RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE [49 PA. CODE CHS. 16 AND 18] Physician Assistants

The State Board of Medicine (Board) amends §§ 16.11 and 16.13 (relating to licenses, certificates, and registrations; and licensure, certification, examination and registration fees) and §§ 18.121, 18.122, 18.131, 18.141—18.145, 18.151—18.159, 18.161, 18.162, 18.171, 18.172 and 18.181 regarding physician assistants and their supervising physicians to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Section 8 of the Medical Practice Act of 1985 (act) (63 P. S. § 422.8) authorizes the Board to promulgate standards for licensing of physician assistants consistent with the requirements of sections 13 and 36 of the act (63 P. S. §§ 422.13 and 422.36). Section 13 of the act authorizes the Board to promulgate regulations which define the services and circumstances under which a physician assistant may perform a medical service.

C. Background and Purpose

The Board has determined that its regulations regarding the services and circumstances under which a physician assistant may perform a medical service, which define the supervision and personal direction required by the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth, are unduly restrictive. Since the physician assistant regulations were last amended in 1993, experience in the application of the regulations has demonstrated the need for amendments that reflect the current state-of-the-art of medical practice as can also be observed in the American Medical Association (AMA) guidelines for physician assistants. The existing regulations prevented the effective use of physician assistants to the full extent of their training. Over 1,000 medical doctors, physician assistants and physician organizations wrote to support the proposed rulemaking, noting that the previous regulations were in many ways overly and unnecessarily restrictive.

D. Summary of Comments and Responses to Proposed Rulemaking

Proposed rulemaking was published at 35 Pa.B. 6127 (November 5, 2005). The Board entertained public comment for a period of 30 days during which time the Board received comments from well over 1,000 medical doctors, physician assistants, health care facilities, medical practices, the Philadelphia College of Osteopathic Medicine, professional societies and physician assistant training programs. These individuals and entities were overwhelmingly supportive of the proposed rulemaking. The Pennsylvania Medical Society and the Pennsylvania Society of Physician Assistants were not only involved in the

proposed rulemaking, they were positively disposed to the amendments and urged the rulemaking's expeditious completion.

Specific comments were made by the Pennsylvania Rural Health Association (PRHA), the Pennsylvania Association of Nurse Anesthetists, the Pennsylvania Association for the Treatment of Opioid Dependence, the Pennsylvania State Coroner's Association, The Hospital and Health Association of Pennsylvania (HAP) and Highmark.

Following the close of the public comment period, the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. The following is a summary of the comments and the Board's response.

The Pennsylvania Association of Nurse Anesthetists expressed concern that § 18.145 (relating to biennial registration requirements; renewal of physician assistant license) could be interpreted to allow delegation of authority to physician assistants to administer general anesthetic agents. The Board believes that the Pennsylvania Association of Nurse Anesthetists is actually concerned about the amendment to § 18.151(a) (relating to role of physician assistant), which includes language that permits physician assistants to administer drugs. The physician assistant training program and recertification each 6 years by the National Commission on the Certification of Physician Assistant ensures that physician assistants are constantly kept up to date with the state of technology on general anesthesia and conscious sedation. In addition, oversight by the supervising physician acts as a control on, and verifies the ability of, the physician assistant to competently perform appropriately delegated anesthesia services. Further, administration of general anesthetic agents is generally performed in hospital settings and is subject to additional oversight in that setting.

The Pennsylvania Coroner's Association recommended that language in the amendment to § 18.151(c) be clarified to ensure that the supervising physician or the county coroner, in the event the supervising physician is not available, certify the cause and manner of death. The Board agrees with this recommendation and has included clarifying language.

The PRHA and HAP both commented on § 18.153(b) (relating to executing and relaying medical regimens) in diametrically opposed directions. The PRHA suggested that the amendment which increased the time for reporting of changes to medical regimens from 12 hours to 36 hours was insufficient and too restrictive. It was suggested that 72 hours was a more reasonable time frame. HAP suggested that 24 hours was more than sufficient to communicate the execution or relaying of a medical regimen. In light of numerous favorable comments, the Board has decided not to alter the amendment.

In § 18.155(b)(4) (relating to satellite locations), the PRHA commented that the time frame requirement for physicians to visit satellite facilities ought to be increased from "at least weekly" to every 2 weeks or 10 working days. The PRHA advised that the reason for establishment of satellite facilities would be compromised if weekly visits are required. The Board agrees with the PRHA's recommendation and has reduced the requirement for physician visits to 10 days.

The PRHA requested the deletion of the phrase "originally prescribed by the supervising physician" from § 18.158(a)(3) (related to prescribing and dispensing drugs, pharmaceutical aids and devices), as this requirement would be overly restrictive in rural clinics. IRRC also requested clarification from the Board on the necessity for this language. The Board agrees with the PRHA and has deleted this phrase in this final-form rulemaking.

The Pennsylvania Association for the Treatment of Opioid Dependence expressed concern that § 18.158 would give too much latitude to physician assistants in prescribing methadone and that the "typical PA" would not be in a position to properly prescribe using their own judgment. The Board acknowledges that although methadone is a Schedule II drug with special societal concerns as it relates to addicts, physician assistants who may prescribe this drug are not only specially trained to recognize the signs of addiction, they also work with supervising physicians who are also specially trained in addictions and choose those categories of drugs that physician assistants are permitted to prescribe or dispense.

HAP was generally supportive of the proposed rulemaking. The primary areas of concern for HAP were § 18.142 (relating to written agreements) and § 18.153. Regarding § 18.142, HAP indicated that the written agreement would have limited applicability in the hospital setting, and that it would not be the authoritative document that would dictate physician assistant practice in a licensed acute or specialty hospital. HAP commented that a hospital could decide to limit the practice of a physician assistant in that setting to be more restrictive than in the written agreement. The Board is fully cognizant of how physician assistants operate within health care facilities and notes that their functioning in these environments will not change under the final-form rulemaking. However, to clarify to its licensees that health care facilities may restrict the practice of physician assistants, the Board has added language to that effect in § 18.161 (relating to physician assistant employed by medical care facilities).

The concerns of HAP regarding § 18.153 centered on the issuing of written and oral orders given by physician assistants in the setting of health care facilities. HAP recommended that specific language be drafted to address the issuing of orders by physician assistants within health care facilities. The Board agrees with HAP's recommendation and has included language in § 18.153(c) which addresses HAP's concerns. The remainder of comments by HAP generally address credentialing and licensure matters and not how physician assistants practice in health care facilities or a change in that practice. The Board has decided that further revision to the amendment is not warranted at this time. The Board will continue to monitor the role and utilization of physician assistants as is already established in § 18.156 (relating to monitoring and review of physician assistant utilization).

Highmark was generally supportive of the proposed rulemaking and noted that it reflects the current standards for medical practice and allows for the effective use of physician assistants to the full extent of their training. Highmark specifically commented on § 18.158, requesting that the Board retain language on prohibiting prescribing of Schedule II drugs, prohibiting off-label prescribing and preventing the prescribing and dispensing of drugs until 90 days have elapsed after Food and Drug Administration (FDA) approval. Highmark also suggested that the Board

specify which medications could be ordered by a physician assistant to be refilled annually. As more fully described as follows, this final-form rulemaking brings into line how the medical doctor community utilizes physician assistants. The physician assistant is still subject to the regulations of the Board and the Department of Health regarding dispensing standards, prescribing and labeling. In specialties that deal with chronic pain management and specialties such as oncology, surgery, anesthesiology or in the family practice setting, physician assistants are an integral part of patient care. Managing the patients' pain in these settings often requires the ability to write prescriptions for Schedule II narcotics on both a shortterm and long-term basis. Also, there are many physician assistants that work in settings such as emergency rooms, walk-in clinics and industrial clinics. The inability to write a prescription for a Schedule II narcotic impedes the care of the patient in these settings.

Highmark commented that a requirement be added to § 18.142 requiring specific protocols be laid out for communication between physicians and physician assistants when a patient's condition changes suddenly. The Board sees this as contrary to the purpose of this final-form rulemaking, which provides for the supervising physician to develop protocols based upon the specific nature and setting of the physician's practice. Highmark recommended that language be added to § 18.144 (relating to responsibility of primary supervising physician) that the supervising physician assess the physician assistant's knowledge, abilities and skills on an ongoing basis. Highmark acknowledged that supervising physicians have the ultimate responsibility for the physician assistant's work. Experience has shown that when physicians work with physician assistants or other practitioners on an ongoing basis, there is naturally an ongoing assessment of that individual's skill, abilities and knowledge. The Board notes that physician assistants must maintain National certification which requires, among other things, periodic reexamination.

The HPLC directed that the Board consider the comments made by other commentators. The Board has done so. The HPLC requested that Board obtain comments and recommendations from the State Board of Pharmacy (Pharmacy Board) on physician assistants prescribing or dispensing pharmaceuticals. The Board requested comments from the Pharmacy Board. The Pharmacy Board was generally supportive of the amendments. The Pharmacy Board's main concerns were that using a negative formulary would place a delay on dispensing of medications to a patient while waiting for receipt of a copy of the written agreement from the physician assistant in confirming the physician assistant's prescriptive authority. The Pharmacy Board also commented that some pharmacists report resistance from physician assistants in providing a copy of the written agreement. The Board takes note of this concern. However, the Board is cognizant of the fact that a positive formulary would also have required the pharmacist to obtain a copy of the written agreement. Therefore, delay in dispensing of prescribed medications to patients would not change with this final-form rulemaking. The Pharmacy Board encouraged the Board to remind physician assistants of the requirement to provide a copy of the written agreement when requested, as well as reminding physician assistants to ensure that the supervising physician's name and license number appear on the prescription blank. The Pharmacy Board expressed concern that prescriptions for Schedule II controlled substances might not conform to time limitations of the regulations. The Federal Drug Enforcement

Administration (DEA) makes it incumbent upon the pharmacist who fills the prescription to ensure that the physician assistant is prescribing within the parameters established by the state in which that individual practices. The Board has clarified the language in § 18.158(a)(3) and requires physician assistants to state on the prescription blank when the prescription is for initial therapy (for up to 72 hours) and ongoing therapy (up to a 30-day supply) if it was approved by the supervising physician for ongoing therapy. The Board places the onus of complying with these regulations on the physician assistant and the supervising physician, as the physician assistant must notify the supervising physician within 24 hours of the initial therapy prescription. The Board intends to place an article in its next newsletter reminding physician assistants and supervising physicians of their obligation to comply with requests for production of their written agreement upon implementation of this final-form rulemaking.

The HPLC requested that the Board define "supervising physician" in § 18.122 (relating to definitions). That term was already defined in the proposed rulemaking and continues to be defined. The HPLC requested clarification that all physicians assisted by physician assistants be called supervising physicians. The Board has modified the definition of "supervising physician" in § 18.122 to reflect the HPLC's concern.

The HPLC recommended that, to be consistent with the act, § 18.142 should contain language requiring each physician who supervises a physician assistant to sign the written agreement. The Board notes that requirement is already in the regulations as they were originally promulgated. The HPLC further recommended that language which the Board deleted in the proposed rulemaking concerning the approval of written agreements be restored. The Board has complied with this recommendation. The HPLC recommended that "works with" in § 18.142 be deleted and "assists" be restored for consistency with the act. The Board has complied with that recommendation.

In § 18.151(b), the HPLC recommended that the phrase "training and experience" be added. The Board has no objection to including this language since it does not alter the intent of the subsection and the regulated community believes the language will be understood by practitioners.

The HPLC believes there is a drafting error in § 18.158(a)(3) and recommends that the second sentence be its own paragraph. The Board believes that it is critical that the sentence stay where it is, as it reinforces the mandate for the physician assistant to notify the supervising physician immediately, and no longer than within 24 hours, that a Schedule II drug has been prescribed.

The HPLC requested clarification regarding the duty of confidentiality between a physician assistant and a patient, and how the amendments would impact upon this duty. The Board is not cognizant of any changes in the amendment which would alter the current requirements of patient confidentiality, and how physician assistants interact with patients. There is no change in access to medical records or other patient information from the regulations as they currently exist. The HPLC also requested assurance that the medical regimen changes and countersignature requirement changes, as well as notification and countersignature changes of prescribing of drugs by a physician assistant in § 18.158 are consistent with medical standards of the medical doctor commu-

nity. The Board notified the regulated community that it intended to propose updating its physician assistant regulations and sought predraft input. Numerous medical doctors and physician organizations wrote to support the proposed rulemaking, noting that the regulations were, in many ways, overly and unnecessarily restrictive. It was due to the ground swell of demand for increasing the flexibility of physician assistant regulations, and the recognition that physician assistants are a valuable and indispensable asset to physicians, that the changes have been made.

In § 18.161(b), the HPLC recommended that the language that addresses the number of physician assistant supervisors a physician assistant may have, which was deleted in proposed rulemaking, be restored to be consistent with the act. The Board has complied with that recommendation.

The HPLC recommended that the language in § 18.171 (relating to physician assistant identification), which is amended to state that the typeface be easily readable, be modified to state that it be at least a specified font size. The Board believes this recommendation for additional language is unnecessary. The regulations prohibit a physician assistant from providing medical service to a patient until that individual or their guardian has been notified that the physician assistant is not a physician, and that the patient has the right to be treated by the physician if the patient desires. Therefore, the Board believes the requirement that the identification tag be easily readable is sufficient.

The HPLC further requested detailed information on the following: a list of states which permit physician assistants to prescribe Schedule II drugs and their limitations; the scope of practice of physician assistants in other states; the supervision requirements of physicians in other states; in-depth information on the training, certification, clinical study and continuing education of physician assistants; and a list of the types of documents which may be authenticated by a physician assistant. The Board is providing this information to the HPLC as a supplement to the rulemaking because it is too voluminous to be incorporated into this preamble.

IRRC concurred with, and incorporated, the HPLC's comments as part of its comments. IRRC recommended that in § 18.122 the phrase "personal direction" be restored in the definition of "supervision." The Board is agreeable to inserting the word "personal" in the revised definition of "supervision." IRRC requested clarification that the definition of "supervising physician" includes all physicians who are assisted by physician assistants and that there may be more than one supervising physician. The Board has no objection and has clarified the definition.

IRRC requested clarification on how the Board would interpret personal contact in § 18.142(a)(3) as the definition of "direct supervision" is being deleted. The Board believes that the definition of "supervision," which includes personal direction, in conjunction with the language in § 18.142(a)(3), which states that the written agreement must specify the frequency of personal contact, addresses this concern. Further, the Board is of the opinion that the degree and nature of personal contact is best determined between the supervising physician and the physician assistant. Ultimately, it is the belief of the Board that a form of communication which allows for interactive discussion in some form, be it in person, by telephone, radio, video-conferencing or other means, would accomplish personal contact.

In § 18.158(a)(3), IRRC requested clarification from the Board on the necessity for the phrase "originally prescribed by the supervising physician." The PRHA, as previously noted, requested that this wording be removed. The Board agrees with IRRC and the PRHA and has deleted this wording in the final-form rulemaking. Therefore, clarification is no longer needed.

IRRC commented that "at least weekly" or other specific time period be added to the record review requirement in § 18.159 (relating to medical records). The Board has no objection and has added language that record review be done within 10 days.

E. Description of Amendments

In § 18.121 (relating to purpose), the term "physician assistant supervisor" is replaced with "supervising physician" and at all other places that it appears in Chapters 16 and 18. The change emphasizes that the physician assistant's supervisor must be a physician and eliminates the confusion that sometimes surrounded the term "physician assistant supervisor."

The amendments to § 18.122, in addition to being primarily editorial in nature, clarify and emphasize that all supervising physicians still maintain personal direction over physician assistants. The definition of "supervising physician" reflects that a physician who is so designated in a written agreement is a supervising physician over that particular physician assistant. This is also compatible with the deletion of the definition of "direct supervision," a term which was only found in § 18.162 (relating to emergency medical services). The Board amended that section by deleting the requirement that physician assistants provide emergency services only under the "direct" supervision of a supervising physician.

The definition of "supervision" is also amended to more accurately reflect how physician assistants are actually supervised and more clearly reflect the important responsibility that the physician assistant assumes when serving in this role. The changes primarily ease the need for the physical presence and intervention of the physician in oversight of the physician assistant, although maintaining the requirement for personal direction. The amended definition reiterates that the constant physical presence of the supervising physician is not required so long as the supervising physician and physician assistant are, or can easily be, in contact with one another by radio, telephone or other telecommunication device.

In the definition of "supervision," examples of the "appropriate degree of supervision" are amended to eliminate the requirement for weekly review of patient charts. This amendment more closely aligns with the practicality of a physician's practice. Current requirements of chart review and counter-signature of physician assistant charts are cumbersome and ineffective. A review of selected charts which have specific diagnoses or complex medical management will support a more effective use of physician time and promote quality assurance.

The definition of "medical regimen" is changed to "a therapeutic, corrective or diagnostic measure undertaken or ordered by a physician or physician assistant acting within the physician assistant's scope of practice and in accordance with the written practice agreement between the supervising physician and the physician assistant."

In this final-form rulemaking, the definition of "order" is "an oral or written directive for a therapeutic, corrective or diagnostic measure, including a drug or device to be dispensed for onsite administration in a hospital, medical care facility or office setting." This new language

provides clarity as to the parameters of an order and provides a comprehensive foundation which lends itself to the expanded definition of "medical regimen." This is further delineated as it pertains to medical facilities by language in § 18.161(d). The new language in this section is responsive to the concerns of medical facilities in their utilization of physician assistants and the integration of individuals in the fabric of facility operations.

Section 18.131 (relating to recognized educational programs/standards) amends "approval" of physician assistant training programs to "recognition" of those programs to more accurately reflect that the Board does not approve programs, but rather recognizes those that are accredited as mandated by section 36(b) of the act.

The final-form rulemaking updates the reference to the training program approvals for physician assistants by the AMA's Committee on Allied Health Education and Accreditation (CAHEA), Commission for Accreditation of Allied Health Educational Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or a successor organization. In 1994, the AMA made CAHEA its accreditation body, independent and changed its name to CAAHEP. In 2000, ARC-PA was created due to the overwhelming growth of physician assistant programs and the difficulties that developed in trying to evaluate them appropriately. The AMA and other physician groups remain active in the accreditation process and occupy seats on the committee.

Section 18.142(a)(2) is amended so that the written agreement will no longer be specific as to the requirement for describing how the physician assistant will assist each physician. The section is amended to state that the agreement must list functions that will be delegated to the physician assistant, deleting the requirements that it also describe how the physician assistant will assist each named physician and the details of how the supervising physician will be assisted. Prior to this final-form rulemaking, the regulations specified that the agreement contain procedures selected from the list in § 18.151, all other delegated tasks, instructions for use of the physician assistant in the performance of delegated tasks and medical regimens to be administered or relayed by the physician assistant. This requirement inhibits the effective utilization of physician assistants. In addition, it forces the Board to become more directly involved in the approval of practice guidelines for physicians and physician assistants rather than credentialing health care professionals. The final-form rulemaking also requires the agreement to be signed only by each physician acting as a supervising physician or a substitute supervising physician instead of by each physician in the practice group, as well as the physician assistant.

Sections 18.144 and 18.155 are amended to eliminate the requirement for the supervising physician to see each patient on every third visit or at least once a year. The Board now requires in § 18.144(4) that the physician determine the need to see each patient based upon the patient's individual needs or at the patient's request. The amendment recognizes that the involvement of the supervising physician should be predicated on factors such as the practice type, site and the condition of the patient. This also applies to satellite facilities. Because the previous requirement applied to patients who are treated by a physician assistant, it included within its application situations in which it is virtually impossible for a physician to meet. For example, if a patient is seen by a physician assistant for a minor problem and does not return within 1 year to be seen by the physician, the

physician could not comply with the requirement. Attempts to meet the requirements of the prior regulation resulted in inefficient use of resources. The physician assistant can easily manage a patient with a well-controlled chronic problem who is checked periodically to see if all is well. However, if the patient is checked only once annually, a physician had to be involved due to the requirements of the prior regulation. Experience has demonstrated that the prior regulation was counterproductive. The option remains, as always, for the patient to request to be seen by the supervising physician.

Section 18.151 includes a list of tasks that the physician assistant could perform (subject to the proviso that the list is not all-inclusive). The Board determined that the list of tasks physician assistants could perform was somewhat limiting. Although the regulation stated that the list was not intended to be all-inclusive, the Board is prohibited by court rulings from rendering advisory opinions. Therefore, one is left to speculate as to whether or not a given task not on the list, but critical to a particular practice, would be permitted. This final-form rulemaking replaces the list with statements that the physician assistant may practice medicine with physician supervision and perform duties as delegated by the physician. This section now establishes as a baseline standard that the physician assistant should be authorized to perform any medical service delegated by the physician, and which comports with the skills, training and experience of the physician assistant.

Section 18.152 (relating to prohibitions) currently prohibits a physician assistant from pronouncing death. The amendments to §§ 18.151 and 18.152 allow a physician assistant to pronounce a patient dead and also allow a physician assistant to authenticate with his signature any form related to pronouncing death. Physician assistants who practice in long-term care facilities, hospital wards, hospice care or in hematology/oncology, among other specialties, encounter circumstances when they may be the only medical care provider available at the time of a patient's death. Allowing delegation of the pronouncement of death simplifies procedures for the patient's family at a difficult time. The final-form rulemaking allows only pronouncement of death. Certification as to the cause of death continues to be reserved for the supervising physician or a coroner as set forth in section 502 of the Vital Statistics Law of 1953 (35 P.S. § 450.502). Further, the amendment provides clarity that in situations where the attending physician is not available the county coroner be advised.

Final-form § 18.151 allows the physician assistant to sign any form that otherwise requires a physician's signature as permitted by the supervising physician, State or Federal law and facility protocol, if applicable. This will relieve the physician of much routine paperwork, such as signing forms for school physicals.

Among the list of things in § 18.152 that a physician assistant may not do is the performance of a medical service without physician supervision as set forth in the written agreement.

Amendments to § 18.153 change the 12-hour requirement for the physician assistant to relate all medical regimens executed or relayed while the physician was not present to the supervising physician to 36 hours. This is also reflected in § 18.158 for medications prescribed or dispensed and is applicable to prescribing or dispensing "in accordance with the written agreement." The 12-hour time frame in both aspects of the regulations had proven to be overly restrictive. It is not uncommon that a

treatment for a minor illness done late in the day goes unreported until the start of the next business day, more than 12 hours later. For physician assistants taking weekend calls, the reporting for minor problems would not occur until the following Monday.

The Board is amending § 18.153(b) by extending the period for reporting to the supervising physician from 12 to 36 hours in § 18.155(b)(4), as in § 18.153(c). For satellite facilities, the amendments also lengthen the time for counter-signature to 10 days. During predraft input and proposed rulemaking, the medical doctor community advised the Board that the current 3-day countersignature requirement is too restrictive and causes compliance problems. The regulation does not take into consideration weekends or a supervising physician's vacation schedules. This is particularly troublesome for satellite facilities. By expanding to a 10-day signature, compliance becomes more practical. This amendment is also incorporated into §§ 18.142 and 18.158. In §§ 18.153(c) and 18.161(d), the Board clarifies further that relaying, execution and recordation requirements or medical regimens and orders comply with written policies of medical facilities. The Board clarifies by these amendments that the written policies of medical care facilities may be more restrictive than the regulations of the Board.

Section 18.157 (relating to administration of controlled substances and whole blood and blood components) provides that a physician assistant may administer controlled substances as well as whole blood and blood components if that authority is addressed in the written agreement and is separately ordered by the supervising physician specifying a named drug for a named patient. The Board is eliminating the requirement for the separate order of the supervising physician specifying the drug and patient, and allowing it to be addressed only in the written agreement and be administered by the physician assistant on that authority. The Board believes that the prior language created an unnecessary barrier to utilization of physician assistants in surgical, hematology/oncology, pain management and hospice care.

Section 18.158 includes a formulary of categories of drugs that a physician assistant may prescribe if permission is granted in the written agreement. The supervising physician would review this formulary and choose the categories of drugs that he would allow the physician assistant to prescribe or dispense. The list would become a part of the written agreement that must be submitted to the Board. The final-form rulemaking eliminates the formulary. Instead, new subsections (a) and (b) state that the physician can delegate prescribing, dispensing and administration of drugs and therapeutic devices to the physician assistant if the drug or device is permitted under the written agreement. The physician assistant is subject to the regulations of the Board and the Department of Health regarding dispensing standards, prescribing and labeling. The amendment has the written agreement only containing a list of the categories of drugs that the physician assistant may not prescribe. The formulary suffers from the same limitations noted with the list of tasks a physician assistant can perform. The formulary is out-of-date and places restrictions on common drugs used to treat patient problems routinely managed by physician assistants. For example, the management of warfarin sodium therapy for atrial fibrillation, deep venous thrombosis and mechanical heart valves has become commonplace in the family practice setting. Physician assistants are routinely called upon to adjust medication

levels. The final-form rulemaking deletes current restrictions on prescribing of blood formation or coagulation drugs.

Section 18.158(a)(4) creates a 90-day waiting period after approval by the FDA for a new drug or new uses for a drug before a physician assistant can prescribe it. The final-form rulemaking eliminates that waiting period. The original purpose has been overcome by practice in recent years. Because physicians provide ongoing input and oversight in the treatment of patients by the physician assistants, delaying the prescribing for 90 days is overly restrictive.

The final-form rulemaking also deletes a statement in § 18.158(b)(4) specifying that the supervising physician assumes responsibility for all prescriptions and dispensing of drugs by the physician assistant. However, § 18.144 requires the supervising physician to assume responsibility for the performance of the physician assistant, so this change is editorial in that it simply eliminates redundancy.

The amendments further delete subsection (g), which states that the physician assistant may only prescribe or dispense drugs for a patient under the care of the supervising physician. Physician assistants often provide care to patients in a practice that are new patients or regularly see one of the primary supervisor's partners. This section is also redundant and limiting because the supervising physician assumes ultimate responsibility for every patient seen by the physician assistant as set forth in § 18.402(a)(6) (relating to delegation) and section 17(c) of the act (63 P. S. § 422.17(a)).

The Board is eliminating a prohibition in § 18.158(c)(4)(i) which prevents a physician assistant from prescribing or dispensing a pure form or combination of drugs. The Board finds the prohibition is vague and unnecessary due to the current state of training received by physician assistants. Predraft input suggested that experience has demonstrated that physician assistants have the knowledge and skill to properly perform this function.

Section 18.158(c)(4)(iii) does not allow physician assistants to prescribe medications for uses not approved by the FDA. The final-form rulemaking no longer prohibits this "off-label" prescribing, but instead mandates that the physician assistant follow the supervising physician's instructions and the written agreement. The FDA approves uses of medications for the purpose of marketing by the manufacturer, not for use by physicians. Off-label use may represent the best standard of care. Physicians often prescribe drugs for uses other than those approved by the FDA. This allows physician assistants to use the same drugs that the supervising physician uses for the same purposes. The decision to use a medication for a purpose such as this should be left to the physician. The best example of an off-label use of a drug is the millions of prescriptions for aspirin after myocardial infarction. Off-label use of drugs is common in areas such as AIDS-related treatment, oncology and pediatrics. In pediatrics, as many as 80% of drugs are administered off-label because manufacturers are understandably reluctant to enroll young children in clinical trials of many drugs.

The Board amends § 18.158(c)(4)(iii) and (iv) to eliminate the statement that a physician assistant may not prescribe or dispense drugs not approved by the FDA. Existing law already prevents anyone, including physicians, from prescribing or dispensing drugs not approved by the FDA.

The final-form rulemaking removes from \S 18.158(c)(4)(v) the prohibition on a physician assistant prescribing or dispensing parenteral drugs other than insulin or emergency allergy kits or other approved drugs. Comments provided in predraft input advised that this regulation is overly restrictive.

Section 18.158(c)(4)(viii) stated that a physician assistant may not issue a prescription for more than a 30-day supply of medication except in cases of chronic illness when the physician assistant could write for a 90-day supply. It also stated that the physician assistant can authorize refills up to 6 months from the original prescription. This final-form rulemaking eliminates these limitations. These limitations proved too restrictive. For example, it is not unusual to prescribe contraceptives for 1 year for healthy individuals or to prescribe medications for the management of stable chronic conditions. These limitations could cause patients to incur additional costs for unnecessary office visits to continue receiving the medication.

Section 18.158(a)(5) is amended to add a provision authorizing the physician assistant to receive, sign for and distribute drug samples. This provision will allow the physician assistant to relieve the supervising physician of this duty and allow the physician assistant to dispense samples of medications the physician assistant is already authorized to dispense.

In addition, the amendment to § 18.158(a)(6) specifically requires that the physician assistant who will prescribe controlled substances must register with the DEA. The amendment to § 18.158(b)(2) also specifies that space on prescription blanks must be provided for the physician assistant to record the DEA number. This amendment underscores the requirement to register and serves to bring the physician assistant's practice into conformance with Federal law.

Existing regulations do not allow physician assistants to prescribe or dispense Schedule I or II controlled drugs. The amendment to § 18.158(a)(3) calls for allowing them to prescribe or dispense Schedule II controlled drugs for initial therapy up to a 72-hour dose and requires that they notify the supervising physician within 24 hours. It also allows the physician assistant to write a prescription for a Schedule II controlled drug for up to a 30-day supply if approved for ongoing therapy by the supervising physician. There are many physician and physician assistant specialties that deal with chronic pain management. In specialties such as oncology, surgery, anesthesiology or in the family practice setting, physician assistants are an integral part of patient care. Managing the patients' pain in these settings often requires the ability to write prescriptions for Schedule II narcotics on both a shortand long-term basis. At times, patients may require therapy or need to renew prescriptions when the physi-cian is not immediately available but the physician assistant is available. Also, there are many physician assistants that work in settings such as emergency rooms, walk-in clinics and industrial clinics. The inability to write a prescription for a Schedule II narcotic impedes the care of the patient in these settings. Allowing for a 72-hour supply of medicine until a physician sees that patient enhances the care rendered by the physician

The Board amends § 18.158 to delete the prohibition against a physician assistant compounding ingredients when dispensing drugs except for adding water. There are several medication mixtures that are commonly used in practice. One is the mixture of Benadryl, viscous

Lidocaine and Maalox in the treatment of stomatitis secondary to chemotherapy. Pediatric groups will typically combine decongestants and cough suppressants in other doses than commercially available.

Section 18.159 calls for timely review of medical records. The Board clarifies this to state that the review may not exceed 10 days.

Section 18.161(b) is amended to clarify that health care facilities may have more restrictive requirements for the utilization of physician assistants.

The Board amends § 18.162 by adding subsection (b) to address the practice of physician assistants in emergency situations. The emergency situations addressed are those in a disaster situation and not in the normal course of a medical practice. The additions allow for the use of those licensed in other states to function without the usual requirements for themselves and the physicians working with them.

The amendments to § 18.171 maintain the requirement that a physician assistant wear an identification tag bearing the term "physician assistant," but modify the requirement for it to be in 16 point or larger type to being in an easily readable type. The typeface for 16 point can be excessively large, particularly for individuals with lengthy or hyphenated names. Further, physician assistants are already currently prohibited from rendering medical service to a patient until the patient or legal guardian has been informed that they are not a physician, that they are performing the medical service as an agent of the physician and as directed by the supervising physician and that the patient has a right to be treated by the physician. Finally, the final-form rulemaking renders the regulations gender neutral.

F. Fiscal Impact and Paperwork Requirements

The final-form rulemaking has no adverse fiscal impact or additional paperwork requirements imposed on the Commonwealth, its political subdivisions or the private sector.

G. Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 26, 2005, the Board submitted a copy of the notice of proposed rulemaking, published at 35 Pa.B. 6127, 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 Department has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on October 3, 2006, this final-form rulemaking was approved by the HPLC. On October 18, 2006, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 19, 2006, and approved the final-form rulemaking.

I. Contact Person

Further information may be obtained by contacting Sabina I. Howell, Counsel, State Board of Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649, showell@state.pa.us.

J. Findings

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the 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) This final-form rulemaking does not enlarge the purpose of proposed rulemaking published at 35 Pa.B. 6127.
- (4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing acts identified in Part B of this preamble.

K. Order

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

- (a) The regulations of the Board, 49 Pa. Code Chapters 16 and 18, are amended by amending §§ 16.11, 16.13, 18.121, 18.122, 18.131, 18.141—18.145, 18.151—18.159, 18.161, 18.162, 18.171, 18.172 and 18.181 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 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) This order shall take effect on publication in the *Pennsylvania Bulletin*.

CHARLES D. HUMMER, Jr., M. D. Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 6742 (November 4, 2006).)

Fiscal Note: Fiscal Note 16A-4916 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 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

- (a) The following medical doctor licenses are issued by the Board:
 - (1) License without restriction.
 - (2) Institutional license.
 - (3) Extraterritorial license.
 - (4) Graduate license.
 - (5) Temporary license.
 - (6) Interim limited license.

(b) The following nonmedical doctor licenses are issued by the $\mbox{\sc Board}:$
(1) Midwife license.
(2) Physician assistant license.
(c) The following registrations are issued by the Board:
(1) Registration as a supervising physician of a physi-
cian assistant.
(2) Registration as an acupuncturist.
(3) Registration as an acupuncturist supervisor.
(4) Biennial registration of a license without restric-
tion.
(5) Biennial registration of an extraterritorial license.
(6) Biennial registration of a midwife license.
(7) Biennial registration of a physician assistant certificate.
(8) Biennial registration of a drugless therapist license.
(9) Biennial registration of a limited license-
permanent.
(10) Biennial registration of an acupuncturist registration.
§ 16.13. Licensure, certification, examination and
registration fees.
(a) Medical Doctor License:
License Without Restriction:
Application, graduate of accredited medical college \$35
Application, graduate of unaccredited medical college
Biennial renewal\$360
Extraterritorial License:
Application
Biennial renewal\$80
Graduate License:
Application, graduate of accredited medical college \$30
Application, graduate of unaccredited medical
college\$85
Annual renewal\$15
Interim Limited License:
Application\$30
Biennial renewal\$10
Miscellaneous:
Application, institutional license \$35
Application, temporary license \$45
Biennial renewal, limited license (permanent) \$25
(b) Midwife License:
Application \$30
Biennial renewal
(c) Physician Assistant License:
Application\$30
Biennial renewal \$40

Registration, supervising physician \$35

Registration of additional supervising physicians..... \$5

Satellite location approval \$25

(d) Acupuncturist Registration:
Application\$30
Biennial renewal
Registration, acupuncture supervisor \$30
(e) Drugless Therapist License:
Biennial renewal
(f) Radiology Technician:
Application for examination \$25
(g) Respiratory Care Practitioner Certificate:
$Application, \ temporary \ permit \dots \\ \hspace*{1.5cm} \30
Application, initial certification \$30 $$
Biennial renewal \$25
(h) Verification or Certification:
Verification of status
Certification of records \$25
(i) Examination Fees:

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

The State Board of Medicine has adopted Nationally recognized examinations in each licensing class. Fees are established by the National owners/providers of the examinations and are indicated in the examination applica-

Subchapter D. PHYSICIAN ASSISTANTS GENERAL PROVISIONS

§ 18.121. Purpose.

tions.

This subchapter implements section 13 of the act (63 P. S. § 422.13) pertaining to physician assistants and provides for the delegation of certain medical tasks to qualified physician assistants by supervising physicians when the delegation is consistent with the written agreement

§ 18.122. Definitions.

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

ARC-PA—The Accreditation Review Commission.

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

 ${\it CAAHEP}$ —The Commission for Accreditation of Allied Health Educational Programs.

 $\it CAHEA$ —The Committee on Allied Health Education and Accreditation.

Device—An instrument or tool necessary in the administration of medication or medical care.

Dispense—To deliver a drug or device to or for an ultimate user for limited or continuing use.

Drug—A term used to describe a medication, device or agent which a physician assistant prescribes or dispenses under § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices).

Emergency medical care setting-

- (i) A health care setting which is established to provide emergency medical care as its primary purpose.
- (ii) The term does not include a setting which provides general or specialized medical services that are not routinely emergency in nature even though that setting provides emergency medical care from time to time.

Medical care facility—An entity licensed or approved to render health care services.

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

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

NCCPA—The National Commission on Certification of Physician Assistant.

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

Physician—A medical doctor or doctor of osteopathic medicine.

Physician assistant—An individual who is licensed as a physician assistant by the Board.

Physician assistant examination—An examination to test whether an individual has accumulated sufficient academic knowledge to qualify for licensure as a physician assistant. The Board recognizes the certifying examination of the NCCPA.

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

Prescription—

- (i) A written or oral order for a drug or device to be dispensed to or for an ultimate user.
- (ii) The term does not include an order for a drug which is dispensed for immediate administration to the ultimate user; for example, an order to dispense a drug to a patient for immediate administration in an office or hospital is not a prescription.

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

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

Substitute supervising physician—A supervising physician who is registered with the Board and designated in the written agreement as assuming primary responsibility for a physician assistant when the primary supervising physician is unavailable.

Supervising physician—Each physician who is identified in a written agreement as a physician who supervises a physician assistant.

Supervision—

- (i) Oversight and personal direction of, and responsibility for, the medical services rendered by a physician assistant. The constant physical presence of the supervising physician is not required so long as the supervising physician and the physician assistant are, or can be, easily in contact with each other by radio, telephone or other telecommunications device.
 - (ii) An appropriate degree of supervision includes:
- (A) Active and continuing overview of the physician assistant's activities to determine that the physician's directions are being implemented.
- (B) Immediate availability of the supervising physician to the physician assistant for necessary consultations.
- (C) Personal and regular review within 10 days by the supervising physician of the patient records upon which entries are made by the physician assistant.

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

PHYSICIAN ASSISTANT EDUCATIONAL PROGRAMS

§ 18.131. Recognized educational programs/standards.

- (a) The Board recognizes physician assistant educational programs accredited by the American Medical Association's CAHEA, the CAAHEP, ARC-PA or a successor organization. Information regarding accredited programs may be obtained directly from ARC-PA at its website: www.arc-pa.org.
- (b) The criteria for recognition by the Board of physician assistant educational programs will be identical to the essentials developed by the various organizations listed in this section or other accrediting agencies approved by the Board.

LICENSURE OF PHYSICIAN ASSISTANTS AND REGISTRATION OF SUPERVISING PHYSICIANS

§ 18.141. Criteria for licensure as a physician assistant.

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

- (1) Satisfies the licensure requirements in § 16.12 (relating to general qualifications for licenses and certificates).
- (2) Has graduated from a physician assistant program recognized by the Board.
- (3) Has submitted a completed application together with the required fee, under § 16.13 (relating to licensure, certification, examination and registration fees).
 - (4) Has passed the physician assistant examination.

§ 18.142. Written agreements.

- (a) The written agreement required by section 13(e) of the act (63 P.S. § 422.13(e)) satisfies the following requirements. The agreement must:
- (1) Identify and be signed by the physician assistant and each physician the physician assistant will be assisting who will be acting as a supervising physician. At least one physician shall be a medical doctor.
- (2) Describe the manner in which the physician assistant will be assisting each named physician. The description must list functions to be delegated to the physician assistant.

- (3) Describe the time, place and manner of supervision and direction each named physician will provide the physician assistant, including the frequency of personal contact with the physician assistant.
- (4) Designate one of the named physicians who shall be a medical doctor as the primary supervising physician.
- (5) Require that the supervising physician shall countersign the patient record completed by the physician assistant within a reasonable amount of time. This time period may not exceed 10 days.
- (6) Identify the locations and practice settings where the physician assistant will serve.
- (b) The written agreement shall be approved by the Board as satisfying the requirements in subsection (a) and as being consistent with relevant provisions of the act and regulations contained in this subchapter.
- (c) A physician assistant or supervising physician shall provide immediate access to the written agreement to anyone seeking to confirm the scope of the physician assistant's authority.

§ 18.143. Criteria for registration as a supervising physician.

- (a) The Board will register a supervising physician applicant who:
- (1) Possesses a current license without restriction to practice medicine and surgery in this Commonwealth.
- (2) Has filed a completed registration form accompanied by the written agreement (see § 18.142 (relating to written agreements)) and the required fee under § 16.13 (relating to licensure, certification, examination and registration fees). The registration requires detailed information regarding the physician's professional background and specialties, medical education, internship, residency, continuing education, membership in American Boards of medical specialty, hospital or staff privileges and other information the Board may require.
- (3) Includes with the registration, a list, identifying by name and license number, the other physicians who are serving as supervising physicians of the designated physician assistant under other written agreements.
- (b) If the supervising physician plans to utilize physician assistants in satellite locations, the supervising physician shall provide the Board with supplemental information as set forth in § 18.155 (relating to satellite locations) and additional information requested by the Board directly relating to the satellite location.
- (c) The Board will keep a current list of registered supervising physicians. The list will include the physician's name, the address of residence, current business address, the date of filing, satellite locations if applicable, the names of current physician assistants under the physician's supervision and the physicians willing to provide substitute supervision.

§ 18.144. Responsibility of primary supervising physician.

- A primary supervising physician shall assume the following responsibilities. The supervisor shall:
- (1) Monitor the compliance of all parties to the written agreement with the standards contained in the written agreement, the act and this subchapter.
- (2) Advise any party to the written agreement of the failure to conform with the standards contained in the written agreement, the act and this subchapter.

- (3) Arrange for a substitute supervising physician. (See § 18.154 (relating to substitute supervising physician).)
- (4) Review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.
 - (5) See each patient while hospitalized at least once.
- (6) Provide access to the written agreement upon request and provide clarification of orders and prescriptions by the physician assistant relayed to other health care practitioners.
- (7) Accept full professional and legal responsibility for the performance of the physician assistant and the care and treatment of the patients.

§ 18.145. Biennial registration requirements; renewal of physician assistant license.

- (a) A physician assistant shall register biennially according to the procedure in § 16.15 (relating to biennial registration; inactive status and unregistered status).
- (b) The fee for the biennial registration of a physician assistant license is set forth in § 16.13 (relating to licensure, certification, examination and registration fees).
- (c) To be eligible for renewal of a physician assistant license, the physician assistant shall maintain National certification by completing current recertification mechanisms available to the profession and recognized by the Board.
- (d) The Board will keep a current list of persons licensed as physician assistants. The list will include:
 - (1) The name of each physician assistant.
 - (2) The place of residence.
 - (3) The current business address.
- (4) The date of initial licensure, biennial renewal record and current supervising physician.

PHYSICIAN ASSISTANT UTILIZATION

§ 18.151. Role of physician assistant.

- (a) The physician assistant practices medicine with physician supervision. A physician assistant may perform those duties and responsibilities, including the ordering, prescribing, dispensing, and administration of drugs and medical devices, as well as the ordering, prescribing, and executing of diagnostic and therapeutic medical regimens, as directed by the supervising physician.
- (b) The physician assistant may provide any medical service as directed by the supervising physician when the service is within the physician assistant's skills, training and experience, forms a component of the physician's scope of practice, is included in the written agreement and is provided with the amount of supervision in keeping with the accepted standards of medical practice.
- (c) The physician assistant may pronounce death, but not the cause of death, and may authenticate with the physician assistant's signature any form related to pronouncing death. If the attending physician is not available, the physician assistant shall notify the county coroner. The coroner has the authority to release the body of the deceased to the funeral director.

- (d) The physician assistant may authenticate with the physician assistant's signature any form that may otherwise be authenticated by a physician's signature as permitted by the supervising physician, State or Federal law and facility protocol, if applicable.
- (e) The physician assistant shall be considered the agent of the supervising physician in the performance of all practice-related activities including the ordering of diagnostic, therapeutic and other medical services.

§ 18.152. Prohibitions.

- (a) A physician assistant may not:
- (1) Provide medical services except as described in the written agreement.
- (2) Prescribe or dispense drugs except as described in the written agreement.
- (3) Maintain or manage a satellite location under § 18.155 (relating to satellite locations) unless the maintenance or management is registered with the Board.
- (4) Independently practice or bill patients for services provided.
- (5) Independently delegate a task specifically assigned to him by the supervising physician to another health care provider.
- (6) List his name independently in a telephone directory or other directory for public use in a manner which indicates that he functions as an independent practitioner
- (7) Perform acupuncture except as permitted by section 13(k) of the act (63 P. S. § 422.13(k)).
- (8) Perform a medical service without the supervision of a supervising physician.
 - (b) A supervising physician may not:
- (1) Permit a physician assistant to engage in conduct proscribed in subsection (a).
- (2) Have primary responsibility for more than two physician assistants.

§ 18.153. Executing and relaying medical regimens.

- (a) A physician assistant may execute a written or oral order for a medical regimen or may relay a written or oral order for a medical regimen to be executed by a health care practitioner subject to the requirements of this section.
- (b) As provided for in the written agreement, the physician assistant shall report orally or in writing, to a supervising physician, within 36 hours, those medical regimens executed or relayed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to execute or relay a medical regimen.
- (c) The physician assistant shall record, date and authenticate the medical regimen on the patient's chart at the time it is executed or relayed. When working in a medical care facility, a physician assistant may comply with the recordation requirement by directing the recipient of the order to record, date and authenticate that the recipient received the order, if this practice is consistent with the medical care facility's written policies. The supervising physician shall countersign the patient record within a reasonable time not to exceed 10 days, unless countersignature is required sooner by regulation, policy within the medical care facility or the requirements of a third-party payor.

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

§ 18.154. Substitute supervising physician.

- (a) If the primary supervising physician is unavailable to supervise the physician assistant, the primary supervising physician may not delegate patient care to the physician assistant unless appropriate arrangements for substitute supervision are in the written agreement and the substitute physician is registered as a supervising physician with the Board.
- (b) It is the responsibility of the substitute supervising physician to ensure that supervision is maintained in the absence of the primary supervising physician.
- (c) During the period of supervision by the substitute supervising physician, the substitute supervising physician retains full professional and legal responsibility for the performance of the physician assistant and the care and treatment of the patients treated by the physician assistant.
- (d) Failure to properly supervise may provide grounds for disciplinary action against the substitute supervising physician.

§ 18.155. Satellite locations.

- (a) Registration of satellite location. A physician assistant may not provide medical services at a satellite location unless the supervising physician has filed a registration with the Board.
- (b) *Contents of statement*. A separate statement shall be made for each satellite location. The statement must demonstrate that:
- (1) The physician assistant will be utilized in an area of medical need.
- (2) There is adequate provision for direct communication between the physician assistant and the supervising physician and that the distance between the location where the physician provides services and the satellite location is not so great as to prohibit or impede appropriate support services.
- (3) The supervising physician shall review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.
- (4) The supervising physician will visit the satellite location at least once every 10 days and devote enough time onsite to provide supervision and personally review the records of selected patients seen by the physician assistant in this setting. The supervising physician shall notate those patient records as reviewed.
- (c) Failure to comply with this section. Failure to maintain the standards required for a satellite location may result not only in the loss of the privilege to maintain a satellite location but also may result in disciplinary action against the physician assistant and the supervising physician.

§ 18.156. Monitoring and review of physician assistant utilization.

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

- (1) Supervision of the physician assistant. See $\S\S$ 18.144 and 18.154 (relating to responsibility of primary supervising physician; and substitute supervising physician).
- (2) Presence of the written agreement and compliance with its terms. See § 18.142 (relating to written agreements).
- (3) Utilization in conformity with the act, this subchapter and the written agreement.
- (4) Appropriate identification of physician assistant. See § 18.171 (relating to physician assistant identification).
- (5) Compliance with licensure and registration requirements. See §§ 18.141 and 18.145 (relating to criteria for licensure as a physician assistant; and biennial registration requirements; renewal of physician assistant license).
- (6) Maintenance of records evidencing patient and supervisory contact by the supervising physician.
- (b) Reports shall be submitted to the Board and become a permanent record under the supervising physician's registration. Deficiencies reported will be reviewed by the Board and may provide a basis for loss of the privilege to maintain a satellite location and disciplinary action against the physician assistant and the supervising physician.
- (c) The Board reserves the right to review physician assistant utilization without prior notice to either the physician assistant or the supervising physician. It is a violation of this subchapter for a supervising physician or a physician assistant to refuse to comply with the request by the Board for the information in subsection (a).
- (d) Additional inspections, including follow-up inspections may be conducted if the Board has reason to believe that a condition exists which threatens the public health, safety or welfare.

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

- (a) In a hospital, medical care facility or office setting, the physician assistant may order or administer, or both, controlled substances and whole blood and blood components if the authority to order and administer these medications and fluids is expressly set forth in the written agreement.
- (b) The physician assistant shall comply with the minimum standards for ordering and administering controlled substances specified in § 16.92 (relating to prescribing, administering and dispensing controlled substances).

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

- (a) Prescribing, dispensing and administration of drugs.
- (1) The supervising physician may delegate to the physician assistant the prescribing, dispensing and administering of drugs and therapeutic devices.
- (2) A physician assistant may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substances, Drug, Device, and Cosmetic Act (35 P. S. § 780-104).
- (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the

- prescription. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if it was approved by the supervising physician for ongoing therapy. The prescription must clearly state on its face that it is for initial or ongoing therapy.
- (4) A physician assistant may only prescribe or dispense a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant and only in accordance with the supervising physician's instructions and written agreement.
- (5) A physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients.
- (6) A physician assistant authorized to prescribe or dispense, or both, controlled substances shall register with the Drug Enforcement Administration (DEA).
- (b) *Prescription blanks*. 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 a printed format at the heading of the blank. The supervising physician must also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).
- (2) The signature of a physician assistant shall be followed by the initials "PA-C" or similar designation to identify the signer as a physician assistant. When appropriate, the physician assistant's DEA registration number must appear on the prescription.
- $(3) \ The \ supervising \ physician \ is \ prohibited \ from \\ presigning \ prescription \ blanks.$
- (4) The physician assistant may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.
- (c) Inappropriate prescription. The supervising physician shall immediately advise the patient, notify the physician assistant and, in the case of a written prescription, advise the pharmacy if the physician assistant is prescribing or dispensing a drug inappropriately. The supervising physician shall advise the patient and notify the physician assistant to discontinue using the drug and, in the case of a written prescription, notify the pharmacy to discontinue the prescription. The order to discontinue use of the drug or prescription shall be noted in the patient's medical record by the supervising physician.
- (d) Recordkeeping requirements. Recordkeeping requirements are as follows:
- (1) When prescribing a drug, the physician assistant shall keep a copy of the prescription, including the number of refills, in a ready reference file, or record the name, amount and doses of the drug prescribed, the number of refills, the date of the prescription and the physician assistant's name in the patient's medical records.
- (2) When dispensing a drug, the physician assistant shall record the physician assistant's name, the name of the medication dispensed, the amount of medication dispensed, the dose of the medication dispensed and the date dispensed in the patient's medical records.
- (3) The physician assistant shall report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physi-

- cally 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 within 10 days.
- (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 §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.159. Medical records.

The supervising physician shall timely review, not to exceed 10 days, the medical records prepared by the physician assistant to ensure that the requirements of § 16.95 (relating to medical records) have been satisfied.

MEDICAL CARE FACILITIES AND EMERGENCY MEDICAL SERVICES

§ 18.161. Physician assistant employed by medical care facilities.

- (a) A physician assistant may be employed by a medical care facility, but shall comply with the requirements of the act and this subchapter.
- (b) The physician assistant may not be responsible to more than three supervising physicians in a medical care facility.
- (c) This subchapter does not require medical care facilities to employ physician assistants or to permit their utilization on their premises. Physician assistants are permitted to provide medical services to the hospitalized patients of their supervising physicians if the medical care facility permits it.
- (d) Physician assistants granted privileges by, or practicing in, a medical care facility shall conform to policies and requirements delineated by the facility.

§ 18.162. Emergency medical services.

- (a) A physician assistant may only provide medical service in an emergency medical care setting if the physician assistant has training in emergency medicine, functions within the purview of the physician assistant's written agreement and is under the supervision of the supervising physician.
- (b) A physician assistant licensed in this Commonwealth or licensed or authorized to practice in any other state who is responding to a need for medical care created by a declared state of emergency or a state or local disaster (not to be defined as an emergency situation which occurs in the place of one's employment) may render care consistent with relevant standards of care.

IDENTIFICATION AND NOTICE RESPONSIBILITIES

§ 18.171. Physician assistant identification.

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

- (1) The physician assistant is not a physician.
- (2) The physician assistant may perform the service required as the agent of the physician and only as directed by the supervising physician.
- (3) The patient has the right to be treated by the physician if the patient desires.
- (b) It is the supervising physician's responsibility to be alert to patient complaints concerning the type or quality of services provided by the physician assistant.
- (c) In the supervising physician's office and satellite locations, a notice plainly visible to patients shall be posted in a prominent place explaining that a "physician assistant" is authorized to assist a physician in the provision of medical care and services. The supervising physician shall display the registration to supervise in the office. The physician assistant's license shall be prominently displayed at any location at which the physician assistant provides services. Duplicate licenses may be obtained from the Board if required.
- (d) The physician assistant shall wear an identification tag which uses the term "Physician Assistant" in easily readable type. The tag shall be conspicuously worn.

§ 18.172. Notification of changes in employment.

- (a) The physician assistant is required to notify the Board, in writing, of a change in or termination of employment or a change in mailing address within 15 days. Failure to notify the Board, in writing, of a change in mailing address may result in failure to receive pertinent material distributed by the Board. The physician assistant shall provide the Board with the new address of residence, address of employment and name of registered supervising physician.
- (b) The supervising physician is required to notify the Board, in writing, of a change or termination of supervision of a physician assistant within 15 days.
- (c) Failure to notify the Board of changes in employment or a termination in the physician/physician assistant relationship is a basis for disciplinary action against the physician's license, supervising physician's registration and the physician assistant's license.

DISCIPLINE

§ 18.181. Disciplinary and corrective measures.

- (a) A physician assistant who engages in unprofessional conduct is subject to disciplinary action under section 41 of the act (63 P. S. § 422.41). Unprofessional conduct includes the following:
- (1) Misrepresentation or concealment of a material fact in obtaining a license or a reinstatement thereof.
- (2) Commission of an offense against the statutes of the Commonwealth relating to the practice of physician assistants or regulations adopted thereunder.
- (3) Commission of an act involving moral turpitude, dishonesty or corruption when the act directly or indirectly affects the health, welfare or safety of citizens of this Commonwealth. If the act constitutes a crime, conviction thereof in a criminal proceeding may not be a condition precedent to disciplinary action.
- (4) Conviction of a felony or conviction of a misdemeanor relating to a health profession or receiving probation without verdict, disposition in lieu of trial or an accelerated rehabilitative disposition in the disposition of

felony charges, in the courts of the Commonwealth, a Federal court or a court of another State, territory or country.

- (5) Misconduct in practice as a physician assistant or performing tasks fraudulently, beyond its authorized scope, with incompetence, or with negligence on a particular occasion or negligence on repeated occasions.
- (6) Performance of tasks as a physician assistant while the ability to do so is impaired by alcohol, drugs, physical disability or mental instability.
- (7) Impersonation of a licensed physician or another licensed physician assistant.
- (8) Offer, undertake or agree to cure or treat disease by a secret method, procedure, treatment or medicine; the treating, prescribing for a human condition, by a method, means or procedure which the physician assistant refuses to divulge upon demand of the Board; or use of methods or treatment which are not in accordance with treatment processes accepted by a reasonable segment of the medical profession.
- (9) Violation of a provision of this subchapter fixing a standard of professional conduct.
- (10) Continuation of practice while the physician assistant's license has expired, is not registered or is suspended or revoked.
- (11) Delegating a medical responsibility to a person when the physician assistant knows or has reason to know that the person is not qualified by training, experience, license or certification to perform the delegated task.
- (12) The failure to notify the supervising physician that the physician assistant has withdrawn care from a patient.
- (b) The Board will order the emergency suspension of the license of a physician assistant who presents an immediate and clear danger to the public health and safety, as required by section 40 of the act (63 P. S. \S 422.40).
- (c) The license of a physician assistant shall automatically be suspended, under conditions in section 40 of the act.
- (d) The Board may refuse, revoke or suspend a physician's registration as a supervising physician for engaging in any of the conduct proscribed of Board-regulated practitioners in section 41 of the act.

[Pa.B. Doc. No. 06-2263. Filed for public inspection November 17, 2006, 9:00 a.m.]

STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS

[49 PA. CODE CHS. 47—49] Child Abuse Reporting Requirements

The State Board of Social Workers, Marriage and Family Therapists and Professional Counselors (Board) amends \S 47.52 (relating to suspected child abusemandated reporting requirements) and adds $\S\S$ 48.51—48.57 and 49.51—49.57 (relating to child abuse reporting requirements) to read as set forth in Annex A.

Effective Date

The amendments are effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The Board is authorized to adopt regulations necessary for the administration of its enabling statute under section 6(2) of the Social Workers, Marriage and Family Therapists and Professional Counselors Act (63 P. S. § 1906(2)). The Board is required to adopt regulations regarding the duty of its licensees to report suspected child abuse under 23 Pa.C.S. Chapter 63 (relating to Child Protective Services Law) (CPSL), specifically sections 6311(b) and 6383(b)(2) of the CPSL (relating to persons required to report suspected child abuse; and education and training).

Background and Purpose

This final-form rulemaking is responsive to the statutory mandate of section 6383(b)(2) of the CPSL, which requires that each licensing board with jurisdiction over professional licensees identified as mandated reporters of child abuse promulgate regulations on the responsibilities of mandated reporters. The mandated reporters in section 6311(b) of the CPSL include mental health professionals. The Board has fulfilled its rulemaking responsibilities pertaining to licensed social workers. With the enactment of the act of December 21, 1998 (No. 136, P. L. 1017), which created new licensure classifications of marriage and family therapists and professional counselors, the Board is now promulgating similar reporting provisions for licensed marriage and family therapists and professional counselors.

Summary of Comments and Responses on Proposed Rulemaking

Notice of proposed rulemaking was published at 35 Pa.B. 5525 (October 8, 2005) after which the Board entertained public comment for 30-days under section 201(4) of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1201(4)), known as the Commonwealth Documents Law (CDL). The public did not comment on the proposed rulemaking. Under the Regulatory Review Act (71 P. S. §§ 745.1—745.15), the Board received comments from the Independent Regulatory Review Commission (IRRC) and the House Professional Licensure Committee (HPLC). The comments and the Board's responses are broken into the following categories:

§§ 48.51 and 49.51. Definitions relating to child abuse reporting requirements.

IRRC and the HPLC noted that the proposed definition of "child abuse" differs from the definition in the CPSL in that the proposed definition only contained the first of three sections of the statutory definition. The HPLC and IRRC recommended that the Board add the missing text from the statutory definition to the regulatory definition of "child abuse."

Section 6303(b)(2) of the CPSL (relating to definitions) provides:

"No child shall be deemed to be physically or mentally abused based on injuries that result solely from environmental factors that are beyond the control of the parent or person responsible for the child's welfare, such as inadequate housing, furnishings, income, clothing and medical care."

Section 6303(b)(3) of the CPSL provides, in part:

"If, upon investigation, the county agency determines that a child has not been provided needed medical or surgical care because of seriously held religious beliefs of the child's parents, guardian or person responsible for the child's welfare, which beliefs are consistent with those of a bona fide religion, the child shall not be deemed to be physically or mentally abused...."

The Board believes that the purpose of these provisions in the CPSL is to place the responsibility for deciding whether environmental factors or religious beliefs are the causative agents of the injury on the county agencies, not mandated reporters. The Board believes that including these provisions in its definition would be contrary to the purpose of the final-form rulemaking, which is to encourage more complete timely reporting of suspected child abuse. Moreover, while licensees may become aware of environmental factors affecting children they treat, these factors may not be within the readily obtainable knowledge of practitioners at the time reporting is mandated. The Board notes also that other licensing boards with mandated reporters have adopted an identical regulatory approach with regard to section 6303(b)(2) and (3) of the CPSL. For example, see the regulations of the State Board of Medicine in § 16.101 (relating to definitions), notwithstanding a similar recommendation of Independent Regulatory Review Commission (see 26 Pa.B. 5386 (November 9, 1996)). Therefore, the Board has decided not to make changes to this definition in this final-form rulemaking.

§§ 48.52 and 49.52. Suspected child abuse-mandated reporting requirements.

The HPLC and IRRC noted that the CPSL provides that reports are to be made to both the county children and youth agency and to the Department of Public Welfare (Department) and recommended that the Board add language to §§ 48.52(a) and 49.52(a) to reflect these requirements. The Board agrees with this comment and has amended the language accordingly.

Both the HPLC and IRRC commented that the CPSL requires that written reports be made to the county children and youth agency and recommended that the phrase "to the county agency" be inserted after the words "written reports shall be made" in §§ 48.52(c)(2) and 49.52(c)(2). The Board has agreed and added this language in this final-form rulemaking.

IRRC commented that proposed §§ 48.52(d)(10) and 49.52(d)(10) require the reporter to include "other information which the Department of Public Welfare may require by regulation." IRRC noted that the Department promulgated regulations on the filing of written reports by a required reporter and that the Board should either provide a citation to the Department's regulation or use the exact language in that regulation. The Board has agreed and references the Department's regulation in §§ 48.52(c)(2) and 49.52(c)(2).

Chapter 47. State Board of Social Workers, Marriage and Family Therapists and Professional Counselors.

IRRC noted that if the Board amended the proposed rulemaking, it will differ from existing regulations for social workers on reporting suspected child abuse in Chapter 47. IRRC suggested that the Board amend Chapter 47 to be consistent with the similar provisions pertaining to marriage and family therapists and professional counselors. The Board has agreed with this suggestion and has amended § 47.52 in this final rulemaking. *Miscellaneous*

The HPLC noted that some of the sections in the proposed rulemaking were numbered incorrectly. The

Legislative Reference Bureau fixed the numbers of these sections when it was published as proposed rulemaking.

The HPLC also recommended that language be added to §§ 48.57 and 49.57 (relating to noncompliance) to indicate that §§ 48.56 and 49.56 (relating to confidentiality—waived) be respected. However, the Board notes that § 47.56 (relating to confidentiality—waived) and §§ 48.56 and 49.56 do not impose specific duties on licensees which could lead to disciplinary action. These sections merely provide that the duty to report suspected child abuse takes precedence over principles of confidentiality, ethical principles and other professional standards. Accordingly, the Board has decided not to add that language in this final-form rulemaking.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no fiscal impact on the Commonwealth or its political subdivisions. As mandated reporters, licensed marriage and family therapists and professional counselors may incur additional paperwork in complying with the child abuse reporting requirements adopted in this final-form rulemaking.

Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on September 26, 2005, the Board submitted a copy of the notice of proposed rulemaking, published at 35 Pa.B. 5525, to IRRC and the Chairpersons of the HPLC and the Senate Consumer Protection and Professional Licensure Committee (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 Department has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on October 3, 2006, the final-form rulemaking was approved by the HPLC. On October 18, 2006, the final-form rulemaking was deemed approved by SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 19, 2006, and approved the final-form rulemaking.

Contact Person

Interested persons may obtain information regarding the final-form rulemaking by contacting Beth Sender Michlovitz, Board Counsel, State Board of Social Workers, Marriage and Family Therapists and Professional Counselors, P.O. Box 2659, Harrisburg, PA 17105-2649, bmichlovit@state.pa.us.

Findings

The Board finds that:

- (1) Notice of proposed rulemaking was given under section 201 of the CDL and section 202 of the CDL (45 P. S. § 202) and the 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 the final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 35 Pa.B. 5525.

(4) This final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing acts.

Order

The Board orders that:

(a) The regulations of the Board, 49 Pa. Code Chapters 47—49, are amended by amending § 47.52 and adding §§ 48.51—48.57 and 49.51—49.57 to read as set forth in Annex A.

(*Editor's Note*: The amendment to § 47.52 was not included in the proposed rulemaking published at 35 Pa.B. 5525.)

- (b) The Board shall submit this order and Annex A to the Office of General Counsel and o the Office of Attorney General 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) This order shall take effect on publication in the *Pennsylvania Bulletin*.

RONALD HAYS, Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 6742 (November 4, 2006).)

Fiscal Note: Fiscal Note 16A-6910 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 47. STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS

CHILD ABUSE REPORTING REQUIREMENTS

- § 47.52. Suspected child abuse—mandated reporting requirements.
- (a) General rule. Under 23 Pa.C.S. § 6311 (relating to persons required to report suspected child abuse), licensed social workers who, in the course of their employment, occupation or practice of their profession, come into contact with children shall report or cause a report to be made to the Department of Public Welfare and to the appropriate county agency when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse
- (b) Staff members of public or private agencies, institutions and facilities. Licensed social workers who are staff members of a medical or other public or private institution, school, facility or agency, and who, in the course of their employment, occupation or practice of their profession, come into contact with children shall immediately notify the person in charge of the institution, school, facility or agency or the designated agent of the person in charge when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse. Upon

notification by the licensed social worker, the person in charge or the designated agent shall assume the responsibility and have the legal obligation to report or cause a report to be made in accordance with subsections (a), (c) and (d).

- (c) Reporting procedure. Reports of suspected child abuse shall be made by telephone and by written report.
- (1) *Oral reports.* Oral reports of suspected child abuse shall be made immediately by telephone to ChildLine, (800) 932-0313.
- (2) Written reports. Written reports shall be made to the appropriate county agency within 48 hours after the oral report is made by telephone and must contain, at a minimum, the information required by the Department of Public Welfare in 55 Pa. Code § 3490.18 (relating to filing of a written report by a required reporter).

CHAPTER 48. STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS—LICENSURE OF MARRIAGE AND FAMILY THERAPISTS

CHILD ABUSE REPORTING REQUIREMENTS

§ 48.51. Definitions relating to child abuse reporting requirements.

The following words and terms, when used in this section and §§ 48.52—48.57 (relating to child abuse reporting requirements), have the following meanings, unless the context clearly indicates otherwise:

Child abuse—The term includes any of the following:

- (i) A recent act or failure to act by a perpetrator which causes nonaccidental serious physical injury to a child under 18 years of age.
- (ii) An act or failure to act by a perpetrator which causes nonaccidental serious mental injury to or sexual abuse or sexual exploitation of a child under 18 years of age.
- (iii) A recent act, failure to act or series of acts or failures to act by a perpetrator which creates an imminent risk of serious physical injury to or sexual abuse or sexual exploitation of a child under 18 years of age.
- (iv) Serious physical neglect by a perpetrator constituting prolonged or repeated lack of supervision or the failure to provide the essentials of life, including adequate medical care, which endangers a child's life or development or impairs the child's functioning.

ChildLine—An organizational unit of the Department of Public Welfare, which operates a 24-hour-a-day Statewide toll-free telephone system for receiving reports of suspected child abuse, referring reports for investigation and maintaining the reports in the appropriate file.

Individual residing in the same home as the child—An individual who is 14 years of age or older and who resides in the same home as the child.

Perpetrator—A person who has committed child abuse and is a parent of the child, a person responsible for the welfare of a child, an individual residing in the same home as a child or a paramour of a child's parent.

Person responsible for the child's welfare—

(i) A person who provides permanent or temporary care, supervision, mental health diagnosis or treatment, training or control of a child in lieu of parental care, supervision and control.

(ii) The term does not include a person who is employed by or provides services or programs in a public or private school, intermediate unit or area vocational-technical school.

Recent acts or omissions—Acts or omissions committed within 2 years of the date of the report to the Department of Public Welfare or county agency.

Serious mental injury—A psychological condition, as diagnosed by a physician or licensed psychologist including the refusal of appropriate treatment, that does one or more of the following:

- (i) Renders a child chronically and severely anxious, agitated, depressed, socially withdrawn, psychotic or in reasonable fear that the child's life or safety is threatened
- (ii) Seriously interferes with a child's ability to accomplish age-appropriate developmental and social tasks.

Serious physical injury—An injury that causes a child severe pain or significantly impairs a child's physical functioning, either temporarily or permanently.

Sexual abuse or exploitation—The employment, use, persuasion, inducement, enticement or coercion of a child to engage in or assist another person to engage in sexually explicit conduct or a simulation of sexually explicit conduct for the purpose of producing a visual depiction, including photographing, videotaping, computer depicting or filming, of sexually explicit conduct or the rape, sexual assault, involuntary deviate sexual intercourse, aggravated indecent assault, molestation, incest, indecent exposure, prostitution, statutory sexual assault or other form of sexual exploitation of children.

§ 48.52. Suspected child abuse-mandated reporting requirements.

- (a) General rule. Under 23 Pa.C.S. § 6311 (relating to persons required to report suspected child abuse), licensed marriage and family therapists who, in the course of their employment, occupation or practice of their profession, come into contact with children shall report or cause a report to be made to the Department of Public Welfare and the appropriate county agency when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse.
- (b) Staff members of public or private agencies, institutions and facilities. Licensed marriage and family therapists who are staff members of a medical or other public or private institution, school, facility or agency, and who, in the course of their employment, occupation or practice of their profession, come into contact with children shall immediately notify the person in charge of the institution, school, facility or agency or the designated agent of the person in charge when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse. Upon notification by the licensed marriage and family therapist, the person in charge or the designated agent shall assume the responsibility and have the legal obligation to report or cause a report to be made in accordance with subsections (a), (c) and (d).
- (c) Reporting procedure. Reports of suspected child abuse shall be made by telephone and by written report.
- (1) *Oral reports.* Oral reports of suspected child abuse shall be made immediately by telephone to ChildLine, (800) 932-0313.

(2) Written reports. Written reports shall be made to the appropriate county agency within 48 hours after the oral report is made by telephone and must contain, at a minimum, the information required by the Department of Public Welfare in 55 Pa. Code § 3490.18 (relating to filing of a written report by a required reporter).

§ 48.53. Photographs, medical tests and X-rays of child subject to report.

A licensed marriage and family therapist may take or cause to be taken photographs of the child who is subject to a report and, if clinically indicated, cause to be performed a radiological examination and other medical tests on the child. Medical summaries or reports of the photographs, X-rays and relevant medical tests taken shall be sent to the county children and youth social service agency at the time the written report is sent or as soon thereafter as possible. The county children and youth social service agency shall have access to actual photographs or duplicates and X-rays and may obtain them or duplicates of them upon request.

§ 48.54. Suspected death as a result of child abuse—mandated reporting requirement.

A licensed marriage and family therapist who has reasonable cause to suspect that a child died as a result of child abuse shall report that suspicion to the coroner of the county where death occurred or, in the case where the child is transported to another county for medical treatment, to the coroner of the county where the injuries were sustained.

§ 48.55. Immunity from liability.

Under 23 Pa.C.S. § 6318 (relating to immunity from liability), a licensed marriage and family therapist who participates in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs shall have immunity from civil and criminal liability that might result by reason of the licensed marriage and family therapist's actions. For the purpose of any civil or criminal proceeding, the good faith of the licensed marriage and family therapist shall be presumed. The Board will uphold the same good faith presumption in any disciplinary proceeding that might result by reason of a licensed marriage and family therapist's actions in participating in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs.

§ 48.56. Confidentiality—waived.

To protect children from abuse, the reporting requirements of §§ 48.52—48.54 (relating to suspected child abuse-mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse—mandated reporting requirement) take precedence over the provisions of any client confidentiality, ethical principle or professional standard that might otherwise apply.

§ 48.57. Noncompliance.

(a) Disciplinary action. A licensed marriage and family therapist who willfully fails to comply with the reporting requirements in §§ 48.52—48.54 (relating to suspected child abuse—mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse—mandated reporting requirement) will be subject to disciplinary action under section 11 of the act (63 P. S. § 1911).

(b) Criminal penalties. Under 23 Pa.C.S. § 6319 (relating to penalties for failure to report), a licensed marriage and family therapist who is required to report a case of suspected child abuse who willfully fails to do so commits a summary offense for the first violation and a misdemeanor of the third degree for a second or subsequent violation.

CHAPTER 49. STATE BOARD OF SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS AND PROFESSIONAL COUNSELORS—LICENSURE OF PROFESSIONAL COUNSELORS

CHILD ABUSE REPORTING REQUIREMENTS

§ 49.51. Definitions relating to child abuse reporting requirements.

The following words and terms, when used in this section and §§ 49.52—49.57 (relating to child abuse reporting requirements), have the following meanings, unless the context clearly indicates otherwise:

Child abuse—A term meaning any of the following:

- (i) A recent act or failure to act by a perpetrator which causes nonaccidental serious physical injury to a child under 18 years of age.
- (ii) An act or failure to act by a perpetrator which causes nonaccidental serious mental injury to or sexual abuse or sexual exploitation of a child under 18 years of age.
- (iii) A recent act, failure to act or series of acts or failures to act by a perpetrator which creates an imminent risk of serious physical injury to or sexual abuse or sexual exploitation of a child under 18 years of age.
- (iv) Serious physical neglect by a perpetrator constituting prolonged or repeated lack of supervision or the failure to provide the essentials of life, including adequate medical care, which endangers a child's life or development or impairs the child's functioning.

ChildLine—An organizational unit of the Department of Public Welfare, which operates a 24-hour-a-day Statewide toll-free telephone system for receiving reports of suspected child abuse, referring reports for investigation and maintaining the reports in the appropriate file.

Individual residing in the same home as the child—An individual who is 14 years of age or older and who resides in the same home as the child.

Perpetrator—A person who has committed child abuse and is a parent of the child, a person responsible for the welfare of a child, an individual residing in the same home as a child or a paramour of a child's parent.

Person responsible for the child's welfare-

- (i) A person who provides permanent or temporary care, supervision, mental health diagnosis or treatment, training or control of a child in lieu of parental care, supervision and control.
- (ii) The term does not include a person who is employed by or provides services or programs in a public or private school, intermediate unit or area vocational-technical school.

Recent acts or omissions—Acts or omissions committed within 2 years of the date of the report to the Department of Public Welfare or county agency.

Serious mental injury—A psychological condition, as diagnosed by a physician or licensed psychologist including the refusal of appropriate treatment, that does one or more of the following:

- (i) Renders a child chronically and severely anxious, agitated, depressed, socially withdrawn, psychotic or in reasonable fear that the child's life or safety is threatened.
- (ii) Seriously interferes with a child's ability to accomplish age-appropriate developmental and social tasks.

Serious physical injury—An injury that causes a child severe pain or significantly impairs a child's physical functioning, either temporarily or permanently.

Sexual abuse or exploitation—The employment, use, persuasion, inducement, enticement or coercion of a child to engage in or assist another person to engage in sexually explicit conduct or a simulation of sexually explicit conduct for the purpose of producing a visual depiction, including photographing, videotaping, computer depicting or filming, of sexually explicit conduct or the rape, sexual assault, involuntary deviate sexual intercourse, aggravated indecent assault, molestation, incest, indecent exposure, prostitution, statutory sexual assault or other form of sexual exploitation of children.

§ 49.52. Suspected child abuse—mandated reporting requirements.

- (a) General rule. Under 23 Pa.C.S. § 6311 (relating to persons required to report suspected child abuse), licensed professional counselors who, in the course of their employment, occupation or practice of their profession, come into contact with children shall report or cause a report to be made to the Department of Public Welfare and to the appropriate county agency when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse.
- (b) Staff members of public or private agencies, institutions and facilities. Licensed professional counselors who are staff members of a medical or other public or private institution, school, facility or agency, and who, in the course of their employment, occupation or practice of their profession, come into contact with children shall immediately notify the person in charge of the institution, school, facility or agency or the designated agent of the person in charge when they have reasonable cause to suspect on the basis of their professional or other training or experience, that a child coming before them in their professional or official capacity is a victim of child abuse. Upon notification by the licensed professional counselor, the person in charge or the designated agent shall assume the responsibility and have the legal obligation to report or cause a report to be made in accordance with subsections (a), (c) and (d).
- (c) Reporting procedure. Reports of suspected child abuse shall be made by telephone and by written report.
- (1) Oral reports. Oral reports of suspected child abuse shall be made immediately by telephone to ChildLine, $(800)\ 932\text{-}0313$.
- (2) Written reports. Written reports shall be made to the appropriate county agency within 48 hours after the oral report is made by telephone and must contain, at a minimum, the information required by the Department of Public Welfare in 55 Pa. Code § 3490.18 (relating to filing of a written report by a required reporter).

§ 49.53. Photographs, medical tests and X-rays of child subject to report.

A licensed professional counselor may take or cause to be taken photographs of the child who is subject to a report and, if clinically indicated, cause to be performed a radiological examination and other medical tests on the child. Medical summaries or reports of the photographs, X-rays and relevant medical tests taken shall be sent to the county children and youth social service agency at the time the written report is sent or as soon thereafter as possible. The county children and youth social service agency shall have access to actual photographs or duplicates and X-rays and may obtain them or duplicates of them upon request.

§ 49.54. Suspected death as a result of child abuse—mandated reporting requirement.

A licensed professional counselor who has reasonable cause to suspect that a child died as a result of child abuse shall report that suspicion to the coroner of the county where death occurred or, in the case where the child is transported to another county for medical treatment, to the coroner of the county where the injuries were sustained.

§ 49.55. Immunity from liability.

Under 23 Pa.C.S. § 6318 (relating to immunity from liability), a licensed professional counselor who participates in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs shall have immunity from civil and criminal liability that might result by reason of the licensed professional counselor's actions. For the purpose of any civil or criminal proceeding, the good faith of the licensed professional counselor shall be presumed. The Board will uphold the same good faith presumption in any disciplin-

ary proceeding that might result by reason of a licensed professional counselor's actions in participating in good faith in the making of a report, cooperating with an investigation, testifying in a proceeding arising out of an instance of suspected child abuse or the taking of photographs

§ 49.56. Confidentiality—waived.

To protect children from abuse, the reporting requirements of §§ 49.52—49.54 (relating to suspected child abuse-mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse-mandated reporting requirement) take precedence over the provisions of any client confidentiality, ethical principle or professional standard that might otherwise apply.

§ 49.57. Noncompliance.

- (a) Disciplinary action. A licensed professional counselor who willfully fails to comply with the reporting requirements in §§ 49.52—49.54 (relating to suspected child abuse—mandated reporting requirements; photographs, medical tests and X-rays of child subject to report; and suspected death as a result of child abuse—mandated reporting requirement) will be subject to disciplinary action under section 11 of the act (63 P. S. § 1911).
- (b) Criminal penalties. Under 23 Pa.C.S. § 6319 (relating to penalties for failure to report), a licensed professional counselor who is required to report a case of suspected child abuse who willfully fails to do so commits a summary offense for the first violation and a misdemeanor of the third degree for a second or subsequent violation.

[Pa.B. Doc. No. 06-2264. Filed for public inspection November 17, 2006, 9:00 a.m.]