Regulatory Analysis Form (Completed by Promulgating Agency)	INDEPENDENT REGULATORY REVIEW COMMISSION				
(All Comments submitted on this regulation will appear on IRRC's webs	RECEIVED				
(1) Agency	Independent Regulatory				
Department of State, Bureau of Professional and	Review Commission November 6, 2025				
Occupational Affairs, State Board of Osteopathic	1 (0 (elimo el 0, 2025				
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(2) Agency Number: 16A	IRRC Number: 3464				
Identification Number: 5337					
(3) PA Code Cite:					
49 Pa. Code §§ 25.1, 25.161, 25.163, 25.201, 25.219, 25.241- 25.244, 25.246, 25.271, 25.601-25.607, and 25.608-25.609					
(4) Short Title:					
Education and Volunteer Services					
(5) A	14.11				
(5) Agency Contacts (List Telephone Number and Email Address):					
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Secondary Contact: Ashley B. Goshert, Board Counsel, State Board of Osteopathic Medicine, P.O. Box 69523, Harrisburg, PA 17106-9523; phone (717) 783-7200; fax (717) 787-025; agoshert@pa.gov .					
(6) Type of Rulemaking (check applicable box):					
∑ Proposed Regulation	☐ Emergency Certification Regulation;				
Final Regulation	Certification by the Governor				
Final Omitted Regulation	Certification by the Attorney General				
(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)					

The State Board of Osteopathic Medicine (board) proposes this rulemaking to implement section 9.1(a) of the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. § 872.9a). Section 9.1(a) of the ABC-MAP Act requires prescribers and dispensers to obtain mandatory education regarding pain management or the identification of addiction, education in the practices of prescribing or dispensing of opioids and opioid continuing education (collectively, "opioid education") as a condition of biennial renewal. The board also proposes to include provisions applicable to osteopathic physicians and physician assistants to make it clear that violations of the Safe Emergency Prescribing Act (35 P.S. §§ 873.1—873.9) will subject licensees to discipline. In addition, this proposed rulemaking would implement section 8628 of the Probate, Estates and Fiduciaries Code (Probate Code) (20 Pa.C.S. § 8628) (relating to requirements for physician and nurse training relative to organ and tissue donation and recovery) in that osteopathic physicians must complete at least 2 hours of board-approved continuing education in the organ

and tissue donation and recovery process one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever occurs first. Finally, this proposed rulemaking will also conform the board's regulations to amendments made over the past 25 years to the Volunteer Health Services Act (VHSA) (35 P.S. § 449.41-449.53).

(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.

Section 16 of the Osteopathic Medical Practice Act (act) (63 P.S. § 271.16) provides the board with broad authority to adopt regulations as are reasonably necessary to carry out the purposes of the act.

Under the amendments to section 9.1 of the ABC-MAP Act (35 P.S. § 872.9a) and the Probate Code, specifically 20 Pa. C.S. § 8628, the board is required to implement the mandatory education requirements.

The act of November 2, 2016 (P.L. 987, No. 126) (Act 126 of 2016), codified at 35 Pa.C.S. § 5102 (relating to safe opioid prescription education), requires the board to adopt an opioid education curriculum to be offered in colleges or by providers approved by the board.

The Safe Emergency Prescribing Act (35 P.S. §§ 873.1-873.9) imposes restrictions on osteopathic physicians and physician assistants prescription of opioid drug products to individuals seeking treatment in an emergency department, urgent care center or in observation status in a hospital. Under section 7 of the Safe Emergency Prescribing Act (35 P.S. § 873.7), health care practitioners are subject to discipline by the licensing boards for violations of the Safe Emergency Prescribing Act.

This proposed rulemaking would also conform the board's regulations to the amendments made to the Volunteer Health Services Act (VHSA) (35 P.S. § 449.41-449.53) by the acts of October 18, 2000 (P.L. 599, No. 76) (Act 76 of 2000); June 19, 2002 (P.L. 406, No. 58) (Act 58 of 2002); July 8, 2007 (P.L. 91, No. 29) (Act 29 of 2007); and July 2, 2014 (P.L. 820, No. 86) (Act 86 of 2014).

Under section 711(j)(3) of the Medical Care Availability and Reduction of Error Act (MCARE Act) (40 P.S. § 1303.711)(j)(3)), a retired licensed participating health care provider who provides care only to themselves or their immediate family members (including a parent, a spouse, a child or an adult sibling residing in the same household) are exempt from medical professional liability insurance requirements under the MCARE Act.

Section 506 of the Administrative Code of 1929 (71 P.S. §186) empowers the heads of all administrative departments, the several independent administrative boards and commissions, the several departmental administrative boards and commissions to prescribe rules and regulations not inconsistent with law, for the government of their respective departments, boards or commissions.

(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 9.1 of the ABC-MAP Act and 20 Pa.C.S. § 8628 require the board to implement the mandatory education requirements for licensees of the board. The Probate Code, specifically 20 Pa. C.S. § 8628, requires the board to implement mandatory education requirements relating to organ and tissue donation and recovery. Otherwise, this rulemaking is not mandated by any Federal or state law or court order, or Federal regulation.

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

In 2016, the Legislature amended the ABC-MAP act by including the requirement imposed on all prescribers and dispensers who hold either a DEA registration or use the DEA number of another to obtain 2 hours of mandatory education regarding pain management or the identification of addiction, 2 hours of education in the practices of prescribing or dispensing of opioids (collectively, "opioid education") within 1 year of obtaining prescriptive authority, and an additional 2 hours of education in any of the three topics per biennium as a condition of biennial renewal.

In addition, 20 Pa. C.S. § 8628 requires osteopathic physicians to complete at least 2 hours of board-approved continuing education in organ donation one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever comes first. The proposed amendments would update the board's existing continuing education regulations on both subjects to be consistent with the aforementioned acts. Licensees will benefit by receiving mandatory training about their responsibilities under the Probate Code and all potential organ donors and recipients will benefit from this information. Currently, there are approximately 11,605 active licensed osteopathic physicians (including volunteer status licensees) that will have to complete this education.

Similarly, as the cases and dangers of opioid addiction are being readily discussed in the media and in healthcare communities, patients will benefit from the enhanced knowledge of this opioid education. That benefit has occurred because osteopathic physicians and physician assistants have been required to complete the opioid education at the time of application and on renewal since January 1, 2017. Additionally, while the Safe Emergency Prescribing Act only imposes an obligation on the Department of Health to promulgate regulations, because the board has opioid prescribing regulations, it believes it is in the interest of licensees to know their obligations underthat act.

Regarding the amendments made to update the volunteer license regulations, the purpose of the act is to increase the availability of primary health care services, including mental health services, by establishing a procedure through which physicians and other health care practitioners who are no longer actively practicing may provide professional services within their scope of practice as a volunteer in approved clinics serving financially qualified persons and in approved clinics located in medically underserved areas or health professionals shortage areas. It also serves to increase the availability of mental health services to military personnel and their families by establishing a procedure through which physicians and other health care practitioners who are no longer actively practicing may provide mental health services within their scope of practice as a volunteer upon referral from approved organizations. The updated regulations will be beneficial to the regulated community in that the regulatory standards will be updated and consistent with the VHSA. Moreover, the proposed regulations will fully implement the amendments to the VHSA, which will benefit individuals who are or seek to be treated by volunteer health care providers.

(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 standards on the topic.

(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 proposed regulations update the board's regulations to reflect and implement opioid and organ donation continuing education required by statutory amendments, as well as update volunteer license regulations to reflect amendments to the VHSA.

Of the six contiguous states within the Northeast region (New York, West Virginia, New Jersey, Delaware, Ohio and Maryland), all six states require education regarding opioid prescription pain management or substance use disorder for osteopathic physicians and physician assistants. Five of the states require 2 or more hours of education each renewal period. Three of the states have specific requirements for opioid education with the other states only requiring controlled substance abuse related education. Concerning organ donation, only one state currently requires specific organ and tissue donation education for osteopathic physicians (New Jersey). Another state currently has a bill pending for osteopathic physicians educational requirements in organ and tissue donation (New York). Two other states, while not requiring specific organ and tissue donation education of osteopathic physicians, do require training for hospital staff that approach potential donors' families to request donations (Delaware and Maryland). Regarding the proposed amendments to the volunteer license regulations, of the six contiguous states within the Northeast region, four states currently have provisions for physician volunteer licenses (West Virginia, Delaware, Ohio and Maryland).

West Virginia

The West Virginia Board of Osteopathic Medicine requires osteopathic physicians and physician assistants who prescribe controlled substances within the renewal reporting period to complete 3 hours of continuing medical education (CME) in drug diversion training and best practice prescribing of controlled substances training every 2 years. The state of West Virginia does not have specific organ and tissue donation education requirements for osteopathic physicians. West Virginia has provisions for volunteer physician licenses.

New Jersey

In New Jersey, on February 15, 2017, the "Opioid Law," (P.L. 2017, c. 28) was signed, which required the State Board of Medical Examiners to include 1 CME concerning prescription opioid drugs each biennial renewal period for osteopathic physicians and physician assistants, including courses or training on responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. Under New Jersey's State Board of Medical Examiners Law, each college of medicine within the state is required to include instruction in organ and tissue donation and recovery designed to address clinical aspects of the donation and recovery process and the rights of living organ donors. This instruction would be a required condition for receiving a diploma and would also be offered for CE credit. Physicians who did not receive this instruction as part of their initial diploma program are encouraged to complete the training within 3 years of enactment of the amended act (2021). While New Jersey allows volunteer services of actively licensed physicians for CME credits, there is no volunteer license.

Delaware

Under Delaware's Uniform Controlled Substances Act Regulations, licensed practitioners, including osteopathic physicians and physician assistants, who prescribe controlled substances are required to apply for and renew biennially a controlled substance registration. Initial registration requires a 1 hour, two part course on safe prescribing and distributing of controlled substances, treatment of pain, and recognizing and treating opioid use disorder. Biennial renewal requires 2 hours continuing education (CE) in the areas of controlled substance prescribing practices, treatment of chronic pain, or other topics related to prescribing controlled substances. These courses are not counted toward other CME

requirements and are regulated under the Delaware Division of Professional Regulation – Controlled Substances Advisory Committee. While the Delaware Board of Medical Licensure and Discipline does not have specific requirements for osteopathic physicians to obtain organ and tissue donation education, the Uniform Anatomical Gift Act defines a "designated requestor" as a hospital employee who has completed a course offered by the federally certified organ procurement organization (OPO) on how to approach potential donor families and request organ and tissue donation. Delaware also allows for volunteer physicians to practice medicine in a nonprofit medical clinic or service site provided they do not receive any direct compensation.

New York

In New York, pursuant to the Public Health Law § 3309-A(3), all licensed prescribers, including osteopathic physicians and physician assistants, who have a DEA registration number to prescribe controlled substances must complete at least 3 hours of course work or training in pain management, palliative care and addiction every 3 years. Similar to the Pennsylvania sponsored program, the New York State Department of Health, through the University at Buffalo, sponsored a free, comprehensive course covering the eight required topic areas (4 credits) entitled "Opioid Prescriber Education Program." While New York does not currently have specific educational requirements for osteopathic physicians on organ and tissue donations, bill A2702 was introduced in the New York Assembly January 22, 2025 concerning anatomical gifts. If enacted, this bill would amend New York's education law to require physicians' (including osteopathic physicians') educational programs to include instruction in organ and tissue donation and recovery as a requirement for a diploma. This bill would also require the same courses to be offered as part of CE. The proposed language encourages all physicians to complete the trainings within 3 years of enactment. New York allows actively licensed physicians to submit an Affidavit of Non-Compensation which waives the registration fee but there is no licensure for volunteers.

Ohio

The State Medical Board of Ohio requires osteopathic physicians and physician assistants who provide treatment for opioid use to complete at least 8 hours of CME relating to substance use disorder and addiction every 2 years. The state of Ohio does not have specific organ and tissue donation education requirements for osteopathic physicians. The State Medical Board may also issue a volunteer's certificate to a practitioner who is retired so that the practitioner may provide medical services to indigent and uninsured persons at any location, including a free clinic. The holder of a volunteer's certificate is subject to the immunity provisions regarding the provision of services to indigent and uninsured persons in section 2305.234 of Ohio's Revised Code.

Maryland

The Maryland Depart of Health – Prescription Drug Monitoring Program requires prescribers with prescriptive authority relating to controlled dangerous substances, including osteopathic physicians and physician assistants, to complete 2 hours of specific course CE in prescribing or dispensing of controlled substances. The Maryland Board of Physicians does not have specific requirements for osteopathic physicians to obtain organ and tissue donation education, but under Maryland Code, Health-General § 19-310(a)(1), a "designated requestor" is defined to be a hospital employee who has completed a course offered by an organ, tissue, or eye recovery agency on how to approach potential donor families and request organ or tissue donation. There are provisions for a volunteer license to practice medicine without remuneration while also not engaging in the private practice of medicine, including an exemption from license fee under a volunteer license.

The proposed regulation updates the board's regulations to include the statutorily mandated opioid

education, which has already been implemented by the board. Therefore, the board does not have discretion to require less opioid based education. Surrounding states have similar opioid education requirements; therefore, this proposed regulation will not place Pennsylvania at a competitive disadvantage by requiring the opioid education, but rather, will have a positive impact because board-regulated practitioners will be better educated in this area.

The organ donation education/continuing education is statutorily mandated; therefore, the board does not have discretion to require less education. Nonetheless, the board does not believe this proposed regulation will result in a competitive disadvantage as no additional continuing education hours must be taken to satisfy this requirement. The organ donation education may be used to satisfy the existing continuing education requirements. Both licensees and the public will benefit from this additional education. Further, the required organ donation education is a statutory requirement for which the board did not use any discretion.

Regarding the proposed amendments to the volunteer license regulations, the board is updating its existing regulations to reflect statutory updates to the VHSA. The board does not believe this proposed regulation will result in a competitive disadvantage, as four neighboring states also have provisions for volunteer physician licenses. Also, the regulated community will benefit from the updates to the volunteer license regulations as the standards set forth therein will provide clarity because the regulations will reflect the amendments to the VHSA.

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

No. The regulation does not affect any other regulations of the agency or other state agencies. However, there are additional boards that are or will be promulgating similar regulations.

(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.)

The board discusses its regulatory proposals at regularly scheduled public meetings of the board. Representatives of the professional associations representing the regulated community routinely attend those meetings.

Beginning in February 2021 and continuing through March, 2023, representatives from the Department of Health's Division of Nutrition and Physical Activity, Bureau of Health Promotion & Risk Reduction, Center for Organ Recovery and Education (CORE), Donate Life PA (Donate PA) and Gift of Life Donor Program (Gift of Life), organ procurement organizations (OPOs) designated for the region by the United States Secretary of Health and Human Services, and Counsel for the board, the State Board of Osteopathic Medicine and the State Board of Nursing formed a workgroup to discuss implementation of 20 Pa. C.S. § 8628 and the development of the required curriculum by the OPOs. The OPOs have advised that the curriculum is now available for providers.

In accordance with the requirements of Executive Order 1996-1 (4 Pa. Code §§ 1.371—1.382), the board sent an exposure draft of this proposed rulemaking to interested parties on June 11, 2025. The board submitted the exposure draft to stakeholders and individuals who indicated an interest in the board's regulatory agenda. The board received no comments on the exposure draft. On August 13, 2025,

the board voted to promulgate the proposed regulation.

(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?

According to the Small Business Administration (SBA), there are approximately 1,169,008 small businesses in Pennsylvania, which is 99.6% of all Pennsylvania businesses. Of the 1,169,008 small businesses, 230,244 are small employers (those with fewer than 500 employees) and the remaining 938,764 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses.

There are approximately 11,605 active osteopathic physicians (including volunteers) who are licensed by the board that would be required to comply with this regulation as it pertains to opioid and organ donation education, including those that are, or work for, small businesses. A board-regulated practitioner seeking to maintain or obtain volunteer licenses under the board would be required to comply with the proposed volunteer regulations. There are approximately 3,706 osteopathic physician assistants who are licensed by the board and who may be required to comply with the regulation as it pertains to opioid education, including those that are, or work for, small businesses. The opioid education requirement would not include active osteopathic physicians and physician assistants who do not hold a current DEA registration nor utilize the DEA registration number of another person or entity.

According to the Pennsylvania Department of Labor and Industry in 2022, osteopathic physicians and physician assistants provide their services for a variety of private and public sector employers.

The majority of physicians (osteopathic and other fields) generally work for offices of physicians (48.07%), general medical and surgical hospitals (20.64%), federal government (8.39%) and specialty (except psychiatric and substance abuse) hospitals (7.51%). Other employment for physicians includes being self-employed workers as a primary job (3.52%) and offices of other health practitioners (1.16%). General practitioners with a focus on healthcare diagnosing or treating have the highest estimated employment at general medical and surgical hospitals (41.28%), the Federal government (40.18%), and being self-employed workers as a primary job (7.39%). Some of these classifications would include approved clinics and approved organizations for volunteer licensure.

The majority of physician assistants (osteopathic and other fields) work for offices of physicians (53.41%), general medical and surgical hospitals (20.61%) and outpatient care centers (15.87%). Other employment for physician assistants includes offices of other health practitioners (2.14%), being self-employed workers as a primary job (2.10%) and individual and family services (0.62%).

For the business entities listed above, small businesses are defined in Section 3 of Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's (SBA) Small Business Size Regulations under 13 CFR Ch. 1 Part 121. Specifically, the SBA has established these size standards at 13 CFR 121.201 for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where licensees may work, offices of physicians (except mental health specialists) have a small business threshold of \$16.0 million (NAICS# 621111), general medical and surgical hospitals (NAICS# 622110), and specialty (except psychiatric and substance abuse) hospitals (NAICS# 622310) have a threshold of 47.0 million. Offices of all other miscellaneous health practitioners have a small business threshold of \$10.0 million (NAICS# 621399), diagnostic imaging centers have a threshold of \$19.0 million (NAICS#

621512) and all other outpatient care centers of \$25.5 million (NAICS# 621498). Other individual and family services have a small business threshold of \$16.0 million (NAICS# 624190).

Many of the hospitals and health systems in Pennsylvania would not be considered small businesses under these thresholds. However, the board does not collect information on the size of the businesses where its licensees are employed. Also, NAICS does not set thresholds for federal, state and local government bodies, which should not be considered small business. It is reasonable to assume that most self-employed workers would not exceed small business thresholds. Accordingly, for purposes of determining the economic impact on small businesses, the board assumes that a large number of its licensees either are owners of, or work for, small businesses as that term is defined by the SBA and Pennsylvania's Regulatory Review Act.

Concerning the proposed regulations that incorporate opioid education, the board has already implemented the statutorily required educational requirements; therefore, this proposed regulation will not have any impact on licensees other than having the clarity of updated regulations. The board has not yet effectuated the requirements of 20 Pa. C.S. § 8628 because, unlike the opioid education, there was not an approved curriculum for continuing education in organ donation, which had to be developed.

Concerning the proposed regulations that update the volunteer services provisions, board-regulated osteopathic physicians seeking to maintain or obtain volunteer licenses under the board would be required to comply with the proposed regulations. The amendments are being proposed to conform with amendments to the VHSA that have already been implemented by the board; therefore, the amendments to the volunteer services regulations do not affect the regulated community because the statutory requirements went into effect upon enactment of the various laws amending the VHSA. The regulated community will be positively impacted in that the board's regulations are consistent with and reflect the amendments to the VHSA.

There are no additional costs to the regulated community related to this proposed rulemaking and the board does not believe this regulation would adversely affects any business, be it large or small. Licensees are already required to complete educational requirements for initial licensure or registration and renewal. There is no adverse fiscal impact of the regulation because the regulations do not increase the number of continuing education hours that must be completed per biennium, just a portion of the course content.

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

There are approximately 11,605 active osteopathic physicians (including volunteers) who are licensed by the board that would be required to comply with this regulation as it pertains to opioid and organ donation education, including those that are, or work for, small businesses. A board-regulated practitioner seeking to maintain or obtain volunteer licenses under the board would be required to comply with the proposed volunteer regulations. There are approximately 3,706 osteopathic physician assistants who are licensed by the board and who may be required to comply with the regulation as it pertains to opioid education, including those that are, or work for, small businesses. The opioid education requirement would not include active osteopathic physicians and physician assistants who do not hold a current DEA registration nor utilize the DEA registration number of another person or entity.

(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 board does not anticipate significant fiscal impact or paperwork requirements relating to the rulemaking. Because osteopathic physicians and physician assistants are already required to complete mandatory continuing education, and the additional hours for opioid related education and organ donation are incorporated in the existing requirement, there would be no increased burden. Also, because licensees are already required to maintain evidence to support their completion of the continuing education requirement, there are no additional paperwork requirements imposed on licensees. There is no fiscal impact or paperwork requirements associated with the Safe Emergency Prescribing Act. The regulation benefits all licensees, by requiring additional education in the aforementioned areas which in turn will benefit Pennsylvania patients. Regarding the proposed amendments to the volunteer services regulations, the regulated community will not experience a fiscal impact nor will it experience additional paperwork requirements. The regulated community will benefit from the updates to the volunteer license regulations as the standards set forth therein will provide clarity because they reflect amendments to the VHSA.

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

Education on pain management, the identification of addiction and the practices of prescribing and dispensing of opioids as well as organ donation education benefits both the regulated community and patients of these caregivers. The regulation does not impose any increased costs, as the number of continuing education hours that must be completed by licensees per biennium is not being increased, and there are no adverse effects. There are no adverse effects as a result of the proposed volunteer regulations. The proposed volunteer regulations will benefit the regulated community because the regulations reflect amendments to the VHSA, which will eliminate confusion on requirements and standards for volunteer licenses.

(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 additional costs associated with compliance with the organ donation education as it does not increase the total number of hours that must be obtained by these licensees/certificate holders as a condition of biennial renewal, just the distribution of those hours.

Similarly, there are no additional costs associated with the addition of the opioid education as the initial education would most likely be incorporated within the academic program and the continuing education credits, as explained above, are included in the total number of hours required for licensure renewal. Additionally, there is no significant fiscal impact or paperwork requirements associated with the Safe Emergency Prescribing Act.

Further, the proposed amendments to the volunteer services regulations would not require additional compliance, legal, accounting or consulting procedures.

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

There are no costs or savings to local governments associated with compliance with the rulemaking.

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

There are no additional costs directly associated with implementing this regulation as the addition of the opioid and organ donation continuing education does not increase the total number of hours that must be obtained by these licensees, just the distribution of those hours. There are no significant fiscal impact or paperwork requirements associated with the Safe Emergency Prescribing Act or the updates to the VHSA. These proposed amendments would not require additional compliance, legal, accounting or consulting procedures for the state government.

(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.

There are no additional legal, accounting or consulting procedures or additional reporting, recordkeeping or other paperwork requirements required of the regulated community. Licensees are currently required to keep records of their continuing education for submission to the board upon audit. On renewal, they will continue to check off whether they completed the required education and minimum total. The addition of the opioid and organ donation education does not increase the total number of hours that must be obtained by these licensees, just the distribution of those hours. Further, the proposed amendments to the volunteer services regulations would not require additional compliance, legal, accounting or consulting procedures.

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

Yes, current renewal forms will have to be revised include verification of completion of continuing education in organ and tissue donation and recovery process one time within 5 years of initial license or within 5 years of licensure renewal. Board application forms currently reflect the mandatory opioid education requirements and volunteer services requirements; therefore, no changes to the forms are necessary for these proposed amendments.

(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.

The Bureau of Professional and Occupational Affairs (Bureau) uses an online platform for the submission of applications for licensure through PALS, including volunteer licenses. Within the online platform, applicants are asked a series of questions, including questions about mandatory educational and training requirements, including child abuse training and opioid education. When the board implemented the opioid education requirements, it updated PALS to require verification of opioid education for initial applications and in renewal applications in 2016. Upon the effective date of the training relative to organ and tissue donation and recovery, the board will include in its electronic application and renewal application processes requiring verification of 2 hours of continuing education

in organ and tissue donation and recovery process one time within 5 years of initial license or within 5 years of licensure renewal.

(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 25-26	FY +1 26-27	FY +2 28-29	FY +3 29-30	FY +4 31-32	FY +5 32-33
SAVINGS:						
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government	N/A	N/A	N/A	N/A	N/A	N/A
State Government	N/A	N/A	N/A	N/A	N/A	N/A
Total Savings	\$0	\$0	\$0	\$0	\$0	\$0
COSTS:						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	N/A	N/A	N/A	N/A	N/A	N/A
State Government	N/A	N/A	N/A	N/A	N/A	N/A
Total Costs	\$0	\$0	\$0	\$0	\$0	\$0
REVENUE LOSSES:						
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government	N/A	N/A	N/A	N/A	N/A	N/A
State Government	N/A	N/A	N/A	N/A	N/A	N/A
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 -3 2022-2023	FY -2 2023-2024	FY -1 2024-2025	Current FY 2025-2026
State Board of Osteopathic Medicine	\$ 1,477,994.74	\$ 1,772,985.91	\$ 1,755,423.62	\$1,889,000

⁽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) The regulation has no adverse impact on small business. Licensees are currently required to complete continuing education and maintain proof of completion in the event of an audit. Employers, including small businesses, are not required to pay the costs associated with their employee's compliance with the continuing education requirement.
- (b) This rulemaking will not impose additional reporting, recordkeeping or other administrative costs on small businesses.
- (c) Health care facilities, include small businesses, potential organ donors and recipients will benefit by practitioners receiving mandatory training about their responsibilities under the Probate Code concerning organ and tissue donation. Similarly, patients and health care facilities benefit because practitioners with prescriptive authority have enhanced knowledge due to this opioid education. And finally, the regulated community, approved clinics and organizations will benefit from the increased clarity of updates to the volunteer license regulations as the standards set forth therein will now reflect amendments to the VHSA.
- (d) The board could discern no less costly or less intrusive alternative methods to effectuate the purpose of the statutory requirements under the ABC-MAP Act, the Probate Code and the VHSA.
- (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 has identified no special groups that needed special provisions. The ABC-MAP Act, the Probate Code and the VHSA apply equally to all mandated licensees.

(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 have been considered as the additional continuing education content added by these regulations is mandated by the statutes. Further, the board believes these regulations provide the least burdensome means of complying with amendments to the ABC-MAP Act, the Probate Code and the VHSA.

- (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.

Because there is minimal anticipated adverse impact on small business, a regulatory flexibility analysis was not conducted. No less stringent compliance or reporting requirements, or less stringent schedules

or deadlines for compliance for small businesses, would be consistent with the goals of the ABC-MAP Act, the Probate Code or the VHSA. There are no design or operational standards in the regulation. Exempting small businesses or employees of small businesses from any of the requirements contained in the regulation would not be consistent with the intent of the ABC-MAP Act, the Probate Code or the VHSA.

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

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 public meetings or hearings will be held:

Mo public hearings were scheduled or held.

The board discusses its regulatory proposals

at regularly scheduled meetings. This rulemaking was recently discussed at public

board meetings on December 4, 2024, February 12, 2025 and August 13, 2025.

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

Spring of 2026.

D. The expected effective date of the final-form

regulation:

<u>Upon publication as final,</u>

except that provisions relating to required training relative to organ and tissue donation and recovery will be effective on May 1,

<u>2026.</u>

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

th the <u>Upon publication as final</u>, ired: except that provisions rela

except that provisions relating to required training relative to organ and tissue donation and recovery will be effective on May 1,

2026.

F. The 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 continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The board reviews its regulatory proposals at regularly scheduled public meetings. The board's remaining meetings scheduled for 2025 are: October 8 and December 10. More information can be found on the board's website.

FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

Independent Regulatory Review Commission

November 6, 2025

	I DO NOT W	RITE IN THIS SPACE		
Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.		
Amy M Digitally signed by Amy M Elliott		Digitally signed by Cynthia K. Montgomery DN: cn=Cynthia K. Montgomery, o, ou, email=cymontgome@pa.gov,		
BY: Elliott Date: 2025.10.16 10:24:33 -04'00' (DEPUTY ATTORNEY GENERAL)	State Board of Osteopathic Medicine (AGENCY)	BY: C=US Date: 2025.09.17 12:41:11-0400' (Deputy General Counsel, Independent Agency) (Strike inapplicable title)		
	DOCUMENT/FISCAL NOTE NO. 16A-5337	(came mappingatic and)		
	DATE OF ADOPTION:			
DATE OF APPROVAL Check if applicable Copy not approved. Objections attached.	0 1/10	September 17, 2025		
	BY: Xandy & Witman DO	DATE OF APPROVAL		
	RANDY LITMAN, D.O.	Check if applicable. No Attorney General approval or objection within 30 days after submission.		
	TITLE BOARD CHAIRPERSON			
	(EVECUTIVE OFFICED CHAIDMAN OR SECRETARY)			

PROPOSED RULEMAKING

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

TITLE 49 PA CODE CHAPTER 25

§§ 25.1, 25.161, 25.163, 25.201, 25.219, 25.241- 25.244, 25.246, 25.271, 25.601-25.607, 25.608-25.609

EDUCATION AND VOLUNTEER SERVICES

The State Board of Osteopathic Medicine (board) proposes to amend §§ 25.1, 25.161, 25.163, 25.201, 25.241--25.244, 25.246, 25.271, 25.601-25.607 and proposes to add §§ 25.219, 25.608 and 25.609 (relating to additional grounds for discipline; prescription of medication to family members; and exemptions) to read as set forth in Annex A.

Effective date

This proposed rulemaking will be effective upon publication of final-form rulemaking in the *Pennsylvania Bulletin*, except that provisions relating to required training relative to organ and tissue donation and recovery will be effective on May 1, 2026. The board has chosen May 1, 2026, as the effective date for the organ donation regulations because the Bureau of Professional and Occupational Affairs (Bureau) would like to roll out the board's organ donation regulations at the same time as the organ donation regulations for the other impacted boards, including the State Board of Nursing and the State Board of Medicine. Additionally, the Bureau is transitioning to a new online application platform and the board and Bureau wish to include the implementation of the organ donation requirement into the new platform, which is anticipated to be completed by May 1, 2026.

Statutory authority

Section 16 of the Osteopathic Medical Practice Act (act) (63 P.S. § 271.16) provides the board with broad authority to adopt regulations as are reasonably necessary to carry out the purposes of the act. Under the amendments to section 9.1 of the Achieving Better Care By Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. § 872.9a) and 20 Pa. C.S. § 8628 (relating to requirements for physician and nurse training relative to organ and tissue donation and

recovery), the board is required to implement mandatory education requirements. In addition, under 35 Pa.C.S. § 5102 (relating to safe opioid prescription education), the board is required to adopt an opioid education curriculum which may be offered in colleges or by providers approved by the board. Further, the Safe Emergency Prescribing Act (35 P.S. §§ 873.1-873.9) imposes restrictions on osteopathic physicians' and physician assistants' prescription of opioid drug products to individuals seeking treatment in an emergency department, urgent care center or in observation status in a hospital. Under section 7 of the Safe Emergency Prescribing Act (35 P.S. § 873.7) health care practitioners are subject to discipline by licensing boards for violations of the Safe Emergency Prescribing Act.

This proposed rulemaking would also conform the board's regulations to the amendments made to the Volunteer Health Services Act (35 P.S. §§ 449.41--449.53) (VHSA) by the acts of October 18, 2000 (P.L. 599, No. 76); June 19, 2002 (P.L. 406, No. 58); July 8, 2007 (P.L. 91, No. 29); and July 2, 2014 (P.L. 820, No. 86).

Under section 711(j)(3) of the Medical Care Availability and Reduction of Error Act (MCARE Act) (40 P.S. § 1303.711)(j)(3)), a retired licensed participating health care provider who provides care only to themselves or their immediate family members (including a parent, a spouse, a child or an adult sibling residing in the same household) are exempt from medical professional liability insurance requirements under the MCARE Act.

Finally, section 506 of the Administrative Code of 1929 (71 P.S. §186) empowers the heads of all administrative departments, the several independent administrative boards and commissions, the several departmental administrative boards and commissions to prescribe rules and regulations not inconsistent with law, for the government of their respective departments, boards or commissions.

Background and purpose

Opioid and organ donation education

In 2016, the Legislature amended the ABC-MAP Act, including the requirement imposed by section 9.1(a) on all prescribers and dispensers to obtain 2 hours of mandatory education regarding pain management or the identification of addiction, and 2 hours of education in the practices of prescribing or dispensing of opioids (collectively, "opioid education") within 1 year of obtaining prescriptive authority, and an additional 2 hours of continuing education in pain management, identification of addiction or the practices of prescribing or dispensing of opioids per biennium as a condition of biennial renewal. The board implemented these educational requirements and has required the mandatory opioid education since January 1, 2017.

Shortly after enactment of section 9.1 of the ABC-MAP Act, representatives of the Bureau, on behalf of the impacted licensing boards, met with representatives of the Department of Health (DOH) to discuss approval of curricula for the opioid education required under section 9.1(b). Because the require opioid education was readily available from multiple providers and is incorporated into many osteopathic physician and physician assistant education programs' advanced pharmacology courses, a decision was made not to mandate a specific curriculum similar to what is being required for organ and tissue donation and recovery process (collectively, "organ donation") for osteopathic physicians, discussed below. Nonetheless, for guidance, DOH has posted seven modules that fit within the topics of the mandated education on its webpage at www.health.pa.gov/topics/programs/PDMP/Pages/education.aspx.

3

Under 35 Pa.C.S. § 5102, the board is required to adopt an opioid education curriculum that may be offered in colleges or by providers approved by the board. Under 35 Pa.C.S. § 5102, the curriculum must include all of the following:

- (1) Current, age-appropriate information relating to pain management.
- (2) Multimodal treatments for chronic pain that minimize the use of a controlled substance containing an opioid.
- (3) If a controlled substance containing an opioid is indicated, instruction on safe methods of prescribing a controlled substance containing an opioid that follow guideline-based care.
- (4) Identification of patients who have risk factors for developing problems with prescription of a controlled substance containing an opioid.
- (5) Training on managing substance use disorders as a chronic disease.

The board has adopted the PA-SUPPORT opioid education curriculum. The PA-SUPPORT curriculum, entitled "Source for Understanding Pain, Prescribing Opioids, and Recovery Treatment" is posted on the Lewis Katz School of Medicine at Temple University's website. A link to the adopted curriculum is posted on the board's website.

Additionally, consistent with the Safe Emergency Prescribing Act, the board proposes to include provisions applicable to osteopathic physicians and physician assistants providing that violations of the Safe Emergency Prescribing Act subjects licensees to discipline.

The board also proposes to amend its regulations to conform to the amendments to the Probate, Estates and Fiduciaries Code (20 Pa.C.S. §§ 8610-8632), including the requirement imposed in 20 Pa.C.S. § 8628 (relating to requirements for physician and nurse training relative to

organ and tissue donation and recovery) that osteopathic physicians complete at least 2 hours of continuing education in organ donation one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever occurs first. In drafting organ donation regulations, the board has worked with the DOH and other agencies regarding the development of an approved curriculum for continuing education in organ donation. Representatives from the Department of Health's Division of Nutrition and Physical Activity, Bureau of Health Promotion and Risk Reduction, the Center for Organ Recovery and Education (CORE), Donate Life PA (Donate PA) and Gift of Life Donor Program (Gift of Life), organ procurement organizations (OPOs) designated for the region by the United States Secretary of Health and Human Services, and Counsel for the State Board of Medicine, State Board of Osteopathic Medicine and State Board of Nursing formed a workgroup to discuss implementation of 20 Pa.C.S. § 8628 and the development of the required curriculum by the OPOs. The OPOs have advised that the curriculum is now available for providers.

Volunteer Health Services Act (VHSA)

Regarding the VHSA, the purpose of the act is to increase the availability of primary health care services, including mental health services, by establishing a procedure through which physicians and other health care practitioners who are retired from active practice, or otherwise no longer actively practicing, may provide professional services within their scope of practice as a volunteer in approved clinics serving financially qualified persons and in approved clinics located in medically underserved areas or health professionals shortage areas. It also serves to increase the availability of mental health services to military personnel and their families by establishing a procedure through which physicians and other health care practitioners who are retired from active

practice, or otherwise no longer actively practicing, may provide mental health services within their scope of practice as a volunteer upon referral from approved organizations.

In 2000, the VHSA was amended by adding section 10.1 (35 P.S. § 449.51) authorizing the holder of a volunteer license to prescribe medication for family members. This section allows a holder of a volunteer license, who was previously able to prescribe medication as an active, nonvolunteer licensee, to prescribe medication to any family member, as defined within the section.

In 2002, the VHSA was amended by adding sections on indemnity and defense for active practitioners and on optional liability coverage. Section 10.2 (35 P.S. § 449.52) relating to indemnity and defense provides that a health care practitioner who offers health care services at an approved clinic without remuneration under an active, nonvolunteer license shall be entitled to indemnity and defense under the liability insurance coverage that is maintained by the practitioner as required under the MCARE Act as part of the active, nonvolunteer licensee's regular practice. Section 10.3 (35 P.S. § 449.53) relating to optional liability coverage provides that holders of volunteer licensees or approved clinics acting on behalf of volunteer licensees are not obligated to purchase excess insurance coverage through the Medical Professional Catastrophe Loss Fund or the MCARE Fund.

The 2002 amendments included several other changes and additions, including amendments to the definition of "volunteer license" and to section 4 of the VHSA (35 P.S. § 449.44), pertaining to volunteer status. Under the definition of volunteer license, a health care practitioner must document to the board that the health care practitioner will practice only in approved clinics without remuneration and is either a retired health care practitioner or a nonretired health care practitioner who is not required to maintain liability insurance because the health care

practitioner is not practicing medicine in this Commonwealth. Under the amendments to section 4 of the VHSA, to qualify for a volunteer license, an applicant has to hold a current, active, unrestricted license and be either a retired health care practitioner or a nonretired health care practitioner who is not required to maintain professional liability insurance under the MCARE Act, because the health care practitioner is not otherwise practicing medicine or providing health care services in this Commonwealth. In addition, section 9 of the VHSA (35 P.S. § 449.49), pertaining to exemptions, was amended to include a reference to the MCARE Act.

In 2007, the General Assembly amended the VHSA to address continuing education requirements for a physician who holds a volunteer license and for physicians who hold an unrestricted license to practice medicine. Physicians who hold a volunteer license must complete a minimum of 20 credit hours of American Medical Association Physician's Recognition Award Category 2 Activities during the preceding biennial period as a condition of biennial renewal and are otherwise exempt from any continuing education requirement imposed by the MCARE Act. Physicians who hold an unrestricted license to practice and are covered by section 10.2 of the VHSA shall complete the continuing medical education requirements established by the board under the MCARE Act in § 25.271(c) (relating to requirements for renewal) to be eligible for renewal of the unrestricted license.

In 2014 the VHSA was amended to increase the availability of mental health services in underserved areas or health professional shortage areas and to increase availability of mental health services for military personnel and their family members; to provide for mental health services upon referral from an approved organization and to set forth the procedures for approval of nonprofit organizations.

In accordance with the requirements of Executive Order 1996-1 (4 Pa. Code §§ 1.371—

1.382), the board sent an exposure draft of this proposed rulemaking to interested parties on June

11, 2025. The board did not receive any comments. On August 13, 2025, the board adopted the

proposed regulation.

Description of the proposed amendments for opioid and organ donation education

Purpose and definitions

The board proposes to define "PA-SUPPORT curriculum" in § 25.1 (relating to definitions)

as a safe opioid prescription education curriculum approved by the board under 35 Pa.C.S. § 5102

(relating to safe opioid prescription education). The board proposes to add this definition because

35 Pa.C.S. § 5102 requires licensing boards to implement a safe prescription of a controlled

substance containing an opioid curriculum. The curriculum may be offered in colleges or by

providers approved by the licensing boards and must include (1) current, age-appropriate

information relating to pain management; (2) multimodal treatments for chronic pain that

minimize the use of a controlled substance containing an opioid; (3) if a controlled substance

containing an opioid is indicated, instruction on safe methods of prescribing a controlled substance

containing an opioid that follow guideline-based care; (4) Identification of patients who have risk

factors for developing problems with prescription of a controlled substance containing an opioid;

and (5) training on managing substance use disorders as a chronic disease. This curriculum is

available to colleges and providers, and it is not a required curriculum. Colleges and providers may

at their discretion use the PA-SUPPORT curriculum or may develop or utilize other curricula.

Education

8

In connection with opioid prescription by osteopathic physicians and physician assistants who hold prescriptive authority, the board is also proposing to amend §§ 25.161(c)(6), 25.241(5.2), 25.242(6.2), 25.243(b)(2.2), 25.244(b)(1.2) and 25.246(b)(2.2) to include the requirement from section 9.1 of the ABC-MAP Act that osteopathic physicians and physician assistants complete 2 hours of mandatory education regarding pain management or the identification of addiction and 2 hours of education in the practices of prescribing or dispensing of opioids within 1 year of obtaining prescriptive authority.

Proposed §§ 25.161(c)(6)(i), 25.241(5.2)(i), 25.242(6.2)(i), 25.243(b)(2.2)(i), 25.244 (b)(1.2)(i) and 25.246(b)(2.2)(i) would clarify that the specified opioid education may be taken as part of the applicant's academic degree in osteopathic medicine and surgery or physician assistant educational program, as applicable, or as part of an approved continuing education course. Under proposed §§ 25.161(c)(6)(ii), 25.241(5.2)(ii), 25.242(6.2)(ii), 25.243(b)(2.2)(ii), 25.244(b)(1.2)(ii) and 25.246(b)(2.2)(ii), the board clarifies that the PA-SUPPORT curriculum satisfies the opioid education requirement but that this curriculum is not mandatory. Proposed §§ 25.161(c)(6)(iii), 25.241(5.2)(iii), 25.242(6.2)(iii), 25.243(b)(2.2)(iii), 25.244(b) (1.2)(iii) and 25.246(b)(2.2)(iii) also clarify that only osteopathic physicians and physician assistants who hold a current Drug Enforcement Administration (DEA) registration number or utilize the DEA registration number of another person or entity are required to comply with the initial opioid education within 1 year of licensure.

The board proposes amendments to §§ 25.163(c) and 25.271(c) to include the ABC-MAP Act's (35 P.S. § 872.9a) continuing education requirement for osteopathic physicians and physician assistants. The provisions codify the board's implementation of the ABC-MAP

requirement that osteopathic physicians and physician assistants who hold a current DEA registration or utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner, shall complete 2 hours of continuing education in pain management, identification of addiction or the practices of prescribing or dispensing of opioids per biennium as a condition of biennial renewal. Proposed amendments to § 25.163(c) will delete the child abuse recognition and reporting requirement in subsection (c) and place it in proposed paragraph (c)(1). The board also proposes to update § 25.271(c)(2) to clarify continuing education standards and update the renewal requirements relating to verification of continuing education to conform to the board's current, online procedures.

Additionally, the board is proposing to amend § 25.271 (c)(2) and add subsection (c)(6) to include the requirement from 20 Pa.C.S. § 8628 that osteopathic physicians complete at least 2 hours of board-approved continuing education in organ and tissue donation and recovery (organ donation) one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever occurs first. Specifically, under 20 Pa.C.S. § 8628, osteopathic physicians shall complete a 2-hour course on organ donation designed to address the clinical aspects of the donation and recovery process as a condition of license renewal. The course may include information about donation of hands, facial tissue and limbs and other vascularized composite allografts. Proposed § 25.271 (c)(6) would apply to existing licensees at the time the regulation is published in final form. Paragraph (6)(i)(B) would apply to licensees who obtain their licenses on or after the effective date and paragraph (6)(i)(C) would apply to licensees who renew or reactivate expired or inactive licensees on or after the effective date.

Concomitantly, the board proposes to add § 25.271 (c)(6)(ii), which delineates the mandatory organ donation curriculum. Unlike the opioid curriculum, which is already established and in use by medical programs, there was no established organ donation curriculum. In light of the statutory mandate and the lack of an established curriculum, the board decided that a specific pre-approved curriculum was needed. The curriculum was jointly developed by CORE, Donate PA and Gift of Life and approved by the board. The curriculum is composed of six parts: an overview of the organ donation and transplantation system, the tissue donation process, the organ donation process, determining death and family communication, caring for families and organ donor management. The first part describes the National, state and local systems for organ and tissue donation. Organ transplant waiting lists are discussed as well as transplantable organs and tissues, including vascularized composite allografts. The second part describes common applications for transplantable tissue and a framework for an effective hospital process. The third part describes commonly transplantable organs, and the entire organ donation process from the initial referral to the recovery of organs. It also defines the role of the OPO and the healthcare team, including optimal practices for communication and collaboration. The fourth part describes a historical perspective for determining death and effective communication techniques to aid in family conversations. The fifth part addresses considerations for providing compassionate end of life care for families and assessing readiness for the donation conversation. It also addresses information and techniques for debunking common myths and misconceptions. The last part describes the organ donation pathways, medical assessment for eligibility and clinical management strategies for optimizing end organ function, the surgical recovery phase, and coroner/medical examiner communication. It also highlights practices for maintaining optimal communication and collaboration. Like all other providers of education, a provider of organ donation education must

follow existing regulations regarding continuing education. Under subsection (c)(6)(ii), a copy of the board-approved organ donation curriculum will be posted on the board's website. Like with other continuing education aside from child abuse, licensees will be required to submit certificates of attendance only upon audit but will be required to verify completion on their biennial renewal applications.

Because the organ donation education is relevant to patient care and osteopathic medicine generally, it falls within approved activities required by § 25.271 (c). Proposed § 25.271 (c)(2) would add certification by an organ procurement organization as defined in 20 Pa.C.S. § 8601 (relating to definitions) as acceptable documentation for Category 1 activities. Approved OPOs are listed on the Pennsylvania Department of Health and Human Services website under "Additional Resources" at https://www.health.pa.gov/topics/programs/Organ%20Donation/Pages/Organ%20Donation.aspx and the US Department of Health Resources & Services Administration at organdonor.gov.

Finally, the board is proposing to add §§ 25.201(a)(10) and 25.219 (relating to grounds for complaint; and additional grounds for discipline) to notify physician assistants and osteopathic physicians, respectively, that a violation of the Safe Emergency Prescribing Act subjects them to discipline.

Description of the proposed amendments for VHSA amendments

Purpose and definitions

The board proposes to amend § 25.601(a) (relating to volunteer license) by updating the statutory citation to reflect amendments to the VHSA and deleting substantive provisions that

currently exist in the purpose section of the board's regulations, which are more appropriately moved elsewhere in substantive provisions.

The board proposes to add a definition of "active-retired status" in § 25.1 to ensure that applicable licensure statuses are addressed in this proposed regulation as they pertain to osteopathic physicians with volunteer licenses. Under section 711(j)(3) of the MCARE Act (40 P.S. § 1303.711(j)(3)), a retired licensed participating health care provider, which includes osteopathic physicians, who provide care only to themselves or their immediate family members are exempt from medical professional liability insurance requirements under the MCARE Act. In this instance, the board assigns an active-retired status to the osteopathic physician license. Under section 910(d)(3) of the MCARE Act, retired osteopathic physicians who provide care only to immediate family members are also exempt from the board's continuing medical education requirement. The board also proposes to move the definition of unrestricted license from § 25.601(b) (relating to purpose and definitions) to § 25.1 because this term is relevant to other sections in Chapter 25.

To provide clarity to the regulated community, the board proposes to add definitions of "family member," "approved organization" and "primary health care services" to § 25.601. The definitions are consistent with terms defined in the VHSA. The board also proposes to define the terms "nonretired board-regulated practitioner" and "retired board-regulated practitioner" as the terms "nonretired" and "retired" are used in the VHSA but not specifically defined.

Volunteer license

The board proposes restructure § 25.602 to conform to amendments to the VHSA and to clarify requirements. There is some confusion in the regulated community regarding what it means to be a retired board-regulated practitioner and a nonretired board-regulated practitioner. Under

the proposed regulations, the board clarifies and updates the requirements for eligibility for a volunteer license for retired and nonretired board-regulated practitioners. The board further clarifies that it may issue a volunteer license to a retired board-regulated practitioner with an inactive, expired or active-retired license if the practitioner reactivates the inactive, expired or active-retired license, registration or certificate to active, unrestricted status and documents to the satisfaction of the board that the practitioner will practice only in approved clinics or upon referral from approved organizations without renumeration. As a part of the proposed amendment to § 25.602 (relating to volunteer license), and consistent with the VHSA, the board includes updated language regarding referrals from approved organizations.

Applications and validity of license

In § 25.603 (relating to applications), the board proposes to update the application process because the board no longer uses paper applications. Additionally, the board proposes to exclude the child abuse recognition and reporting requirement in the existing volunteer services regulation. Any board-regulated practitioner who applies for a volunteer license either has a currently renewed active license, registration or certificate or a reactivated license, registration or certificate. Child abuse recognition and reporting compliance would have already been verified for these practitioners; therefore, this provision is redundant. The board also proposes to include the term "approved organization" in this section and in § 25.604 (relating to validity of licenses) to conform to amendments in the VHSA.

Renewal of license

In § 25.605 (relating to biennial renewal), the board proposes to update the application process because the board no longer uses paper applications. Additionally, the board proposes to

amend this section to include the ABC-MAP Act's (35 P.S. § 872.9a) continuing education requirement for volunteer licensees who hold a current DEA registration or utilizes the DEA registration number of another person or entity, as permitted by law. This provision codifies the board's implementation of the ABC-MAP Act's requirement for licensees who hold or utilize the DEA registration of another to complete 2 hours of education in pain management, identification of addiction or the practices of prescribing or dispensing of opioids per biennium as a condition of biennial renewal. Additionally, the board proposes amendments that would clarify continuing education requirements for licensees by including a cross reference to the VHSA and by updating the citation to the MCARE Act.

The board proposes to add paragraph 3 to include the requirement from 20 Pa.C.S. 8628 that osteopathic physicians must complete at least 2 hours of board-approved continuing education in organ and tissue donation and recovery (organ donation) one time within 5 years of initial licensure or within 5 years of licensure renewal.. This paragraph would require osteopathic physicians to complete the continuing education in accordance with § 25.271(c)(6) (relating to requirements for renewal), which is described above..

Practice

In § 25.606 (relating to return to active practice), the board proposes to amend the heading for clarification and to add subsection (a), which indicates that a volunteer licensee may practice only in approved clinics, or upon referral from approved organizations, without remuneration. This provision was previously in the definition and purpose section in § 25.601(a). This type of substantive provision is more appropriately included within the substantive regulations. The board also proposes to clarify the requirements for a volunteer license holder who desires to return to active practice in subsection (b).

Disciplinary provisions

In § 25.607 (relating to disciplinary provisions), the board proposes to update the citation to the VHSA.

Prescription of medication for family members

The board proposes to add § 25.608 (relating to prescription of medication for family members) to conform to section 7 of the VHSA (35 P.S. 449.47(a)). This proposed section provides that a volunteer licensee who was able to prescribe medication while an active licensee may prescribe medication to family members. The board also incorporates the liability provisions under 35 P.S. § 449.47(a) and also makes clear that nothing in this section may be construed to allow a volunteer licensee to prescribe medication to a family member if the type or manner of prescription is prohibited by the laws of this Commonwealth.

Exemptions

The board proposes to add subsection § 25.609 (relating to exemptions) to conform to section 9 of the VHSA (35 P.S. § 449.49) relating to exemptions from the maintenance of liability insurance coverage required by the MCARE Act. This proposed section would provide that volunteer licensees who are otherwise subject to the provisions of the MCARE Act are exempt from the MCARE Act's requirements for the maintenance of liability insurance coverage.

Fiscal Impact and Paperwork Requirements

The board does not anticipate any significant fiscal impact or paperwork requirements relating to these amendments. Osteopathic physicians, physician assistants and volunteer license holders are already required to complete mandatory continuing education, and as these hours are incorporated in the existing requirement, there would be no increased burden. Also, like with other

continuing education, aside from the mandatory child abuse education, licensees are required to keep copies of their continuing education certificates in the event of an audit. There is no fiscal impact or paperwork requirements associated with the Safe Emergency Prescribing Act. The board does not anticipate any fiscal impact of the updates to the volunteer license regulation as the purpose of the proposed regulation is to update the regulations to be in conformance with statutory amendments that have already been implemented.

Sunset Date

The board continuously monitors the effectiveness of its regulations on a fiscal year and biennial basis. 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 6, 2025, the board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Consumer Protection and Professional Licensure Committee of the Senate and to the Chairpersons of the Professional Licensure Committee of the House of Representatives. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review prior to

16A-5337 Education and Volunteer Licenses Proposed Preamble November 6, 2025

final publication of the rulemaking by the board, the General Assembly and the Governor.

Public Comment

Interested persons are invited to submit written comments, suggestions, or objections regarding this proposed rulemaking to Regulatory Counsel, State Board of Osteopathic Medicine, P.O. Box 69523, Harrisburg, PA 17106-9523, RA-STRegulatoryCounsel@pa.gov within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference 16A-5337 (Education and Volunteer licenses) when submitting comments.

Randy Litman, D.O. Chairperson

18

ANNEX A

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

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter A. GENERAL PROVISIONS

§ 25.1. Definitions.

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

* * * * *

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

Active-retired status – The Board's licensure status designation for medical doctors that limits the scope of practice to providing care for themselves and their immediate family members.

Agreement of affiliation—A written document evidencing the agreement between an approved hospital and an urgent care center, emergency center, surgicenter, office of a private practitioner

or other health care facility for the training of osteopathic interns, residents or fellows.

* * * * *

National Board Examination—The NBOME COMLEX, or its successor examination.

<u>PA-SUPPORT curriculum</u>—The safe opioid prescription education curriculum approved by the Board under 35 Pa.C.S. § 5102 (relating to safe opioid prescription education).

PGY—Post-graduate year.

<u>Unrestricted license—A license which is not restricted or limited by order of the Board</u> under its disciplinary power.

Subchapter C. PHYSICIAN ASSISTANT PROVISIONS LICENSURE OF PHYSICIAN ASSISTANTS AND REGISTRATION OF SUPERVISING PHYSICIANS

§ 25.161. Criteria for licensure as a physician assistant.

* * * * *

(c) The Board will approve for licensure as a physician assistant an applicant who:

* * * * *

- (5) Has completed at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (6) Has completed, or certifies that the applicant will complete, at least 2 hours of

 Board approved education in pain management or the identification of addiction and

 2 hours of Board-approved education in the practices of prescribing or dispensing of

 opioids within 1 year of obtaining licensure.
 - (i) The education may be taken during a physician assistant training program certified by the Board delineated in § 25.152 (relating to listing of certified physician assistant educational programs) or through continuing medical education under § 25.163(c) (relating to approval and effect of licensure; biennial renewal of physician assistants; registration of supervising physicians).

- (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.
- (iii) This requirement applies only to holders of a current Drug

 Enforcement Administration (DEA) registration or those who utilize the DEA

 registration number of another person or entity, as permitted by law, to

 prescribe controlled substances in any manner.
- (d) The physician assistant may amend information regarding his education and work experience submitted under the requirements of subsection (c)(3), by submitting to the Board in writing additional detailed information. No additional fee will be required. The file for each physician assistant will be reviewed by the Board to determine whether the physician assistant possesses the necessary skills to perform the tasks that a physician, applying for registration to supervise and utilize the physician assistant, intends to delegate to him as set forth in the protocol contained in the physician's application for registration.

* * * * *

§ 25.163. Approval and effect of licensure; biennial renewal of physician assistants; registration of supervising physicians.

* * * * *

(c) To be eligible for renewal of a physician assistant license, the physician assistant shall complete continuing medical education as required by NCCPA[, including at least 2 hours of approved courses in child abuse recognition and reporting in accordance with § 25.417(b) (relating to child abuse recognition and reporting—mandatory training requirement)] and maintain National certification by completing current certification and recertification mechanisms available to the profession, identified on NCCPA's web site and recognized by the Board. The

Board recognizes certification through NCCPA and its successor organizations and certification through any other National organization for which the Board publishes recognition of the organization's certification of physician assistants on the Board's web site. **The continuing medical education shall include:**

- (1) At least 2 hours of approved courses in child abuse recognition and reporting in accordance with § 25.417(b) (relating to child abuse recognition and reporting—mandatory training requirement).
- (2) At least 2 hours of education in pain management, the identification of addiction or in the practices of prescribing or dispensing opioids if the physician assistant has prescriptive authority under the act and holds a current Drug Enforcement Administration (DEA) registration or utilizes the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner.
- (d) Upon approval of an application for registration as a supervising physician, the Board will issue a supervising physician registration certificate which contains the name of the supervising physician, his registration number and the name of the physician assistant that he is authorized to supervise under that specific registration. The registration is not subject to renewal. When the physician submits a request to modify a protocol with respect to a physician assistant he is already registered to utilize, no new registration certificate will be issued; however, the physician will receive a letter from the Board confirming its approval of the expanded utilization.

* * * * *

DISCIPLINARY ACTION AGAINST LICENSE OF
PHYSICIAN ASSISTANT

§ 25.201. Grounds for complaint.

(a) The basis upon which the Board may take disciplinary action against the license of a physician assistant are set forth in section 15(b) of the act (63 P. S. § 271.15(b)). A complaint against a physician assistant shall allege that the physician assistant is performing tasks in violation of statute, regulation or good and acceptable standards of practice of physician assistants. The grounds include those specifically enumerated in section 15(b) of the act. Unprofessional conduct shall include, but is not limited to, the following:

* * * * *

- (9) Violation of this chapter fixing a standard of professional conduct.
- (10) The failure to comply with the Safe Emergency Prescribing Act (35 P.S. §§ 873.1-873.9).
- (b) Subsection (a) supplements 1 Pa. Code § 35.10 (relating to form and content of formal complaints).

Subchapter D. MINIMUM STANDARDS OF PRACTICE

* * * * *

§ 25.219. Additional grounds for discipline.

In addition to the grounds set forth in section 15 of the act (63 P.S. § 271.15) and in this subchapter, an osteopathic physician who fails to comply with the Safe Emergency Prescribing Act (35 P.S. §§ 873.1-873.9) will be subject to disciplinary action.

Subchapter G. LICENSING, EDUCATION AND GRADUATE TRAINING LICENSURE REQUIREMENTS

§ 25.241. Unrestricted license by examination.

To secure an unrestricted license for the practice of osteopathic medicine and surgery by examination, the applicant shall meet the following educational and professional requirements. The applicant shall have:

- (5.1) Completed at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (5.2) Completed, or certified that the applicant will complete, at least 2 hours of

 Board approved education in pain management or the identification of addiction and

 2 hours of Board-approved education in the practices of prescribing or dispensing of

 opioids within 1 year of obtaining licensure.
 - degree in medicine and surgery from an osteopathic medical college or through continuing education meeting AOA Category 1 or 2 standards under § 25.271 (relating to requirements for renewal).
 - (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.
 - Enforcement Administration (DEA) registration or those who utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner.

(6) Completed an application obtained from the Board detailing education and experience and indicating compliance with the applicable provisions of the act and this chapter, submitted with the required fees.

§ 25.242. Unrestricted license by endorsement under section 9 of the act.

To secure an unrestricted license for the practice of osteopathic medicine and surgery by endorsement, the applicant shall meet the following educational and professional requirements. The applicant shall have:

- (6.1) Completed at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (6.2) Completed, or certified that the applicant will complete, at least 2 hours of

 Board approved education in pain management or the identification of addiction and

 2 hours of Board-approved education in the practices of prescribing or dispensing of

 opioids within 1 year of obtaining licensure.
 - (i) The education may be taken as a part of the applicant's academic degree in medicine and surgery from an osteopathic medical college or through continuing education meeting AOA Category 1 or 2 standards under § 25.271 (relating to requirements for renewal).
 - (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.

- Enforcement Administration (DEA) registration or those who utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner.
- (7) Completed an application obtained from the Board detailing education and experience and indicating compliance with the applicable provisions of the act and this chapter, submitted with the required fees.

§ 25.243. Boundary license.

* * * * *

(b) Specific requirements for boundary licensure are as follows. The applicant shall:

- (2.1) Complete at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (2.2) Complete at least 2 hours of Board approved education in pain management or the identification of addiction and 2 hours of Board-approved education in the practices of prescribing or dispensing of opioids within 1 year of obtaining licensure.
 - (i) The education may be taken as a part of the applicant's academic degree in medicine and surgery from an osteopathic medical college or through continuing education meeting AOA Category 1 or 2 standards under § 25.271 (relating to requirements for renewal).

- (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.
- (iii) This requirement applies only to holders of a current Drug

 Enforcement Administration (DEA) registration or those who utilize the DEA

 registration number of another person or entity, as permitted by law, to

 prescribe controlled substances in any manner.
- (3) Submit an application obtained from the Board, together with the required fee.

* * * * *

§ 25.244. Temporary graduate training license.

* * * * *

(b) Specific requirements for temporary graduate training license are as follows.

The applicant shall have:

- (1) Graduated from an approved osteopathic medical college.
- (1.1) Completed at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (1.2) Completed, or certified that the applicant will complete, at least 2 hours of Board approved education in pain management or the identification of addiction and 2 hours of Board-approved education in the practices of prescribing or dispensing of opioids within 1 year of obtaining licensure.

- (i) The education may be taken as a part of the applicant's academic degree in medicine and surgery from an osteopathic medical college or through continuing education meeting AOA Category 1 or 2 standards under § 25.271 (relating to requirements for renewal).
- (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.
- Enforcement Administration (DEA) registration or those who utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner.
- (2) Submitted an application obtained from the Board, together with the required fee.

* * * * *

§ 25.246. Short-term camp physician license.

- (b) Specific requirements for short-term camp licensure are as follows. The applicant shall:
 - (1) Possess a valid, current and unrestricted license in another state or territory of the United States or Canada. The physician shall arrange for certification of licensure to be transmitted to the Board by the authorized licensing body of the other jurisdiction.
 - (2) Comply with the malpractice insurance requirements of the Medical Care
 Availability and Reduction of Error (MCARE) Act (40 P.S. § § 1303.101—1303.910)
 and regulations thereunder.

- (2.1) Complete at least 3 hours of mandatory training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).
- (2.2) Complete at least 2 hours of Board approved education in pain management or the identification of addiction and 2 hours of Board-approved education in the practices of prescribing or dispensing of opioids within 1 year of obtaining licensure.
 - degree in medicine and surgery from an osteopathic medical college or through continuing education meeting AOA Category 1 or 2 standards under § 25.271 (relating to requirements for renewal).
 - (ii) The PA-SUPPORT curriculum satisfies this requirement. This curriculum may be offered by providers, but it is not required curriculum.
 - Enforcement Administration (DEA) registration or those who utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner.
- (3) Submit an application obtained from the Board, together with the required fee.

LICENSURE RENEWAL AND CONTINUING EDUCATION

§ 25.271. Requirements for renewal.

biennial period including at least 2 hours of approved [courses] training in child abuse recognition and reporting in accordance with § 25.417(b) (relating to child abuse recognition and reporting—mandatory training requirement) [, in the preceding biennial period] and at least 2 hours of continuing education in pain management, the identification of addiction or in the practices of prescribing or dispensing of opioids in AOA Category 1 or 2 activities will be required for licensure renewal for osteopathic physicians.

* * * * *

- (2) Physicians shall retain official documentation of [attendance] completion for 2 years after renewal, and shall [certify completed activities on a form provided by the Board for that purpose, to be filed with] verify completion on the biennial renewal [form] application. Official documentation proving attendance shall be produced, upon Board demand, pursuant to random audits of reported credit hours. To show compliance with organ and tissue donation and recovery process training required in paragraph (6), a physician shall retain documentation of attendance from an organ procurement organization as defined in 20 Pa.C.S. § 8601 (relating to definitions). Electronic submission of documentation is permissible to prove compliance with this subsection. Noncompliance may result in disciplinary proceedings under section 15(a)(6) of the act (63 P. S. § 271.15(a)(6)).
- (3) The following exemptions apply for certain physicians:

* * * * *

(iv) A physician who is on inactive status shall be exempt from the continuing medical education requirement, except that a physician who is seeking to reinstate

an inactive or lapsed license shall show proof of compliance with the continuing education requirement for the preceding biennium.

- (v) A physician who does not hold a current DEA registration or utilize the DEA registration number of another person or entity, as permitted by law, to prescribe controlled substances in any manner is exempt from completing the 2 hours of continuing education in pain management, the identification of addiction or in the practices of prescribing or dispensing opioids.
- (4) A physician suspended for disciplinary reasons is not exempt from the requirements of this section.

* * * * *

(6) Additional education requirement.

- credit hours of the required continuing medical education hours in organ and tissue donation and recovery process. This is a one-time requirement that shall be completed within 5 years of initial licensure or licensure renewal or reactivation. The 2 credit hours may be attributed to the continuing medical education hours required for biennial renewal during which it is completed.
 - (A) An osteopathic physician who obtains initial licensure prior to May

 1, 2026, shall verify completion of the 2 credit hours one time within 5

 years of licensure renewal.
 - (B) An osteopathic physician who obtains a license on or after May 1, 2026, shall verify completion of the 2 credit hours one time within 5 years of initial licensure.

- (C) An osteopathic physician who reactivates an expired or inactive license on or after May 1, 2026, shall verify completion of the 2 credit hours one time within 5 years of reactivation.
- (ii) The education required to satisfy subparagraph (i) shall consist of the following Board-approved curriculum which addresses the clinical aspects of the donation and recovery process and is posted on the Board's website:
 - (A) Overview of the organ donation & transplantation system.
 - (B) Tissue donation process.
 - (C) Organ donation process.
 - (D) Determining death and family communication.
 - (E) Caring for families.
 - (F) Organ donor management.

Subchapter L. VOLUNTEER LICENSE

§ 25.601. Purpose and definitions.

(a) This subchapter implements the Volunteer Health Services Act (35 P. S. § § 449.41—[449.50] 449.53) and provides for the issuance of a volunteer license to a qualified Board-regulated practitioner as defined in section 2 of the act (63 P. S. § 271.2)[, who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic without remuneration].

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

Approved clinic—An organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

Approved organization—A nonprofit organization as defined under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. § 501(c)(3))(relating to exemption from tax on corporations, certain trusts, etc.)) approved by the Department of Military and Veterans Affairs and whose purpose is to refer military personnel and their families, regardless of income and who are in need of mental health services, to licensed volunteers who provide mental health services, whether or not the mental health services are provided at an approved clinic.

<u>Family member</u> – A volunteer license holder's spouse, child, daughter-in-law, son-in-law, mother, father, sibling, mother-in-law, father-in-law, sister-in-law, brother-in-law, grandparent, grandchild, niece, nephew or cousin.

Nonretired Board-regulated practitioner - A Board-regulated practitioner who holds a currently renewed, active, unrestricted license, registration or certification and is not required to maintain professional liability insurance under section 711 of the MCARE Act (40 P.S. § 1303.711) because the practitioner does not otherwise currently practice or provide health care services in this Commonwealth.

<u>Primary health care services</u> – The term includes, but is not limited to, regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, health education and mental health services.

<u>Retired Board-regulated practitioner</u> – A Board-regulated practitioner who has retired from active practice at the time the applicant applies for a volunteer license.

[Unrestricted license—A license which is not restricted or limited by order of the Board under its disciplinary power.]

§ 25.602. Volunteer license.

[A volunteer license may be issued to a Board-regulated practitioner who documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics and meets one of the following conditions:

- (1) Holds a currently renewed, active, unrestricted license, registration or certificate in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.
- (2) Retires from the active practice in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A retired licensee, registrant or certificate holder shall meet any requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal.]

 (a) Retired or nonretired Board-regulated practitioners. The Board may issue a volunteer license to a retired or nonretired Board-regulated practitioner who holds a currently renewed, active, unrestricted license, registration or certificate and documents to the satisfaction of the Board that the applicant will practice only in approved clinics or upon referral from approved organizations without remuneration.

(b) Retired Board-regulated practitioners with an inactive, expired or active-retired license. The

Board may issue a volunteer license to a Board-regulated practitioner with an inactive,

expired or active-retired license who meets the following conditions:

- (1) Reactivates the inactive, expired or active-retired license, registration or certificate to an active, unrestricted license, registration or certificate.
- (2) Documents to the satisfaction of the Board that the Board-regulated practitioner will practice only in approved clinics or upon referral from approved organizations without remuneration.

§ 25.603. Applications.

[An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide or cause to be provided:] A Board-regulated practitioner who meets the requirements of § 25.602(a) or (b) may apply for a volunteer license and shall submit an application in the manner and format prescribed by the Board, which shall include:

- (1) An executed verification on forms provided by the Board certifying that the applicant intends to practice exclusively:
 - (i) Without personal remuneration for professional services.
 - (ii) In an approved clinic or upon referral from an approved organization.
- (2) A letter signed by the director or chief operating officer of an approved clinic <u>or approved</u> organization that the applicant has been authorized to provide volunteer services in the named

clinic <u>or upon referral from the approved organization</u> by the governing body or responsible officer of the clinic <u>or approved organization</u>.

(3) [Evidence that the applicant has completed at least 3 hours of approved training in child abuse recognition and reporting in accordance with § 25.417(a) (relating to child abuse recognition and reporting—mandatory training requirement).] {Reserved}.

§ 25.604. Validity of license.

A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic, approved organization or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

§ 25.605. Biennial renewal.

A volunteer license shall be renewed biennially [on forms provided] in the manner and format prescribed by the Board.

(1) As a condition of biennial renewal, the applicant shall satisfy the [same] continuing education requirements [as the holder of an active, unrestricted license] under § 25.271 (relating to requirements for renewal) in accordance with section 6(c) or (d) of the Volunteer Health Services Act (35 P.S. § 449.46 (c) and (d)), including at least 2 hours in approved courses in child abuse recognition and reporting [in accordance with] under § 25.417(b) (relating to child abuse recognition and reporting—mandatory training requirement), and if the volunteer licensee holds a current Drug Enforcement Administration (DEA) registration or is utilizing the DEA registration of another, at least 2 hours of Board-approved continuing education in

pain management, the identification of addiction or in the practices of prescribing or dispensing opioids, in the 2 years prior to renewal.

(2) The applicant [shall be] is exempt from § 25.231 (relating to schedule of fees) pertaining to the biennial renewal fee and [shall be] is exempt from § 25.283 (relating to biennial renewal of license) with regard to the maintenance of liability insurance coverage under [section 701 of the Health Care Services Malpractice Act (40 P. S. § 1301-701)] section 711 of the MCARE Act (35 P.S. § 1303.711), as provided in section 9 of the Volunteer Health Services Act (35 P.S. § 449.49).

(3) Effective May 1, 2026, an osteopathic physician with a volunteer license shall complete at least 2 hours of the required continuing medical education credit hours in organ and tissue donation and recovery process in accordance with § 25.271(c)(6) (relating to requirements for renewal). This is a one-time requirement that shall be completed within 5 years of licensure renewal. A volunteer license holder who obtains licensure on or after the effective date shall complete the 2 hours within 5 years of initial licensure.

§ 25.606. [Return to active practice] Practice.

[A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.]

- (a) Except as provided in § 25.608 (relating to prescription of medication to family members), a volunteer license authorizes the holder to practice only in approved clinics or upon referral from approved organizations without remuneration.
- (b) A volunteer license holder who desires to return to active practice in this Commonwealth shall change the status of the volunteer license to inactive status in the manner and format

prescribed by the Board. If the license to practice the profession is expired, inactive or in an active-retired status, to return to active practice the licensee's license must be reactivated in accordance with this chapter.

§ 25.607. Disciplinary provisions.

A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. § § 449.41—[449.50] 449.53) or this subchapter may also constitute grounds for disciplinary action.

§ 25.608. Prescription of medication for family members.

A holder of a volunteer license, who was able to prescribe medication under the laws of this Commonwealth while an actively practicing Board-regulated practitioner, may prescribe medication to a family member notwithstanding the family member's ability to pay for that member's own care or whether that family member is being treated at an approved clinic or upon referral from an approved organization. A holder of a volunteer license who prescribes medication to a family member is liable under section 7(a) of the Volunteer Health Services Act (35 P.S. § 449.47), whether or not the holder of a volunteer license has complied with section 7(b) of the Volunteer Health Services Act. Nothing in this section may be construed to allow a volunteer license holder to prescribe medication of a type or in a manner prohibited by the laws of this Commonwealth.

§ 25.609. Exemptions.

Volunteer licensees who are otherwise subject to the provisions of the MCARE Act are exempt from the requirements of that act with regard to the maintenance of liability insurance coverage.



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

Post Office Box 2649 Harrisburg, PA 17105-2649 1-833-367-2762

November 6, 2025

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

Re: Proposed Rulemaking

State Board of Osteopathic Medicine

16A-5337: Education and Volunteer Services

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Osteopathic Medicine pertaining to Education and Volunteer Services.

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

Sincerely,

Randy Litman, D.O., Chairperson State Board of Osteopathic Medicine

Parky Mamin DO

RL/JAW/dps Enclosure

cc: Arion Claggett, Acting Commissioner of Professional and Occupational Affairs K. Kalonji Johnson, Deputy Secretary for Regulatory Programs Robert Beecher, Policy Director, Department of State 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 Ashley B. Goshert, Counsel, State Board of Osteopathic Medicine State Board of Osteopathic Medicine



Independent Regulatory Review Commission

From: Bulletin November 6, 2025

To: Solomon, Douglas; Leah Brown; Adeline E. Gaydosh

Cc: Abelson, Addie; Rizzi, Alicia (GC); Keys, Jaclyn (GC); GC, Regulations; Giurintano, Jason; Davis, Thomas;

Wolfgang, Jacqueline; Worthington, Amber; Fuhrman, Rebecca; Roland, Joel; DeLaurentis, Carolyn; Farrell,

Marc, Cassel, Jamison, Goshert, Ashley

Subject: [External] Re: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Date: Thursday, November 6, 2025 8:07:04 AM

Attachments: <u>image001.png</u>

ATTENTION: This email message is from an external sender. Do not open links or attachments from unknown senders. To report suspicious email, use the <u>Report Phishing</u> button in Outlook.

Good morning Douglas!

Thank you for sending this proposed rulemaking. Someone from our office will be in touch regarding the publication date of this proposed rulemaking.

I hope you have a great day!

Leah

From: Solomon, Douglas <dousolomon@pa.gov>

Sent: Thursday, November 6, 2025 7:55 AM

To: Bulletin <bulletin@palrb.us>; Leah Brown <lbrown@palrb.us>; Adeline E. Gaydosh <agaydosh@palrb.us>

Cc: Abelson, Addie <adabelson@pa.gov>; Rizzi, Alicia (GC) <arizzi@pa.gov>; Keys, Jaclyn (GC)

<jackeys@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>; Giurintano, Jason

<igiurintan@pa.gov>; Davis, Thomas <tmdavis@pa.gov>; Wolfgang, Jacqueline

<jawolfgang@pa.gov>; Worthington, Amber <agontz@pa.gov>; Fuhrman, Rebecca

<refuhrman@pa.gov>; Roland, Joel <joeroland@pa.gov>; DeLaurentis, Carolyn

<cdelaurent@pa.gov>; Farrell, Marc <marcfarrel@pa.gov>; Cassel, Jamison <jamcassel@pa.gov>;

Goshert, Ashley <agoshert@pa.gov>

Subject: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Please be advised that the State Board of Osteopathic Medicine is **electronically delivering** the below-identified proposed rulemaking today **Thursday November 6, 2025.**

• 16A-5337 Education and Volunteer Services—State Board of Osteopathic Medicine

The State Board of Osteopathic Medicine (board) proposes this rulemaking to implement section 9.1(a) of the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. § 872.9a). Section 9.1(a) of the ABC-MAP Act requires prescribers and dispensers to obtain mandatory education regarding pain management or the identification of addiction, education in the practices of prescribing or dispensing of opioids and opioid continuing education (collectively, "opioid education") as a condition of biennial renewal. The board also proposes to include provisions applicable to osteopathic physicians and physician assistants to make it clear that violations of the Safe Emergency Prescribing Act (35 P.S. §§ 873.1—873.9) will subject licensees to discipline. In addition, this proposed rulemaking would implement section 8628 of the Probate,

Estates and Fiduciaries Code (Probate Code) (20 Pa.C.S. § 8628) (relating to requirements for physician and nurse training relative to organ and tissue donation and recovery) in that osteopathic physicians must complete at least 2 hours of board-approved continuing education in the organ and tissue donation and recovery process one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever occurs first. Finally, this proposed rulemaking will also conform the board's regulations to amendments made over the past 25 years to the Volunteer Health Services Act (VHSA) (35 P.S. § 449.41-449.53).

The State Board of Osteopathic Medicine is requesting a written (email) confirmation of receipt of this delivery from the designated contact person(s) from your office to effectuate the electronic delivery.

Thank you for your attention to this matter.



Independent Regulatory
Review Commission

November 6, 2025



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

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Independent Regulatory Review Commission

 From:
 Emily Hackman

 To:
 Solomon, Douglas

 November 6, 2025

Cc: Solomon, Dougla Cc: Cindy Sauder

Subject: RE: [EXTERNAL]: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Date: Thursday, November 6, 2025 9:12:46 AM

Attachments: <u>image001.png</u>

Received! Thank you.

Emily Epler Hackman | Senior Policy Analyst

Pennsylvania House of Representatives Health Committee (R) 141 Ryan Office Building Phone: (717) 260-6351

From: Solomon, Douglas <dousolomon@pa.gov> Sent: Thursday, November 6, 2025 8:47 AM

To: Nicole Sidle <Nsidle@pahousegop.com>; Cindy Sauder <Csauder@pahousegop.com>; Emily Hackman <Ehackman@pahousegop.com>

Cc: Abelson, Addie <adabelson@pa.gov>; Rizzi, Alicia (GC) <arizzi@pa.gov>; Keys, Jaclyn (GC) <jackeys@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>; Giurintano, Jason <jgiurintan@pa.gov>; Davis, Thomas <tmdavis@pa.gov>; Wolfgang, Jacqueline <jawolfgang@pa.gov>; Worthington, Amber <agontz@pa.gov>; Fuhrman, Rebecca <refuhrman@pa.gov>; Roland, Joel <joeroland@pa.gov>; DeLaurentis, Carolyn <cdelaurent@pa.gov>; Farrell, Marc <marcfarrel@pa.gov>; Cassel, Jamison <jamcassel@pa.gov>; Goshert, Ashley <agoshert@pa.gov>

Subject: [EXTERNAL]: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Importance: High

Please be advised that the State Board of Osteopathic Medicine is **electronically delivering** the below-identified proposed rulemaking today **Thursday November 6, 2025.**

• 16A-5337 Education and Volunteer Services—State Board of Osteopathic Medicine

The State Board of Osteopathic Medicine (board) proposes this rulemaking to implement section 9.1(a) of the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. § 872.9a). Section 9.1(a) of the ABC-MAP Act requires prescribers and dispensers to obtain mandatory education regarding pain management or the identification of addiction, education in the practices of prescribing or dispensing of opioids and opioid continuing education (collectively, "opioid education") as a condition of biennial renewal. The board also proposes to include provisions applicable to osteopathic physicians and physician assistants to make it clear that violations of the Safe Emergency Prescribing Act (35 P.S. §§ 873.1—873.9) will subject licensees to discipline. In addition, this proposed rulemaking would implement section 8628 of the Probate, Estates and Fiduciaries Code (Probate Code) (20 Pa.C.S. § 8628) (relating to requirements for physician and nurse training relative to organ and tissue donation

and recovery) in that osteopathic physicians must complete at least 2 hours of board-approved continuing education in the organ and tissue donation and recovery process one time within 5 years of initial licensure or within 5 years of licensure renewal, whichever occurs first. Finally, this proposed rulemaking will also conform the board's regulations to amendments made over the past 25 years to the Volunteer Health Services Act (VHSA) (35 P.S. § 449.41-449.53).

The State Board of Osteopathic Medicine is requesting a written (email) confirmation of receipt of this delivery from the designated contact person(s) from your office for the Chair of your office to effectuate the electronic delivery.

Thank you for your attention to this matter.

RECEIVED

Independent Regulatory Review Commission

November 6, 2025



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

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ndependent Regulatory Review Commission

November 6, 2025

From: Monoski, Jesse

To: Solomon, Douglas; Dimm, Ian; Kelly, Joseph; Vazquez, Enid

Cc: Abelson, Addie; Rizzi, Alicia (GC); Keys, Jaclyn (GC); GC, Regulations; Giurintano, Jason; Davis, Thomas;

Wolfgang, Jacqueline; Worthington, Amber; Fuhrman, Rebecca; Roland, Joel; DeLaurentis, Carolyn; Farrell,

Marc; Cassel, Jamison; Goshert, Ashley

Subject: Re: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Date: Thursday, November 6, 2025 9:02:22 AM

Attachments: <u>image001.png</u>

Notice received. Thank you.

Jesse Monoski

Office of Senator Boscola

Get Outlook for Android

From: Solomon, Douglas <dousolomon@pa.gov> Sent: Thursday, November 6, 2025 8:38:14 AM

To: Monoski, Jesse <jesse.monoski@pasenate.com>; Dimm, lan <lan.Dimm@pasenate.com>; Kelly,

Joseph <Joseph.Kelly@pasenate.com>; Vazquez, Enid <enid.vazquez@pasenate.com>

Cc: Abelson, Addie <adabelson@pa.gov>; Rizzi, Alicia (GC) <arizzi@pa.gov>; Keys, Jaclyn (GC)

<jackeys@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>; Giurintano, Jason

<igiurintan@pa.gov>; Davis, Thomas <tmdavis@pa.gov>; Wolfgang, Jacqueline

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<cdelaurent@pa.gov>; Farrell, Marc <marcfarrel@pa.gov>; Cassel, Jamison <jamcassel@pa.gov>;

Goshert, Ashley <agoshert@pa.gov>

Subject: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

■ EXTERNAL EMAIL ■

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Thank you for your attention to this matter.

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Independent Regulatory Review Commission

November 6, 2025

From: Orchard, Kari L.

To: Solomon, Douglas

Subject: RE: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Date: Thursday, November 6, 2025 9:20:58 AM

Attachments: image001.png

Received – thank you!

Kari Orchard

Executive Director (D) | House Professional Licensure Committee Chairman Frank Burns, 72nd Legislative District

From: Solomon, Douglas <dousolomon@pa.gov> Sent: Thursday, November 6, 2025 8:42 AM

To: Orchard, Kari L. <KOrchard@pahouse.net>; Barton, Jamie <JBarton@pahouse.net>; Brett, Joseph D. <JBrett@pahouse.net>

Cc: Abelson, Addie <adabelson@pa.gov>; Rizzi, Alicia (GC) <arizzi@pa.gov>; Keys, Jaclyn (GC)

<jackeys@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>; Giurintano, Jason

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Independent Regulatory Review Commission November 6, 2025

From: Smeltz, Jennifer

To: Solomon, Douglas

Subject: RE: DELIVERY NOTICE OF: REGULATION # 16A-5337 (Education and Volunteer Services)

Date: Thursday, November 6, 2025 9:46:18 AM

Attachments: image001.png

Received.

Jen Smeltz, Executive Director Consumer Protection and Professional Licensure Committee Office of Senator Pat Stefano

Phone: (717) 787-7175

From: Solomon, Douglas <dousolomon@pa.gov> **Sent:** Thursday, November 6, 2025 8:32 AM **To:** Smeltz, Jennifer <jmsmeltz@pasen.gov>

Cc: Abelson, Addie <adabelson@pa.gov>; Rizzi, Alicia (GC) <arizzi@pa.gov>; Keys, Jaclyn (GC)

<jackeys@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>; Giurintano, Jason

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Goshert, Ashley <agoshert@pa.gov>

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