry level credentialing examination" at § 25.506(b) and at § 25.507(1)(i) (relating to criteria for licensure as a respiratory therapist).

At § 25.509a (relating to requirement of continuing education), the Board amends subsection (a)(3) to make the traditional and nontraditional continuing education requirements the same for both the Board and the State Board of Medicine. The provision provides that respiratory therapists must complete at least 10 hours of traditional continuing education such as classroom lecture, clinical presentation, real-time web-case or other sessions where a presenter is involved to meet the biennial continuing education requirement.

Finally, the Board amended § 25.509a(b) to clarify that new licensees are exempt from the continuing education requirement for the first biennial renewal period. The new language states: "An individual applying for the first time for licensure in this Commonwealth is exempt from completing the continuing education requirements during the initial biennial renewal period in which the license is issued."

Fiscal Impact and Paperwork Requirements

There are minimal fiscal impacts upon physician assistants because physician assistants are already required to complete continuing education to maintain National certification, and because virtually all physician assistants already hold professional liability insurance. There will be no adverse fiscal impact on the Commonwealth or its political subdivisions. Likewise, the amendments in this rulemaking will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector. The proposed amendments will have only a minor fiscal impact on respiratory therapists who must take an additional 10 credit hours of continuing education during a biennial period; and may impact those small businesses who pay continuing education costs for employed respiratory therapists.

Sunset Date

The Board continuously monitors 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)), on May 2, 2012, the Board submitted a copy of the notice of proposed rulemaking, published at 42 Pa. B. 2474, to the Independent Regulatory Review Commission and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

The Board received one public comment from the Pennsylvania Society for Respiratory Care, Inc. The HPLC and IRRC also submitted comments. The SCP/PLC did not comment. In preparing the final-form rulemaking, the Board considered all comments.

Under s	ection 5.1(j	(.2) of the R	legulatory Revie	ew Act (7	1 P.S. §	745.5a(j.2))), on
		the final-fo	rm rulemaking	was app	roved by	y HPLC.	On
	, 2013	3, the final-for	m rulemaking w	as deemed	approved	by the SCP/	PLC.
Under section 5	$\overline{5.1(e)}$ of the	Regulatory I	Review Act, IRF	RC met on			,
2013, and appro	ved the final	l-form rulemal	king.				

Findings

The Board 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 1202), and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 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 42 Pa. B. 2474.
- 4. This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act identified in this Preamble.

<u>Order</u>

The Board, acting under its authorizing statute, orders that:

- (A) The regulations of the Board at 49 Pa. Code §§ 25.141, 25.142, 25.161, 25.163, 25.164, 25.176, 25.191, 25.192, 25.201, 25.215, 25.231, and 25.501 25.510 are amended to read as set forth in Annex A.
- (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 immediately upon publication in the *Pennsylvania Bulletin*.

Samuel J. Garloff, D.O. Chairman

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter C. PHYSICIAN ASSISTANT PROVISIONS

GENERAL PROVISIONS

§ 25.141. Purpose.

The purpose of this subchapter is to implement the provisions of the act which provide for the [certification] <u>licensure</u> of physician assistants. The legislation provides for more effective utilization of certain skills of osteopathic physicians enabling them to delegate certain medical tasks to qualified physician assistants when such delegation is consistent with the patient's health and welfare.

§ 25.142. Definitions.

The following words and terms, when used in this [chapter] <u>subchapter</u>, have the following meanings, unless the context clearly indicates otherwise:

Certification—The [approval of an individual by the Board to serve as a physician assistant; and the] approval of a program by the Board for the training and education of physician assistants.

NCCPA—The National Commission on Certification of Physician Assistants, THE ORGANIZATION RECOGNIZED BY THE BOARD TO CERTIFY AND RECERTIFY

PHYSICIAN ASSISTANTS BY REQUIRING CONTINUING EDUCATION AND EXAMINATION.

[CERTIFICATION] <u>LICENSURE</u> OF PHYSICIAN ASSISTANTS AND REGISTRATION OF SUPERVISING PHYSICIANS

§ 25.161. Criteria for [certification] licensure as a physician assistant.

- (c) The Board will approve for [certification] <u>licensure</u> as a physician assistant an applicant who:
- (e) A person who has been [certified] <u>licensed</u> as a physician assistant by the State Board of Medicine shall make a separate application to the Board if he intends to provide physician assistant services for a physician licensed to practice osteopathic medicine and surgery without restriction.
- (f) An application for [certification] <u>licensure</u> as a physician assistant by the Board may be obtained by writing to the Harrisburg office of the Board.

§ 25.163. Approval and effect of [certification] <u>licensure</u> and; biennial renewal of physician assistants and; registration of supervising physicians.

- (a) Upon approval of an application for [certification] <u>licensure</u> as a physician assistant, the Board will issue a physician assistant [certificate] <u>license</u> which contains [his] <u>the licensee's</u> name, [his certificate] <u>license</u> number and the date of issuance, after payment of the fee required [by] <u>under</u> § 25.231 (relating to schedule of fees).
- (b) A physician assistant's right to continue [his practice] <u>practicing</u> is conditioned upon biennial renewal and the payment of the fee required [by] <u>under</u> § 25.231. Upon receipt of the form provided to the physician assistant by the Board in advance of the renewal period and the required fee, the Board will issue the physician assistant a biennial renewal certificate containing [his] <u>the licensee's</u> name, [his certification] <u>licensee</u> number and the beginning and ending dates of the biennial renewal period.
- (c) To be eligible for renewal of a physician assistant license, the physician assistant shall complete continuing medical education as required by NCCPA and maintain National certification by completing current certification and recertification mechanisms available to the profession, IDENTIFIED ON NCCPA'S WEBSITE and recognized by the Board. The Board recognizes certification through NCCPA and its successor organizations and certification through any other National organization for which the Board publishes recognition of the organization's certification of physician assistants ON THE BOARD'S WEBSITE.
- (d) Upon approval of an application for registration as a supervising physician, the Board will issue a supervising physician registration certificate which contains the name of the supervising physician, his registration number and the name of the physician assistant that he is authorized to supervise under that specific registration. The registration is not subject to renewal. When the physician submits a request to modify a protocol with respect to a physician assistant he is

already registered to utilize, no new registration certificate will be issued; however, the physician will receive a letter from the Board confirming its approval of the expanded utilization.

- [(d)] (e) Only a physician registered with the Board may use the services of physician assistants. A physician assistant shall have a clearly identified supervising physician who is professionally and legally responsible for the physician assistant's services. Whenever a physician assistant is employed by a professional corporation or partnership, an individual physician must still register as the supervising physician. Each member of a professional corporation or partnership may register as a supervising physician. When a physician assistant is employed by a professional corporation or partnership, the registered supervising physician is not relieved of the professional and legal responsibility for the care and treatment of patients attended by the physician assistant under his supervision.
- [(e)] (f) The Board will keep a current register of persons [certified] <u>licensed</u> as physician assistants. This register will include the name of each physician assistant, [his] <u>the physician assistant's</u> mailing address of record, [his] current business <u>address</u>, the date of initial [certification] <u>licensure</u>, biennial renewal record and current supervising physician. This register is available for public inspection.
- [(f)] (g) The Board will keep a current register of approved registered supervising physicians. This register will include the physician's name, his mailing address of record, his current business address, the date of his initial registration, his satellite operation if applicable, the names of current physician assistants under his supervision and the names of physicians willing to provide substitute supervision in his absence. This register will be available for public inspection.

§ 25.164. Professional liability insurance coverage for licensed physician assistants.

- (a) A licensed physician assistant shall maintain a level of professional liability insurance coverage as required under section 10(g.3) of the act (63 P. S. § 271.10(g.3)).
 - (b) Proof of professional liability insurance coverage may include:
- (1) A certificate of insurance or copy of the declaration page from the applicable insurance policy setting forth the effective date, expiration date and dollar amounts of coverage.
- (2) Evidence of a plan of self-insurance approved by the Insurance Commissioner of the Commonwealth under regulations of the Insurance Department in 31 Pa. Code Chapter 243 (relating to medical malpractice and health-related self-insurance plans).
- (c) A license that was issued in reliance upon a letter from the applicant's insurance carrier indicating that the applicant will be covered against professional liability effective upon the issuance of the applicant's license as permitted under section 10(g.3)(2) of the act will become inactive as a matter of law 30 days after issuance of the license if the licensee has not provided proof of professional liability insurance coverage and will remain inactive until the licensee provides proof of insurance coverage.
- (d) A licensee who does not have professional liability insurance coverage as required under section 10(g.3) of the act may not practice as a physician assistant in this Commonwealth.

PHYSICIAN ASSISTANT UTILIZATION

§ 25.176. Monitoring and review of physician assistant utilization.

5

(b) Reports shall be submitted to the Board and become a permanent record under the supervising physician's registration. Deficiencies reported shall be reviewed by the Board and may provide a basis for disciplinary action against the [certification] <u>license</u> of the physician assistant and the license or registration, or both, of the supervising physician.

PHYSICIAN ASSISTANT REQUIREMENTS IN EMPLOYMENT

§ 25.191. Physician assistant identification.

(c) In the supervising physician's office and a satellite operation, a notice plainly visible to patients shall be posted in a prominent place explaining the meaning of the term "physician assistant." The supervising physician shall display his registration to supervise the office. The physician assistant's [certificate] <u>license</u> shall be prominently displayed in all facilities in which he may function. Duplicate certificates may be obtained from the Board if required.

§ 25.192. [Notfication] Notification of termination of employment; change of address.

(c) Failure to notify the Board of a termination in the physician/physician assistant relationship shall provide a basis for disciplinary action against the physician assistant's [certificate] <u>license</u>, the supervising physician's license or registration as a supervising physician.

DISCIPLINARY ACTION AGAINST [CERTIFICATION] <u>LICENSE</u> OF PHYSICIAN ASSISTANT

§ 25.201. Grounds for complaint.

- (a) The bases upon which the Board may take disciplinary action against the [certification] license of a physician assistant are set forth in section 15(b) of the act (63 P. S. § 271.15(b)). A complaint against a physician assistant shall allege that the physician assistant is performing tasks in violation of statute, regulation or good and acceptable standards of practice of physician assistants. The grounds include those specifically enumerated in section 15(b) of the act [(63 P. S. § 271.15(b))]. Unprofessional conduct shall include, but is not limited to, the following:
- (1) Misrepresentation or concealment of a material fact in obtaining a [certificate] <u>license</u> or a reinstatement thereof.

(7) Impersonation of a licensed physician or another [certified] licensed physician assistant.

Subchapter D. MINIMUM STANDARDS OF PRACTICE

§ 25.215. Definitions.

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

Board-regulated practitioner—An osteopathic physician, physician assistant, respiratory [care practitioner] therapist, athletic trainer, acupuncturist or an applicant for a license or certificate issued by the Board.

Subchapter F. FEES

§ 25.231. Schedule of fees.

An applicant for a license, certificate, registration or service shall pay the following fees at the time of application:

Application for physician assistant [certificate] license......\$30

Subchapter K. RESPIRATORY [CARE PRACTITIONERS] THERAPISTS

§ 25.501. Purpose.

This subchapter implements sections 10.1 and 10.2 of the act (63 P.S. §§ 271.10a and 271.10b), which were added by section 3 of the act of July 2, 1993 (P.L. 418, No. 59) to provide for the [certification] licensure of respiratory [care practitioners] therapists.

§ 25.502. Definitions.

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

Act—The Osteopathic Medical Practice Act (63 P. S. §§ 271.1—271.18).

<u>CoARC</u>—The Committee on Accreditation for Respiratory Care, an organization which accredits respiratory care programs.

[CRTT—The Certification Examination For Entry Level Respiratory Therapy Practitioners, a National uniform examination developed and administered by the NBRC for certified respiratory care therapy practitioners.]

* * * * *

[JRCRTE—The Joint Review Committee on Respiratory Therapy Education, which accredits respiratory care programs.]

NBRC—The National Board for Respiratory Care, the agency recognized by the Board to certify respiratory [care practitioners] therapists.

PRACTICE BUILDING—MARKETING OR ANY OTHER ACTIVITY THAT HAS AS ITS
PRIMARY PURPOSE INCREASING THE BUSINESS VOLUME OR REVENUE OF A
LICENSEE OR THE LICENSEE'S EMPLOYER.

Respiratory [care practitioner] therapist—A person who has been [certified] licensed in accordance with the act and this subchapter.

§ 25.503. Fees.

The following is the schedule of fees charged by the Board:

(3) [Certification] <u>Licensure</u> examination......\$100

5) Diamnial renoval of [contification] licensum \$25

(5) Biennial renewal of [certification] <u>licensure</u>.......... \$25

§ 25.504. [Certification] <u>Licensure</u> of respiratory [care practitioners] <u>therapists</u>; practice; exceptions.

(a) A person may not practice or hold himself out as being able to practice as a respiratory [care practitioner] therapist in this Commonwealth unless the person holds a valid, current temporary permit or [certificate] license issued by the Board, or the State Board of Medicine

under Chapter 18 (relating to State Board of Medicine—practitioners other than medical doctors), or is exempted under section 10.1(e) of the act (63 P.S. § 271.10a(e)) or section 13.1(e) of the Medical Practice Act of 1985 (63 P.S. § 422.13a(e)).

(b) A person may not use the words "licensed respiratory therapist" or "respiratory care practitioner," the letters ["R.C.P."] "LRT," "RT" or "RCP" or similar words and related abbreviations to imply that respiratory care services are being provided, unless the services are provided by a respiratory [care practitioner] therapist who holds a valid, current temporary permit or [certificate] license issued by the Board or the State Board of Medicine and only while working under the supervision of a licensed physician.

§ 25.505. Functions of respiratory [care practitioners] therapists.

(a) Under section 10.1(d) of the act (63 P.S. § 271.10a(d)), a respiratory [care practitioner] therapist may implement direct respiratory care to an individual being treated by either a licensed medical doctor or a licensed doctor of osteopathic medicine, upon [physician] prescription or referral by a physician, certified registered nurse practitioner or physician assistant, or under medical direction and approval consistent with standing orders or protocols of an institution or health care facility. This care may constitute indirect services such as consultation or evaluation of an individual and also includes, but is not limited to, the following services:

* * * * *

(b) Under section 10.1(d) of the act, a respiratory [care practitioner] therapist may perform the activities listed in subsection (a) only upon [physician] prescription or referral by a physician, certified registered nurse practitioner or physician assistant or while under medical direction consistent with standing orders or protocols in an institution or health care facility.

§ 25.506. Temporary permits.

- (a) A temporary permit will be issued to an applicant, WHO IS NOT YET A LICENSEE, who submits evidence satisfactory to the Board, on forms supplied by the Board, that the applicant has met one or more of the following criteria:
 - (1) Has graduated from a respiratory care program approved by the [JRCRTE] <u>CoARC</u>.
- (2) Is enrolled in a respiratory care program approved by the [JRCRTE] <u>CoARC</u> and expects to graduate within 30 days of the date of application to the Board for a temporary permit.
- (3) [Has continuously provided respiratory care services for a minimum of 12 months immediately preceding December 28, 1993] Meets the applicable requirements and is recognized as a credentialed respiratory therapist by the NBRC.
- (b) A temporary permit is valid for 12 months and for an additional period as the Board may, in each case, specially determine except that a temporary permit expires if the holder fails the CRTT ENTRY LEVEL CREDENTIALING EXAMINATION. An applicant who fails the CRTT ENTRY LEVEL CREDENTIALING EXAMINATION may apply to retake it.

§ 25.507. Criteria for [certification] <u>licensure</u> as a respiratory [care practitioner] therapist.

The Board will approve for [certification] <u>licensure</u> as a respiratory [care practitioner] <u>therapist</u> an applicant who:

(1) Submits evidence satisfactory to the Board, on forms supplied by the Board, that the applicant has met one or more of the following criteria:

- (i) Has graduated from a respiratory care program approved by the [JRCRTE] <u>CoARC</u> and passed the [CRTT] ENTRY LEVEL <u>credentialing examination</u> as determined by the NBRC.
- (ii) [Has been credentialed as a Certified Respiratory Therapy Technician or Registered Respiratory Therapist by the NBRC.
- (iii)] Holds a valid license, certificate or registration as a respiratory [care practitioner] therapist in another state, territory or the District of Columbia which has been issued based on requirements substantially the same as those required by the Commonwealth, including the examination requirement.
- [(iv) Has continuously provided respiratory care services for a minimum of 12 months immediately preceding December 28, 1993, and has passed the CRTT as determined by the NBRC.]
- (2) Has paid the appropriate fee in [the form of a check or money order] <u>a form acceptable to</u> the Board.

§ 25.508. Change of name or address.

A [certificateholder] <u>licensee</u> shall inform the Board in writing within 10 days of a change of name or mailing address.

§ 25.509. Renewal of [certification] <u>licensure</u>.

(a) A [certification] <u>license</u> issued under this subchapter expires on December 31 of every even-numbered year unless renewed for the next biennium.

* * * * *

- (c) To retain the right to engage in practice, the [certificateholder] <u>licensee</u> shall renew [certification] <u>licensure</u> in the manner prescribed by the Board, pay the required fee and comply with the continuing education requirement of § 25.509a (relating to requirement of continuing education), prior to the expiration of the current biennium.
- (d) When a [certification] <u>license</u> is renewed after December 31 of an even-numbered year, a penalty fee of \$5 for each month or part of a month of practice beyond the renewal date will be charged in addition to the renewal fee.

§ 25.509a. Requirement of continuing education.

- (a) [Commencing with the biennial period January 1, 2007, through December 31, 2008, and each subsequent biennial period, an] An applicant for biennial renewal or reactivation of [certification] <u>licensure</u> is required to complete a minimum of [20] <u>30</u> hours of continuing education as set forth in section 10.2(f)(2) of the act (63 P.S. § 271.10b(f)(2)) subject to the following:
- (1) No more than 10 credit hours may be completed in AT LEAST 10 CONTINUING EDUCATION HOURS SHALL BE OBTAINED THROUGH TRADITIONAL CONTINUING EDUCATION SUCH AS CLASSROOM LECTURE, CLINICAL PRESENTATION, REAL-TIME WEB-CAST OR OTHER LIVE SESSIONS WHERE A PRESENTER IS INVOLVED. FOR nontraditional continuing education such as prerecorded presentations, Internet-based presentations and journal review programs.—To, TO qualify FOR CREDIT, the provider shall make available documented verification of completion of the course or program.

- (2) One hour [each] must be completed in medical ethics, and 1 hour must be completed in patient safety.
- (3) Credit will not be given for continuing education in basic life support, including basic cardiac life support and cardiopulmonary resuscitation. In any given biennial renewal period, a licensee may receive credit for no more than 8 continuing education hours in advanced life support, including advanced cardiac life support, neonatal advanced life support/neonatal resuscitation and pediatric advanced life support.
- (4) A licensee will not receive continuing education credit for participating in a continuing education activity with objectives and content identical to those of another continuing education activity within the same biennial renewal period for which credit was granted.
- (b) An individual applying for the first time for [certification] <u>licensure</u> in this Commonwealth is exempt from COMPLETING the continuing education requirement REQUIREMENTS for the DURING THE INITIAL biennial renewal period following initial [certification] <u>licensure</u> IN WHICH THE LICENSE IS ISSUED.
- (c) The Board may waive all or a portion of the requirements of continuing education in cases of serious illness, undue hardship or military service. It shall be the duty of each [certificateholder] <u>licensee</u> who seeks a waiver to notify the Board in writing and request the waiver prior to the end of the renewal period. The request must be made in writing, with appropriate documentation, and include a description of circumstances sufficient to show why the [certificateholder] <u>licensee</u> is unable to comply with the continuing education requirement. The Board will grant, deny or grant in part the request for waiver and will send the [certificateholder] <u>licensee</u> written notification of its approval or denial of the waiver request. A

[certificateholder] <u>licensee</u> who requests a waiver may not practice as a respiratory [care practitioner] <u>therapist</u> after the expiration of the [certificateholder's] <u>licensee's</u> current [certificate] <u>licensee</u> until the Board grants the waiver request.

(d) A [certificateholder] <u>licensee</u> shall maintain the information and documentation concerning compliance with the continuing education requirement or the waiver granted for a period of at least 2 years <u>after the end of the biennial renewal period to which the continuing education or waiver applies, the date of completion of the continuing education or grant of the waiver, whichever is latest, and provide the information and documentation to representatives of the Board upon request.</u>

§ 25.509b. Approved educational programs.

* * * * *

- (b) Advanced course work in respiratory care successfully completed at a degree-granting institution of higher education approved by the United States Department of Education which offers academic credits are also approved for continuing education credit by the Board. Advanced course work is course work beyond the academic requirements necessary for [certification] <u>licensure</u> as a respiratory [care practitioner] <u>therapist</u>.
- (c) The Board will not accept courses of study which do not relate to the actual provision of respiratory care. Examples of unacceptable courses are those in office management [and financial procedures] or practice building.

§ 25.510. Inactive status.

- (a) A [certificateholder] <u>licensee</u> who does not intend to practice in this Commonwealth and who does not desire to renew [certification] <u>licensure</u> shall inform the Board in writing. Written confirmation of inactive status will be forwarded to the [certificate-holder] <u>licensee</u>.
- (b) A [certificateholder] <u>licensee</u> shall notify the Board, in writing, of [his] <u>the licensee's</u> desire to reactivate the [registration] <u>licensee</u>.
- (c) A [certificateholder] <u>licensee</u> who is applying to return to active status is required to pay fees which are due for the current biennium and submit a sworn statement stating the period of time during which the [certificateholder] <u>licensee</u> was not engaged in practice in this Commonwealth.

STATE BOARD OF OSTEOPATHIC MEDICINE 16A-5321 – PHYSICIAN ASSISTANTS AND RESPIRATORY THERAPISTS

LIST OF PUBLIC COMMENTATORS

Eileen Censullo, MBA, RRT Pennsylvania Society for Respiratory Care, Inc. c/o 225 Hampshire Drive Sellersville, PA 18960-2876



COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF OSTEOPATHIC MEDICINE

Post Office Box 2649 Harrisburg, Pennsylvania 17105-2649 (717) 783-4858

October 29, 2013

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 Osteopathic Medicine 16A-5321

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Osteopathic Medicine pertaining to Physician Assistants and Respiratory Therapists.

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

Sincerely,

Geffrey Heebner 20.

Jeffery A. Heebner, D.O., Chairperson State Board of Osteopathic Medicine

SG/TL:ld

Enclosure

cc: Kathy J. Barley, Acting Commissioner
Professional and Occupational Affairs
Patricia Allen, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Teresa Lazo, Counsel
State Board of Osteopathic Medicine
State Board of Osteopathic Medicine

RECEIVE TO

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBE	R: 16A-5321				
SUBJECT:	PHYSICIAN ASSISTANT AND RESPIRATORY THERAPIST				
AGENCY:	DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF OSTEOPATHIC MEDICINE	_			
	TYPE OF REGULATION	3			
	Proposed Regulation				
X	Final Regulation	29			
	Final Regulation with Notice of Proposed Rulemaking Omitted	And Congress (And Congress) (And Congress) (And Congress) (And Congress) (And Congress) (And Congress) (And Congress)			
	120-day Emergency Certification of the Attorney General	씺			
	120-day Emergency Certification of the Governor				
	Delivery of Tolled Regulation a. With Revisions b. Without Revisions				
	FILING OF REGULATION				
DATE	<u>SIGNATURE</u> <u>DESIGNATION</u>				
	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE				
1429/13)	MAJORITY CHAIR Julie Harhart	· ·			
	MINORITY CHAIR				
	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE				
19/29/13	MAJORITY CHAIR Robt. M. Tomlinson	<u>n</u>			
	MINORITY CHAIR				
10/29/13	K Coper Independent regulatory review commission				
	ATTORNEY GENERAL (for Final Omitted only)	į			
	LEGISLATIVE REFERENCE BUREAU (for Proposed only)				