Physician Assistant Scope of Practice; Practice Requirements; Supervision; Recordkeeping; Requirements for Issuing Medications; Eligibility for Licensure; License Renewal; License Reactivation; License Reinstatement; and Medical Malpractice Coverage


Adopted: February 14, 2018, by the State Board of Medical Examiners, J. Paul Carniol, M.D., F.A.C.S., President.

Filed: May 1, 2018, as R.2018 d.120, with non-substantial changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).
Summary of Public Comments and Agency Responses:

The official comment period ended October 20, 2017. The State Board of Medical Examiners (Board), Physician Assistant Advisory Committee (Committee), received comments from:

1. Rebecca Levy, Esq., on behalf of Summit Medical Group, P.A.;
2. Denise L. Sanders, Capehart Scatchard, Attorneys at Law; and

1. COMMENT: One commenter expressed support for the proposed amendments, repeals, and new rules to implement P.L. 2015, c. 224. The commenter stated that the law and the proposed rules revise the scope of practice for physician assistants, allowing physician assistants to practice to the fullest extent of their education and training, and best serve their patients in all practice settings.

RESPONSE: The Committee thanks the commenter for its support.

2. COMMENT: One commenter sought clarification whether if a single-specialty practice delegates the same tasks and the same protocols addressed in N.J.A.C. 13:35-2B.10(f)3 to all of its physician assistants, then N.J.A.C. 13:35-2B.10(f)1 would be satisfied by having only one delegation agreement that is signed by each physician assistant and each supervising physician. The commenter believes, for example, that if there are 15 physician assistants and 30 physicians in a practice and there is no variation in the terms of the delegation agreement for each physician assistant in the practice, one delegation agreement should cover all of the physician assistants and physicians in the practice. The commenter further stated that otherwise a practice would have to have 15 identical delegation agreements, with each one signed by the individual physician assistant and by all 30 individual doctors. The commenter believes that, as long as the delegating physicians and the physician assistants have each read the agreement, multiple agreements should not be necessary.

3. COMMENT: One commenter sought clarification as to what constitutes a "single-specialty practice." The commenter stated that the term should include a practice in which all physicians provide substantially
identical services, even if their board certifications are not identical. The commenter stated, for example, that a primary care practice should be treated as a "single-specialty practice" even though some of the practice sites will have a delegating physician who is a board-certified family practice physician and some of the practice sites have a delegating physician who is a board-certified internal medicine physician. The commenter further elaborated that, even if the practice physicians have different board certifications, if all physicians in the practice provide substantially identical services, the practice has standard protocols for its physician assistants that apply regardless of the supervising physician, and that do not vary from site-to-site, or amongst physician assistants, the practice should qualify as a "single-specialty practice" and have one "standard" delegation agreement that is signed by all supervising physicians. The commenter believes that this would alleviate the physicians from having to sign multiple agreements, on at least an annual basis, that do not vary and do not serve any clinical purpose tied to the added paperwork for both the practitioners and the Board.

RESPONSE TO COMMENTS 2 AND 3: Consistent with the statutory requirements of N.J.S.A. 45:9-27.17, proposed N.J.A.C. 13:35-2B.10(f) provides that a physician assistant shall sign a separate written delegation agreement with each supervising physician who delegates medical services. The statute and rule further provide that a written delegation agreement may be executed by a single-specialty physician practice, signed by all of the delegating physicians supervising the physician assistant. In addition, the statute and rule provide that, for a multi-specialty physician practice, a written delegation agreement may be executed for each physician specialty within the practice, provided it is signed by all of the delegating physicians supervising the physician assistant in that specialty area. As specifically set forth in N.J.S.A. 45:9-27.17.d and N.J.A.C. 13:35-2B.10(f)2, nothing shall authorize the execution of a global written delegation agreement between a physician assistant and a multi-specialty physician practice. A delegation agreement may be executed by multiple physician assistants and physicians, as long as they are all within the same single-specialty physician practice and the tasks delegated to the physician assistant are the same.

The Committee believes that determining whether a practice is deemed a single-specialty or multi-specialty is fact sensitive. The Committee, moreover, does not believe that the board certifications, if any, of the physicians in the practice, nor the commonality of the tasks delegated to a physician assistant, are sole determining factors.

4. COMMENT: One commenter recommended that the rules clarify that the Committee accepts electronic signatures on a delegation agreement.
RESPONSE: The Committee will accept electronic signatures on a delegation agreement. The Committee does not believe that it is necessary to amend the rules to provide clarification.

5. COMMENT: One commenter stated that it is supportive of many provisions within the rulemaking, and agrees that it will have a positive impact on both the general public, as well as physician assistants. The commenter also stated, however, that it believes that there are several proposed amendments that are not aligned with large physician practices and would be unduly burdensome to large multi-specialty private physician practices.

The commenter requested clarification that the supervisory ratio of no more than four physician assistants at any one time does not preclude a supervising physician from entering into delegation agreements with more than four physician assistants. The commenter recommended that the Committee amend N.J.A.C. 13:35-2B.10(c) to add:

"However, this shall not preclude a supervising physician from entering into delegation agreements with more than four (4) physician assistants, provided that no more than four (4) physician assistants are scheduled to be supervised by a single supervising physician at any one given time."

RESPONSE: The Committee agrees that the supervisory ratio of no more than four physician assistants at any one time does not preclude a supervising physician from entering into delegation agreements with more than four physician assistants. The Committee, upon adoption, will change N.J.A.C. 13:35-2B.10(c) to provide clarification.

6. COMMENT: One commenter expressed concern with the requirement at N.J.A.C. 13:35-2B.10(f)3iii to provide the Committee with a copy of each delegation agreement, which could consist of several pages, because it is contrary to its environmental goals to reduce paperwork and will result in reams of documents being sent to the Committee. The commenter noted that, historically, it has sent a summary letter to the Committee, which has been accepted by the Committee, in lieu of the provision of the full agreement. The commenter requested that the Committee change this requirement or, alternatively, for the Committee to consider an electronic option.

RESPONSE: Consistent with N.J.S.A. 45:9-27.17.d(3), the delegation requirement must be provided to, and kept on file by, the Committee. The Committee will accept the electronic submission of the delegation agreements.

Summary of Agency-Initiated Change:
The Board, as recommended by the Committee, and consistent with P.L. 2015, c. 224, upon adoption is deleting N.J.A.C. 13:35-2B.12(b)2, which requires a physician assistant to provide the supervising physician's full name on the prescription blank. P.L. 2015, c. 224 amended N.J.S.A. 45:9-27.19 to delete the requirement for a physician assistant to print on the order or prescription, the supervising physician's name. The removal of the requirement to provide the supervising physician's full name on the prescription blank will lessen the burden on both physician assistants and supervising physicians, without impacting the healthcare of patients.

**Federal Standards Statement**

A Federal standards analysis is not required because the adopted new rules, repeals, and amendments are governed by N.J.S.A. 45:1-7.1, 45:1-7.4, and 45:9-27.10 et seq., and are not subject to any Federal requirements or standards.

**Regulations**

**Full text** of the adopted new rules and amendments follows (additions to proposal indicated in boldface with asterisks *thus*; deletions from proposal indicated in brackets with asterisks *[thus]*):

**SUBCHAPTER 2B. LIMITED LICENSES: PHYSICIAN ASSISTANTS**

13:35-2B.1 Purpose and scope


(b) (No change.)

13:35-2B.2 Definitions

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

... "Physician assistant" means a health professional who meets the qualifications under P.L. 1991, c. 378 (N.J.S.A. 45:9-27.10 et seq.), and holds a current, valid license to practice as a physician assistant in this State.

...
"Supervising physician" means a plenary licensed physician in good standing who, pursuant to N.J.S.A. 45:9-27.18, engages in the supervision of physician assistants whose duties shall be encompassed by the supervising physician's scope of practice.

13:35-2B.3 Practice requirements

(a) A licensee may engage in clinical practice in any medical care setting provided that:

1. The licensee performs medical services within the physician assistant's education, training, and experience under the supervision of a physician pursuant to the provisions of N.J.A.C. 13:35-2B.10;

2. The licensee limits his or her practice to those procedures authorized pursuant to N.J.A.C. 13:35-2B.4 and any other procedures that are delegated to the physician assistant by the supervising physician pursuant to the provisions of N.J.A.C. 13:35-2B.10;

3. (No change.)

4. The licensee conspicuously wears an identification tag using the term "physician assistant" or the designation "PA-C" or "PA" whenever acting in that capacity; and

5. (No change.)

(b) The licensee shall file with the Committee a notification of his or her supervising physician(s) and the supervising physician's license number. The licensee shall report to the Committee any change in the supervising physician within 30 days of the change.

1. Submission to the Committee of the delegation agreement, in accordance with N.J.A.C. 13:35-2B.10(f), will satisfy the notification requirements of this subsection if the delegation agreement contains the name and license number of the supervising physician.

13:35-2B.4 Scope of practice

(a) A licensee who has complied with the provisions of N.J.A.C. 13:35-2B.3 may perform the following procedures on a discretionary and routine basis:

1.-4. (No change.)

5. Assisting a physician in the delivery of services to patients requiring continuing care in a private home, nursing home, extended care facility, private office practice, or other setting, including the review and monitoring of treatment and therapy plans; and
6. Referring patients to, and promoting their awareness of, health care facilities and other appropriate agencies and resources in the community.

(b) A licensee who has complied with the provisions of N.J.A.C. 13:35-2B.3 may perform the following procedures when performance of the procedure is delegated to the physician assistant by the supervising physician as authorized under (c) below or, in the absence of a delegation agreement, only when directed, ordered, or prescribed by the supervising physician:

1.-3. (No change.)

4. Writing prescriptions or ordering medications in an inpatient or outpatient setting in accordance with N.J.A.C. 13:35-2B.12;

5. Prescribing the use of patient restraints; and

6. In the operating room, assisting a supervising surgeon as a first assistant or as a second assistant when deemed necessary by the supervising surgeon and when a qualified assistant physician is not required by N.J.A.C. 13:35-4.1.

(c) A physician assistant may perform medical services beyond those explicitly authorized in this section, when such services are delegated by a supervising physician with whom the physician assistant has signed a delegation agreement pursuant to N.J.A.C. 13:35-2B.10. The procedures delegated to a physician assistant shall be limited to those customary to the supervising physician's specialty and within the supervising physician's and the physician assistant's competence and training.

(d) Notwithstanding (c) above, a physician assistant shall not be authorized to measure the powers or range of human vision, determine the accommodation and refractive states of the human eye, or fit, prescribe, or adapt lenses, prisms, or frames for the aid thereof. Nothing in this subsection shall be construed to prohibit a physician assistant from performing a routine visual screening.

[page=1370] 13:35-2B.5 Eligibility for licensure

(a) An applicant for licensure shall submit to the Board, with the completed application form, a Certification and Authorization Form for a Criminal History Background Check, and the required fee, evidence that the applicant:

1.-2. (No change.)

3. Has successfully completed an education program for physician assistants that is accredited by the Accreditation Review Commission on
Education for the Physician Assistant, Inc. (ARC-PA), or its predecessor or successor; and

4. Has passed the examination administered by the National Commission on Certification of Physician Assistants (NCCPA), or its successor.

(b) An applicant who submits satisfactory proof that he or she holds a current license, certification or registration to practice as a physician assistant in a state that has standards substantially equivalent to those of this State shall be deemed to satisfy the requirements set forth in (a)1 through 4 above.

13:35-2B.10 Supervision

(a) A physician assistant shall engage in practice only under the supervision of a physician.

(b) Supervision of a physician assistant shall be continuous but shall not be construed as necessarily requiring the physical presence of the supervising physician, provided that the supervising physician and physician assistant maintain contact through electronic or other means of communication.

(c) The supervisory ratio shall be no more than four physician assistants to one physician at any one time. Upon application to the Board, the Board may alter the supervisory ratios.

*1. The supervisory ratio shall not limit the number of physician assistants with whom a supervising physician may enter into a delegation agreement.*

(d) (No change.)

(e) It is the obligation of each supervising physician and physician assistant to ensure that:

1. The physician assistant's scope of practice is identified;

2. Delegation of medical tasks is appropriate to the physician assistant's level of competence;

3. The relationship of, and access to, the supervising physician is defined; and

4. A process for evaluation of the physician assistant's performance is established.

(f) A physician assistant shall sign a separate written delegation agreement with each supervising physician who delegates medical services in accordance with the provisions of N.J.A.C. 13:35-2B.4(c).
1. A written delegation agreement may be executed by a single-specialty physician practice, provided it is signed by all of the delegating physicians supervising the physician assistant.

2. In the case of a multi-specialty physician practice, a written delegation agreement may be executed for each physician specialty within the practice, provided it is signed by all of the delegating physicians supervising the physician assistant in that specialty area. Nothing in this section shall authorize the execution of a global written delegation agreement between a physician assistant and a multi-specialty physician practice.

3. The delegation agreement shall:

   i. State that the physician will exercise supervision over the physician assistant in accordance with the provisions of P.L. 1991, c. 378 (N.J.S.A. 45:9-27.10 et seq.), and this subchapter;

   ii. Be signed and dated annually by the physician and the physician assistant and updated as necessary to reflect any changes in the practice or the physician assistant's role in the practice;

   iii. Be kept on file at the practice site, be provided to the Physician Assistant Advisory Committee, and be kept on file by the Committee; and

   iv. At a minimum, include the following provisions:

      (1) The physician assistant's role in the practice, including any specific aspects of care that require prior consultation with the supervising physician;

      (2) A determination of whether the supervising physician requires personal review of all charts and records of patients and countersignature by the supervising physician of all medical services performed under the delegation agreement, including prescribing and administering medication as authorized under N.J.A.C. 13:35-2B.12. This provision shall state the specified time period in which a review and countersignature shall be completed by the supervising physician. If no review and countersignature is necessary, the agreement must specifically state such provision; and

      (3) The locations of practice where the physician assistant may practice under the delegation agreement, including licensed facilities in which the physician authorizes the physician assistant to provide medical services.

4. Notwithstanding this subsection, a supervising physician, in his or her discretion, may require a written delegation agreement with the physician assistant for all delegated medical services.
13:35-2B.11 Recordkeeping

(a) Licensees shall make contemporaneous, permanent entries into professional treatment records that shall accurately reflect the treatment or services rendered. To the extent applicable, professional treatment records shall reflect:

1.-6. (No change.)

7. Treatment ordered. If medications are ordered, the patient record shall include:

i. (No change.)

Recodify existing iii. and iv. as ii. and iii. (No change in text.)

(b) (No change.)

(c) The physician assistant shall sign each entry in the patient record and record the designation "PA-C," "PA," or use the term "physician assistant" following his or her signature.

(d) (No change.)

13:35-2B.12 Requirements for issuing prescriptions for medications; special requirements for issuance of CDS

(a) A physician assistant may order, prescribe, dispense, and administer medications and medical devices to the extent delegated by a supervising physician only in accordance with the requirements contained in this section.

(b) A physician assistant shall provide the following on all prescription blanks:

1. The physician assistant's full name, professional identification ("PA-C," "PA," or "physician assistant"), license number, address, and telephone number. This information shall be printed on all prescription blanks;

*[2. The supervising physician's full name, printed or stamped;]*

Recodify proposed 3.-10. as *2.-9.* (No change in text.)

(c) A physician assistant may order or prescribe controlled dangerous substances (CDS) if:

1. (No change.)

2. The physician assistant has registered with and obtained authorization to order or prescribe controlled dangerous substances
from the Federal Drug Enforcement Administration and any other appropriate State and Federal agencies; and

3. (No change.)

(d)-(e) (No change.)

(f) The dispensing of medication or a medical device by a physician assistant shall comply with relevant Federal and State rules and regulations, and shall occur only if:

1. Pharmacy services are not reasonably available;
2. It is in the best interest of the patient; or
3. The physician assistant is rendering emergency medical assistance.

(g) A physician assistant may request, receive, and sign for prescription drug samples and may distribute those samples to patients.

13:35-2B.13 (Reserved)

13:35-2B.14 License renewal

(a) The Board shall send a notice of renewal to each licensee, at least 60 days prior to the expiration of the license. The notice of renewal shall explain inactive renewal and advise the licensee of the option to renew as inactive. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew provided that the license is renewed within 60 days from the date the notice is sent or within 30 days following the date of license expiration, whichever is later.

(b) A licensee shall renew his or her license for a period of two years from the last expiration date. The licensee shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:35-6.13, prior to the date of license expiration.

(c) A licensee may renew his or her license by choosing inactive status. A licensee electing to renew his or her license as inactive shall not engage in the practice of a physician assistant, or hold herself or himself out as eligible to engage in the practice of a physician assistant, in New Jersey until such time as the license is returned to active status.

(d) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee, and a late fee as set forth in N.J.A.C. 13:35-6.13. During this 30-day
period, the license shall be valid and the licensee shall not be deemed practicing without a license.

(e) A licensee who fails to submit a renewal application within 30 days of license expiration shall have his or her license suspended without a hearing.

(f) A licensee who continues to engage in the practice of a physician assistant with a suspended license shall be deemed to be engaging in the unauthorized practice of a physician assistant and shall be subject to action consistent with N.J.S.A. 45:1-14 et seq. and N.J.S.A. 45:9-22, even if no notice of suspension has been provided to the individual.

13:35-2B.15 License reactivation

(a) A licensee who holds an inactive license pursuant to N.J.A.C. 13:35-2B.14(c) may apply to the Board for reactivation of the inactive license. A licensee seeking reactivation of an inactive license shall submit:

1. A renewal application;

2. A certification of employment listing each job held during the period the license was inactive, which includes the name, address, and telephone number of each employer;

3. The renewal fee for the biennial period for which reactivation is sought as set forth in N.J.A.C. 13:35-6.13.

i. If the renewal application is sent during the first year of the biennial period, the applicant shall submit the renewal fee as set forth in N.J.A.C. 13:35-6.13.

ii. If the renewal application is sent during the second year of the biennial period, the applicant shall submit one-half of the renewal fee as set forth in N.J.A.C. 13:35-6.13; and

4. Evidence of having completed all continuing education credits that were required to be completed during the biennial period immediately prior to the renewal period for which reactivation is sought, consistent with the requirements set forth in N.J.A.C. 13:35-2B.8.

i. An applicant who holds a valid, current license in good standing issued by another state to engage in the practice of a physician assistant and submits proof of having satisfied that state's continuing education requirements for that license, shall be deemed to have satisfied the requirements of (a)4 above. If the other state does not
have any continuing education requirements, the requirements of (a)4 above apply.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reactivation, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reactivation of the license. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant, as a condition of reactivation of licensure, to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the license subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the license. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of duration license was inactive;
2. Employment history;
3. Professional history;
4. Disciplinary history and any action taken against the applicant's license by any licensing board;
5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of a physician assistant or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or any other jurisdiction;
6. Pending proceedings against a professional or occupational license issued to the licensee by a professional board in New Jersey, any other state, the District of Columbia, or any other jurisdiction; and
7. Civil litigation related to the practice of a physician assistant or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or any other jurisdiction.

13:35-2B.16 License reinstatement

(a) A licensee who has had his or her license suspended pursuant to N.J.A.C. 13:36-2B.14(e) above may apply to the Board for reinstatement. A licensee applying for reinstatement shall submit:
1. A reinstatement application;

2. A certification of employment listing each job held during the period of suspended license, which includes the names, addresses, and telephone numbers, of each employer;

3. The renewal fee for the biennial period for which reinstatement is sought;

4. The past due renewal fee for the biennial period immediately preceding the renewal period for which reinstatement is sought;

5. The reinstatement fee set forth in N.J.A.C. 13:35-6.13; and

6. Evidence of having completed all continuing education credits that were required to be completed during the biennial period immediately prior to the renewal period for which reinstatement is sought, consistent with the requirements set forth in N.J.A.C. 13:35-2B.8.

   i. An applicant who holds a valid, current license in good standing issued by another state to engage in the practice of a physician assistant and submits proof of having satisfied that state's continuing education requirements for that license, shall be deemed to have satisfied the requirements of (a)6 above. If the other state does not have any continuing education requirements, the requirements of (a)6 above apply.

(b) If a Board review of an application establishes a basis for concluding that there may be practice deficiencies in need of remediation prior to reinstatement, the Board may require the applicant to submit to and successfully pass an examination or an assessment of skills, a refresher course, or other requirements as determined by the Board prior to reinstatement of the license. If that examination or assessment identifies deficiencies or educational needs, the Board may require the applicant, as a condition of reinstatement of licensure, to take and successfully complete any education or training or to submit to any supervision, monitoring, or limitations as the Board determines is necessary to assure that the applicant practices with reasonable skill and safety. The Board, in its discretion, may restore the license subject to the applicant's completion of the training within a period of time prescribed by the Board following the restoration of the license. In making its determination whether there are practice deficiencies requiring remediation, the Board shall consider the following non-exhaustive issues:

1. Length of duration license was suspended;

2. Employment history;
3. Professional history;

4. Disciplinary history and any action taken against the applicant's license by any licensing board;

5. Actions affecting the applicant's privileges taken by any institution, organization, or employer related to the practice of a physician assistant or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or any other jurisdiction;

6. Pending proceedings against a professional or occupational license issued to the licensee by a professional board in New Jersey, any other state, the District of Columbia, or any other jurisdiction; and

7. Civil litigation related to the practice of a physician assistant or other professional or occupational practice in New Jersey, any other state, the District of Columbia, or any other jurisdiction.

13:35-2B.17 Medical malpractice coverage; letter of credit

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

"Authorized" means recognized by a governmental agency to offer medical malpractice insurance products.

"Covered" means ongoing maintenance of insurance in the sum of $1 million per occurrence and $3 million dollars per policy year, with extended reporting endorsement coverage for claims made (tail coverage) issued by a carrier or other entity authorized to write medical malpractice policies.

"Letter of credit" means a non-assignable, non-transferable, unexpired, continuous irrevocable obligation, liability bond, or other instrument issued by a bank or saving association authorized to do business in this State, payable to the physician assistant as the beneficiary within 30 days after a demand for payment and the presentation of a final judgment or settlement in a medical malpractice action.

"Not available" means that a physician assistant is unable to purchase medical malpractice insurance coverage from a carrier authorized to write medical malpractice insurance, including through programs relating to risk retention groups deemed eligible by the Department of Banking and Insurance, surplus lines registered with the Department of Banking and Insurance, self-insurance trusts, or captive insurance companies approved by the New Jersey Health Care Facilities Financing
Authority in the Department of Health. "Not available" for purposes of this section does not mean "not affordable."

(b) A physician assistant licensed to practice in this State who engages in clinical practice shall be covered by medical malpractice liability insurance or, if medical malpractice liability insurance is not available, shall secure and maintain a letter of credit in the sum of at least $500,000 or more.

(c) A physician assistant who is not covered by medical malpractice insurance shall present to the Board a true copy of the letter of credit required pursuant to (b) above and shall notify the Board, within seven days, whenever:

1. A demand for payment on the letter has been made; or

2. The continuing viability of the letter has been affected, for whatever reason.

(d) A physician assistant who practices in violation of this rule shall be deemed to have engaged in professional misconduct within the meaning of N.J.S.A. 45:1-21.e and shall be subject to disciplinary action and civil penalties pursuant to N.J.S.A. 45:1-21, 45:1-22, and 45:1-25.