

# RULES AND REGULATIONS

## Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

### STATE BOARD OF MASSAGE THERAPY

[ 49 PA. CODE CH. 20 ]

#### Fees

The State Board of Massage Therapy (Board) amends § 20.3 (relating to fees) to read as set forth in Annex A.

#### *Effective Date*

The amendments will be effective upon publication of this final-form rulemaking in the *Pennsylvania Bulletin*. The increased application fees will be implemented immediately; the increased biennial renewal fees will be implemented beginning with the January 31, 2019, biennial renewal.

#### *Statutory Authority*

Section 11(a) of the Massage Therapy Law (act) (63 P.S. § 627.11(a)) requires the Board to increase fees by regulation to meet or exceed projected expenditures if the revenues raised by fees, fines and civil penalties imposed under the act are not sufficient to meet expenditures over a 2-year period.

#### *Background and Need for Amendments*

Under section 11(a) of the act, the Board is required by law to support its operations from the revenue it generates from fees, fines and civil penalties. In addition, the act provides that the Board shall increase fees if the revenue raised by fees, fines and civil penalties is not sufficient to meet expenditures over a 2-year period. The Board raises the majority of its revenue through biennial renewal fees. A small percentage of its revenue comes from application fees, fines and civil penalties.

Under section 49 of the act (63 P.S. § 627.49), initial operating funds were transferred from the Professional Licensure Augmentation Account (PLAA) to the Board to be repaid to the PLAA within 3 years of the beginning of the issuance of licenses. The current fee schedule in § 20.3 was established with the Board's initial rulemaking in 2011 based upon an estimate of the costs of administering the functions of the Board at that time. See 41 Pa.B. 16 (January 1, 2011). However, since the Board began issuing licenses in 2011, it has not produced enough revenue to cover its current operating expenses. In fact, the deficit balance in the Board's account as of the beginning of Fiscal Year (FY) 2018-2019 is projected by the Bureau of Finance and Operations (BFO) to be \$1,592,560.78.

Therefore, the Board determined that it is necessary to raise fees to meet or exceed projected expenditures, in compliance with section 11(a) of the act. Based on recommendations from the BFO, the Board published its proposed rulemaking at 48 Pa.B. 3736 (June 23, 2018), in which the Board proposed three amendments to the Board's fee schedule. As proposed, the Board would have amended § 20.3 to increase the application fee for initial licensure from \$65 to \$100; to increase the application fee for approval of a continuing education program from \$65 to \$100; and to increase the biennial renewal fee from \$75 to \$200. The Board had also proposed to eliminate subsection (d) as outdated because the National Certification Board for Therapeutic Massage and Bodywork no

longer provides an examination. During the 30-day public comment period and thereafter, the Board received 413 comments from the regulated community, including comments from Deborah Dunn, President of the Lancaster School of Cosmetology and Therapeutic Bodywork; Tracy Becker, Executive Director of the Clarion Area Chamber of Commerce; and approximately 410 individual licensed massage therapists. Virtually all of these comments objected to the increase in the biennial renewal fee for licensed massage therapists, and to a lesser degree to the increased application fee and continuing education approval fee. On August 22, 2018, the Board received comments from the Independent Regulatory Review Commission (IRRC).

#### *Summary of Comments and the Board's Response*

After summarizing many of the public comments, IRRC asked the Board to address the adverse economic impacts that commenters have asserted will result from the significant biennial renewal fee increase. The Board reviewed all of the public comments and offers the following response.

Of the 413 public commenters, the vast majority objected to the increase in the biennial renewal fee from \$75 to \$200. In fact, only three were supportive, and 17 were neutral. A large number simply said that the proposed fee increase was too large and burdensome, especially for many massage therapists who only practice part-time. Many felt that such an increase would result in existing licensees choosing not to renew their licenses, thus resulting in less revenue, not more. Licensees also commented that with costs associated with continuing education, insurance and equipment, such an increase is excessive. Many complained that unlike other health-related services, massage therapy is generally not covered by insurance and during economic down turns, people will cut out massages as an unnecessary expense. There were a number of commenters who compared the proposed fee with those paid by other professions in this Commonwealth and with the fees paid by massage therapists in other states. The commenters generally asked for no increase, a smaller increase or a graduated increase.

Because the Board is required to support its operations with the revenue it raises from fees, fines and civil penalties, the option to not increase fees at this time is untenable. As noted, the Board's deficit has grown to approximately \$1.5 million at the beginning of this fiscal year. Revenues capable of being produced under the current fee structure each biennium are approximately \$925,000; while expenditures are approximately \$1.3 million, resulting in a biennial operating deficit of approximately \$375,000. The act requires the Board to set its fees at a level high enough to cover its expenditures over a 2-year period. Thus, an increase is necessary.

However, the original proposal put forth by the BFO of a \$200 biennial renewal fee would have eliminated the deficit over two renewal periods. As a result of its review of the regulated community's comments, the Board asked the BFO to consider recouping the deficit over a period of 10 years (in that it has taken 10 years to get into this financial hole, it should take no less than 10 years to dig out of it). In addition, the Board asked the BFO to consider a graduated fee increase so that licensees would have the ability to budget for the increase, rather than be surprised by a large increase when they apply for renewal in 2019.

The BFO returned to the Board at its meeting on September 18, 2018, and provided a revised proposal which would: 1) allow the Board adequate revenue to cover its projected biennial expenditures; 2) eliminate the deficit over a period of 10 years (by FY 2027-2028); and 3) provide for a graduated increase to make it possible for licensees to budget for the necessary increases. The new proposal would increase the biennial renewal fee for licensed massage therapists from \$75 to \$125 for the 2019—2021 biennial renewal period; to \$150 for the 2021—2023 biennial renewal period; and to \$175 for the 2023—2025 renewal period. While the Board recognizes that many of the commenters will still not be happy paying more to renew their licenses, it has endeavored to find a compromise that addresses as many of the licensees' concerns as possible, while still eliminating the deficit and returning the Board to sound financial condition.

Commenters offered a number of suggestions for the Board to balance its budget without an increase in fees. Many suggested that the Board should shift the burden to those who would practice without a license or who violate the licensing laws in the form of increased civil penalties. Some commenters chastised the Board, indicating there remains too much unlicensed practice, or that the Board is somehow not policing the profession adequately. Some suggested that the Board should require licensure for Asian bodyworkers, a profession that is exempt from licensure under section 13 of the act (63 P.S. § 627.13(6)). IRRRC asked the Board to explain what steps the Board is taking to increase revenues by shifting the burden from licensees to unlicensed individuals through fines and civil penalties. The revenue produced through civil penalties is unreliable at best and is not intended to be used to balance a board's budget. Instead, the Board imposes civil penalties on unlicensed individuals and on licensees who have violated the act or the Board's regulations as a deterrent—to those who have violated the law and to other similarly situated individuals. Indeed, the courts have ruled that excessive civil penalties are punitive, rather than deterrent, and have set them aside. The enforcement efforts of the Board, like all other boards and commissions under the Bureau of Professional and Occupational Affairs (Bureau), are primarily complaint driven. Based on the most recent figures provided to the Board from the Office of Chief Counsel, since the Board began its operations in FY 2010-2011 through the end of FY 2016-2017, there have been approximately 1,177 complaints filed relating to massage therapy. Each complaint is investigated to determine if a violation of the act or regulations has occurred. Each investigation requires the expenditure of funds—funds which are unlikely to be recouped through the imposition of civil penalties by the Board. Often an investigation does not result in a prosecution. Many activities that one may consider part of "massage therapy" are specifically exempt from licensure under section 13 of the act, including acupressure, Asian bodywork therapy, polarity therapy bodywork, quigon, reiki, shiatsu and tui na. Complaints are routinely filed against practitioners and upon investigation, it is determined that they are exempt from licensure such that no civil penalties may be imposed. Additionally, those who practice massage therapy without a license are unlikely to pay a civil penalty imposed by the Board, which is then turned over to the Office of the Attorney General for collection. Recently, a new law was passed (the act of October 20, 2017 (P.L. 379, No. 40)) (71 P.S. § 307.6a) which amended the Administrative Code of 1929 to permit the Attorney General's office to retain 25% of all funds they collect on behalf of a board. For these reasons,

balancing the Board's budget by imposing greater civil penalties would simply not work.

Other commenters suggest that the Board should cut the salaries of its staff or the Board members themselves should have their salaries cut. The majority of the Board's costs are personnel related, and much of those costs are not within the Board's control. Staff are generally employees of the Commonwealth, most of whom are civil service personnel, and many are union positions. For these employees, the Board is bound by the negotiated contract. Personnel costs associated with investigation and enforcement depend largely on the number of complaints received that need to be investigated, and the number of those matters that result in disciplinary action. The Board has no control over the number of complaints that are filed against licensees and unlicensed individuals, nor may they control which matters are or are not prosecuted. Board members themselves receive \$60 per day when attending to Board business—an amount set forth in section 3 of the act (63 P.S. § 627.3). Board members are also entitled to receive "reasonable traveling, hotel and other necessary expenses incurred in the performance of their duties." The actual "Board member expenses" budgeted for FY 2018-2019 amount to \$15,000, out of the \$667,000 projected budget, or approximately 2.2%. Thus, cutting Board member expenses would have little effect on the bottom line. To those commenters who feel that the Board is out-of-touch, wants a larger paycheck, is fleecing the regulated community, or otherwise does not care about the average licensee, it should be noted that the Board is made up of a majority of professional members—licensed massage therapists—who will also be required to pay the increased biennial renewal fees.

In response to those commenters who objected to the increase because they are only part-time practitioners, the Board cannot distinguish between licensees based on the number of hours they work, as the Board has no control over that number. Nor can the Board distinguish between licensees based on their annual income. However, the Board hopes that the new lower, graduated fee approach will allow licensees to budget for the increases, which now amount to a \$50 increase in 2019, a \$25 increase in 2021 and a \$25 increase in 2023. In addition, the Board has committed to reassessing the fee in 2027 when the accumulated deficit has been eliminated.

Additionally, the Board members recognize that the biennial renewal fee is not the only expense a licensed massage therapist incurs related to licensure, as many commenters pointed out. Section 6 of the act (63 P.S. § 627.6) requires each licensee to maintain current CPR certification and to complete a minimum of 24 hours of continuing education in the field of massage therapy as a condition of license renewal. These are statutory requirements set forth by the General Assembly. Many commenters mentioned the increased costs associated with continuing education courses, 16 of which are required by the Board's regulations to be completed in the physical presence of an instructor or supervisor. Although the Board cannot alter the number of hours of continuing education required by the act, the Board will take this comment under advisement when considering amendments to its continuing education regulations.

Many commenters compared the Board's proposed fees with fees paid by other professions licensed in this Commonwealth, including nurses and physical therapists. Each board is required to be funded by the fees, fines and civil penalties it generates. Comparing one board with another is difficult—like comparing apples to oranges. For example, the State Board of Nursing has been in exist-

ence since the early 1900s and has over 300,000 licensees. The Board was created in 2008 and has only 9,176 licensees. Comparing a relatively new board with an established board, especially one with 33 times as many licensees, is not instructive. More instructive may be a board of comparable size and budget—for example, the State Board of Barber Examiners. The Barber board has approximately 9,235 licensees (compared to 9,176 licensees licensed by the Board) and annual expenditures of approximately \$700,000 (compared to \$667,000 for the Board). Biennial renewal fees range from \$109 to \$174 for barbers, barber managers and barber teachers, which is comparable to the new proposed biennial renewal fee structure for massage therapists.

Other commenters compared the Board's proposed biennial renewal fee with those paid by massage therapists in other states. Again, because the Board is required to set its fees to cover the cost of its operations, comparisons with other states may not be instructive because not all states have similar licensure schemes and funding streams. However, a review of fees in the Northeast region of the United States indicates that the average renewal fee for massage therapists is \$125.25, with a low of \$65 (New York) and a high of \$255 (Connecticut). Thus, the revised fee structure is in line with nearby states.

A few commenters objected to the increase in the initial license fee from \$65 to \$100. They believe that many massage therapists will forego licensure and practice without a license. The new proposed fee is based on the actual cost of processing an application for licensure as a massage therapist. If the fee is not increased, the general licensee population would essentially be underwriting these costs for individual applicants who may or may not ever obtain licensure. A review of nearby states indicates that the average initial licensing fee in the Northeast region is \$174.80, with a low of \$65 (Rhode Island) to a high of \$450 (Maryland). Thus, the Board finds the initial licensure fees to be appropriate and not overly burdensome. The Board would encourage all licensees to report unlicensed practice for investigation.

Finally, a few commenters noted that the increased fee for approval of a continuing education course (from \$65 to \$100) would simply be passed on to massage therapists by the continuing education providers. As previously noted, this fee has been calculated based on the actual cost of processing the application for approval. Additionally, this fee is only charged to those providers of continuing education who are not preapproved by the Board as set forth in § 20.33 (relating to continuing education content and providers). The preapproved providers provide the vast majority of continuing education to the Board's licensees, as the Board only approves a handful of courses each year, out of the hundreds of available courses for massage therapists. At the present time, there are only six courses for continuing education approved by the Board that are not offered by preapproved providers.

In addition to asking the Board to address the economic impacts identified by the commenters, IRRC also asked the Board to address the Board's debt to the PLAA. Specifically, IRRC asked how much the Board initially borrowed and what remaining balance is owed to the PLAA. The following chart shows the initial funds (\$89,628.94) that were advanced by the PLAA during years when the Board had no revenue prior to the issuance of licenses in FY 2010-2011. The Board had received sufficient revenue to cover all start up fees once they began issuing licenses. However, those revenues failed to also cover the Board's other operational expendi-

tures. Thus, while the funds advanced from the PLAA were technically returned to the PLAA, the Board has been depending on the PLAA to subsidize its expenditures that are not covered by the current fee structure since its inception and currently "owes" \$1,571,455.03 to the PLAA. Provided the revised incremental renewal fee increase is approved, the Board's debt to the PLAA should be erased within the next decade.

<i>Fiscal Year</i>	<i>Expenses</i>	<i>Revenue</i>
FY 2008-2009	(\$8,265.15)	\$0.00
FY 2009-2010	(\$81,363.82)	\$0.00
FY 2010-2011	(\$211,749.61)	\$203,105.00
FY 2011-2012	(\$413,876.64)	\$293,876.80
FY 2012-2013	(\$596,442.21)	\$608,164.13
FY 2013-2014	(\$601,282.08)	\$129,889.26
FY 2014-2015	(\$664,644.20)	\$679,902.08
FY 2015-2016	(\$635,539.01)	\$196,667.41
FY 2016-2017	(\$653,584.41)	\$701,421.77
FY 2017-2018	(\$587,017.68)	\$133,840.08
FY 2018-2019 (FYTD)	(\$82,539.97)	\$17,983.22
TOTAL	(\$4,536,304.78)	\$2,964,849.75

IRRC also asked the Board to explain whether the costs, as presented, are strictly Board expenses, or include State Department overhead, and how the Board reconciles its deficit with the Department's budget. The Board is required to pay for charges to various support offices within the agency including the Executive Offices, Office of Policy, Office of Legislative Affairs, Office of Chief Counsel, Office of Communications and Press, Office of Human Resources, the Bureau of Finance and Operations and the Office for Information Technology. All charges are based on work completed for the Board. On average, 5%—8% of the Board's total annual expenses are attributed to the work completed by these support entities. The Board's expenditures are a part of the overall budget of the agency. Furthermore, the Board resides among 25 other Boards and Commissions under the PLAA account. In accordance with section 11(c) of the act, all fees, fines and civil penalties collected by the Board are paid into the PLAA. In accordance with section 301 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-301), money in the account may only be used "for the support of the operation of the [B]ureau and the various regulatory boards." Each year the General Assembly appropriates from the PLAA for the operation of the various regulatory boards, and for other general costs of Bureau operations, monies available from the PLAA. Thus, although each board is expected to support its operations from revenues it produces from fees, fines and civil penalties, excess funds in the PLAA are used temporarily to cover outstanding expenses unable to be covered by revenue received by the Board.

IRRC pointed out that the "Fee Report Form" related to the biennial renewal fee does not include "Fee-Related Activities and Costs," and asked that the Board explain, without these costs, how the proposed fee was determined. Generally, the Bureau's Revenue Office creates a fee report form when calculating fees for services performed by the Boards to individuals (for example, processing applications, verification of status of licensure/letters of good standing, approval of a continuing education course, and the like) based on the cost associated with that specific activity/service. In that way, the individual pays for the service, rather than the costs being spread

across the licensee population. Other costs, however, such as departmental overhead, board administration, investigation and enforcement, legal office costs (including prosecution, counsel, hearing expenses, and the like) cannot be attributed to a specific individual and are borne by the general licensee population through the biennial renewal fee. In layman's terms, through collaboration with the various offices within the agency, BFO projects expected expenditures over a 2-year period, estimates the amount of "non-renewal" revenue that is produced through other fees, fines and civil penalties, and then determines the amount that is needed to cover the remaining projected expenditures. This amount must be funded through the biennial renewal fee and is divided equally among the current licensee population. Therefore, the "Fee-related Activities and Costs" related to the biennial renewal fee are all costs that are unrelated to a specific service provided to an individual by the Board.

Additionally, IRRC asked the Board to explain why the initial estimate of the costs of administering the functions of the Board resulted in the Board not producing enough revenue to cover its operating expenses since it began issuing licenses in 2011. At the time of drafting its initial regulations, including the fee schedule, the Board looked to other established boards within the Bureau which the Board felt would be comparable. However, the Board failed to discern the large number of applicants who would apply as "existing practitioners," that would result in hearings relating to their qualifications. Once the deadline to obtain licensure passed, the Board experienced an influx of "unlicensed practice" complaints that resulted in investigative and legal expenses. For example, in 2013, there were 96 matters involving unlicensed practice resolved by the Board. Even today this category of case continues to demand a great deal of resources of the Board, as noted by the commenters. During FY 2016-2017, 46 cases involving unlicensed practice concluded. Finally, the Board underestimated the significant costs that would be incurred related to investigating and prosecuting sexual misconduct cases before the Board. During FY 2016-2017, there were 15 matters involving sexual misconduct concluded, seven of which resulted in significant discipline (suspension or revocation of a license). It is unfortunate that the Board did not anticipate these circumstances, which resulted the Board underestimating the necessary expenditures and setting the initial fees too low to support the level of enforcement demanded under the act.

Finally, IRRC asked the Board to remove references to section 11(b) of the act from the statutory authority sections of the Preamble and the Regulatory Analysis Form (RAF), since this citation references the authority of the Bureau, not the Board. The Board has made this amendment to both the Preamble and the RAF. However, the Board believes it is prudent to point out that under section 11(b), should the Board not raise its fees to cover the minimum enforcement efforts required by the act, then the Bureau is required to step in and increase the fees.

#### *Description of Amendments to this Final-Form Rulemaking*

This final-form rulemaking amends § 20.3 to increase the application fee for initial licensure from \$65 to \$100 and to increase the fee for approval of a continuing education program from \$65 to \$100, as originally proposed. These fees are designed to cover the costs to process the application and should be borne by the individual applicant. However, in response to the many comments received, the Board has revised the increase to

the biennial renewal fee to provide a graduated fee increase: from \$75 to \$125 for FY 2018-2019; from \$125 to \$150 for FY 2020-2021; and from \$150 to \$175 for FY 2022-2023 and thereafter, unless changed by the Board. The Board is committed to reassessing the fee structure when the deficits have been eliminated and the "debt" to the PLAA is repaid, currently projected to be after the 2027 biennial renewal.

#### *Fiscal Impact*

This final-form rulemaking will increase the biennial renewal fees, the initial application fees and the fee for approval of continuing education programs. There are currently approximately 9,176 licensees that will be required to pay \$50 more to renew their licenses in 2019; \$25 more to renew their licenses in 2021; and \$25 more to renew their licenses in 2023, and thereafter. There are currently approximately 1,000 initial applicants annually who will have to pay \$35 more to obtain an initial license. The sponsors of continuing education programs that are not preapproved will have to pay \$35 more for the approval of their continuing education programs. The Board only processes a handful of continuing education program approvals each year. This final-form rulemaking will have no other fiscal impact on the private sector, the general public or political subdivisions of the Commonwealth.

#### *Paperwork Requirements*

This final-form rulemaking requires the Board to alter some of its forms to reflect the new fees; however, this final-form rulemaking will not create additional paperwork for the regulated community or for the private sector.

#### *Sunset Date*

The act requires the Board to monitor its revenue and costs on a fiscal year and biennial basis. Therefore, no sunset date has been assigned. However, the Board is committed to reviewing the fee structure once the deficits have been eliminated and the moneys owed to the PLAA are repaid.

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on June 13, 2018, the Board submitted a copy of the proposed rulemaking, published at 48 Pa.B. 3736, to IRRC and the chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

In preparing the final-form rulemaking, the Board has considered all comments received from the public and from IRRC. The Board received no comments from the Senate Consumer Protection and Professional Licensure Committee or from the House Professional Licensure Committee.

On October 10, 2018, the Board delivered this final-form rulemaking to IRRC, the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 14, 2018, this final-form rulemaking was deemed approved by the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on November 15, 2018, and approved the final-form rulemaking.

Additional Information

Further information may be obtained by contacting Carol Niner, Board Administrator, State Board of Massage Therapy, P.O. Box 2649, Harrisburg, PA 17105-2649, RA-MASSAGETHERAPY@pa.gov.

Findings

The Board finds that:

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

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

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 48 Pa.B. 3736.

(4) This final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Massage Therapy Practice Act.

Order

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

(a) The regulations of the Board at 49 Pa. Code § 20.3 are amended to read as set forth in Annex A.

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

(c) The Board shall submit this order and Annex A to IRRC, the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee as required by law.

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

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

BECKY D. CAUFMAN, LMT, Chairperson

(Editor's Note: See 48 Pa.B. 7494 (December 1, 2018) for IRRC's approval order.)

Fiscal Note: 16A-724. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 20. STATE BOARD OF MASSAGE THERAPY

GENERAL PROVISIONS

§ 20.3. Fees.

(a) The following fees are charged for services provided by the Board:

Table with 2 columns: Service and Fee. Application for initial licensure \$100, Application for temporary practice permit \$65, Verification of licensure or letter of good standing \$15.

Table with 2 columns: Service and Fee. Certification of licensure history \$25, Reactivation of license \$65, Restoration after suspension or revocation \$65, Approval of continuing education program \$100.

(b) The following fees are charged to sustain the operations of the Board:

Table with 2 columns: Service and Fee. Biennial renewal fee for biennial period February 1, 2019—January 31, 2021 \$125.

Table with 2 columns: Service and Fee. Biennial renewal fee for biennial period February 1, 2021—January 31, 2023 \$150.

Table with 2 columns: Service and Fee. Biennial renewal fee for biennial period February 1, 2023—January 31, 2025, and each biennial renewal period thereafter \$175.

(c) In addition to the application fee prescribed in subsection (a), which is payable directly to the Board, a candidate for the MBLEx shall be responsible for any fees charged by the FSMTB for taking the examination.

[Pa.B. Doc. No. 18-1856. Filed for public inspection November 30, 2018, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[ 49 PA. CODE CH. 27 ]

Standards of Practice and Prospective Drug Review and Patient Counseling

The State Board of Pharmacy (Board) amends §§ 27.18 and 27.19 (relating to standards of practice; and prospective drug review and patient counseling) to read as set forth in Annex A.

Background and Purpose

Beginning January 10, 2018, Governor Tom Wolf has signed Statewide disaster declarations to address the heroin and opioid abuse crisis. One of his initiatives is to increase access to naloxone and to "allow pharmacists to partner with other organizations, including prisons and treatment programs to make naloxone available to at-risk individuals upon discharge from these facilities." Naloxone, a noncontrolled prescription drug, is an opioid antagonist used to reverse opioid overdose.

As recently as April 5, 2018, the United States Surgeon General issued an advisory that more Americans should carry the opioid overdose-reversing drug, naloxone, noting that the drug can very quickly restore normal breathing in someone suspected of overdosing on opioids, including heroin and prescription pain medications. The Surgeon General stated that "[r]esearch shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities." See, https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.

"The risk of death from overdose is greatly increased in the weeks following release from prison. A pre-release program of overdose prevention education, including naloxone prescription, for inmates with a history of opiate addiction would likely prevent many overdose deaths." Wakeman, SE, et al., Preventing Death Among the Re-

cently Incarcerated: An Argument for Naloxone Prescription Before Release, *Journal of Addiction Disease*, 2009;28(2): 124.

Correctional facilities, prisons and jails often identify inmates who are pending release, and residential drug treatment facilities identify patients pending discharge, who are at-risk for opioid abuse and overdose. Some of these facilities are large enough to maintain their own medical clinic and pharmacy, while others do not, but instead contract with medical practitioners. For the larger facilities, the in-house pharmacy or physician may dispense directly to the individual. It is the smaller correctional facilities, prisons, jails and residential drug treatment facilities that wish to allow outside pharmacies to deliver naloxone to the facility for the individual pending release.

There are two potential regulatory impediments. The first is § 27.18(e), which limits the pharmacy’s ability to “enter into an arrangement or agreement with a nonlicensed person [facility employee] whereby . . . prescription drugs . . . may be regularly . . . delivered. . . .” The proposed change would provide an exception for naloxone delivered to a facility for an identified individual.

The second potential impediment is § 27.19. This section requires pharmacists to perform a prospective drug review (PDR) prior to dispensing or delivering a new prescription. The purpose of the PDR is to help assure that a drug dispensed is not likely to have an adverse medical result and involves a pharmacist’s review of a patient profile maintained in the pharmacy. It is likely that although the facility requesting delivery of naloxone will provide the individual’s name to the pharmacy, the pharmacy will not have a current profile for that person, and the pharmacist will not have the necessary information, including medical and prescription history, the ability to create a profile.

Section 27.19(c)(3) provides four exceptions to the PDR requirement. This final-omitted rulemaking would provide an additional exception for naloxone delivered to a facility for an identified individual.

*Omission of Proposed Rulemaking*

Under section 204(3) of the Commonwealth Documents Law (CDL) (45 P.S. § 1204(3)), the Board is authorized to omit the procedures for the proposed rulemaking in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) if the Board finds that the specified procedures are impracticable, unnecessary or contrary to the public interest.

Publication of the proposed rulemaking is contrary to the public interest under the circumstances previously set forth because the final-omitted rulemaking is needed to fulfill an urgent and immediate need to provide this potentially life-saving drug to individuals identified as at risk for overdose and death upon their release from incarceration or their discharge from a residential drug treatment facility, consistent with the Governor’s Proclamation of Disaster Emergency.

*Statutory Authority*

Section 6(k)(9) of the Pharmacy Act (act) (63 P.S. § 390-6(k)(9)) authorizes the Board to promulgate rules and regulations to effectuate the purposes of the act and to regulate the distribution of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare.

*Fiscal Impact and Paperwork Requirements*

There is no fiscal impact and no paperwork requirements are associated with this final-omitted rulemaking.

*Regulatory Review*

Under section 5.1(c) of the Regulatory Review Act (RRA) (71 P.S. § 745.5a(c)), on October 10, 2018, the Board submitted copies of the final-omitted rulemaking to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. On the same date, the Board submitted a copy of the final-omitted rulemaking to the Office of Attorney General under the Commonwealth Attorneys Act (71 P.S. §§ 732-101—732-506).

Under sections 5.1(e) and (j.2) of the RRA (71 P.S. § 745.5a(e) and (j.2)), the amendment was deemed approved by the House Professional Licensure Committee on November 14, 2018, deemed approved by the Senate Consumer Protection and Professional Licensure Committee on November 14, 2018, and approved by IRRC on November 15, 2018.

*Additional Information*

For additional information about this final-omitted rulemaking, submit inquires to Melanie Zimmerman, RPh, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649, ST-PHARMACY@pa.gov.

*Findings*

The Board finds that:

(1) Public notice of the Board’s intention to amend its regulations under the procedures in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) has been omitted under section 204 of the CDL (45 P.S. § 1204) because publication of proposed rulemaking is contrary to the public interest under the circumstances previously set forth because the final-omitted rulemaking is needed to fulfill an urgent and immediate need to provide this potentially life-saving drug to individuals identified as at risk for overdose and death upon their release from incarceration or their discharge from a drug treatment facility, consistent with the Governor’s Proclamation of Disaster Emergency.

(2) The amendment of the Board’s regulations in the manner provided in this order is necessary and appropriate to effectuate the purposes of the act and to regulate the distribution of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare.

*Order*

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

(a) The regulations of the Board hereby are amended by amending §§ 27.18 and 27.19 to read as set forth in Annex A.

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

(c) The Board shall submit this order and Annex A to the IRRC, the Senate Consumer Protection and Professional Licensure Committee, and the House Professional Licensure Committee as required by law.

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

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

JANET GETZEY HART, RPh,  
*Chair*

(*Editor's Note:* See 48 Pa.B. 7494 (December 1, 2018) for IRRC's approval order.)

**Fiscal Note:** 16-5431. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 27. STATE BOARD OF PHARMACY STANDARDS**

**§ 27.18. Standards of practice.**

\* \* \* \* \*

(e) No pharmacist may enter into an arrangement or agreement with a nonlicensed person whereby prescription orders or prescription drugs and devices may be regularly left with, picked up from, solicited by, accepted by or delivered to the nonlicensed person or whereby a pharmacist pays or has an arrangement or agreement with the nonlicensed person to perform these functions. Nothing in this section shall prohibit a licensee from picking up a prescription or delivering a prescription drug or device, at the request of the patient, at the office or

home of the prescriber or patient, at an institution in which a patient is confined, at another place as the patient designates for his safety and convenience, or by means of an employe, the mails or common carrier. Nothing in this section shall prohibit a licensee from delivering naloxone to an identified employee of a Pennsylvania correctional facility, prison, jail or residential drug treatment facility under a prescription and for an identified individual who is pending release or discharge from the correctional facility, prison, jail or residential drug treatment facility.

\* \* \* \* \*

**§ 27.19. Prospective drug review and patient counseling.**

\* \* \* \* \*

(c) *Scope.*

\* \* \* \* \*

(3) The following are examples of situations in which a PDR is not required:

\* \* \* \* \*

(iv) A pharmacist dispenses a drug to a medical practitioner which the practitioner will administer to a patient.

(v) A pharmacist delivers naloxone to an identified employee of a Pennsylvania correctional facility, prison, jail or residential drug treatment facility under a prescription and for an identified individual who is pending release or discharge from the correctional facility, prison, jail or residential drug treatment facility.

\* \* \* \* \*

[Pa.B. Doc. No. 18-1857. Filed for public inspection November 30, 2018, 9:00 a.m.]

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