

55 N.J.R. 67(a)

VOLUME 55, ISSUE 1, JANUARY 3, 2023

RULE ADOPTIONS

Reporter

55 N.J.R. 67(a)

NJ - New Jersey Register > 2023 > JANUARY > JANUARY 3, 2023 > RULE ADOPTIONS > LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS

Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF MEDICAL EXAMINERS

Administrative Code Citation

Adopted New Rule: N.J.A.C. 13:35-6.20A

Text

Radiologist Assistant Performing Procedures

Proposed: December 6, 2021, at 53 N.J.R. 1982(a).

Adopted: June 8, 2022, by the State Board of Medical Examiners, Otto F. Sabando, D.O.

Filed: November 28, 2022, as R.2023 d.001, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3) **and with N.J.A.C. 13:35-6.20A(c)2xii, (c)2xiii, (c)6viii, (c)6x, (d), and (e) not adopted.**

Authority: N.J.S.A. 45:9-2.

Effective Date: January 3, 2023.

Expiration Date: April 3, 2025.

Summary of Public Comments and Agency Responses:

The official comment period ended February 4, 2022. The State Board of Medical Examiners (Board) received comments from the following individuals:

1. John Gravelli, ASRT, RT/RRA
2. Stacey Gravelli, BSN, RN, CRN, Department of Nursing, Clinical Nurse III, Radiology MSK Monmouth
3. Robert W. Evers, RTR, MR, CV, CT, Board Eligible Radiologist Assistant
4. Taylor Merriman, B.S. R.T. (R) (CT) (AART), Interventional Radiologic Technologist, Radiologist Assistant Student--Rutgers University
5. Vicki Dillard, MSRS, RRA, RT(R) (CV) (CT), Associate Professor, RA Program Clinical Coordinator, Shimadzu School of Radiologic Sciences
6. Rajiv Biswal, MD, University Radiology
7. Murina Sahadeo, RRA RT(R) (CT), Department of Interventional Radiology, New York Presbyterian
8. Chirag Patel, BSRS, RT(R) (MR) (CT)
9. Raquel Perez, M.S., R.R.A., (M) (RT) (ARRT)
10. Gladys Montane, Ed.D., R.T., (R) (M), Dept. of Clinical Laboratory and Medical Imaging Sciences, Director of the B.S. in Radiologic Imaging Modalities Radiologic Imaging Modalities Certificate & M.S Radiologist Assistant Program, Rutgers University-School of Health Professions
11. David Hardwick, MSRS, RRA, RPA, RT, R, President, Society of Radiology Physician Extenders
12. Jerry B. Reid, Ph.D., Executive Director, American Registry of Radiologic Technologists
13. John D. Fanburg, Brach, Eichler, LLC

1. COMMENT: Several commenters support the adopted new rule. Two of the commenters contend that the adopted new rule will assist the radiology community by permitting radiologists to focus on areas needing more expertise while allowing qualified individuals to perform routine tasks. Another commenter supports provisions in the new rule that create three levels of supervision for radiologist assistants. This commenter also supports the requirement that a licensed radiologist assess a radiologist assistant's competency prior to directing the radiologist assistant to perform a procedure and the provision

requiring radiologist assistants to be certified in Advanced Cardiovascular Life Support.

RESPONSE: The Board thanks the commenters for their support.

2. COMMENT: A commenter notes that the Board's summary of the notice of proposal indicated that the proposed rule would prohibit licensed radiologist assistants from performing some procedures that carry risks of bleeding and infection. According to the commenter, the majority of procedures that radiologist assistants are trained to perform carry the risk of bleeding and infection. Thus, the commenter believes that forbidding radiologist assistants from performing certain procedures due to the risk of bleeding and infection is inappropriate. The commenter asks the Board to investigate the prevalence of bleeding and infection for the prohibited procedures and compare that risk to other procedures that radiologist assistants are permitted to perform. The commenter contends that radiologist assistants should not be prohibited from performing procedures for which they have the requisite training without scientific backing.

RESPONSE: The commenter is correct that the summary of the notice of proposal indicated that two prohibited procedures, hysterosalpingogram procedures and imaging and antegrade pyelogram, carry the risk of infection. In addition, the Summary of the notice of proposal indicated that antegrade pyelogram carries a risk of bleeding. While the commenter may be correct that the majority of procedures that a radiologist assistant is trained to perform may carry the risk of bleeding and infection, the risks associated with hysterosalpingogram procedures and imaging and antegrade pyelograms are elevated and, as the Board discussed in the Summary of the notice of proposal, such procedures should only be performed by a physician.

3. COMMENT: Several commenters contend that radiologist assistants are trained to perform procedures using computerized tomography (CT) and ultrasound guidance. The commenters recognize that radiologist assistants do not receive training in interpreting imaging, but they maintain that radiologist assistants receive training on anatomy and pathology seen in different imaging modalities.

RESPONSE: P.L. 2017, c. 281, sets forth the procedures that a radiologist assistant may perform under the supervision of a licensed radiologist. The law allows radiologist assistants to perform "delegated fluoroscopic procedures." Performing procedures with CT or ultrasound guidance is not included in the statutory definition of "delegated fluoroscopic procedures." As the commenters recognize, radiologist assistants do not receive training in interpreting imaging and the rule does not permit

radiologist assistants to perform procedures which require the reading of a CT scan or ultrasound image.

4. COMMENT: The Summary of the notice of proposal stated that radiologist assistants are not permitted to perform hysterosalpingogram procedures and imaging; antegrade pyelogram; lumbar puncture with contrast; myelogram; and tunneled and non-tunneled chest and abdominal drainage catheters. A commenter supports this position and recommends that these prohibitions be incorporated as a new provision at N.J.A.C. [page=68] 13:35-6.20A. The commenter further recommends that tunneled central venous catheters and tunneled peripherally inserted central venous catheters be added to the list of prohibited procedures for radiologist assistants. The commenter contends that these procedures require the specialized education and experience of a physician.

RESPONSE: The Board thanks the commenter for their support. The Board points out that N.J.A.C. 13:35-6.20A sets forth all of the procedures that a radiologist may authorize a radiologist assistant to perform. Pursuant to N.J.S.A. 45:9-2.1, radiologist assistants may perform delegated fluoroscopic procedures only if the procedures are authorized by the Board; such authorizations are found at N.J.A.C. 13:35-6.20A. They are, therefore, prohibited from performing the procedures addressed in the Summary of the notice of proposal. However, the Board recognizes that, as these procedures are listed in the statutory definition of "delegated fluoroscopic procedures," there may be confusion if the rules do not address these procedures. The Board will consider this matter further and, if it determines that it is necessary to clarify that radiologist assistants are not permitted to perform these procedures, it will explicitly prohibit them in a future rulemaking. The Board agrees that tunneled venous catheters and tunneled peripherally inserted central venous catheters should not be performed by radiologist assistants. Accordingly, these procedures were not included at N.J.A.C. 13:35-6.20A. The Board's consideration as to whether to prohibit radiologist assistants from performing specific procedures will include discussion as to whether it is necessary to address tunneled venous catheters and tunneled peripherally inserted central venous catheters.

5. COMMENT: Several commenters contend that the list of procedures at N.J.A.C. 13:35-6.20A was taken from an organizational document used to develop testing requirements and that this document should not be used to establish a scope of practice for radiologist assistants. The commenters contend that the procedures that were excluded from the rule (hysterosalpingogram procedure and imaging; antegrade pyelogram; lumbar puncture with contrast; myelogram; and tunneled and non-tunneled chest and abdominal drainage catheters) are taught in

radiologist assistant programs and, therefore, should not be prohibited. In particular, lumbar puncture and myelogram are procedures that a student must perform to be eligible for the certification examination.

RESPONSE: The list of procedures at N.J.A.C. 13:35-6.20A was not taken from an organizational document. This list was taken from the definition of "delegated fluoroscopic procedures" at P.L. 2017, c. 281. This definition was meant to establish the scope of practice for radiologist assistants, to the extent that the procedures were "approved by the State Board of Medical Examiners." As explained in the notice of proposal, the Board has reviewed the procedures included in the definition of "delegated fluoroscopic procedures," and has determined that the five procedures identified by the commenters cannot be safely and effectively performed by radiologist assistants, regardless of their education and training.

6. COMMENT: A commenter states that N.J.A.C. 13:35-6.20A only recognizes fluoroscopic procedures. The commenter contends that, during clinical education as a radiologist assistant, the commenter completed procedures that do not fall within the definition of fluoroscopic procedures, including ultrasound-guide biopsies, paracentesis, thoracentesis, and joint injections pursuant to CT guidance. The commenter recommends that the rule be amended to include any imaging modality.

RESPONSE: As discussed in the response to other comments, P.L. 2017, c. 281, limits radiologist assistants to performing "delegated fluoroscopic procedures." The Board does not have the power to exceed that statutory authority, as the commenter recommends.

7. COMMENT: Several commenters recommend that the Board not adopt N.J.A.C. 13:35-6.20A(c), which sets forth the list of procedures that a radiologist may direct a radiologist assistant to perform and the supervision required for these procedures; N.J.A.C. 13:35-6.20A(d), which allows a radiologist to direct radiologist assistants to perform additional specific procedures after the radiologist notifies the Board that the radiologist assistant will be performing such procedures; and N.J.A.C. 13:35-6.20A(e), which sets forth the information which must be included in the notification required at subsection (d). Several commenters also recommended that the Board amend N.J.A.C. 13:35-6.20A(b) to remove the reference to subsections (c) and (d). This rule allows a licensed radiologist to direct a radiologist assistant to perform tasks as long as the licensed radiologist certifies that the radiologist assistant is competent to perform the task, the licensed radiologist is responsible for the choice of and ordering of pharmaceuticals and contrast materials, and the radiologist assistant is certified in Advanced

Cardiovascular Life Support (ACLS) by the American Heart Association. The rule also requires that, if the patient is a child, the licensed radiologist have pediatric experience. The commenters contend that the list of permissible procedures a radiologist assistant is authorized to perform will change as practice needs or education requirements change. The commenters contend that a radiologist assistant should be permitted to perform any tasks that the radiologist assistant and a licensed radiologist agree the assistant can perform. Some of the commenters argue that hospital credentialing boards should be authorized to establish the procedures radiologist assistants can perform. The commenters maintain that there are some procedures that cannot be performed by radiologist assistants and recommend that N.J.A.C. 13:35-6.20A(b) be amended to prohibit radiologist assistants from performing the final interpretation of images and from prescribing medications or therapies.

RESPONSE: As discussed in the responses to other comments, the procedures that a radiologist assistant may perform are set forth in the definition of "delegated fluoroscopic procedures" at P.L. 2017, c. 281. The Board proposed N.J.A.C. 13:35-6.20A to effectuate this statutory provision. The commenters' recommended amendments do not comport with P.L. 2017, c. 281. Allowing a radiologist assistant to perform any procedure a radiologist or hospital credentialing board deems appropriate would violate the strictures of the statute. The Board agrees that radiologist assistants are not permitted to perform the final interpretation of images or prescribe medications or therapies, nor can they perform any other procedure that is not enumerated at N.J.A.C. 13:35-6.20A.

8. COMMENT: N.J.A.C. 13:35-6.20A(b)1 requires a radiologist, or another plenary-licensed physician, or the head of the pertinent department in a licensed health care facility, to personally certify and document that a radiologist assistant is competent to perform a procedure. A commenter recommends that the process for certifying and documenting competency be formalized. According to the commenter, the Board should require a radiologist to establish written policies and procedures specifying the criteria for determining if a radiologist assistant is competent to perform procedures. These policies and procedures should include a process for re-evaluating competency and a requirement that radiologist assistants engage in activities to maintain competency.

RESPONSE: The Board believes that a radiologist should be able to determine the procedures at N.J.A.C. 13:35-6.20A that a radiologist assistant can perform safely and effectively. The Board does not believe that these determinations would be made more efficiently or accurately if the rule were amended as the

commenter recommends. If a radiologist deems it necessary to establish written policies and procedures, which include re-evaluation of competency and a requirement that radiologist assistants engage in activities to maintain competency, a radiologist is free to institute such policies and procedures. The Board believes that requiring this level of oversight of radiologists is unnecessary and would prove burdensome for radiologists.

9. COMMENT: A commenter recommends that the Board propose a new rule that would require radiologist assistants to complete continuing education. The commenter notes that Texas, Connecticut, Florida, and Massachusetts impose continuing education requirements for radiologist assistants.

RESPONSE: The Board points out that the Radiologic Technology Board of Examiners in the New Jersey Department of Environmental Protection has authority over licensure requirements for radiologist assistants, such as the continuing education requirements recommended by the commenter. The Board has the power to regulate a radiologist's decision to delegate a task to a radiologist assistant, but the power to set licensing requirements for radiologist assistants lies with the Department of Environmental Protection pursuant to N.J.S.A. 26:2D-29. The Board also notes that there is no statutory requirement for radiologist assistants to complete continuing education in order to maintain licensure.

10. COMMENT: Two commenters contend that the list of procedures a radiologist assistant may perform should be expanded, as radiologist [page=69] assistants perform a variety of procedures under the supervision of radiologists. One of the commenters contends that the list of procedures at N.J.A.C. 13:35-6.20A does not include all of the procedures on which radiologist assistants are educated and tested. The commenter recognizes that radiologist assistants do not receive education on reading or interpreting images, but contends that they do receive training in anatomy, pathology, and pathophysiology.

RESPONSE: As discussed in the responses to other comments, the procedures that a radiologist assistant may be authorized to perform are established by the definition of "delegated fluoroscopic procedures" at P.L. 2017, c. 281, and subject to approval by the Board. As this list of procedures is set by statute, it cannot be expanded by rule as the commenters recommend, regardless of the training radiologist assistants complete.

11. COMMENT: N.J.A.C. 13:35-6.20A(c)2vii, xii, and xiii permit a radiologist to direct a radiologist assistant to perform specific procedures under general supervision. General supervision requires a procedure to be performed under a

radiologist's direction and control but does not require the radiologist's presence in the office suite or department when the procedure is performed. The specific procedures covered by these rules include recognizing and responding to medical emergencies; administering contrast agents as prescribed by the licensed radiologist; and administering general medications, except for oral medications and radiopharmaceuticals and sedating medications, as prescribed by a licensed radiologist. A commenter contends that a radiologist assistant is not competent to handle the potential complications related to these procedures without a physician on-site and recommends that N.J.A.C. 13:35-6.20A be amended so that a radiologist assistant may perform these procedures only under direct supervision, which requires the presence of a supervising radiologist in the office suite or department where a procedure is performed.

RESPONSE: The Board believes that radiologist assistants are trained to recognize and respond to medical emergencies, and should be authorized to do so when performing procedures that otherwise require general supervision, as it would not be in the best interests of patient safety to require that any such emergency response be deferred, pending the arrival of an otherwise qualified responding provider. Further, the Board is satisfied that the procedures that radiologist assistants are authorized to perform under general supervision are procedures that do not have heightened risk levels that would support the Board's requiring that the procedures only be performed under direct supervision. The Board has reviewed the tasks involved in administering general medications and administering contrast agents and agrees that there are concerns as to whether radiologist assistants can safely perform these procedures without a radiologist being present on-site. The Board will review this matter further and determine whether N.J.A.C. 13:35-6.20A(c)2xii and xiii should be changed to require direct supervision in a future rulemaking. At this time, the Board is not adopting N.J.A.C. 13:35-6.20A(c)2xii and xiii.

12. COMMENT: N.J.A.C. 13:35-6.20A(c)6viii permits a radiologist to direct a radiologist assistant to perform a retrograde urethrogram under direct supervision. The rule prohibits a radiologist assistant from placing a suprapubic catheter. A commenter recommends that N.J.A.C. 13:35-6.20A(c)6viii be deleted and N.J.A.C. 13:35-6.20A(c)6vi be amended to refer to urethrogram. The commenter's recommended amendment at N.J.A.C. 13:35-6.20A(c)6vi would read: "Cystogram and urethrogram, except that a radiologist assistant shall not place a suprapubic catheter." The commenter contends that all urethrograms should be subject to direct supervision, not just retrograde urethrograms. The commenter also contends that retrograde urethrograms are never performed with suprapubic catheters and

the limitation at N.J.A.C. 13:35-6.20A(c)6viii is, therefore, unnecessary.

RESPONSE: N.J.A.C. 13:35-6.20A(c)6viii permits a radiologist assistant to perform retrograde urethrograms pursuant to a radiologist's direct supervision. N.J.A.C. 13:35-6.20A does not allow radiologist assistants to perform any other kind of urethrograms. Changing N.J.A.C. 13:35-6.20A(c)6vi as the commenter recommends would extend the procedures that radiologist assistants may perform, and the Board does not believe that radiologist assistants can safely and effectively perform any kind of urethrogram other than a retrograde urethrogram. The Board believes that retrograde urethrograms carry fewer risks than other kinds of urethrograms, and that other kinds of urethrograms must, therefore, be performed by a radiologist. However, the Board believes there may be some value to combining provisions regarding cystograms and retrograde urethrograms, and the Board agrees with the commenter that retrograde urethrograms are not performed with suprapubic catheters. The Board will review whether it is necessary to combine the provisions regarding cystograms and retrograde urethrograms into one provision and, if it determines that such a combination is appropriate, it will amend N.J.A.C. 13:35-6.20A at a future date. At this time, the Board is not adopting proposed N.J.A.C. 13:35-6.20A(c)6viii.

13. COMMENT: N.J.A.C. 13:35-6.20A(c)6x permits a radiologist to direct a radiologist assistant to perform a fistulogram/sonogram under direct supervision. A commenter recommends that this rule be amended to remove "sonogram." The commenter contends that fistulograms are not performed with sonograms and that radiologist assistants should not be permitted to perform all sonograms, but rather only those sonograms specifically identified at N.J.A.C. 13:35-6.20A.

RESPONSE: N.J.A.C. 13:35-6.20A(c)6x is the only provision at N.J.A.C. 13:35-6.20A that authorizes a radiologist assistant to perform sonograms. The Board will review this provision further to determine if it is appropriate to remove reference to sonograms, as the commenter recommends, in a future rulemaking. At this time, the Board is not adopting proposed N.J.A.C. 13:35-6.20A(c)6x.

14. COMMENT: Two commenters recommend that N.J.A.C. 13:35-6.20A(c)6xiv be amended to permit a radiologist assistant to place a catheter. As proposed, the rule allows a radiologist assistant to monitor paracentesis and thoracentesis with appropriate imaging after a catheter has been placed by a radiologist. The commenters note that radiologist assistant students must complete a minimum of 20 thoracenteses and 10 paracenteses to qualify for the certification examination. The

commenters contend that if a radiologist determines that a radiologist assistant is competent to perform these procedures, the Board should not limit radiologist assistants to monitoring paracentesis and thoracentesis after a catheter has been placed by a radiologist.

RESPONSE: The Board does not believe that a radiologist assistant has the education or training to safely and effectively place a catheter. The Board will not change N.J.A.C. 13:35-6.20A as the commenters recommend.

15. COMMENT: N.J.A.C. 13:35-6.20A(c)7i and ii allow radiologist assistants to perform joint injections and arthrograms pursuant to the personal supervision of a radiologist. Personal supervision requires the presence of the supervising radiologist in the room where a procedure is being performed. Two commenters note that radiologist assistants must perform at least 20 arthrograms, 10 joint injections, and 10 aspirations to qualify to take the certification examination. The commenters believe that these procedures have a low risk of injury and one of the commenters contends that these procedures are performed by other health care providers without imaging guidance. Accordingly, the commenters recommend that N.J.A.C. 13:35-6.20A(c)7i and ii be amended so that radiologists assistants may perform these procedures pursuant to the direct supervision of a radiologist, which requires the presence of the supervising radiologist in the office suite or department where a procedure is being performed, but does not require the presence of the supervisor in the room where a procedure is being performed.

RESPONSE: The Board does not believe that radiologist assistants have the level of education or training in the area of performing joint injections and aspirations or arthrograms to allow these procedures to be performed pursuant to anything but direct supervision, which requires the presence of a supervising radiologist in the room when these procedures are being performed.

16. COMMENT: Several commenters contend that radiologist assistants should be permitted to perform any procedure that a supervising radiologist determines they are competent to perform. As all procedures must be supervised by a radiologist, the radiologist should determine whether a radiologist assistant can perform a task based on training, the complexity of the procedure, and a patient's status. One of the commenters recommends that N.J.A.C. 13:35-6.20A(d) be amended to read: "After providing written notification to the Board as required by (e) below and receiving confirmation from the Board that the information has been reviewed, a licensed radiologist may direct a radiologist assistant to [page=70] perform procedures pursuant to supervision from the licensed radiologist."

RESPONSE: The scope of procedures that a radiologist assistant may be authorized to perform is established by the definition of "delegated fluoroscopic procedures" at P.L. 2017, c. 281, and subject to approval by the Board. The Board does not have the authority to change N.J.A.C. 13:35-6.20A to expand the scope of procedures that a radiologist assistant may perform beyond those identified in the statutory definition of "delegated fluoroscopic procedures."

17. COMMENT: N.J.A.C. 13:35-6.20A(d) sets forth procedures that a radiologist may direct a radiologist assistant to perform only after notifying the Board and receiving confirmation that the Board has received notification. A commenter recommends that this provision be amended to require a radiologist to provide either direct or personal supervision when a radiologist assistant performs any of these procedures. The commenter contends that the risks associated with the procedures identified in the rule necessitate the presence of the supervising radiologist on-site when the procedures are performed by a radiologist assistant.

RESPONSE: When the Board voted to propose N.J.A.C. 13:35-6.20A, the version approved by the Board required that any procedure listed at N.J.A.C. 13:35-6.20A(d) be performed pursuant to the personal supervision of a radiologist. The procedures listed at N.J.A.C. 13:35-6.20A(d) are of a nature that involve increased risk for patients and can only be safely and effectively performed by a radiologist assistant when a radiologist is present in the room when the procedure is being performed. This requirement was left out of N.J.A.C. 13:35-6.20A(d), as published in the New Jersey Register, due to an administrative mistake. The Board is not adopting N.J.A.C. 13:35-6.20A(d) at this time. The Board will publish a notice of proposal in the future that will set forth the provisions at N.J.A.C. 13:35-6.20A(d) with the supervision requirements it intended to propose when it approved the rulemaking. N.J.A.C. 13:35-6.20A(e) explains the notification process required at subsection (d). As the Board is not adopting subsection (d) at this time, subsection (e) will also be part of a future rulemaking and is not being adopted at this time.

18. COMMENT: A commenter observes that the American Registry of Radiologist Technologists (ARRT) requires radiologist assistants to undergo academic and clinical training in performing lumbar punctures, peripherally inserted central catheter (PICC) placements, non-tunneled central line placement, and venous catheter placement for dialysis or breast needle localizations. The commenter asks if any Board members have worked with radiologist assistants prior to determining that these procedures are too risky for radiologist assistants to perform. The commenter contends that radiologist assistants help with

efficiency and workflow, so that radiologists may focus on reading the results of radiologic testing. The commenter recommends that the Board revise N.J.A.C. 13:35-6.20A so that radiologist assistants may perform the procedures for which the ARRT requires them to undergo academic and clinical training.

RESPONSE: The Board points out that N.J.A.C. 13:35-6.20A(c)6xiii recognizes that radiologist assistants can perform peripherally inserted central catheter (PICC) placement. Pursuant to proposed N.J.A.C. 13:35-6.20A(d), if a radiologist provides notice to the Board, the radiologist may direct a radiologist assistant to perform non-tunneled venous central line placement in the femoral vein and venous catheter placement for dialysis. As discussed in the responses to other comments, the Board is not adopting N.J.A.C. 13:35-6.20A(d) at this time, but a future rulemaking will include the provisions regarding non-tunneled central line placement and venous catheter placement. The Board does not believe that radiologist assistants have the education or training to safely perform lumbar punctures and the Board will not change N.J.A.C. 13:35-6.20A to allow radiologist assistants to perform this procedure. The Board has reviewed breast needle localization procedures and is concerned that these procedures require the education and training of a physician and should not be performed by a radiologist assistant. The Board will consider whether breast needle localization should be removed from proposed N.J.A.C. 13:35-6.20A(d) when this provision is proposed at a future date.

19. COMMENT: A commenter points out that N.J.A.C. 13:35-6.20A(d) requires licensed radiologists to provide written notification to the Board if they intend to direct a radiologist assistant to perform specific procedures. The commenter notes that the ARRT establishes the minimum number of procedures a radiologist assistant must perform during training. According to the commenter, a CR-2 evaluation attestation form documents that a student has completed the required number of procedures. The commenter recommends that this form, along with a radiologist assistant obtaining national registration, should be the written notification provided to the Board.

RESPONSE: As discussed in the response to other comments, the Board is not adopting N.J.A.C. 13:35-6.20A(d) and (e) at this time, but the Board disagrees that the documentation recommended by the commenter would satisfy the requirements at N.J.A.C. 13:35-6.20A(e). The documentation identified by the commenter would be issued to every radiologist assistant, meaning that any radiologist assistant could perform the procedures listed at N.J.A.C. 13:35-6.20A(d). The procedures listed at N.J.A.C. 13:35-6.20A(d) are procedures that require specialized abilities on the part of a radiologist assistant due to the increased level of risk associated with these procedures. The requirement

at N.J.A.C. 13:35-6.20A(e) that radiologists notify the Board whenever they intend to direct a radiologist assistant to perform the designated procedures will help ensure that radiologists delegate only those procedures that radiologist assistants are competent to perform.

20. COMMENT: N.J.A.C. 13:35-6.20A(d)iii allows a radiologist assistant to perform venous catheter placement for dialysis if a licensed radiologist provides written notification to the Board. A commenter recommends that N.J.A.C. 13:35-6.20A(d)iii be amended to read: "Non-tunneled venous catheter placement for dialysis." The commenter contends that radiologist assistants should not be permitted to perform tunneled venous catheter procedures, as such procedures require the specialized education and experience of a physician.

RESPONSE: The Board is not adopting N.J.A.C. 13:35-6.20A(d) at this time. However, the Board agrees that venous catheter placement for dialysis is a procedure that involves increased levels of risk for a patient. That is why such procedures must be performed pursuant to the personal supervision of a radiologist and only after a radiologist has informed the Board that the radiologist assistant will perform the procedure. The Board does not believe that tunneled venous catheter procedures are so risky that radiologist assistants could not perform them. Accordingly, the Board will not change N.J.A.C. 13:35-6.20A(d)iii as the commenter recommends.

21. COMMENT: A commenter contends that nurse practitioners, with the proper education, are allowed to perform certain radiographic examinations. The commenter argues that nurse practitioners and physician assistants should not be allowed to perform radiographic procedures and that, if they are allowed to do so, radiologist assistants should be granted reciprocity and allowed to perform procedures that fall within a nurse practitioner's or physician assistant's scope of practice.

RESPONSE: The practices of nurse practitioners and physician assistants are not the subject of this rulemaking. The Board does not believe that the scope of practice of nurse practitioners and physician assistants is relevant to whether radiologist assistants are equipped to perform a given procedure safely and effectively.

Agency-Initiated Changes upon Adoption:

The Board has reviewed N.J.A.C. 13:35-6.20A(b)1, which requires a licensed radiologist or another plenary-licensed physician in the office, or the head of the pertinent department in a licensed health care facility, to certify and document that a radiologist assistant has the training and competency necessary to perform a task prior to directing the radiologist assistant

to perform the task. The Board believes that the process for determining if it is appropriate for a radiologist assistant to perform a specific procedure requires a familiarity and understanding of radiologic procedures that only a radiologist will have. To allow another plenary-licensed physician or the head of a department to make such determinations would harm the health, safety, and welfare of patients who could receive delegated fluoroscopic procedures from radiologist assistants who are not capable of providing such procedures in a safe and effective manner. In order to protect the health, safety, and welfare of patients who are the recipients of procedures performed by radiologist assistants, the Board has changed N.J.A.C. 13:35-6.20A(b)1 upon adoption so that a radiologist will be the only individual who can certify and document a radiologist assistant's competency to perform a task. As the change upon adoption removes reference to "licensed health care [page=71] facility," the Board will change the rule to clarify that a later reference to "facility" is a "licensed health care facility."

Federal Standards Statement

A Federal standards analysis is not required because there are no Federal laws or standards applicable to the adopted new rule.

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

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35-6.20A Radiologist assistant performing procedures

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

"Direct supervision" means that a licensed radiologist must be present in the office suite or department and immediately available to furnish assistance and direction throughout the performance of a procedure, but the licensed radiologist is not required to be present in the room when the procedure is performed.

"General supervision" means that a procedure is performed under a licensed radiologist's direction and control, but the licensed radiologist's presence in the office suite or department is not required during the performance of the procedure.

"Licensed radiologist" means a radiologist as the term is defined at N.J.S.A. 26:2D-26.

"Personal supervision" means that the licensed radiologist must be present in the room during the performance of a procedure.

"Radiologist assistant" means a radiologic technologist licensed by the New Jersey Radiologic Technology Board of Examiners who is certified and registered with a national radiologic certifying body approved by the New Jersey Radiologic Technology Board of Examiners and is credentialed to provide primary advanced-level radiology health care under the supervision of a licensed radiologist.

(b) A licensed radiologist may direct a radiologist assistant to perform the tasks set forth at (c) *[and (d)]* below provided that:

1. The licensed radiologist *[(or another plenary-licensed physician in the office, or in a licensed health care facility, the head of the pertinent Department)]* has personally certified and documented the radiologist assistant's training and competency to perform the task. The documents shall be preserved in the personnel record and retained for at least the duration of such radiologist assistant's employment by or for that licensed radiologist or ***licensed health care*** facility;

2. The licensed radiologist is responsible for the choice and ordering of all pharmaceuticals and contrast materials and for the determination of dosage and route of administration;

3. For pediatric patients, the licensed radiologist shall have experience in the performance of the pertinent procedures with such patients; and

4. The licensed radiologist is currently certified in and has verified that the radiologist assistant is currently certified in Advanced Cardiovascular Life Support (ACLS) by the American Heart Association.

(c) A licensed radiologist may direct a radiologist assistant to:

1. Under general supervision, obtain the clinical history and physical examination of the patient by:

i. Reviewing the patient's medical record to verify the appropriateness of a specific exam or procedure;

ii. Interviewing the patient to obtain, verify, or update medical history;

iii. Explaining a procedure to the patient or significant other of the patient, including a description of the risks, benefits, alternatives, and follow-up care;

iv. Obtaining informed consent, as long as the patient is provided the opportunity to communicate with the licensed radiologist if the patient has any questions;

v. Determining if the patient has followed instructions in preparation for the exam, such as diet and pre-medications;

vi. Assessing risk factors that may be contraindications to the procedure, such as health history, medications, pregnancy, psychological indicators, and alternative medicines and informing the licensed radiologist of the findings;

vii. Obtaining and evaluating vital signs;

viii. Performing the physical examination of the patient and analyzing data, such as signs and symptoms, laboratory values, and significant abnormalities, provided that the licensed radiologist reviews all reported data prior to a procedure being performed; and

ix. Participating in quality improvement activities;

2. Under general supervision, perform the following general procedures:

i. Applying electrocardiography (ECG) leads and recognizing life threatening ECG abnormalities;

ii. Performing urinary catheterization, except for instances where there is a known anatomic anomaly or recent surgery to this area;

iii. Performing venipuncture;

iv. Monitoring intravenous (IV) for flow rate and complications;

v. Positioning patient to perform required procedures, using immobilization devices and modifying technique, as necessary;

vi. Assessing patient's vital signs, levels of anxiety, and pain, informing the licensed radiologist, when appropriate, and bringing to the patient's physician any issues of concern;

vii. Recognizing and responding to medical emergencies, such as drug reactions, cardiac arrest, and hypoglycemia, and activating emergency response systems, including notification of the licensed radiologist;

viii. Administering oxygen, as prescribed;

ix. Operating a fixed or mobile fluoroscopic unit;

x. Assuring documentation of fluoroscopy time; ***and***

xi. Explaining the effects and potential side effects to the patient of pharmaceuticals required for the examination;

*[xii. Administering contrast agents as prescribed by the licensed radiologist; and

xiii. Administering general medications, except for oral medications and excluding radiopharmaceuticals and sedating medications, as prescribed by the licensed radiologist;]*

xii.-xiii. (Reserved)

3. Under general supervision, perform the following post-imaging activities:

i. Reviewing imaging procedures, making initial observations, and communicating observations only to the licensed radiologist;

ii. Communicating the licensed radiologist's report to referring physician;

iii. Providing licensed radiologist-prescribed post-care instructions to patients;

iv. Performing follow-up patient evaluation and communicating findings to the licensed radiologist;

v. Documenting the procedure in appropriate record and documenting exceptions from established protocol or procedure;

vi. Writing patient discharge summary for review and co-signature by licensed radiologist;

vii. Participating in quality improvement activities within the licensed radiologist's practice; and

viii. Assisting with data collection and review for clinical trials or other research;

4. Under direct supervision, perform the following general procedures:

i. Monitoring intravenous (IV) therapy for flow rate and complications;

ii. Administering oral medications;

iii. Monitoring patient for side effects or complications of the pharmaceuticals; and

iv. Administering radiopharmaceuticals as prescribed by the licensed radiologist;

5. Under personal supervision, perform urinary catheterization when there is a known anatomic anomaly or recent surgery to this area;

6. Under direct supervision, perform the following examinations and procedures, including contrast media administration, placement of needle or catheter, and operation of imaging equipment:

- i. Upper GI;
- ii. Esophagus;
- iii. Small bowel studies;
- iv. Barium enema;
- v. Injection of contrast material into percutaneous gastric and enteric tubes;
- [page=72] vi. Cystogram, except that a radiologist assistant shall not place a suprapubic catheter;
- vii. T-Tube cholangiogram, except that a radiologist assistant shall not place a catheter;
- viii. *[Retrograde urethrogram, except that a radiologist assistant shall not place a suprapubic catheter;]* ***(Reserved)***
- ix. Port injections;
- x. *[Fistulogram/sonogram;]* ***(Reserved)***
- xi. Loopogram;
- xii. Swallowing study;
- xiii. Peripherally Inserted Central Catheter (PICC) placement; and
- xiv. Monitoring of paracentesis and thoracentesis with appropriate image guidance after catheter has been placed by a radiologist; and

7. Under personal supervision, perform the following examinations and procedures, including contrast media administration, placement of needle or catheter, and operation of imaging equipment:

- i. Joint injection and aspiration; and
- ii. Arthrogram, including conventional, computerized tomography (CT), and magnetic resonance imaging (MRI).

*(d) After providing written notification to the Board as required at (e) below and receiving confirmation from the Board that the information has been reviewed, a licensed radiologist may direct a radiologist assistant to perform the following procedures:

- i. Lower extremity venography;
- ii. Non-tunneled venous central line placement in the femoral vein;
- iii. Venous catheter placement for dialysis;
- iv. Breast needle localization; and
- v. Ductogram (galactogram).

(e) The notification required at (d) above shall include:

1. The specific procedures at (d) above that the radiologist assistant will perform;

2. The specific training completed by the radiologist assistant in the procedure that the licensed radiologist wishes to direct the radiologist assistant to perform; and

3. The fact that the licensed radiologist has observed the radiologist assistant performing the procedure that the radiologist wishes to direct the radiologist assistant to perform and that the licensed radiologist attests that the radiologist assistant has demonstrated the ability to perform the procedure safely and effectively.]*

***(d) - (e) (Reserved) ***

NEW JERSEY REGISTER

Copyright © 2023 by the New Jersey Office of Administrative Law