RULES AND REGULATIONS

Title 22—EDUCATION

STATE BOARD OF EDUCATION

[22 PA. CODE CH. 14]

General Provisions

The State Board of Education (Board) amends § 14.102 (relating to incorporation of Federal regulation) to read as set forth in Annex A.

Because the Board finds that proposed rulemaking procedures are unnecessary under the circumstances, public notice of the Board's intention to adopt this final-form rulemaking has been omitted as authorized under section 204(3) of the act of July 31, 1968 (P. L. 769, No. 240), known as the Commonwealth Documents Law (CDL) (45 P. S. § 1204(3)). Proposed rulemaking has been omitted as unnecessary because the amendment is mandated under sections 1407(1) and 1412(a) of the Individuals with Disabilities Education Act (IDEA) (Pub. L. No. 108-446), 20 U.S.C.A. §§ 1407 and 1412(a), and 34 CFR 300.15, 300.300 and 300.512 (relating to education; parental consent; and hearing rights), which are among the regulations promulgated by the United States Department of Education (USDOE) on December 1, 2008, implementing the IDEA.

The Board adopted the Federal regulations by reference in its rulemaking published June 28, 2008. Because the USDOE later amended those regulations, it is necessary for the Board to formally adopt by reference the regulations as amended. Failure to conform State regulations to Federal regulations would seriously jeopardize Federal funding of special education programs for IDEA-eligible disabled children. The requirements of Federal law are specific, allowing for no alternative means of compliance. The Department is required to strictly adopt the Federal standards in the amendment. Thus, inasmuch as this rulemaking is necessary to align the Commonwealth's regulations with the new version of Federal regulations, proposed rulemaking is unnecessary.

The new Federal requirements affect three subparagraphs of § 14.102(a)(2) that refer to Federal regulations. Those provisions of § 14.102(a)(2) currently provide as follows:

(a) It is the intent of the Board that children with disabilities be provided with quality special education services and programs. The purposes of this chapter are to serve the following:

(1) To adopt Federal regulations by incorporation by reference to satisfy the statutory requirements under the act (20 U.S.C.A. §§ 1400—1482) . . .

* * * * *

(2) To adopt, except as expressly otherwise provided in this chapter, the requirements of 34 CFR Part 300 (relating to assistance to states for the education of children with disabilities) as published at 71 FR 46540—46845 (August 14, 2006). The following sections are incorporated by reference:

* * * * *

(iii) 34 CFR 300.9—300.15 (relating to consent; core academic subjects; day, business day, school day; educational service agency; elementary school; equipment; and evaluation).

* * * * *

(xxiv) 34 CFR 300.300 and 300.301 (relating to parental consent; and initial evaluations).

* * * * *

(xxx) 34 CFR 300.510—300.516 (relating to resolution process; impartial due process hearing; hearing rights; hearing decisions; finality of decisions, appeal; impartial review; timelines and convenience of hearings and reviews; and civil action).

The regulations as currently published incorporate by reference the Federal regulatory requirements that were published at 71 FR 46540—46845 (August 14, 2006). To fully and formally comply with Federal law and regulation, § 14.102(d)(2) must be amended as follows:

(2) To adopt, except as expressly otherwise provided in this chapter, the requirements of 34 CFR Part 300 (relating to assistance to states for the education of children with disabilities) as published at 71 FR 46540—46845 (August 14, 2006)**, and amended at 73 FR 73006—73029 (December 1, 2008)**. The following sections are incorporated by reference:

* * * * *

Affected Persons

Persons affected by this amendment have been given actual notice of the Board's intention to amend § 14.102 in advance of final-omitted form rulemaking under section 204(2) of the CDL. Specifically, all local educational agencies (LEAs) will receive electronic notice by means of PENN LINK transmission. Organizations representing students with disabilities and their parents will be notified in writing.

Statutory Authority

The Board acts under the authority of sections 1372 and 2603-B of the Public School Code of 1949 (Code) (24 P. S. §§ 13-1372 and 26-2603-B).

Background

Section 14.102 addresses the general provisions of the Commonwealth's special education regulations that adopted by reference certain of the Federal regulations at the time Chapter 14 was amended at 38 Pa.B. 3575 (June 28, 2008). On December 1, 2008, the USDOE amended the Federal regulations effective on December 31, 2008. The changes made in this final-form rulemaking to § 14.102 merely would require compliance with the current Federal regulations.

Purpose of the Amendment

This final-form rulemaking, proposed rulemaking omitted, is necessary to align the Commonwealth's regulations to the December 1, 2008, version of Federal IDEA-implementing regulations. Currently, the Commonwealth's special education regulations adopt by reference the August 14, 2006, version of the Federal mandates. Specifically, the December 1, 2008, amendments to 34 CFR 300 (relating to assistance to states for the education of children with disabilities) modify the prior version to provide as follows:

• A parent has the right unilaterally to withdraw a child with a disability from continued special education and related services, and a public agency may not challenge that parent's decision using Part B dispute resolution procedures. See 34 CFR 300.300.

• If, at any time subsequent to the initial provision of special education and related services, the parent of a child revokes consent in writing for the continued provision of special education and related services, the public agency may not continue to provide special education and related services to that child but must provide prior written notice in accordance with § 300.503 before ceasing the provision of special education and related services. See 34 CFR 300.300(b)(4).

• While a parent may revoke consent for the continued provision of special education and related services, the public agency is not required to amend the child's education records to remove any references to the child's receipt of special education and related services because of the revocation of consent. See 34 CFR 300.9.

• Parties may be accompanied or advised by counsel or by individuals with special knowledge or training with respect to the problems of children with disabilities at a due process hearing; however, State law determines whether or not parties have the right to be represented by non-attorneys during a due process hearing. See 34 CFR 300.512.

Fiscal Impact and Paperwork Requirements

The amendment will have no fiscal impact on the Commonwealth, its political subdivisions or local educational agencies. That is so because the change simply adopts the requirements that were promulgated by the USDOE on December 1, 2008, and were mandatory effective December 31, 2008.

Effective Date

The final-omitted rulemaking is effective upon publication in the *Pennsylvania Bulletin*. However, based upon the USDOE promulgated regulations, these requirements were made effective on December 31, 2008, by force of Federal law.

Sunset Date

In accordance with its policy and practice regarding regulations, the Board will review the effectiveness of this regulation after 4 years. Therefore, no sunset date is necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 3, 2009, a copy of the final-omitted regulation was submitted to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Committees on Education (Committees) for review and comment. A copy of the final-omitted regulation was submitted on the same date to the Attorney General for review and comment under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506).

Under section 5.1(d) of the Regulatory Review Act, the final-omitted regulation was deemed approved by the Committees on July 22, 2009. Under section 5.1(e) of the Regulatory Review Act, on July 23, 2009, IRRC met and approved the final-omitted regulation.

Contact Person

The official responsible for information on this final-form rulemaking is Jim Buckheit, Executive Director, State Board of Education, 333 Market Street, Harrisburg, PA 17126-0333, (717) 787-3787, TDD (717) 787-7367.

Findings

The Board finds that:

(1) Public notice of the intention to amend its regulation as adopted by this order under the procedures specified in sections 201 and 202 of the CDL has been omitted under the authority contained in section 204(3) of the CDL, because the Board has, for good cause, found that the procedures specified in section 201 and 202 of the CDL are, in this circumstances, unnecessary because the requirements of Federal law are specific, allowing for no alternative means of compliance. The Department is required to strictly adopt the Federal standard set forth in these amendments.

(2) The amendment of the regulation of the Board in the manner provided in this order is necessary and appropriate for administration of the *Pennsylvania Code* and the Commonwealth's obligations established by the act.

Order

The Board, acting under authorizing statute, orders that:

(a) The regulations of the Board, 22 Pa. Code Chapter 14, are amended by amending § 14.102 to read as set forth in Annex A, with ellipses referring to the existing text of the regulation.

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

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

(d) This order is effective upon publication in the *Pennsylvania Bulletin*.

JIM BUCKHEIT,
Executive Director

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 4752 (August 8, 2009).)

Fiscal Note: 6-317 (final omitted). No fiscal impact; (8) recommends adoption.

Annex A

TITLE 22. EDUCATION

PART I. STATE BOARD OF EDUCATION

Subpart A. MISCELLANEOUS PROVISIONS

CHAPTER 14. SPECIAL EDUCATION SERVICES AND PROGRAMS

GENERAL PROVISIONS

§ 14.102. Purposes.

(a) It is the intent of the Board that children with disabilities be provided with quality special education services and programs. The purposes of this chapter are to serve the following:

* * * * *

(2) To adopt, except as expressly otherwise provided in this chapter, the requirements of 34 CFR Part 300 (relating to assistance to states for the education of children with disabilities) as published at 71 FR 46540—46845 (August 14, 2006), and amended at 73 FR 73006—73029 (December 1, 2008). The following sections are incorporated by reference:

* * * * *

[Pa.B. Doc. No. 09-1415. Filed for public inspection August 7, 2009, 9:00 a.m.]

DEPARTMENT OF EDUCATION
[22 PA. CODE CH. 711]
General Provisions and Supervision

The Department of Education (Department) amends § 711.3 (relating to incorporation of Federal regulation) to read as set forth in Annex A.

Because the Department finds that proposed rulemaking procedures are unnecessary under the circumstances, public notice of the Department's intention to adopt this final-form rulemaking has been omitted as authorized under section 204(3) of the act of July 31, 1968 (P. L. 769, No. 240), known as the Commonwealth Documents Law (CDL) (45 P. S. § 1204(3)). Proposed rulemaking has been omitted as unnecessary because the amendment mandated under sections 1407(1) and 1412(a) of the Individuals With Disabilities Education Act (IDEA) (Pub. L. No.108-446), 20 U.S.C.A. §§ 1407 and 1412(a), and 34 CFR 300.15, 300.300 and 300.512 (relating to evaluation; parental consent; and hearing rights), which are among the regulations promulgated by the United States Department of Education (USDOE) on December 1, 2008, implementing the IDEA.

The Department adopted the Federal regulations by reference in its rulemaking published at 38 Pa.B. 3593 (June 28, 2008). Because the USDOE later amended those regulations, it is necessary for the Department to formally adopt by reference the regulations as amended. Failure to conform State regulations to Federal regulations would seriously jeopardize Federal funding of special education programs for IDEA-eligible disabled children. The requirements of Federal law are specific, allowing for no alternative means of compliance. The Department is required to strictly adopt the Federal standards in this amendment. Thus, inasmuch as this rulemaking is necessary to align the Commonwealth's regulations with the new version of Federal regulations, proposed rulemaking is unnecessary.

The new Federal requirements affect three paragraphs of § 711.3(b) that refer to Federal regulations. Those provisions of § 711.3 currently provide as follows:

> **(a)** Charter schools and cyber charter schools assume the duty to ensure that a FAPE is available to a child with a disability in compliance with IDEA and its implementing regulations in 34 CFR Part 300 (relating to assistance to states for the education of children with disabilities) and section 504 and its implementing regulations in 34 CFR Part 104 (relating to nondiscrimination on the basis of handicap in programs and activities receiving federal financial assistance).
>
> **(b)** The requirements of 34 CFR Part 300 as published at 71 FR 46450—46845 (August 14, 2006) are incorporated by reference, as follows:
>
> * * * * *
>
> (2) 34 CFR 300.9—300.15 (relating to consent; core academic subjects; day, business day, school day; educational service agency; elementary school; equipment; and evaluation).
>
> * * * * *
>
> (21) 34 CFR 300.300 and 300.301 (relating to parental consent; and initial evaluations).
>
> * * * * *
>
> (27) 34 CFR 300.510—300.516 (relating to resolution process; impartial due process hearing; hearing rights; hearing decisions; finality of decisions, appeal; impartial review; timelines and convenience of hearings and reviews; and civil action).

The regulations as currently published incorporate by reference the Federal regulatory requirements that were published at 71 FR 46540—46845 (August 14, 2006). To fully and formally comply with Federal law and regulation, § 711.3(b) must be amended as follows:

> **(b)** The requirements of 34 CFR Part 300 as published at **71 FR 46540—46845** (August 14, 2006), **amended at 73 FR 73006—73029 (December 1, 2008)** are incorporated by reference, as follows:
>
> * * * * *

Affected Persons

Persons affected by this amendment have been given actual notice of the Department's intention to amend § 711.3(b) (relating to incorportation of Federal regulations) in advance of final-omitted form rulemaking under section 204(2) of the CDL. Specifically, all local educational agencies (LEAs) will receive electronic notice by means of PENN LINK transmission. Organizations representing students with disabilities and their parents will be notified in writing.

Statutory Authority

The Department acts under the authority of sections 1732-A(c)(2) and 1749-A(b)(8) of the Public School Code of 1949 (Code) (24 P. S. §§ 17-1732-A(c)(2) and 17-1749-A(b)(8)).

Background

Section 711.3 addresses the general provisions of the Commonwealth's special education regulations that adopted by reference certain of the Federal regulations at the time Chapter 711 was amended on June 27, 2008. On December 1, 2008, the USDOE amended the Federal regulations effective on December 31, 2008. The changes made in this final-form rulemaking to § 711.3(b) merely would require compliance with the current Federal regulations.

Purpose of the Amendment

This final-form rulemaking, proposed rulemaking omitted, is necessary to align the Commonwealth's regulation to the December 1, 2008, version of Federal IDEA-implementing regulations. Currently, the Commonwealth's special education regulations adopt by reference the August 14, 2006, version of the Federal mandates. Specifically, the December 1, 2008, amendments to 34 CFR 300 (relating to assistance to states for the education of children with disabilities) modify the prior version to provide as follows:

- A parent has the right unilaterally to withdraw a child with a disability from continued special education and related services, and a public agency may not challenge that parent's decision using Part B dispute resolution procedures. See 34 CFR 300.300.
- If, at any time subsequent to the initial provision of special education and related services, the parent of a child revokes consent in writing for the continued provision of special education and related services, the public agency may not continue to provide special education and related services to that child but must provide prior written notice in accordance with § 300.503 before ceasing the provision of special education and related services. See 34 CFR 300.300(b)(4).

• While a parent may revoke consent for the continued provision of special education and related services, the public agency is not required to amend the child's education records to remove any references to the child's receipt of special education and related services because of the revocation of consent. See 34 CFR 300.9.

• Parties may be accompanied or advised by counsel or by individuals with special knowledge or training with respect to the problems of children with disabilities at a due process hearing; however, State law determines whether or not parties have the right to be represented by nonattorneys during a due process hearing. See 34 CFR 300.512.

Fiscal Impact and Paperwork Requirements

The amendment will have no fiscal impact on the Commonwealth, its political subdivisions or local educational agencies. That is so because the change simply adopts the requirements that were promulgated by the USDOE on December 1, 2008, and were mandatory effective December 31, 2008.

Effective Date

The final-omitted rulemaking is effective upon publication in the *Pennsylvania Bulletin*. However, based upon the USDOE promulgated regulations, these requirements were made effective on December 31, 2008, by force of Federal law.

Sunset Date

In accordance with its policy and practice regarding regulations, the Department will review the effectiveness of this regulation after 4 years. Therefore, no sunset date is necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 3, 2009, a copy of the final-omitted regulation was submitted to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Committees on Education (Committees) for review and comment. A copy of the final-omitted regulation was submitted on the same date to the Attorney General for review and comment under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506).

Under section 5.1(d) of the Regulatory Review Act, the final-omitted regulation was deemed approved by the Committees on July 22, 2009. Under section 5.1(e) of the Regulatory Review Act, on July 23, 2009, IRRC met and approved the final-omitted regulation.

Contact Person

The official responsible for information on this final-form rulemaking is John Tommasini, Director, Bureau of Special Education, 333 Market Street, Harrisburg, PA 17126-0333, (717) 783-6134, TDD (717) 783-6139.

Findings

The Department finds that:

(1) Public notice of the intention to amend its regulation as adopted by this order under the procedures specified in sections 201 and 202 of the CDL has been omitted under the authority contained in section 204(3) of the CDL, because the Department has, for good cause, found that the procedures specified in sections 201 and 202 of the CDL are, in this circumstance, unnecessary because the requirements of Federal law are specific, allowing for no alternative means of compliance. The Department is required to strictly adopt the Federal standard set forth in the amendment.

(2) The amendment of the regulation of the Department in the manner provided in this order is necessary and appropriate for administration of the *Pennsylvania Code* and the Commonwealth's obligations established by the IDEA.

Order

The Department, acting under authorizing statute, orders that:

(a) The regulations of the Department, 22 Pa. Code Chapter 711, are amended by amending § 711.3 to read as set forth in Annex A, with ellipses referring to the existing text of the regulation.

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

(c) The Secretary of Education shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order is effective upon publication in the *Pennsylvania Bulletin*.

GERALD L. ZAHORCHAK, D. Ed.,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 4750 (August 8, 2009).)

Fiscal Note: 6-320 (final omitted). No fiscal impact; (8) recommends adoption.

Annex A

TITLE 22. EDUCATION

PART XX. DEPARTMENT OF EDUCATION

CHAPTER 711. CHARTER SCHOOL AND CYBER CHARTER SCHOOL SERVICES AND PROGRAMS FOR CHILDREN WITH DISABILITIES

GENERAL PROVISIONS AND SUPERVISION

§ 711.3. Incorporation of Federal regulations.

* * * * *

(b) The requirements of 34 CFR Part 300 as published at 71 FR 46540—46845 (August 14, 2006), amended at 73 FR 73006—73029 (December 1, 2008) are incorporated by reference, as follows:

* * * * *

[Pa.B. Doc. No. 09-1416. Filed for public inspection August 7, 2009, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Physician Assistant Prescriptive Authority

The State Board of Osteopathic Medicine (Board) is amending its regulations by amending §§ 25.142 and 25.162 (relating to definitions; and criteria for registration as supervising physician) and adding §§ 25.177 and 25.178 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices; and medical records), to read as set forth in Annex A.

Description and Need for the Rulemaking

Section 10(p) of the Osteopathic Medical Practice Act (act) (63 P. S. § 271.10(p)) authorizes the Board to promulgate jointly with the State Board of Pharmacy regulations "to permit a physician assistant to prescribe and dispense drugs at the direction of a licensed physician." Because the Board has not yet promulgated regulations to implement this statutory provision, physician assistants practicing under the direction of a physician licensed by the Board do not yet have prescriptive privileges. This situation has caused a great deal of confusion in health care settings, because a physician assistant licensed by the State Board of Medicine (Medical Board) is permitted to prescribe and dispense drugs under the direction of a physician licensed by the Medical Board in accordance with the Medical Board's regulation in § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices). This rulemaking is intended to resolve this confusion by permitting physician assistants who are practicing under the direction of an osteopathic physician to prescribe drugs in a manner similar to the practice of physician assistants under the direction of physicians licensed by the Medical Board.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 37 Pa.B. 5598 (October 20, 2007) with a 30-day public comment period. The Board received written comments from the following members of the public: the Pennsylvania Rural Health Association, the Pennsylvania Society of Physician Assistants, the Pennsylvania Osteopathic Medical Association (POMA) and the Pennsylvania Medical Society. The Board also received written public comments from a large number of physician assistant students, certified physician assistants (practicing under the supervision of both medical doctors and osteopathic physicians), medical doctors and osteopathic physicians, instructors in physician assistant education programs, osteopathic medical students, and pharmacists, all of whom generally urged the Board to finally promulgate regulations authorizing a physician assistant practicing under the supervision of an osteopathic physician to prescribe drugs. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P. S. §§ 745.1—745.12). The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

Many commentators strongly encouraged the Board to align its physician assistant prescription authority regulations with those of the Medical Board. Because ensuring the provisions mandate the same requirements for both areas of medical practice would alleviate any confusion and provide consistency in the various practice settings, the HPLC also commented that the Board's regulations should be consistent with those of the Medical Board. IRRC agreed and urged the Board to amend proposed §§ 25.177(a)(3), (c), (d)(1), (d)(4) and 25.178 to match corresponding provisions of the Medical Board's physician assistant prescriptive authority regulations. The Board has attempted to be as consistent as possible with the Medical Board's requirements for physician assistant prescribing and dispensing of drugs.

The HPLC noted that proposed § 25.177(a)(3) required a physician assistant to notify the supervising physician "as soon as possible, but in no event longer than 24 hours from the issuance of" a prescription for a Schedule II controlled substance. The HPLC questioned whether the means of notifying the supervising physician is left to the discretion of the physician or physician assistant. The Board has not set forth in its regulation the means of notification, but will leave that to the physician assistant and the supervising physician to determine as part of their practice, whether or not included in the written agreement. The Medical Board also does not specify the means of notification in its requirement in § 18.158(a)(3).

The HPLC also noted that proposed § 25.177(a)(3) would permit a physician assistant to write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal of a prior prescription and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to writing the renewal. The HPLC contrasted this provision with the Medical Board regulation in § 18.158(a)(3) (physician assistant may write prescription for Schedule II controlled substance for up to a 30-day supply if approved by supervising physician for ongoing therapy). POMA opposed permitting a physician assistant to prescribe Schedule II narcotics without the involvement of the supervising physician. In response to these comments, the Board initially revised the rulemaking to permit a physician assistant to write a prescription for a Schedule II controlled substance for up to a 30-day supply of ongoing therapy if the patient was examined within the first 30 days by the supervising physician. However, upon disapproval by IRRC as discussed in this preamble, the Board again revised this provision to read as follows (with emphasis to identify the revised provisions):

> (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. **The physician assistant shall have no authority to prescribe a Schedule II controlled substance after the initial therapy of up to a 72-hour dose, until the patient has been examined by the supervising physician and the supervising physician has reviewed and approved the prescription of a Schedule II controlled substance by the physician assistant for up to a 30-day supply. Thereafter, (i) if the supervising physician determines and documents that the patient is chronically ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply of the Schedule II con-**

trolled substance, only if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 30 days; and (ii) if the supervising physician determines and documents that the patient is terminally ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 120 days. The prescription must clearly state on its face that it is for initial or ongoing therapy.

As stated in the Board's report under section 7(c) of the Regulatory Review Act (71 P. S. § 745.7(c)):

The Board adopted this revision of § 25.177(a)(3) to clarify the words of the regulation and implement the intent of a majority of the Board members when it took formal action to approve the rulemaking.

The Board focused on the clarity and scope of the words "ongoing therapy" in the sentence: "A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30 day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician." Board members were concerned that this language is unduly vague, could be subject to multiple interpretations and did not adequately express the intent of the Board that there be ongoing physician involvement in the prescription of Schedule II controlled substances by physician assistants with respect to chronic conditions. The added language was adopted to make crystal clear the intent and requirements of the rulemaking.

It is important to note that this subsection deals with **only** the prescription of Schedule II controlled substances. These are defined in Pennsylvania law as substances with "**a high potential for abuse**, currently accepted medical use in the United States, or currently accepted medical use with severe restrictions, **and abuse may lead to severe psychic or physical dependence**." 35 P. S. § 780-104(2) (emphasis added). The Board strongly believes that, for the protection of the public, ongoing physician supervision and involvement with patient care is essential for the long-term prescription of Schedule II controlled substances. The Board believes that this revision clarifies the wording of the rulemaking. The requirement for ongoing involvement of physicians is particularly important with respect to the prescription of substances where, in the words of the statute, "abuse may lead to severe psychic or physical dependence." The language adopted by the Board will help to make certain that the public is protected when physician assistants prescribe Schedule II controlled substances.

The HPLC questioned whether the term "professional samples" as used in proposed § 25.177(a)(5) (physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients) would include scheduled drugs and, if so, whether there would be appropriate oversight. These professional samples do not include scheduled drugs. Believing that doing so should be the responsibility of the physician, POMA also opposed permitting a physician assistant to request, receive, sign for or distribute professional samples. The supervising physician, who is responsible to supervise the physician assistant, through the written agreement may set the parameters of the physician assistant's prescribing and dispensing of drugs, including involvement with professional samples. The Board has not revised the rulemaking in response to this comment. The Medical Board's requirement in § 18.158(a)(5) is identical.

The HPLC questioned when it would be appropriate for the physician assistant's Drug Enforcement Administration (DEA) registration number to appear on the prescription as required under proposed § 25.177(b)(2) (signature of physician assistant must be followed by initials "PA-C" or similar designation to identify signer as physician assistant; when appropriate, physician assistant's DEA registration number must appear on prescription). It is appropriate to include the DEA registration number of a prescriber who prescribes a Schedule II drug. The Medical Board's requirement in § 18.158(b)(2) is identical.

The HPLC asked for clarification as to whether a pharmacy would be responsible for filling a prescription outside the physician assistant's authority and therefore an inappropriate prescription for which proposed § 25.177(c) would require the physician assistant or supervising physician to notify the pharmacy to discontinue. A pharmacist is always free to question a prescription, including contacting the physician assistant or supervising physician for additional information. Upon receipt of information that the physician assistant is not permitted to prescribe the specified drug or is otherwise prescribing outside the scope of the written agreement or Board requirements, the pharmacist may refuse to fill the prescription. The Board has also corrected the typographical error of the term "supervision physician" in § 25.177(c) to "supervising physician" as noted by the HPLC.

Finally, the HPLC questioned why proposed § 25.177(d)(4) required the supervising physician to countersign the patient record at least weekly and proposed § 25.178 required the supervising physician to review the medical records at least weekly, although the Medical Board only requires it to be done within 10 days. The Board believes that this shorter period of time of a round single week is easier to remember and simpler to apply. Additionally, within the definition of "supervision" in § 25.142, the Board previously set forth an appropriate degree of supervision to include "periodic and regular—at least weekly—review by the supervising physician of the patient records upon which entries are made by the physician assistant." And as discussed in the preamble, new § 25.162(a)(4)(vi) also requires the supervising physician to countersign the patient record within 10 days.

IRRC also noted that the Board had not defined the term "written agreement," though the Medical Board has defined it in § 18.122 (written agreement is defined as the agreement between the physician assistant and supervising physician, which satisfies the requirements of § 18.142 (relating to written agreements)). In § 25.142 (relating to definitions), the Board has now defined "written agreement" as "the agreement between the physician assistant and supervising physician, which satisfies the requirements of § 25.162(a)(4)." Because the proposed regulations did not include any provision equivalent to § 18.142, the Board has also revised § 25.162(a)(4) revised to include requirements substantially equivalent to those of § 18.142, substituting of course the term "osteopathic physician" for "medical doctor." In addition, § 25.162(a)(4)(ii) requires that the description of the manner in which the physician assistant will assist each

named physician be in detail and that the functions to be delegated to the physician assistant include the procedures enumerated in § 25.171(a) (relating generally to physician assistant utilization). Section 25.162(a)(4)(iii) requires that the written agreement must describe detailed instructions for the use of the physician assistant in the performance of delegated tasks. Section 25.162(a)(4)(iv) requires that the method and frequency, in addition to the time, place and manner, of supervision and direction each named physician will provide must be described in the written agreement. And, § 25.162(a)(4)(viii) requires that the written agreement provide the name, address and telephone number of at least two physicians who can substitute for the supervising physician whenever unavailable.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions and will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Effective date

The final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

The final-form rulemaking is authorized under section 10(h) and (p) of the act.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 10, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 5598, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

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

The Board delivered the final-form rulemaking to IRRC and the Chairpersons of the HPLC and the SCP/PLC on February 26, 2009. Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on March 10, 2009, the HPLC approved the final-form rulemaking. On April 1, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on April 2, 2009, and disapproved the final-form rulemaking. As stated in IRRC's order of disapproval received by the Board on April 13, 2009, IRRC disapproved the final-form regulation at the request of the Board, acting through its Chairperson, to permit the Board to revise § 25.177(a)(3).

Under section 7(c) of the Regulatory Review Act (71 P. S. § 745.7(c)), on May 22, 2009, the Board delivered a revised final-form rulemaking to IRRC and the chairpersons of the HPLC and the SCP/PLC, including the report required by that section. Under section 7(c.1) of the Regulatory Review Act, IRRC met on June 11, 2009, and approved the final-form rulemaking. Under section 7(d) of the Regulatory Review Act (71 P. S. § 745.7(d)), on June 26, 2009, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Regulatory Unit Counsel, Department of State, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-4858, st-osteo@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1202 and 1202) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

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

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 37 Pa.B. 5598.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the act.

Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 25, are amended, by amending §§ 25.142 and 25.162 and by adding §§ 25.177 and 25.178 to read as set forth in Annex A.

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

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

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

JOSEPH C. GALLAGHER, Jr., D. O.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 3297 (June 27, 2009).)

Fiscal Note: Fiscal Note 16A-5318 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter C. PHYSICIAN ASSISTANT PROVISIONS

GENERAL PROVISIONS

§ 25.142. Definitions.

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

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

Direct supervision—The physical presence of the supervising physician on the premises so that the supervising physician is immediately available to the physician assistant when needed. Where emergency rooms are concerned, direct supervision requires the presence of the supervising physician in the emergency room suite.

NCCPA—The National Commission on the Certification of Physician Assistants.

Protocol—Written treatment instructions prepared by the supervising osteopathic physician for use by the physician assistant, containing a detailed description of the manner in which the physician assistant will assist the physician in his practice, a list of functions to be delegated to the physician assistant including the procedures enumerated in § 25.171(a) (relating to generally) and other specified delegated tasks, detailed instructions for the use of the physician assistant in the performance of delegated tasks, the method and frequency of supervision and the geographic location where the physician assistant will serve.

Registration—The approval by the Board of an osteopathic physician, licensed to practice osteopathic medicine and surgery without restriction, to supervise and utilize a specified physician assistant.

Satellite operations—An office or clinic separate and apart from the office of the supervising physician established by the physician and manned exclusively by a physician assistant.

Supervising physician—A physician licensed to practice osteopathic medicine and surgery in this Commonwealth who registers with the Board and who accepts the responsibility for the supervision of services rendered by physician assistants.

Supervision—The opportunity or ability of the physician, or in his absence a substitute supervising physician, to provide or exercise control and direction over the services of physician assistants. Constant physical presence of the supervising physician on the premises is not required so long as the supervising physician and the physician assistant are or can easily be in contact with each other by radio, telephone or telecommunication. Supervision requires the availability of the supervising physician to the physician assistant. An appropriate degree of supervision includes:

(i) Active and continuing overview of the physician assistant's activities to determine that the physician's directions are being implemented.

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

(iii) Personal and regular—at least weekly—review by the supervising physician of the patient records upon which entries are made by the physician assistant.

(iv) Periodic—at least monthly—education and review sessions held by the supervising physician for the physician assistant under his supervision for discussion of specific conditions, protocols, procedures and specific patients.

Written agreement—The agreement between the physician assistant and supervising physician, which satisfies the requirements of § 25.162(a)(4) (relating to criteria for registration as supervising physician).

CERTIFICATION OF PHYSICIAN ASSISTANTS AND REGISTRATION OF SUPERVISING PHYSICIANS

§ 25.162. Criteria for registration as supervising physician.

(a) The Board will approve for registration as a supervising physician, an applicant who:

(1) Possesses a current unrestricted license to practice osteopathic medicine and surgery in this Commonwealth.

(2) Has submitted a completed application together with the required fee. The application shall require detailed information regarding the physician's professional background and specialties, medical education, internship, residency, continuing education, membership in American Boards of medical specialty, hospital or staff privileges and other information the Board may require.

(3) Has submitted a statement that he will direct and exercise supervision over the physician assistant in accordance with the provisions of this subchapter and that he recognizes that he retains full professional and legal responsibility for the performance of the physician assistant and the care and treatment of his patients.

(4) Has submitted a written agreement that satisfies the following requirements. The agreement must:

(i) Identify and be signed by the physician assistant and each physician the physician assistant will be assisting who will be acting as a supervising physician. At least one physician shall be an osteopathic physician.

(ii) Describe in detail the manner in which the physician assistant will be assisting each named physician. The description must list functions to be delegated to the physician assistant including the procedures enumerated in § 25.171(a) (relating to generally) and other delegated tasks.

(iii) Describe detailed instructions for the use of the physician assistant in the performance of delegated tasks.

(iv) Describe the time, place and manner, method and frequency of supervision and direction each named physician will provide the physician assistant, including the frequency of personal contact with the physician assistant.

(v) Designate one of the named physicians who shall be an osteopathic physician as the primary supervising physician.

(vi) Require that the supervising physician shall countersign the patient record completed by the physician assistant within a reasonable amount of time. This time period may not exceed 10 days.

(vii) Identify the locations and practice settings where the physician assistant will serve.

(viii) Provide the name, address and telephone number of at least two physicians who can substitute for the applicant when he is either absent or otherwise unavailable.

(b) An application for registration as a supervising physician shall be submitted for each physician assistant the physician intends to utilize and shall be accompanied by the fee required by § 25.231 (relating to schedule of fees). A physician may not be registered to supervise more than two physician assistants at any time. To expand the protocol for a physician assistant for whom the physician is already registered to supervise and utilize, the physician shall first secure approval from the Board. This can be accomplished by the physician submitting to the Board, in writing, a request for modification of the

physician assistant utilization which enumerates the expanded manner in which the physician assistant will function and which contains additional instructions for the use of the physician assistant and other information pertinent to the intended departure from the former manner of practice, method and frequency of supervision, or geographic location. The fee required is that specified for initial registration in § 25.231. The Board will notify the physician, in writing, as to its approval or rejection of the requested modification. Departure from the original protocol is not permitted until the Board approves the request for modification.

(c) After the physician submits an initial application for registration as a supervising physician, which conforms with the requirements of subsection (a), for a second application and ensuing applications for registration, the physician shall only submit an abbreviated application which will be provided by the Board upon request. Only additions and deletions to the information provided in the initial application will be required.

(d) If the applicant supervising physician plans on utilizing physician assistants in satellite operations, he shall provide the Board with supplemental information as set forth in § 25.175 (relating to physician assistants and satellite operations) for specific approval.

(e) An application for registration as a supervising physician may be obtained by writing to the Harrisburg office of the Board.

PHYSICIAN ASSISTANT UTILIZATION

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

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

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

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

(3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. The physician assistant shall have no authority to prescribe a Schedule II controlled substance after the initial therapy of up to a 72-hour dose, until the patient has been examined by the supervising physician and the supervising physician has reviewed and approved the prescription of a Schedule II controlled substance by the physician assistant for up to a 30-day supply.

(i) If the supervising physician determines and documents that the patient is chronically ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply of the Schedule II controlled substance, only if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 30 days.

(ii) If the supervising physician determines and documents that the patient is terminally ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 120 days.

(iii) The prescription must clearly state on its face that it is for initial or ongoing therapy.

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

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

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

(b) *Prescription blanks.* The requirements for prescription blanks are as follows:

(1) Prescription blanks must bear the license number of the physician assistant and the name of the physician assistant in printed format at the heading of the blank. The supervising physician's name and license number must also be printed or preprinted on the prescription.

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

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

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

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

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

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

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

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

(4) The supervising physician shall countersign the patient record at least weekly in accordance with § 25.178 (relating to medical records).

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

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

§ 25.178. Medical records.

The supervising physician shall timely review, at least weekly, the medical records prepared by the physician assistant to ensure that the requirements of § 25.213 (relating to medical records) have been satisfied.

[Pa.B. Doc. No. 09-1417. Filed for public inspection August 7, 2009, 9:00 a.m.]