Comments of the Independent Regulatory Review Commission



State Board of Medicine Regulation #16A-4955 (IRRC #3390)

Physician Assistants

February 15, 2024

We submit for your consideration the following comments on the proposed rulemaking published in the December 16, 2023 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

1. Section 18.142. Written agreements. –Implementation procedures; Reasonableness

Subsection (b)

Section 18.142(b) proposes to delete the requirement that written agreements be approved by the Board. It is replaced with language that specifies that written agreements must be "filed" with the Board. Additional language is proposed to be added to clarify that the written agreements become effective upon submission to the Board. These amendments make the Board's regulations consistent with the requirements of Act 79 of 2021 (Act 79).

Act 79 requires the Board to conduct a full review of 10% of all written agreements submitted. In addition to providing a framework for written agreements subject to review, the legislation required the Board to publish notice of the review process. This notice was published in the February 12, 2022, edition of the *Pennsylvania Bulletin*. Along with other administrative responsibilities and procedures related to Act 79, the notice details the review process for those written agreements, subject to the 10 percent review, and provides for discrepancy notices. It reads:

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

assistant and supervising physician must submit an entirely new written agreement. The new written agreement is effective upon submission and is subject to 10% review. If a response to the discrepancy is received by the Board outside of the 2-week period, a second discrepancy notice will be sent to the parties indicating that the response is outside of the 2-week period and informing the parties that a new written agreement application must be submitted." (Emphasis added).

Since inaction or delayed response to a discrepancy notice can trigger a change of status and require the submittal of a new written agreement by the physician, physician assistant, or their designee, we ask the Board to consider including these key provisions in the final-form regulation or explain why it is unnecessary to do so.

2. Section 18.151. Role of physician assistant. – Clarity.

Subsection (c)

This subsection proposes to delete the prohibition that a physician assistant may not determine the cause of death. The Preamble to the proposed regulation explains that the amendment is intended to update the language to comply with the act of July 7, 2017 (P.L. 296, No. 17) (Act 17). Act 17 amended the Vital Statistics Law of 1953 to authorize physician assistants to medically certify a report of a death or fetal death to the Pennsylvania Department of Health's Bureau of Health Statistics and Registry.

In 2012, similar legislation granting the same authority to certified registered nurse practitioners was implemented with the act of June 22, 2012 (P.L. 644, No. 68) (Act 68). In addition to updating Sections 502 (relating to Death and Fetal Death Registration: Information for Certificates) and 503(relating to Death and Fetal Death Registration: Coroner Referrals) of the Vital Statistics Law, which identifies the list of medical professionals that can supply medical certification of death and make referrals to a coroner, Act 68 also revised Section 507 (relating to Death and Fetal Death Registration: Pronouncement of Death by a Professional Nurse). Specifically, Subsection (d) of Section 507 reads:

"...(d) Except as provided for under sections 502 and 503, this section provides for the pronouncement of death by professional nurses in accordance with the "Uniform Determination of Death Act," but in no way authorizes a nurse to determine the cause of death. The responsibility for determining the cause of death remains with the physician, certified registered nurse practitioner or the coroner as provided under this act." (Emphasis added).

Based on this language in Section 507(d), we are unable to discern if "determine the cause of death" is the same as to medically certify a report of death. On one hand, this section seems to affirm that determining the cause of death is meant to be synonymous with certifying a death. While on the other hand, we cannot ignore whether there is any relevance in the exclusion of physician assistants from the list of medical professionals under Section 507(d). We do not question the statutory authority of physician assistants to medically certify death and sign death certificates, but we take caution not to assume that "determining the cause of death" is the same as

certifying a report of death. We ask the Board to clarify whether "determine" and "certify" are the same or different under the Vital Statistics Law and to modify, if necessary, this section in the final-form regulation.

We also ask the Board to review this subsection to determine whether there is a role for the substitute supervising physician. Specifically, should the substitute supervising physician, if the attending physician or primary supervising physician is not available, be notified before contacting the coroner? Lastly, the Board should review and revise, if necessary, this section to ensure the consistent use of terms. Namely, we question whether "attending physician" and "not available" should be replaced by the proposed defined terms "primary supervising physician" and "unable to supervise," respectively.