Regulatory Analysis Form

(Completed by Promulgating Agency)

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

INDEPENDENT REGULATORY REVIEW COMMISSION

RECEIVED

Independent Regulatory Review Commission

March 11, 2025

IRRC Number: 3390

(1) Agency
Department of State,
Bureau of Professional and Occupational Affairs,
State Board of Medicine

(2) Agency Number: 16A

Identification Number: 4955

(3) PA Code Cite:

49 Pa. Code §§ 18.122, 18.141-18.144, 18.151-18.159, 18.161, 18.162, 18.171, and 18.172.

(4) Short Title: Physician Assistants

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

Primary Contact: Dana M. Wucinski, Board Counsel, State Board of Medicine, Department of State, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251); dwucinski@pa.gov.

Secondary Contact: Jacqueline Wolfgang, Senior Regulatory Counsel, Department of State, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251) jawolfgang@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)

This final rulemaking package is necessary to amend the regulations of the State Board of Medicine ("Board") to effectuate the act of October 7, 2021 (P.L. 418, No. 79) (Act 79). The final regulation incorporates the language of Act 79 into the Board's regulations as it relates to definitions, written agreement requirements, criteria for registration and responsibilities of supervising physicians, countersignature requirements, the role of the physician assistant, prohibitions on practice, and prescribing by physician assistants. It also updates terminology and removes outdated provisions of the regulations.

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

The primary statutory authority for this final rulemaking is granted by Act 79 which amends the Medical Practice Act ("act") at 63 P.S. § 422.13 by removing certain restrictions on physician assistant practice to allow greater autonomy in the practice of the profession. Section 4 of Act 79 requires the Board to promulgate regulations necessary to carry out the act.

Section 13(c) of the act (63 P.S. § 422.13(c)) authorizes the Board to promulgate regulations which define the services and circumstances under which a physician assistant may perform a medical service. Section 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt such regulations as are reasonably necessary to carry out the purposes of the act, including the licensure of physician assistants. In addition, sections 502 and 503 of the Vital Statistics Law of 1953 (35 P.S. §§ 450.502 and 450.503) authorize physician assistants to medically certify a report of death or fetal death to the Pennsylvania Department of Health's Bureau of Health Statistics and Registry.

(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. Section 4 of Act 79 requires the Board to promulgate regulations necessary to carry out Act 79.

(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.

This final rulemaking is needed to effectuate Act 79, which was passed to help physician assistants work and practice with increased efficiency in this Commonwealth, which is one of the premier states for physician assistant education with more than 20 physician assistant programs offered throughout this Commonwealth. While many physician assistants receive their education in Pennsylvania, prior legislation made it less appealing for physician assistants to stay and practice within the state. Act 79 modernizes physician assistant practice in this Commonwealth by (1) placing a physician assistant on the Board with a permanent seat, (2) removing the requirement that a supervising physician countersign 100% of the patient files, (3) allowing all written agreements between physicians and physician assistants to be "filed" with the Board instead of "approved" by the Board, (4) outlining appropriate supervision requirements based on the needs of the physicians, physician assistants and overall healthcare system and (5) increasing the number of physician assistants a supervising physician may have primary responsibility over to six.

The final rulemaking will benefit physician assistants, their supervising physicians, the overall health systems that employ physician assistants, the citizens of this Commonwealth and the Pennsylvania Department of State ("Department").

There are approximately 12,902 licensed physician assistants in this Commonwealth who will benefit from this rulemaking. The amendments to the act allow physician assistants to practice within their full scope of education and training. This will result in greater autonomy in physician assistant practice. There will be more employment opportunities in Pennsylvania because of these changes which will provide physician

assistants more flexibility in choosing their places of employment. Between 2020 and 2022 there were approximately 2,800 written agreements filed with the Board annually. In 2023, 3,340 written agreements were filed with the Board. Physician assistants will no longer have to wait for Board approval to begin practicing the profession.

The final rulemaking will no longer require supervising physicians to "directly and personally supervise" physician assistants. This will give the supervising physician greater flexibility in providing care to patients and will allow the supervising physician to utilize the physician assistant practice more efficiently. The supervising physician will no longer be required to countersign 100% of patient records within 10 days, except in limited instances required by law, but instead allows the physician to come up with a supervision plan that is appropriate for each physician assistant that they supervise. This will greatly lessen the supervising physician's workload to allow them more time to provide healthcare services. Finally, the supervising physician will be permitted to supervise up to six physician assistants instead of being limited to two under the regulation, which will allow the supervising physician to maintain more patients.

Health systems, especially community health centers, will benefit if more physician assistants remain in Pennsylvania following their graduation from school. This will result in the health centers having more staff to assist with healthcare shortages which will increase access to care, especially in rural and underserved areas. Greater accessibility to healthcare in the primary care setting, will result in less non-emergent visits to the emergency departments. Health systems will eventually be able to provide quality healthcare at lower costs to patients.

The citizens of the Commonwealth will benefit if more physician assistants remain in Pennsylvania after completing their education. With more flexibility offered to physician assistants, there will be more employment opportunities for physician assistants which will result in an increase of access to care. The effect of physician shortages will be mitigated as more practitioners are available to see patients who might not otherwise see a physician. This will especially assist in underprivileged or rural areas that suffer most with physician shortages. The Board believes that utilization of routine preventative healthcare will eventually result in lower healthcare costs for patients.

The Department will benefit from this rulemaking because Act 79 only requires 10% review of all written agreements filed with the Board. Prior to the passage of Act 79, between 2020 and 2022 there were approximately 2,800 written agreements were filed with the Board annually. On average, approximately 28% of those written agreements require legal review by Board counsel, totaling almost 800 written agreements being reviewed by legal each year. After the implementation of Act 79, only 10% of written agreements filed with the Board require review. Therefore, during this time the Board reviewed approximately 280 written agreements annually with Board counsel reviewing approximately 1% of those written agreements. This results in approximately 3 written agreements per year requiring legal review. Thus, the Board saved over $120,000 in 2022, which gave the Board and legal staff additional time to work on other matters pending before the Board. *See* Attachment "A". In 2023, approximately 3,340 written agreements were filed with the Board. The Board saved over $151,518 in 2023 and anticipates saving at least this amount in future years. Since the implementation of Act 79, the backlog of written agreements waiting for Board approval has been resolved, and Board staff is better able to manage the review of written agreements. *See* Attachment "B".

(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.

No. There are no Federal licensure standards for physician assistants.

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

The final rulemaking will positively affect Pennsylvania's ability to compete with other states. In comparing this final rulemaking with the regulations of surrounding states, the Board analyzed the following areas: the number of physician assistants that a supervising physician may supervise, countersignature requirements, written agreement requirements and whether physician assistants have a permanent seat on the other states' Boards.

The final rulemaking increases the number of physician assistants a supervising physician may have primary responsibility over to six. Most of the surrounding states also limit the number of physician assistants that a supervising physician may supervise. Specifically, Delaware, Maryland, New Jersey, and New York limit the ratio to four physician assistants per supervising physician, while Ohio and West Virginia limit the ratio to five physician assistants for each supervising physician. There is only one surrounding state, Connecticut, that allows the supervising physician to supervise as many physician assistants as medically appropriate. The regulations in Maine, Rhode Island and Vermont contain no provision relating to supervision ratios and New Hampshire allows the healthcare institution to decide the appropriate ratio. In comparison, Pennsylvania will have a competitive edge over surrounding states because of the states that limit the ratio, Pennsylvania allows for the highest ratio. This will result in more physician assistant jobs in Pennsylvania and will provide greater access to care for the citizens of the Commonwealth.

The final rulemaking removes the 100% countersignature requirement in most scenarios unless the physician assistant is within their first 12 months of practice post-graduation or in the first 12 months of practice in a new specialty. Additionally, it removes the requirement that countersignature must occur within 10 days. Instead, the supervising physician can determine appropriate countersignature requirements and the time in which the countersignature must occur. Many surrounding states, including Connecticut, Delaware, Maine, Maryland, Vermont, and Rhode Island do not have countersignature provisions. However, there are several states that have similar provisions to Pennsylvania that allow the supervising physician to determine the appropriate review of physician assistant work, including New Hampshire, New Jersey, New York, Ohio, and West Virginia. This rulemaking will make Pennsylvania more in line with surrounding states while still ensuring that there is appropriate oversight of physician assistant practice.

The final rulemaking amends the written agreement requirements in Pennsylvania to allow physician assistants to work within the full scope of their education and training and to allow the supervising physician to determine the appropriate degree of supervision. It also allows physician assistants to begin practicing upon submission of the written agreement to the Board. It appears that the surrounding states have varying levels of written agreement requirements. One state, West Virginia, has very limited

requirements for written agreements such as the submission of practice notification to the Board. Another state, Maine, requires the submission of the written agreement to the Board for approval by the Board much like Pennsylvania's old language. Some surrounding states have very detailed requirements for written agreements. For example, in Connecticut, written agreements must reference or include applicable hospital policies, protocols, and procedures in the written delegation agreement, which must be reviewed annually by the supervising physician. Other states require that written or collaborative agreements exist, but do not require that they be submitted to the Board. Instead, they are kept on site at the hospital or clinic and must be made available to the Board upon request. States that do this are Delaware, New Hampshire, New Jersey, and Ohio. Some states, such as Maine, have very stringent written agreement requirements, but only until the physician assistant has acquired 4,000 hours of clinical practice. Thereafter, there is no written agreement requirement. Maryland requires approval of a delegation agreement only if the physician assistant is not employed in a hospital or ambulatory surgical facility. It appears that there is no continuity among states regarding written agreements. However, the final rulemaking eases written agreement requirements to give more deference to the supervising physician. The supervising physician is the individual in the best position to evaluate the physician assistant's scope of training and experience and to make delegations based on that determination as opposed to what the Board approves. The amendments make it so that Pennsylvania is no longer among the strictest states regarding the filing and approval of written agreements which will ultimately place Pennsylvania at a competitive advantage while still allowing the Board to maintain some aspect of oversight of the profession.

Though not part of the changes in this rulemaking, it is worth noting that Act 79 added a permanent seat on the Board for a physician assistant. Every other Board in the surrounding states has at least one physician assistant seat on their Board. Like Pennsylvania, some states like Connecticut, New Jersey and Maryland have one physician assistant seat on the Board. Other states including Maine, Delaware, New York, Rhode Island, and West Virginia have two physician assistant seats on their Board. A few states, including New Jersey and Maryland, also have a physician assistant advisory committee in addition to the permanent seat. By placing a permanent physician assistant seat on the Board, Pennsylvania has put itself more in line with surrounding states. This will ultimately increase Pennsylvania's competitive advantage which will enable the state to meet the needs of the citizens of this Commonwealth just as well as, or better than, surrounding states.

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

The State Board of Osteopathic Medicine also has regulations related to the practice of physician assistants. *See* 49 Pa. Code § 25.141-25.201. As the State Board of Osteopathic Medicine is a distinct licensing board which also has statutory jurisdiction over the practice of physician assistants, the Board's final rulemaking will not affect the State Board of Osteopathic Medicine's regulations. The State Board of Osteopathic Medicine will be submitting its own rulemaking package to effectuate the act of Oct. 7, 2021, P.L. 412, No. 78 (Act 78), which is identical to Act 79.

(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.)

All the rulemaking activities of the Board are discussed and voted on in public board meetings which are routinely attended by representatives of the public and the regulated community. The Board circulated one exposure draft to over 200 individuals/organizations to solicit comments from the public and regulated community. *See* Attachment "C".

Most comments received on the exposure draft were from physician assistants practicing in the field. All comments were positive and applauded the Board on the proposed amendments. There were a few comments from hospital systems and statewide organizations suggesting very minor changes to the proposed language to accurately reflect the intent of Act 79. The Board incorporated those recommended changes into this rulemaking package.

The Board published a notice of proposed rulemaking at 53 Pa.B. 7896 (December 16, 2023), for 30 days of public comment. The Board received over 300 public comments, most of which were supportive of the proposed regulation. Additionally, the Board received comments from the Independent Regulatory Review Commission (IRRC). Neither the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) nor the House Professional Licensure Committee (HPLC) submitted comments. The Board considered the comments at its March 5, 2024, board meeting. Then, at its September 17, 2024, board meeting, the Board adopted the final rulemaking.

(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?

The Board licenses approximately 12,902 physician assistants. For purposes of this final rulemaking, the Board estimates that approximately 1,033 individuals apply for licensure as a physician assistant each year and approximately 3,340 written agreements will be filed with the Board each year with 10% of those written agreements subject to Board review.

According to the Small Business Administration (SBA), there are approximately 1,082,000 small businesses in Pennsylvania, which is 99.6% of all Pennsylvania businesses. Of the 1,082,000 small businesses, 225,401 are small employers (those with fewer than 500 employees) and the remaining 856,626 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses.

According to the Pennsylvania Department of Labor and Industry, approximately 65% of physician assistants are employed in offices of physicians, 20 % in hospitals, 12% in outpatient care centers, 1% are self-employed and 1% work in colleges, universities and professional schools.

For the businesses listed above, small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size

Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where licensees may work, a small business under NAICS Code 622110 (General Medical and Surgical Hospitals) is considered a small business if they have $47.0 million or less in average annual receipts; offices of physicians (NAICS code 621111) are considered small businesses if they have $16 million or less in average annual receipts; outpatient care centers (NAICS code 621498) are considered small businesses if they have $25.5 million or less in average annual receipts; and educational services including colleges, universities and professional schools (NAICS code 611310) are considered small businesses if they have $34.5 million or less in average annual receipts. Based on this variety of employers, the Board believes that most physician assistants in Pennsylvania are employed in small businesses. The Board does not collect information on the size of the businesses where its licensees are employed. However, for purposes of determining the economic impact on small businesses, the Board must assume that many of its licensees work for small businesses as that term is defined by the SBA and Pennsylvania's Regulatory Review Act.

This rulemaking will affect physician assistants and supervising physicians working in small businesses in this Commonwealth. The rulemaking will also affect hospital systems and other health systems in which physician assistants are employed. Supervising physicians will no longer be required to "directly and personally supervise" physician assistants and they will be permitted to have responsibility for up to six physician assistants. Additionally, supervising physicians will no longer be required to review and countersign 100% of patient files. Instead, the supervising physicians, along with their healthcare system, will be permitted to determine appropriate supervising requirements based on the needs of the physicians, the physician assistants, and overall healthcare system. Finally, physician assistants will be able to begin practicing immediately upon submission of their written agreement to the Board instead of having to wait for Board review and approval. This will positively affect the physician assistant, the supervising physician, the overall healthcare systems, and the citizens of this Commonwealth by having more practitioners enter the healthcare field faster. This will result in increased access to care and lower healthcare costs to patients.

(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.

Approximately 12,902 individuals currently licensed as physician assistants will be required to comply with the regulation, as well as all future applicants for licensure. Additionally, all supervising physicians and employers of physician assistants will have to comply with the rulemaking. In 2023, the Board received approximately 1,033 applications for physician assistants and approximately 3,340 written agreements were filed with the Board.

(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 citizens of the Commonwealth will benefit from the final rulemaking because Act 79 will help ease healthcare shortages by enticing more physician assistants to remain in this Commonwealth after completing their education and by allowing physician assistants greater autonomy in treating patients.

This will allow physician assistants to take a larger role in the primary care of patients. Physician assistants will have the opportunity to bring their full knowledge and skill set to patients by allowing the physician assistant to provide services within their own scope of education and training as opposed to being limited to services outlined in a Board-approved written agreement under the scope of practice of their supervising physician. As a result, physician assistants will be better able to provide care to those who otherwise may not be able to see a physician. It will also provide greater access to medical care in underserved areas, including rural areas because each supervising physician will be permitted to have responsibility for up to six physician assistants.

Health systems and physician offices alike will benefit from this rulemaking both financially and economically because they will be able to make greater use of physician assistants due to the supervising physician no longer having to supervise the physician assistant "directly and personally" and because the supervising physicians will be able to take responsibility for more than two physician assistants. There is a growing shortage of physicians across the Pennsylvania, especially in rural areas. This rulemaking will allow physician assistants to take a larger role in the care of patients by not requiring 100% countersignature, immediate review of patient records and active and continuing review. However, patient safety is still ensured since there is still a component of supervision under the supervising physician.

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

This rulemaking will not result in increased costs to the Commonwealth, its licensees, businesses, or the public. Instead, it will ease the burden of the written agreement review process, lessen supervision requirements, and allow physician assistants to practice with greater autonomy. There are no known adverse effects of this final regulation. However, the Board is certain that the benefits that will result from this rulemaking would outweigh any unknown adverse effects because it will result in greater access to healthcare for the citizens of this Commonwealth and lower healthcare costs.

(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.

There are no estimated cost or savings to the regulated community.

(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 expected costs or savings for local governments.

(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.

There is expected cost savings to the Department because Board staff will no longer be required to review every written agreement filed with the Board. Instead, written agreements will be "filed" with the Board with only 10% review. Between 2020 and 2022, Board staff reviewed and approved approximately 2,800 written agreements per year. *See* Attachment "A". In 2023, there was in increase in the number of written agreements filed with the Board (3,340) and the Board reviewed approximately 334 written agreements, which resulted in a savings of $151,518. *See* Attachment "B". The Board anticipates similar savings in future years due to having to only review 10 % of the written agreements.

(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.

The Board is unaware of any legal, accounting or consulting procedures which will be required for implementation of the regulation by organizations or individuals.

(22a) Are forms required for implementation of the regulation?

No.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

N/A

(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 24-25	**FY +1 25-26**	**FY +2 26-27**	**FY +3 27-28**	**FY +4 28-29**	**FY +5 29-30**
SAVINGS:						
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government						
State Government	$151,518	$151,518	$151,518	$151,518	$151,518	$151,518
Total Savings	$151,518	$151,518	$151,518	$151,518	$151,518	$151,518
COSTS:						
Regulated Community	$0	$0	$0	$0	$0	$0

Local Government	$0	$0	$0	$0	$0	$0
State Government	$0	$0	$0	$0	$0	$0
Total Costs	$0	$0	$0	$0	$0	$0
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	$0	$0	$0	$0	$0	$0

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

Program	**FY -2 21-22**	**FY -1 22-23**	**FY -1 23-24 (estimated)**	**Current FY 24-25 (budgeted)**
State Board of Medicine	$7,161,301.36	$7,752,409.87	$8,175,528.48	$11,025,000

(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) This rulemaking will not have an adverse impact on small businesses.

(b) This rulemaking will not impose additional reporting, recordkeeping, or other administrative costs on small businesses.

(c) The probable effect on impacted small businesses would be positive because Act 79 will result in more physician assistants remaining in the Commonwealth after finishing school, greater flexibility in the utilization of physician assistants, ability to provide more access to healthcare, less burden on supervising physicians employed by the small business and less waiting time for physician assistants to begin practice pending approval of their written agreement.

(d) The Board could discern no less costly or less intrusive alternative method to effectuate the purpose of Act 79 that would be consistent with the Board's mandate to administer the act in the public interest.

(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.

The Board could perceive no particular needs of any of these groups that needed to be accommodated.

(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.

No alternative regulatory provisions were considered and rejected. The Board believes this rulemaking represents the least burdensome acceptable alternative.

(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 performance 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.

a) & b) The Board did not consider less stringent reporting requirements or deadlines for small businesses or for applicants that intend to work for small businesses. All applicants for licensure are treated equally.

c) There is no compliance or reporting requirements that could be consolidated or simplified. The application process is the same whether a particular licensee is employed by a small business or a large business.

d) The regulations do not contain design or operational standards that need to be altered for small businesses.

e) To exclude any applicant from the requirements contained in the regulation based on the size of their employers would not be consistent with Act 79.

(28) 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 data, studies or references were used to justify the regulation.

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

A. The length of the public comment period: .....30 days

B. The date or dates on which any public meetings or hearings will be held: ... The Board meets in public session 9 times each year. Upcoming dates are set forth in (30) below.

C. The expected date of delivery of the final-form regulation: .....Spring of 2025

D. The expected effective date of the final-form regulation: .....Upon publication as final

E. The expected date by which compliance with the final-form regulation will be required:.....Upon publication as final

F. The expected date by which required permits, licenses or other approvals must be obtained: ..... N/A

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

The Board continuously evaluates the effectiveness of the Board's regulations and implementation of regulations. The Board discusses all regulatory proposals in conjunction with its regularly scheduled public meetings. The Board meets 9 times a year. The Board is scheduled to meet on the following upcoming dates in 2025 in March 4, April 8, May 20. July 1, August 19, September 30, November 18, and December 30.

ATTACHMENT “A”

Total Agreements per year

2020	2,315
2021	2,913
2022	3,173
AVERAGE	2,800

Job Classification	Time to Review	% of Agreements Reviewed	# of Agreements Reviewed	Hourly Rate	total cost
Clerical Assistant 3	1.00	100%	2,800	$39.86	$111,621.29
Attorney 4	0.25	28%	784	$89.54	$17,551.93
Board Administrator	0.25	28%	784	$46.53	$9,120.97
					$138,294.18

Job Classification	Time to Review	% of Agreements Reviewed	# of Agreements Reviewed	Hourly Rate	total cost
Clerical Assistant 3	1.00	10%	280	$39.86	$11,162.13
Attorney 4	0.25	1%	3	$89.54	$62.69
Board Administrator	0.25	1%	3	$46.53	$32.57
					$11,257.39

TOTAL ESTIMATED ANNUAL SAVINGS TO THE BOARD: $127,036.79

ATTACHMENT “B”

Total Agreements per year

2023	3,340
	3,340

Job Classification	Time to Review	% of Agreements Reviewed	# of Agreements Reviewed	Hourly Rate	total cost
Clerical Assistant 3	1.00	100%	3,340	$39.86	$133,132.40
Attorney 4	0.25	28%	935	$89.54	$20,934.45
Board Administrator	0.25	28%	935	$46.53	$10,878.71
					$164,945.57

Job Classification	Time to Review	% of Agreements Reviewed	# of Agreements Reviewed	Hourly Rate	total cost
Clerical Assistant 3	1.00	10%	334	$39.86	$13,313.24
Attorney 4	0.25	1%	3	$89.54	$74.77
Board Administrator	0.25	1%	3	$46.53	$38.85
					$13,426.86

TOTAL ESTIMATED ANNUAL SAVINGS TO THE BOARD: $151,518.71

ATTACHMENT “C”

Salutation	First Name	Last Name	Professional Designation	Business Address	Address Line 1
Dr.	Julie	Lachman	ND		1432 Easton Rd, 3G
Dr.	Marie	Winters	ND		737 Dudley St
Dr.	Heidi	Weinhold	ND	PANP	105 Rockingham Lane
Ms.	Angie	Armbrust		The Winter Group	234 N 3rd St
Ms.	Susan	DeSantis	PA-C	Pennsylvania Society of Physician Assistants	P.O. Box 128
Mr.	Alex	Bonner		PA State Nurses Association	3605 Vartan Way, Suite 204
Mr.	Ted	Mowatt	CAE	Ass'n for Prof. Acupunture	908 N 2nd St
Ms.	Jennifer	Sporay	RDN-AP, CSO, LDN, CNSC, FAND		1438 Bridge St.
Attorney	Andrew	Harvan	Esq.	Pennsylvania Medical Society	777 E Park Dr
Mr.	Doug	Richards		Long Nyquist & Assoc.	121 State St
Ms.	Carrie	Hillman		Milliron Goodman, LLC	200 N 3rd St, Suite 1500
Mr.	Edward	Nielsen	M.H.S	Pennsylvania Chiropractic Association	1335 North Front St
Representative	Mark	Mustio			Suite 220
Representative	Mark	Mustio		PA House of Representatives	416 Irvis Office Bldg
Representative	Harry	Readshaw		PA House of Representatives	107 Irvis Office Bldg
Representative	Harry	Readshaw			1917 Brownsville Rd
Senator	Lisa	Boscola		Pennsylvania Senate	Senate Box 203018
Senator	Lisa	Boscola			Suite 120
Senator	Robert	Tomlinson			3207 Street Rd
Senator	Robert	Tomlinson		Pennsylvania Senate	Senate Box 203006
				PA Assoc of Naturopathic Physicians	P.O. Box 5615
				PA Academy of Nutrition and Dietetics	P.O. Box 211025
Dr.	Paul	Gannon	ND	Cancer Treatment Centers Of America	Eastern Regional Medical Center

Dr.	Naina	Kohli	ND	Cancer Treatment Centers Of America	Eastern Regional Medical Center
				North American Bd of Naturopathic Examiners	Suite 119, #321
Ms.	Leia	Anderson		Natural Paths To Wellness	3601 Gettysburg Rd
Dr.	Maria	Ciuferri-Wanasacz	ND, L Ac	Healing Arts Center At Northeastern	Rehabilitation Associates Pc
Dr.	John	Laird	ND	UPMC Center For Integrative Medicine	580 S Aiken Ave
Dr.	Sari	Cohen	ND	UPMC Center For Integrative Medicine	580 S Aiken Ave

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DeSantis		Greensburg	PA	15601	pspa@pspa.net
Bonner		Harrisburg	PA	19110	abonner@psna.org
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Anderson		Camp Hill	PA	17011	
Ciuferri-Wanasacz	5 Morgan Hwy, Ste 4	Scranton	PA	18508	
Laird		Pittsburgh	PA	15232	
Cohen		Pittsburgh	PA	15232	

Salutation	First Name	Last Name	Professional Designation	Business Address	Address Line 1
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				Marcus Institute for Integrative Medicine	of Jefferson Hospital
				Physicians Comm for Responsible Medicine	Suite 400
				American Assoc. of Naturopathic Physicians	Suite 250
Dr.	Andrew	Neville	ND	Clymer Healing Center	5916 Clymer Road
Dr.	Michael	Reece	ND		4233 Oregon Pike
Dr.	Alison	Finger	ND		148 E State St
Dr.	Brian	Freeman	ND		1430 Bridge St #2
Dr.	Jaie	Bosse	ND		Lower Level

Attorney	Jann	Bellamy	JD	Society for Science-Based Medicine	
Dr.	Heather	Deluca	ND		250 Pierce St
				Health for Life Clinic	112 Cornell Ave
Dr.	Kayla	Evan	ND		972 Lincoln Rd
Dr.	Maureen	Tighe	ND, MSOM	Trillium Natural Medicine	3043 W Liberty Ave
Ms.	Lynn	Feinman			53 Darby Road C
Dr.	Jeremy	Wolf	ND	Falcone Center for Cosmetic, Functional and Integrative Medicine	Suite B104
Dr.	Henriette	Alban	ND		103 S 5th St
Dr.	Marty	Edwards	ND		529 S Juniper St
Dr.	Jill	Hoffman	ND	Center City Naturopathic	111 Sibley Ave
President	Anne	Walsh		Fed'n of Naturopathic Medicine Regulatory Auth.	Oregon Bd of Naturpathic Medicine
				Alaska Dept of Cmty and Econ Dev.	Div of Occup Licensing - Naturpathic Section
Executive Directo	Gail	Anthony		AZ Naturopathic Bd of Medical Exam'rs	#230
				Colorado Dept of Regulatory Auth.	Office of Naturopathic Doctor Registration
				Connecticut Bd of Naturopathic Examiners	P.O. Box 340308
Executive Officer	Candace	Ito		Hawaii Bd of Examiners in Naturopathy	DCCA-PVL Attn: NAT

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	5100 Wisconsin Ave NW	Washington	DC	20016	
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Reece		Ephrata	PA	17522	
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		Lancaster	PA	17603	
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Tighe		Pittsburgh	PA	15216	
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Alban		Reading	PA	19602	
Edwards		Philadelphia	PA	19147	
Hoffman		Ardmore	PA	19003	
Walsh	Suite 119 #321 9220 SW Barbur Blvd	Portland	OR	97219	
	P.O. Box 110806	Juneau	AK	99811-0806	
Anthony	1400 W Washington Ave	Phoenix	AZ	85007	
	1560 Broadway, Ste 1350	Denver	CO	80202	
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Salutation	First Name	Last Name	Professional Designation	Business Address	Address Line 1
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				Maryland Bd of Physicians	Reference Allied Health Practitioners
Dr.	Molly	Schwanz	ND	MN Bd. of Med. Practice	University Park Plaza - Ste 500
				Montana Alternative Health Care Bd	P.O. Box 200513
				North Dakota Bd of Integrative Health Care	705 E Main Ave
				New Hampshire Dept of Health and Human Services	Licensing & Regulative Services
				Oregon Bd of Naturopathic Examiners	Suite 407
				Utah Naturopathic Physicians Licensing Bd	160 E 300 S
Mr.	Ronald	Klein	RPh	Vermont Office of the Secretary of State	Office of Professional Regulation
				WA State Dept of Health - Naturopathy Program	Health Professions Quality Assurance
Attorney	Traci	Hobson	Esq.	American Ass'n of Naturopathic Physicians	Suite 250
				Council On Naturopathic Medical Educ.	P.O. Box 178
Dr.	Kathy	Ferraro	MD	Center for Holistic Medicine	9 Brookwood Ave
Dr.	Jessica	Shoemaker	BS, ND	Natural Paths to Wellness	3601 Gettysburg Rd
Dr.	Timothy	Salotto	ND		645 N 12 St, Suite 301
Dr.	Bill	Maguire	ND		924-A Colonial Ave
Executive Directo	Allison	McIntosh		Pennsylvania Physical Therapy Ass'n	#106
				Ass'n for Prof Acupuncture in Pennsylvania	P.O. Box 1081
				Pennsylvania Chiropractic Association	1335 N Front St
				Homeopathic Med Soc'y of the State of PA	637 W Lincoln Hwy
				PA Health Care Association	315 North Second St

Ms.	Mary	Marshall		The Hospital & Healthsystem Assoc	30 N 3rd St, Ste 600
Ms.	Betsey	Zych		PA Academy of Nutrition & Dietetics	P.O. Box 211025
	Jan	Cox		Independence Blue Cross	1919 Market St
Ms.	Margaret	Rowe			21 Foxanna Dr

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		Bismark	ND	58501	
		Concord	NH	03301-3857	
	800 NE Oregon St	Portland	OR	97232	
		Salt Lake City	UT	84111	
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Shoemaker		Camp Hill	PA	17011	

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		Harrisburg	PA	17102	
		Exton	PA	19341	
		Harrisburg	PA	17101	
Marshall		Harrisburg	PA	17101-1703	mmarshall@haponline.org
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Cox		Philadelphia	PA	19103-1480	
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Salutation	First Name	Last Name	Professional Designation	Business Address	Address Line 1
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Dr.	Diane	Hawk	ND		1270 Greensprings Dr
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Dr.	Michael	Di Palma	ND	Medical Center of Richboro	778 2nd Street Pk
Dr.	Elizabeth	Gaby	ND		301 Dorwood Dr
Dr.	Jeannine	Maschak	ND	Integrative Health & Wellness	PO Box 1621
Dr.	Darrell	Misak	ND, RPh	Pittsburgh Alternative Health, Inc.	20 Cedar Blvd
Dr.	Suzanne	Peppell	ND		400 Northampton St.
Dr.	Michelle	Qaqundah	ND	Cancer Treatment Centers of America	1331 East Wyoming Avenue
Dr.	Joy	Sakonyi	ND	Wellspring Whole Health	The Nuin Center
Dr.	Gurneet	Singh	LAc, ND	Lotus Healing, LLC	Triune
Mr.	Dwayne	Haus		Int. RBTI Pract. Assn	P.O. Box 621 P.O. Box 621
President	Heather	Shutlz		Assoc. for Prof. Acupuncture in Pennsylvania	

Ms.	Linda	Rosa	RN	Colorado Citizens for Science in Medicine	
Dr.	Britt	Hermes	ND (ret.)		
Mr.	Alex	Murdoch			
Dr.	Valerie	Nelson	ND	Abundant Life Wellness	
Ms.	Nancy	Wagner	MBA, RD, LDN		
Dr.	Filippos	Diamantis		American Naturopathic Medical Association	
Mr.	Randy	Stevens		Pennsylvania Orthotic and Prosthetic Society	
Dr.	Khadija	Douglas	ND	Julie Lachman, ND, LLC	1432 Easton Rd, 3G
Ms.	Katrina	Molnar-Dietz			800 Campbell Drive
Ms.	Julie	Derwart-Reh	CNM,CNWC,BNS,MPH		508 York St.
Dr.	JoAnn	Yánez	ND, MPH, CAE	American Association of Accredited Naturopathic Medical Colleges	
Dr.	Shannon	Braden	ND	Federation of Naturopatic Medicine Regulatory Authorities	
Dr.	Christa	Louise	M.S., Ph.D.		
Dr.	Barbara	Myers	ND		828 Long Meadow Dr.

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Gaby		Carlisle	PA	17013	
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Qaqundah	Suite 2030	Philadelphia	PA	19124	
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Louise					ChristaLouise@nabne.org
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Salutation	First Name	Last Name	Professional Designation	Business Address	Address Line 1
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Dr.	Marilyn	Heine	M.D.		900 Twining Rpad

Ms.	Margaret	Durkin		Bravo Group, Inc.	20 N. 2nd St

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Heine		Dresher	PA	19025-1726	mjheine12@aol.com
Durkin		Harrisburg	PA	17101	durkin@thebravogroup.com

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

Independent Regulatory
Review Commission

March 11, 2025

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BY: _____ (DEPUTY ATTORNEY GENERAL)	Department of State State Board of Medicine (AGENCY)	BY: _____ (Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title) Digitally signed by Cynthia K. Montgomery DN: cn=Cynthia K. Montgomery, o, ou, email=cymontgome@pa.gov, c=US Date: 2025.02.27 10:55:59 -05'00'
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 16A-4955 DATE OF ADOPTION: _____	2/27/2025 DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	BY: _____ Donald M. Yealy, M.D. Board Chair TITLE _____ (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

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

49 PA. CODE CHAPTER 18

§§ 18.122, 18.141-18.144, 18.151-18.154, 18.156, 18.158, 18.157, 18.159, 18.161, 18.162, 18.171, 18.172 and 18.155

PHYSICIAN ASSISTANTS

The State Board of Medicine (Board) hereby amends Chapter 18, Subchapter D (relating to physician assistants) to read as set forth in Annex A. Specifically, the Board is amending §§ 18.122, 18.141-18.144, 18.151-18.154, 18.156-18.159, 18.161, 18.162, 18.171, and 18.172. The Board is also deleting § 18.155 (relating to satellite locations).

Effective Date

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

Statutory Authority

The primary statutory authority for this final rulemaking is the act of October 7, 2021 (P.L. 418, No. 79) (Act 79), which amended section 13 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.13) by removing certain restrictions on physician assistant practice to provide greater autonomy in the practice of the profession. Under section 4 of Act 79, the Board is authorized to promulgate regulations necessary to carry out Act 79.

Section 13(c) of the act authorizes the Board to promulgate regulations which define the services and circumstances under which a physician assistant may perform a medical service. Section 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt such regulations as are reasonably necessary to carry out the purposes of the act, including the licensure of physician assistants. In addition, sections 502 and 503 of the Vital Statistics Law of 1953 (35 P.S. §§ 450.502, 450.503), authorize physician assistants to medically certify a report of death or fetal death to the Pennsylvania Department of Health's Bureau of Health Statistics and Registry.

Background and Need for Amendments

This final-form rulemaking is needed to effectuate Act 79 which is meant to help physician assistants work and practice with increased efficiency in this Commonwealth. Pennsylvania is one of the premier states for physician assistant education with more than 20 physician assistant programs offered in this Commonwealth. While many physician assistants receive their education in this Commonwealth, prior legislation made it less appealing for physician assistants to stay and practice here. Act 79 modernizes physician assistant practice in this Commonwealth by (1) placing a physician assistant on the Board with a permanent seat, (2) removing the requirement that a supervising physician countersign 100% of the patient files, (3) allowing all written agreements between physicians and physician assistants to be "filed" with the Board instead of "approved" by the Board, (4) outlining appropriate supervision requirements based on the needs of the physicians, physician assistants, and overall healthcare system and (5) increasing the number of physician assistants a supervising physician may have primary responsibility over to six physician assistants.

Summary and Response to Comments

Notice of the proposed rulemaking was published at 53 Pa.B. 7896 (December 16, 2023). Publication was followed by a 30-day public comment period during which the Board received 309 public comments. Of the 309 comments, 298 were from physician assistants and physician assistant students (of which 273 were form letters); three from medical doctors that work with physician assistants. The Board received comments from the following organizations: St. Lukes University Health Network, Geisinger Health, UPMC, Pennsylvania Society of Physician Assistants, PA Association of Community Health Centers, PA Rural Health Association, Pennsylvania Alliance of Advanced Practice Leaders and Hospital and Health system Association of Pennsylvania (HAP).

Additionally, the Board received comments from the Independent Regulatory Review Commission (IRRC). Neither the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) nor the House Professional Licensure Committee (HPLC) submitted comments.

Public comments

All public comments submitted, except for one, were in support of the proposed regulation. Most of the public comments relayed the same sentiment that the proposed changes will modernize the delivery of patient care by the physician/physician assistant teams in Pennsylvania. Commentors were happy that the proposed regulation has caught up to the ever-evolving field of medicine which relies heavily on physician assistant care.

The Pennsylvania Society of Physician Assistants (PSPA) indicated that it worked over the past several years to modernize the practice of physician assistants to improve the delivery of patient care by the physician/physician assistant teams. PSPA commented that it supports the proposed regulations and indicated that Pennsylvania physician assistants look forward to filling the gap and providing the much-needed health care for the citizens of this Commonwealth. The Pennsylvania Association of Community Health Centers and the Pennsylvania Rural Health Association both wrote in support of the proposed rulemaking.

HAP is also supportive of the rule making and appreciates the Board's commitment to the timely promulgation of regulations implementing Act 79. HAP indicated in their letter that the implementation of Act 79 empowers physician assistants to practice to the top of their licenses while giving hospitals and health systems the ability to operate more efficiently. Similarly, the Pennsylvania Alliance of Advanced Practice Leaders submitted a comment indicating that their organization wholeheartedly supports the proposed rulemaking and that it is a pivotal step forward in modernizing the act for physician assistants. They especially appreciate the creation of a permanent seat for a physician assistant on the Board. It is their belief that the changes proposed by the Board will significantly benefit the health of the citizens of Pennsylvania by ensuring that physician and physician assistant teams can operate to their highest potential. UPMC submitted a similar comment in which they fully endorsed the proposed rulemaking and thank the Board for their valuable work. St. Lukes University Health network commented that the proposed

rulemaking will modernize the delivery of patient care by the physician-physician assistant teams in this Commonwealth. Geisinger Health supports of the proposed rulemaking, commenting that Act 79 was as significant step in the modernization of physician assistant regulations and that the rulemaking will allow for improved efficiency inpatient care, will make it more appealing for new-graduate physician assistants to seek employment in this Commonwealth and will benefit the citizens of this Commonwealth by growing their access to healthcare services.

One comment, which was submitted following the close of the public comment period, suggested that the Board should be made up of all physician assistants and one medical doctor because physician assistants are very capable of making policy that will maintain the safety and excellent care of patients. In response to this comment, the Board notes that it governs many health professions and is composed of "nine members appointed by the Governor, one of whom shall be a physician assistant, seven of whom shall be medical doctors with unrestricted licenses to practice medicine and surgery in this Commonwealth for five years immediately preceding their appointment and one who shall be a nurse midwife, respiratory therapist, licensed athletic trainer or perfusionist licensed or certified under the laws of this Commonwealth." See, 63 P.S. § 422.3. As such, the Board is dutybound to follow the act regarding the composition of the Board. Additionally, the scope of practice for physician assistants is statutorily defined under the act. The request of this commentator is something that would require legislative change to the act, which is out of the Board's control.

Three commentors compared the standards of a certified registered nurse practitioner (CRNP), questioning why standards for physician assistants are different than CRNPs, including continuing education requirements, recertification requirements and levels of independence. As one commentor noted, physician assistant training is based upon the medical model whereas the CRNP training is based on the nursing model. The standards governing each profession are different because they are governed by different scopes of practice within the act (for physician assistants) and the Professional Nursing Law (63 P.S. §§ 211-226). The Board does not have any control over how CRNPs are regulated. This final regulation is based upon changes in the act due to Act 79.

IRRC Comment

IRRC submitted the following comments on the proposed rulemaking.

1. *Section 18.142. Written Agreements. – Implementation procedures; Reasonableness*

IRRC first comments that Act 79 requires the Board to conduct a full review of 10% of all written agreements submitted. In addition to providing a framework for written agreements submit to review, the legislation required the Board to publish a notice of the review process. As IRRC points out, this notice was published in the Pennsylvania Bulletin at 52 Pa.B. 1096 (February 12, 2022). The notice details the review process utilized by the Board for those written agreements subject to the 10% review and provides for discrepancy notices. The language published reads as follows:

> The written agreement is prepared and submitted by the primary supervising physician, physician assistant or a delegate of the supervising physician and physician assistant. If the written agreement does not meet the requirements outlined in 4(a)—(d), Board staff sends a discrepancy notice to the supervising physician and physician assistant indicating that the written agreement application is subject to the 10% review. Within that discrepancy notice, Board staff provides the list of items that need to be remedied within the written agreement and a notification that the parties have 2 weeks to respond to the discrepancy notice. If the parties do not respond to the discrepancy notice within 2 weeks, the written agreement is void and the application status will be changed to expired. The physician assistant and supervising physician must submit an entirely new written agreement. The new written agreement is effective upon submission and is subject to 10% review.

IRRC is concerned about this procedure because inaction or delayed responses to a discrepancy notice can trigger a change of status and require the submittal of a new written agreement by the physician, physician assistant or their designee. IRRC questions whether the Board should consider including these key provisions in the final-form regulation or explain why it is unnecessary to do so.

In response, the Board does not think it is necessary to include this language in the regulation. Act 79 required that the Board publish its review process in the *Pennsylvania Bulletin* within 120 days of the effective date of Act 79. While the Board understands the need to notify the regulated community, including potential employers, of a change in the Board's review process and procedures in light of a newly enacted law, boards and commissions under the Bureau of Professional and Occupational affairs generally do not include auditing procedures as a part of their regulations. This discrepancy notice process is an internal operating procedure for Board staff. The 10 % of individuals who are selected for audit will receive a letter from the Board, with detailed instructions and deadlines. Moreover, Act 79 contains provisions that address these procedures. Under Act 79, a "written agreement subject to a review shall remain in effect for two weeks after the board notifies the primary supervising physician and the physician assistant with remedies, if necessary, on the outcome of the review." See, 63 P.S. § 422.13 (e)(6). Additionally, this provision goes on to provide that the "primary supervising physician, physician assistant or delegate...must submit a new written agreement which shall be effective upon submission to the board." Therefore, because Act 79 has created the "binding norm," which is enforceable without the need to include it in the Board's regulations, the Board does not find it necessary to include it in this final-form regulation.

Section 18.151. Role of Physician Assistant. – Clarity

IRRC's second comment points out that § 18.151(c) proposes to delete the prohibition that a physician assistant may not determine the cause of death which is intended to update the language to comply with the act of July 7, 2017 (P.L. 296, No. 17) (Act 17), which amended sections 502 and 503 of the Vital Statistics Law of 1953 (35 P.S. §§ 450.502, 450.503) to authorize physician assistants to medically certify a report of death or fetal death to the Pennsylvania Department of

Health's Bureau of Health Statistics and Registry. In doing so, the Board proposed the following amendment:

> (c) The physician assistant may pronounce death, [but not] determine the cause of death, and may authenticate with the physician assistant's signature any form related to pronouncing death. If the attending physician is not available, the physician assistant shall notify the county coroner. The coroner has the authority to release the body of the deceased to the funeral director.

IRRC questioned the use of the term "determine" in subsection (c) and questioned whether "determining the cause of death" is synonymous with "medically certifying a report of death." After consideration of IRRC's comment, the Board has concluded that "determining the cause of death" is not synonymous with "medically certifying a report of death." Among other things, a medical certification of death includes both pronouncement of death and determination of the cause of death. Prior to Act 17, physician assistants had the authority to pronounce death; Act 17 gave physician assistants the authority to also determine and certify the cause of death. The Board prefers to use "determining the cause of death" because it provides more guidance to physician assistants. In this final rulemaking, the Board amends subsection (c) to clarify that physician assistants may authenticate with the physician assistant's signature any form related to pronouncing and determining the cause of death. IRRC also asked the Board to evaluate whether section 507(d) of the act of June 22, 2012 (P.L.644, No. 68) (Act 68), which amended 35 P.S. § 450.507, impacts a physician assistant's authority to determine the cause of death. Act 68 addresses a professional nurse's authority to "pronounce" death in certain circumstances. Section 507(d) provides, *"[e]xcept as provided in sections 502-503*…[t]he responsibility for determining the cause of death remains with the physician, certified registered nurse practitioner or the coroner as provided under this act." (Emphasis added). As indicated above, Act 17, which amended section 502 of the Vital Statistics Law of 1953 in 2017, (5 years after Act 68) clearly provides the legal authority to physician assistants to determine the cause of death. Accordingly, Act 68 does not impact a physician assistant's authority under section 502 of the Vital Statistics Law of 1953.

IRRC also asked whether there is a role for the substitute supervising physician if the attending physician or primary supervising physician is unavailable under § 18.151(c). Specifically, IRRC asked whether the substitute supervising physician should be notified before contacting the coroner if the attending physician or primary supervising physician is not available and suggested changing "attending physician" and "not available" to "primary supervising physician" and "unable to supervise." The substitute supervising physician does not have to be notified before contacting the coroner in this situation; however, the Board agrees with IRRC that this language should be updated to include the role of supervising physician. The Board therefore deletes the term "attending physician" as it is an outdated and undefined term. The final rulemaking requires that either the supervising physician or the physician assistant notify the county coroner.

Amendment for clarity

In § 18.122 (relating to definitions), the term "hospital" is used in the definition of prescription. The Board intended to update this term throughout the proposed rulemaking, but mistakenly did not update it here. Consistent with amendments made elsewhere in the proposed

rulemaking where the Board proposed to delete the term "hospital," the Board amends this definition to delete the term "hospital" and replaces it with the term "health care facility" so that this provision would apply to all licensed facilities and not just hospitals.

Fiscal Impact and Paperwork Requirements

The regulation will not have any fiscal impact on licenses, the Board, or the Commonwealth, nor is any additional paperwork anticipated.

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 November 27, 2023, the Board submitted a copy of the notice of proposed rulemaking, published at 53 Pa.B 7896 (December 16, 2023) and a copy of a Regulatory Analysis form to IRRC and the chairpersons of the SCP/PLC and HPLC for review and comment. A copy of this material is available to the public upon request.

Under section 5(c) of the Regulatory Review Act, the Board provided IRRC, SCP/PLC and HPLC with copies of the comments received on the regulation, as well as other documents when requested. In preparing this final-form rulemaking, the Board has considered all comments received from IRRC and the public comments received.

Under section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)), on March 11, 2025, the Board delivered this final-form rulemaking to IRRC, the SCP/PLC and HPLC. Under section 5.1(j.2) of the Regulation Review Act, the final-form rulemaking was deemed approved by the SCP/PLC and HPLC on _____, 2025. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2025, and approved the final-form rulemaking.

Additional Information

Additional information may be obtained by writing to Board Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, Pennsylvania, 17106-5923, RA-STRegulatoryCounsel@pa.gov

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 and 1202), known as the Commonwealth Documents Law and the regulations promulgated thereunder, 1 Pa. Code

§§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law, and all comments received were considered in drafting this final-form rulemaking.

(3) The amendments to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking published at 53 Pa.B 7896 (December 16, 2023).

(4) This final-form rulemaking is necessary and appropriate for the administration of the act of October 7, 2021 (P.L. 418, No. 79), which amended section 13 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.13).

Order

The Board, therefore, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 18 are amended by amending §§ 18.122, 18.141-18.144, 18.151-18.154, 18.156-18.159, 18.161, 18.162, 18.171, and 18.172. The regulations of the Board are also amended by deleting § 18.155 (relating to satellite locations).

(b) The Board shall submit the final-form regulation to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall submit the final-form regulation to IRRC, the SCP/PLC and HPLC as required by law.

(d) The Board shall certify the final-form regulation and deposit it with the Legislative Reference Bureau as required by law.

(e) This final-form regulation shall take effect upon publication in the *Pennsylvania Bulletin.*

Donald M. Yealy, M.D.
Chair, State Board of Medicine

16A-4955 Commentator List

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Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 18. STATE BOARD OF MEDICINE – PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter D. PHYSICIAN ASSISTANTS

GENERAL PROVISIONS

§ 18.122. Definitions.

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

ARC-PA—The Accreditation Review Commission on Education for Physician Assistants.

Administration—The direct application of a drug, whole blood, blood components, diagnostic procedure or device, whether by injection, inhalation, ingestion, skin application or other means, into the body of a patient.

* * * * *

Emergency medical care setting-

(i) A health care setting which is established to provide emergency medical care as its primary purpose.

(ii) The term does not include a setting which provides general or specialized medical services that are not routinely emergency in nature even though that setting provides emergency medical care from time to time.

Health care facility – As defined in section 103 of the Health Care Facilities Act (35 P.S. § 448.103).

[*Medical care facility*- an entity licensed or approved to render health care services.]

Medical regimen-A therapeutic, corrective or diagnostic measure performed or ordered by a physician, or performed or ordered by a physician assistant acting within the physician assistant's scope of practice, and in accordance with the written agreement between the supervising physician and the physician assistant.

Medical service—An activity which lies within the scope of practice of medicine and surgery.

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.

Order—An oral or written directive for a therapeutic, corrective or diagnostic measure, including a drug to be dispensed for onsite administration [in a hospital, medical care facility or office setting].

Physician—A medical doctor or doctor of osteopathic medicine.

* * * * *

Physician assistant program—A program for the training and education of physician assistants which is recognized by the Board [and] or accredited by the CAHEA, the CAAHEP, ARC-PA or a successor agency.

Prescription—

(i) A written, electronic, or oral order for a drug or device to be dispensed to or for an ultimate user.

(ii) The term does not include an order for a drug which is dispensed for immediate administration to the ultimate user; for example, an order to dispense a drug to a patient for immediate administration in an office or ~~hospital~~ HEALTH CARE FACILITY is not a prescription.

Primary supervising physician—A medical doctor who is registered with the Board and designated in the written agreement as having primary responsibility for [directing and personally] supervising the physician assistant.

[*Satellite location*—A location, other than the primary place at which the supervising physician provides medical services to patients, where a physician assistant provides medical services.]

Scope of practice – The medical services within a physician assistant's skills, training and experience that a physician assistant may perform as set forth in the written agreement.

Substitute supervising physician—A [supervising physician] medical doctor who is [registered with the Board and] designated in the written agreement on file with the Board, or maintained at the practice location, as assuming primary responsibility for a physician assistant when the primary supervising physician is [unavailable] unable to supervise.

Supervising physician- [Each physician who is identified in a written agreement as a physician who supervises a physician assistant] The primary supervising physician and each substitute supervising physician who supervises a physician assistant, who is either identified in a written agreement on file with the Board, or maintained at the practice location where the physician assistant practices.

Supervision—

(i) Oversight [and personal direction of,] and responsibility for the medical services rendered by a physician assistant. The constant physical presence of the supervising physician is not

required so long as the supervising physician and the physician assistant are, or can be, easily in contact with each other [by radio, telephone or other telecommunications device].

(ii) An appropriate degree of supervision includes:

(A) [Active and continuing overview] Overview of the physician assistant's activities [to determine that the physician's directions are being implemented] as provided for in the written agreement.

(B) Immediate availability of the supervising physician to the physician assistant for necessary consultations.

(C) [Personal and regular review within 10 days] Review by the supervising physician of the patient records upon which entries are made by the physician assistant in accordance with § 18.142(5) (relating to written agreements).

Unable to supervise– When the primary supervising physician cannot supervise the physician assistant due to temporary absence, the primary supervising physician is working at another location or the physician assistant is providing services for a substitute supervising physician who is either named in the written agreement on file with the Board or maintained at the practice location.

Written agreement—The agreement between the physician assistant and primary supervising physician, which satisfies the requirements of § 18.142 [(relating to written agreements)].

* * * * *

LICENSURE OF PHYSICIAN ASSISTANTS AND REGISTRATION OF SUPERVISING PHYSICIANS

§ 18.141. Criteria for licensure as a physician assistant.

The Board will approve for licensure as a physician assistant an applicant who meets all of the following requirements:

(1) Satisfies the licensure requirements in § 16.12 (relating to general qualifications for licenses and certificates) including the completion of at least 3 hours of approved training in child abuse recognition and reporting in accordance with § 16.108(a) (relating to child abuse recognition and reporting—mandatory training requirement).

(2) Has graduated from [a] an accredited physician assistant program [recognized by the Board] as provided for under § 18.131 (relating to recognized educational programs/standards).

(3) Has submitted a completed application together with the required fee, under § 16.13 (relating to licensure, certification, examination and registration fees).

(4) Has passed the physician assistant examination.

§ 18.142. Written agreements.

(a) The written agreement required by section 13(e) of the act (63 P. S. § 422.13(e)) satisfies the following requirements. The agreement must:

(1) Identify and be signed by the physician assistant and [each physician the physician assistant will be assisting who will be acting as a] the primary supervising physician. [At least one] The primary supervising physician shall be a medical doctor.

(2) Describe the [manner in which the physician assistant will be assisting each named physician. The description must list functions to be delegated to the physician assistant] physician assistant's scope of practice.

(3) Describe the [time, place and manner of supervision and direction each named] nature and degree of supervision the supervising physician will provide the physician assistant [, including the frequency of personal contact with the physician assistant].

(4) [Designate one of the named physicians who shall be a medical doctor as the primary supervising physician.] Be prepared and submitted by the primary supervising physician, the physician assistant or a delegate of the primary supervising physician and the physician assistant. It shall not be a defense in any administrative or civil action that the physician assistant acted outside of the scope of the Board-filed description or that the supervising physician utilized the physician assistant outside of the scope of the Board-filed description because the supervising physician or physician assistant permitted another person to represent to the Board that the description had been approved by the supervising physician or physician assistant.

(5) Require that the supervising physician shall countersign the patient record [completed by the physician assistant within a reasonable amount of time. This time period may not exceed 10 days] as outlined in the written agreement and as provided for as follows:

(i) The primary supervising physician shall determine countersignature requirements of patient records completed by the physician assistant in a written agreement, except as provided for in subparagraph (ii).

(ii) The primary supervising physician shall countersign 100% patient records completed by the physician assistant within a reasonable time, which may not exceed 10 days, during the following periods:

(A) The first 12 months of the physician assistant's practice post-graduation and after the physician assistant has fulfilled the criteria for licensure set forth in section 36(c) of the act (63 P.S. § 422.36(c)).

(B) The first 12 months of the physician assistant's practice in a new specialty in which the physician assistant is practicing.

(6) Identify the [locations and practice settings] primary practice setting where the physician assistant will serve.

(7) Name at least one substitute supervising physician if the physician assistant intends to practice if the primary supervising physician is permanently unable to supervise.

(b) The written agreement shall be [approved by] filed with the Board [as satisfying the requirements in subsection (a) and as being consistent with relevant provisions of the act and regulations contained in this subchapter] and shall be effective upon submission to the Board by the primary supervising physician, physician assistant or a delegate of the primary supervising physician and physician assistant.

(c) [A] Upon request, a physician assistant or supervising physician shall provide [immediate] access to the written agreement to [anyone seeking to] confirm the scope of the physician assistant's authority.

§ 18.143. Criteria for registration as a supervising physician.

(a) The Board will register a primary supervising physician applicant who:

(1) Possesses a current license without restriction to practice medicine and surgery in this Commonwealth.

(2) Has filed a completed registration form accompanied by the written agreement (see § 18.142 (relating to written agreements)) and the required fee under § 16.13 (relating to licensure, certification, examination and registration fees). The registration requires detailed information regarding the physician's professional background and specialties, medical education, internship, residency, continuing education, membership in American Boards of medical specialty, hospital or staff privileges and other information the Board may require.

(3) Includes with the registration, [a list, identifying by name and license number, the other physicians who are serving as supervising physicians,] the name and license number of at least one other physician who is serving as a substitute supervising physician of the designated physician assistant [under other written agreements]. The physician assistant will refrain from practicing when the primary supervising is permanently unable to supervise unless at least one substitute supervising physician is named in the written agreement on file with the Board.

(b) [If the supervising physician plans to utilize physician assistants in satellite locations, the supervising physician shall provide the Board with supplemental information as set forth in § 18.155 (relating to satellite locations) and additional information requested by the Board directly relating to the satellite location.] [Reserved].

(c) The Board will keep a current list of registered primary supervising physicians. The list will include the primary supervising physician's name, the address [of residence, current business address] on file with the Board, the date [of filing] the written agreement was filed with the Board, [satellite locations if applicable,] the names of current physician assistants under the primary supervising physician's supervision and [the physicians] at least one physician willing to provide substitute supervision in accordance with § 18.154 (relating to substitute supervising physician).

§ 18.144. Responsibility of primary supervising physician.

A primary supervising physician shall assume the following responsibilities. The supervisor shall:

(1) Monitor the compliance of all parties to the written agreement with the standards contained in the written agreement, the act and this subchapter.

(2) Advise any party to the written agreement of the failure to conform with the standards contained in the written agreement, the act and this subchapter.

(3) Arrange for a substitute supervising physician. [(]See § 18.154 (relating to substitute supervising physician).[)]

(4) [Review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.] [Reserved].

(5) [See each patient while hospitalized at least once.] [Reserved].

(6) Provide access to the written agreement upon request and provide clarification of orders and prescriptions [by the physician assistant relayed to other health care practitioners].

(7) [Accept full professional and legal responsibility for the performance of the physician assistant and the care and treatment of the patients.] Maintain oversight and responsibility for the medical services rendered by physician assistant.

(8) Maintain at the practice or facility a current list of all substitute supervising physicians with which a physician assistant will work.

(9) Notify the Board of any change in the primary practice address using a written agreement change form within 15 days.

* * * * *

PHYSICIAN ASSISTANT UTILIZATION

§ 18.151. Role of physician assistant.

(a) The physician assistant practices medicine with physician supervision. A physician assistant may perform those duties and responsibilities, including the ordering, prescribing, dispensing, and administration of drugs and medical devices, as well as the ordering, prescribing, and executing of diagnostic and therapeutic medical regimens, as [directed by the supervising physician] provided in the written agreement.

(b) The physician assistant may provide any medical service [as directed by the supervising physician] when the service is within the physician assistant's [skills, training and experience, forms a component of the physician's] scope of practice, is [included] identified in the written agreement and is [provided with the amount of supervision in keeping] consistent with the accepted standards of medical practice.

(c) The physician assistant may pronounce death, [but not] determine the cause of death, and may authenticate with the physician assistant's signature any form related to pronouncing AND DETERMINING THE CAUSE OF death. ~~If the attending physician is not available,~~ EITHER THE SUPERVISING PHYSICIAN OR the physician assistant shall notify the county coroner. The coroner has the authority to release the body of the deceased to the funeral director.

(d) The physician assistant may authenticate with the physician assistant's signature any form that may otherwise be authenticated by a physician's signature as permitted by the supervising physician, [State or Federal] Federal or State law and facility protocol, if applicable.

(e) The physician assistant shall be considered the agent of the supervising physician in the performance of all practice-related activities including the ordering of diagnostic, therapeutic and other medical services.

§ 18.152. Prohibitions.

(a) A physician assistant may not:

(1) Provide medical services except as described in the written agreement.

(2) [Prescribe or dispense drugs except as described in the written agreement.] [Reserved].

(3) [Maintain or manage a satellite location under § 18.155 (relating to satellite locations) unless the maintenance or management is registered with the Board.] [Reserved].

(4) Independently practice [or bill patients for services provided].

(5) Independently delegate a task specifically assigned to [him] the physician assistant by the supervising physician to another health care provider.

(6) [List his name independently in a telephone directory or other directory for public use in a manner which indicates that he functions] Intentionally advertise as an independent practitioner or hold oneself out as an independent practitioner.

(7) Perform acupuncture except as permitted by section 13(k) of the act (63 P. S. § 422.13(k)).

(8) [Perform a medical service without the supervision of a supervising physician.] [Reserved].

(b) A supervising physician may not:

(1) Permit a physician assistant to engage in conduct proscribed in subsection (a).

(2) Have primary responsibility for more than [two] six physician assistants unless the Board approves supervision of additional physician assistants.

§ 18.153. Executing and relaying medical regimens.

(a) A physician assistant may execute a written or oral order for a medical regimen or may relay a written or oral order for a medical regimen to be executed by a health care practitioner subject to the requirements of this section.

(b) [As provided for in the written agreement, the physician assistant shall report orally or in writing, to a supervising physician, within 36 hours, those medical regimens executed or relayed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to execute or relay a medical regimen.] [Reserved].

(c) The physician assistant shall record, date and authenticate the medical regimen on the patient's chart at the time it is executed or relayed. When working in a [medical care] health care facility, a physician assistant may comply with the recordation requirement by directing the recipient of the order to record, date and authenticate that the recipient received the order, if this practice is

consistent with the [medical care] health care facility's written policies. The supervising physician shall countersign the patient record [within a reasonable time not to exceed 10 days, unless countersignature is required sooner by regulation, policy within the medical care facility or the requirements of a third-party payor] as provided for in the written agreement or as required under § 18.142(a)(5)(ii) (relating to written agreements).

(d) A physician assistant or primary supervising physician shall provide [immediate] access to the written agreement to anyone seeking to confirm the physician assistant's authority to relay a medical regimen or administer a therapeutic or diagnostic measure

§ 18.154. Substitute supervising physician.

(a) If the primary supervising physician is [unavailable] permanently unable to supervise the physician assistant, the primary supervising physician may not delegate patient care to the physician assistant unless [appropriate arrangements for substitute supervision are] at least one substitute supervising physician is named in the written agreement and [the substitute physician is registered as a supervising physician] on file with the Board. A list of all other substitute supervising physicians that the physician assistant may serve must be maintained at the physician assistant's practice location.

(b) It is the responsibility of the substitute supervising physician to ensure that supervision is maintained in the absence of the primary supervising physician.

(c) During the period of supervision by the substitute supervising physician, the substitute supervising physician retains [full professional and legal responsibility for the performance of] responsibility for the medical services that the physician assistant [and the care and treatment of the patients treated by the physician assistant] renders.

(d) Failure to properly supervise may provide grounds for disciplinary action against the substitute supervising physician.

(e) In the event of the primary supervising physician becomes permanently unable to supervise, the substitute supervising physician shall assume primary responsibility for the physician assistant until a new written agreement can be filed for a time period not to exceed 30 days.

§ 18.155. [Satellite locations.] [Reserved].

[(a) *Registration of satellite location*. A physician assistant may not provide medical services at a satellite location unless the supervising physician has filed a registration with the Board.

(b) *Contents of statement*. A separate statement shall be made for each satellite location. The statement must demonstrate that:

(1) The physician assistant will be utilized in an area of medical need.

(2) There is adequate provision for direct communication between the physician assistant and the supervising physician and that the distance between the location where the physician provides services and the satellite location is not so great as to prohibit or impede appropriate support services.

(3) The supervising physician shall review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.

(4) The supervising physician will visit the satellite location at least once every 10 days and devote enough time onsite to provide supervision and personally review the records of selected patients seen by the physician assistant in this setting. The supervising physician shall notate those patient records as reviewed.

(c) *Failure to comply with this section*. Failure to maintain the standards required for a satellite location may result not only in the loss of the privilege to maintain a satellite location but also may result in disciplinary action against the physician assistant and the supervising physician.]

§ 18.156. Monitoring and review of physician assistant utilization.

(a) Representatives of the Board will be authorized to conduct scheduled and unscheduled onsite inspections of the locations where the physician assistants are utilized during the supervising physician's office hours to review the following:

(1) Supervision of the physician assistant. See §§ 18.144 and 18.154 (relating to responsibility of primary supervising physician; and substitute supervising physician).

(2) Presence of the written agreement and compliance with its terms. See § 18.142 (relating to written agreements).

(3) Utilization in conformity with the act, this subchapter and the written agreement.

(4) Appropriate identification of physician assistant. See § 18.171 (relating to physician assistant identification).

(5) Compliance with licensure and registration requirements. See §§ 18.141 and 18.145 (relating to criteria for licensure as a physician assistant; and biennial registration requirements; renewal of physician assistant license).

(6) Maintenance of records evidencing patient and supervisory contact by the supervising physician.

(b) [Reports] <u>Inspection reports</u> shall be submitted to the Board and become a permanent record under the supervising physician's registration. Deficiencies reported will be reviewed by the Board and may provide a basis for [loss of the privilege to maintain a satellite location and] disciplinary action against the physician assistant and the supervising physician.

(c) The Board reserves the right to review physician assistant utilization without prior notice to either the physician assistant or the supervising physician. It is a violation of this subchapter for a supervising physician or a physician assistant to refuse to comply with the request by the Board for the information in subsection (a).

(d) Additional inspections, including follow-up inspections may be conducted if the Board has reason to believe that a condition exists which threatens the public health, safety or welfare.

§ 18.157. Administration of controlled substances and whole blood and blood components.

(a) In a [hospital, medical] <u>health</u> care facility or office setting, the physician assistant may order or administer, or both, controlled substances and whole blood and blood components if the authority to order and administer these medications and fluids is expressly set forth in the written agreement.

(b) The physician assistant shall comply with the minimum standards for ordering and administering controlled substances specified in § 16.92 (relating to prescribing, administering and dispensing controlled substances).

§ 18.158. Prescribing and dispensing drugs, pharmaceutical aids and devices.

(a) *Prescribing, dispensing and administration of drugs*.

(1) The supervising physician may delegate to the physician assistant the prescribing, dispensing and administering of drugs and therapeutic devices.

(2) A physician assistant may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substances, Drug, Device, and Cosmetic Act (35 P. S. § 780-104).

(3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if it was approved by the supervising physician for ongoing therapy. The prescription must clearly state on its face that it is for initial or ongoing therapy.

(4) A physician assistant may only prescribe or dispense a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant and only in accordance with the [supervising physician's instructions and] written agreement.

(5) A physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients.

(6) A physician assistant authorized to prescribe or dispense, or both, controlled substances shall register with the Drug Enforcement Administration (DEA).

(b) [*Prescription blanks*] *Prescriptions*. The requirements for prescription blanks and electronic prescriptions are as follows:

(1) [Prescription blanks] Prescriptions must bear the license number of the physician assistant and the name of the physician assistant in a printed format at the heading of the [blank] prescription. The supervising physician must also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(2) The signature of a physician assistant shall be followed by the initials ''PA-C'' or similar designation to identify the signer as a physician assistant. When appropriate, the physician assistant's DEA registration number must appear on the prescription.

(3) The supervising physician is prohibited from presigning prescription blanks.

(4) The physician assistant may use a prescription blank generated by a [hospital] health care facility provided the information in paragraph (1) appears on the blank.

(c) Inappropriate *prescription*. The supervising physician shall immediately advise the patient, notify the physician assistant and, in the case of a written prescription, advise the pharmacy if the physician assistant is prescribing or dispensing a drug inappropriately. The supervising physician shall advise the patient and notify the physician assistant to discontinue using the drug and, in the case of a written prescription, notify the pharmacy to discontinue the prescription. The order to discontinue use of the drug or prescription shall be noted in the patient's medical record by the supervising physician.

(d) Recordkeeping *requirements*. Recordkeeping requirements are as follows:

(1) When prescribing a drug, the physician assistant shall keep a copy of the prescription, including the number of refills, in a ready reference file, or record the name, amount and doses of the drug prescribed, the number of refills, the date of the prescription and the physician assistant's name in the patient's medical records.

(2) When dispensing a drug, the physician assistant shall record the physician assistant's name, the name of the medication dispensed, the amount of medication dispensed, the dose of the medication dispensed and the date dispensed in the patient's medical records.

(3) [The physician assistant shall report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to prescribe or dispense in accordance with the written agreement.] [Reserved].

(4) The supervising physician shall countersign the patient record [within 10 days] as provided for in the WRITTEN agreement and as required in § 18.142(a)(5)(ii) (relating to written agreements).

(5) [The] Upon request, the physician assistant and the primary supervising physician shall provide [immediate] access to the written agreement to anyone seeking to confirm the physician assistant's authority to prescribe or dispense a drug. The written agreement must list the categories of drugs which the physician assistant is not permitted to prescribe.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs*. A physician assistant shall comply with §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.159. Medical records.

The supervising physician shall timely review [, not to exceed 10 days,] the medical records prepared by the physician assistant to ensure that the requirements of § 16.95 (relating to medical records) have been satisfied as described in the written agreement or as required under § 18.142(a)(5)(ii) (relating to written agreements).

[MEDICAL CARE FACILITIES] HEALTH CARE FACILITIES AND EMERGENCY MEDICAL SERVICES

§ 18.161. Physician assistant employed by [medical] health care facilities.

(a) A physician assistant may be employed by a [medical] health care facility but shall comply with the requirements of the act and this subchapter.

(b) [The physician assistant may not be responsible to more than three supervising physicians in a medical care facility.] [Reserved].

(c) [This subchapter does not require medical care facilities to employ physician assistants or to permit their utilization on their premises.] Physician assistants are permitted to provide medical services to the [hospitalized] patients of their supervising physicians if the [medical] health care facility permits it.

(d) Physician assistants granted privileges by, or practicing in, a [medical] health care facility shall conform to policies and requirements delineated by the facility.

(e) In health care facilities, the attending physician of record for a patient shall act as the primary supervising physician for the physician assistant while the patient is under the care of the attending physician.

§ 18.162. Emergency medical services.

(a) A physician assistant may only provide medical service in an emergency medical care setting if the physician assistant has training in emergency medicine [, functions within the purview of the physician assistant's] and is provided for in the written agreement [and is under the supervision of the supervising physician].

(b) A physician assistant licensed in this Commonwealth or licensed or authorized to practice in any other state who is responding to a need for medical care created by a declared state of

emergency or a state or local disaster (not to be defined as an emergency situation which occurs in the place of one's employment) may render care consistent with relevant standards of care.

* * * * *

IDENTIFICATION AND NOTICE RESPONSIBILITIES

§ 18.171. Physician assistant identification.

(a) A physician assistant may not render medical services to a patient until the patient or the patient's legal guardian has been informed that:

(1) The physician assistant is not a physician.

(2) [The physician assistant may perform the service required as the agent of the physician and only as directed by the supervising physician.] [Reserved].

(3) The patient has the right to be treated by the physician if the patient desires.

(b) It is the supervising physician's responsibility to be alert to patient complaints concerning the type or quality of services provided by the physician assistant.

(c) In the supervising physician's office [and satellite locations], a notice plainly visible to patients shall be posted in a prominent place explaining that a ''physician assistant'' is authorized to assist a physician in the provision of medical care and services. The supervising physician shall display the registration to supervise in the office. The physician assistant's license shall be prominently displayed at any location at which the physician assistant provides services. Duplicate licenses may be obtained from the Board if required.

(d) The physician assistant shall wear an identification tag which uses the term ''Physician Assistant'' in easily readable type. The tag shall be conspicuously worn.

§ 18.172. Notification of changes in employment.

(a) The physician assistant is required to notify the Board [, in writing,] of a change in or termination of employment or a change in mailing address within 15 days. Failure to notify the Board [, in writing,] of a change in mailing address may result in failure to receive pertinent material distributed by the Board. The physician assistant shall provide the Board with the new address of residence, address of employment and name of the registered primary supervising physician.

(b) The primary supervising physician is required to notify the Board [, in writing,] of a change or termination of supervision of a physician assistant within 15 days.

(c) Failure to notify the Board of changes in employment or a termination in the physician/physician assistant relationship is a basis for disciplinary action against the primary supervising physician's license, the primary supervising physician's registration and the physician assistant's license.

* * * * *

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

March 11, 2025

The Honorable George D. Bedwick, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Medicine
16A-4955: Physician Assistants

Dear Chairman Bedwick:

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

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

Sincerely,

Donald M. Yealy, M.D., Chairperson
State Board of Medicine

MBW/JAW/dps
Enclosure

cc: Arion Claggett, Acting Commissioner of Professional and Occupational Affairs
K. Kalonji Johnson, Deputy Secretary for Regulatory Programs
Andrew LaFratte, Deputy Policy Director, Department of State
Jason C. Giurintano, Deputy Chief Counsel, Department of State
Jacqueline A. Wolfgang, Senior Regulatory Counsel, Department of State
Dana M. Archer, Senior Counsel, State Board of Medicine
State Board of Medicine

Worthington, Amber

From: Brett, Joseph D. <JBrett@pahouse.net>
Sent: Tuesday, March 11, 2025 2:42 PM
To: Worthington, Amber; Orchard, Kari L.; Barton, Jamie
Subject: RE: Follow-up RE: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Received. Thank you.

Joe Brett
Research Analyst | House Professional Licensure Committee (D)
Chairman Frank Burns, 72nd Legislative District

From: Worthington, Amber <agontz@pa.gov>
Sent: Tuesday, March 11, 2025 1:18 PM
To: Orchard, Kari L. <KOrchard@pahouse.net>; Barton, Jamie <JBarton@pahouse.net>; Brett, Joseph D. <JBrett@pahouse.net>
Subject: Follow-up RE: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Good Afternoon, we are following up on the below delivery as we have not received a confirmation reply yet.

Thank you,

Amber A. Worthington, PLS | Legal Office Administrator 2
Office of Chief Counsel | Department of State
Governor's Office of General Counsel
P.O. Box 69523 | Harrisburg, PA 17106-9523
Office Phone 717.783.7200 | Fax: 717.787.0251
agontz@pa.gov | www.dos.pa.gov

Preferred Pronouns: We/Us, They/Them/Theirs

From: Worthington, Amber
Sent: Tuesday, March 11, 2025 8:59 AM
To: korchard@pahouse.net; Barton, Jamie <jbarton@pahouse.net>; jbrett@pahouse.net
Subject: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Please provide a written (email) confirmation of receipt of delivery of the attached final rulemaking.

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

Thank you for your attention to this matter.

- 16A-4955 Physician Assistants
  - 16A-4955 – State Board of Medicine – Physician Assistants: This final rulemaking package is necessary to amend the regulations of the State Board of Medicine ("Board") to effectuate the act of October 7, 2021 (P.L. 418, No. 79) (Act 79). The final regulation incorporates the language of Act 79 into the Board's regulations as it relates to definitions, written agreement requirements, criteria for registration and responsibilities of supervising physicians, countersignature requirements, the role of the physician assistant, prohibitions on practice, and prescribing by physician assistants. It also updates terminology and removes outdated provisions of the regulations.

Thank you for your attention to this matter.

Doug P. Solomon |Legal Assistant 2
Office of Chief Counsel |Department of State
Governor's Office of General Counsel
2400 Thea Drive
P.O. Box 69523 |Harrisburg, PA 17106-9523
Office Phone 717.783.7200 |Fax 717.787.0251
dousolomon@pa.gov|www.dos.pa.gov

Worthington, Amber

From: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Sent: Tuesday, March 11, 2025 9:19 AM
To: Worthington, Amber
Subject: RE: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC # 3390

Received.

Jennifer Smeltz, Executive Director
Consumer Protection and Professional Licensure Committee
Office of Senator Pat Stefano
Phone: (717) 787-7175

From: Worthington, Amber <agontz@pa.gov>
Sent: Tuesday, March 11, 2025 9:00 AM
To: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Subject: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Please provide a written (email) confirmation of receipt of delivery of the attached final rulemaking.

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

Thank you for your attention to this matter.

- 16A-4955 Physician Assistants
  - 16A-4955 – State Board of Medicine – Physician Assistants: This final rulemaking package is necessary to amend the regulations of the State Board of Medicine ("Board") to effectuate the act of October 7, 2021 (P.L. 418, No. 79) (Act 79). The final regulation incorporates the language of Act 79 into the Board's regulations as it relates to definitions, written agreement requirements, criteria for registration and responsibilities of supervising physicians, countersignature requirements, the role of the physician assistant, prohibitions on practice, and prescribing by physician assistants. It also updates terminology and removes outdated provisions of the regulations.

Thank you for your attention to this matter.

Doug P. Solomon |Legal Assistant 2
Office of Chief Counsel |Department of State
Governor's Office of General Counsel
2400 Thea Drive
P.O. Box 69523 |Harrisburg, PA 17106-9523
Office Phone 717.783.7200 |Fax 717.787.0251
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RECEIVED

Independent Regulatory
Review Commission

March 11, 2025

Worthington, Amber

From: Monoski, Jesse <Jesse.Monoski@pasenate.com>
Sent: Tuesday, March 11, 2025 9:34 AM
To: Worthington, Amber; Dimm, Ian; joseph.kelly; Vazquez, Enid
Subject: Re: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC # 3390

Received

Thank you

-Jesse

Get Outlook for Android

From: Worthington, Amber <agontz@pa.gov>
Sent: Tuesday, March 11, 2025 8:58:42 AM
To: Monoski, Jesse <jesse.monoski@pasenate.com>; Dimm, Ian <Ian.Dimm@pasenate.com>; Kelly, Joseph <joseph.kelly@pasenate.com>; Vazquez, Enid <enid.vazquez@pasenate.com>
Subject: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Please provide a written (email) confirmation of receipt of delivery of the attached final rulemaking.

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

Thank you for your attention to this matter.

- 16A-4955 Physician Assistants
  - 16A-4955 – State Board of Medicine – Physician Assistants: This final rulemaking package is necessary to amend the regulations of the State Board of Medicine ("Board") to effectuate the act of October 7, 2021 (P.L. 418, No. 79) (Act 79). The final regulation incorporates the language of Act 79 into the Board's regulations as it relates to definitions, written agreement requirements, criteria for registration and responsibilities of supervising physicians, countersignature requirements, the role of the physician assistant, prohibitions on practice, and prescribing by physician assistants. It also updates terminology and removes outdated provisions of the regulations.

Thank you for your attention to this matter.

Doug P. Solomon |Legal Assistant 2
Office of Chief Counsel |Department of State
Governor's Office of General Counsel
2400 Thea Drive
P.O. Box 69523 |Harrisburg, PA 17106-9523
Office Phone 717.783.7200 |Fax 717.787.0251
dousolomon@pa.gov|www.dos.pa.gov

RECEIVED

Independent Regulatory
Review Commission

March 11, 2025

Worthington, Amber

RECEIVED
Independent Regulatory Review Commission
March 11, 2025

From: Nicole Sidle <Nsidle@pahousegop.com>
Sent: Tuesday, March 11, 2025 10:00 AM
To: Worthington, Amber; Sauder, Coty
Cc: Cindy Sauder
Subject: RE: [EXTERNAL]: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Amber, this has been received however you have Cindy's email wrong. Can you please make sure this is corrected in future deliveries? Thanks.

From: Worthington, Amber <agontz@pa.gov>
Sent: Tuesday, March 11, 2025 9:00 AM
To: Nicole Sidle <Nsidle@pahousegop.com>; Sauder, Coty <csauder@pa.gov>
Subject: [EXTERNAL]: DELIVERY NOTICE: STATE BOARD OF MEDICINE, REGULATION 16A-4955, IRRC #3390

Please provide a written (email) confirmation of receipt of delivery of the attached final rulemaking.

Please be advised that the State Board of Medicine is delivering the below final rulemaking.

Thank you for your attention to this matter.

- 16A-4955 Physician Assistants
  - 16A-4955 – State Board of Medicine – Physician Assistants: This final rulemaking package is necessary to amend the regulations of the State Board of Medicine ("Board") to effectuate the act of October 7, 2021 (P.L. 418, No. 79) (Act 79). The final regulation incorporates the language of Act 79 into the Board's regulations as it relates to definitions, written agreement requirements, criteria for registration and responsibilities of supervising physicians, countersignature requirements, the role of the physician assistant, prohibitions on practice, and prescribing by physician assistants. It also updates terminology and removes outdated provisions of the regulations.

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