

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

Manual of Standards for Licensing of Ambulatory Care Facilities

Radiation Oncology: Radiation Oncology Services Quality Improvement Methods

Hospital Licensing Standards

Radiation and Radiation Oncology: Radiation Therapy Continuous Quality

Improvement Methods

Stroke Centers

Proposed Repeal and New Rule: N.J.A.C. 8:43G-7A Appendix

Proposed Amendments: N.J.A.C. 8:43A-1.3, 2.2, 2.3, 2.4, 2.5, 2.8, 2.9, 3.3, 3.4, 3.6, 3.7, 12.7, 16.3, 23.3, 28.3, 28.7, 29.1, 30.7, 30.10, 33.1, and 33.4; and 8:43G-2.13, 5.16, 7.23, 7.28, 7A.6, 12.12, 15.1, 16.1, 23.6, 28.19, 28.24, and 32.23

Authorized By: Shereef M. Elnahal, MD, MBA, Commissioner, Department of Health, with the approval of the Health Care Administration Board.

Authority: N.J.S.A. 26:2H-1 et seq., particularly 26:2H-5.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2019-127.

Submit written comments by October 18, 2019, electronically to www.nj.gov/health/legal/ecomments.shtml or by regular mail to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner
New Jersey Department of Health
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

On August 23, 2018, the Department of Health (Department) received a petition for rulemaking from Laura I. Thevenot, Chief Executive Officer, American Society for Radiation Oncology (ASTRO), Arlington, Virginia. The petitioner requested that the Department make certain amendments to the Manual of Standards for Licensing Ambulatory Care Facilities at N.J.A.C. 8:43A-30.7, Radiation oncology services quality improvement methods, and the Hospital Licensing Standards at N.J.A.C. 8:43G-28.19, Radiation therapy continuous quality improvement methods. The petitioner requested that the Department make changes to N.J.A.C. 8:43A-30.7 and 8:43G-28.19, which currently require radiation oncology facilities to be accredited by either the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO). Specifically, the petitioner requested that the Department:

1. Amend N.J.A.C. 8:43A-30.7(b) and 8:43G-28.19(b) to include ASTRO, or a program found equivalent by the Department, as alternative entities, additional to those the existing rules recognize, by which radiation oncology services and programs that ambulatory care facilities and hospitals operate are to obtain and maintain accreditation; and
2. Amend N.J.A.C. 8:43A-30.7(c) and 8:43G-28.19(c) to require ambulatory care

facilities and hospitals to file accreditation certificates from ASTRO, or a program found equivalent by the Department, within 45 days of receipt of a certificate, as the existing rules require with respect to accreditation certificates that the ACR and the ACRO issue.

Pursuant to N.J.A.C. 1:30-4.1(c), the Department issued a notice acknowledging receipt of the petition. 50 N.J.R. 2177(a). Pursuant to N.J.A.C. 1:30-4.2, the Department issued a notice of action on the petition announcing that the Department had reviewed the petition and determined that it required additional time to consider the petition. 50 N.J.R. 2434(a).

The Department reviewed ASTRO's accreditation standards and determined them to be comparable to the accreditation standards of ACR and ACRO. Therefore, the Department determined to grant the petition to add ASTRO as an accrediting body and to initiate rulemaking to include them among the recognized accrediting entities at N.J.A.C. 8:43A-30.7 and 8:43G-28.19. The Department determined to decline the commenter's suggestion that the Department amend these sections to permit facilities to satisfy the accreditation requirement by obtaining accreditation from "an accreditation program found equivalent by the Department." The Department would review requests for recognition of other accreditation programs, possibly initiated by a petition for rulemaking, on a program-by-program basis, to verify that each program's accreditation standards are as protective of public health to those of ACR, ACRO, or ASTRO. Upon determining to recognize other accrediting bodies, the Department thereafter would initiate rulemaking to include them among the recognized accrediting programs at N.J.A.C. 8:43A-30.7 and 8:43G-28.19, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

Pursuant to N.J.A.C. 1:30-4.2, the Department issued a notice of action on the petition announcing this determination, noting that recognition of an additional accreditation agency might provide more options for providers and result in a more competitive environment among the various accreditation agencies. 51 N.J.R. 177(b).

Therefore, in accordance with its determination on the petition for rulemaking, the Department proposes to amend existing N.J.A.C. 8:43A-30.7(b) and 8:43G-28.19(b) to include ASTRO among the entities from which radiation oncology services and programs that ambulatory care facilities and hospitals operate are to obtain and maintain required accreditation. The Department proposes to amend N.J.A.C. 8:43G-28.19(b) to delete the obsolete requirement that facilities be fully accredited by December 20, 2002, and continuously maintain accreditation thereafter. The Department proposes to delete existing N.J.A.C. 8:43A-30.7(c) and 8:43G-28.19(c) and to merge the requirements therein, that ambulatory care facilities and hospitals submit copies of their accreditation certificates to the Department within 45 days of receipt of a certificate of accreditation, into the respective preceding subsections.

The Department proposes to amend N.J.A.C. 8:43A-1.3 to add a definition of the term "American Society for Radiation Oncology," consistent with the definitions of the other accrediting bodies the Department recognizes at N.J.A.C. 8:43A-30.7.

The Department is proposing additional amendments throughout Chapters 43A and 43G, described below, which are not in response to the petition for rulemaking, to update a form and to correct references to, and contact information for, governmental entities. The Department proposes technical amendments to correct grammar and

syntax, and to eliminate the passive voice, only within the provisions in which it proposes to correct or update references.

The Department proposes to amend the definitions “Commissioner” and “Department” at N.J.A.C. 8:43A-1.3, to reflect the change in the name of the Department pursuant to P.L. 2012, c. 17, § 93, codified in part at N.J.S.A. 26:1A-2.1, and proposes corresponding amendments correcting references to these terms throughout Chapters 43A and 43G.

Throughout Chapters 43A and 43G, the Department proposes to amend references to, and contact information of, programs of the Department to reflect administrative reorganization. Specifically, the Department proposes to delete a definition and references throughout N.J.A.C. 8:43A to the “Office of Acute Care Assessment and Survey” and the “Inspections, Compliance and Complaints Program” and to add in their place a definition and references to the “Division of Health Facility Survey and Field Operations.” The Department proposes to delete a definition and references to the “Office of Certificate of Need and Healthcare Facility Licensure” and the “Licensing, Certification and Standards Program” and to add in their place a definition and references to the “Certificate of Need and Healthcare Facility Licensure Program.”

The Department proposes to amend the definition of “hospital” at N.J.A.C. 8:43A-1.3 to correct a reference to the name of the chapter the definition cross-refers to and to reflect that the term means a “facility,” as N.J.A.C. 8:43G defines that term, because N.J.A.C. 8:43G does not define the term “health care facility.”

The Department proposes to amend N.J.A.C. 8:43A-1.3 to delete the definition of the term “Office of the Ombudsman for the Institutionalized Elderly” and to add a new definition of the term “State Long-Term Care Ombudsman,” to reflect the change in the name of that entity pursuant to P.L. 2017, c. 131, § 202 (see N.J.S.A. 52:27G-1 et seq., particularly 52:27G-3) and changes to that entity’s contact information. The Department proposes corresponding amendments throughout the chapter to correct references to the renamed entity.

The Department proposes to amend N.J.A.C. 8:43A-2.4 to delete the reference to the Health Plan Review “Program” of the Department of Community Affairs and to add in place thereof, reference to that Department’s Health Plan Review “Unit.”

The Department proposes to amend N.J.A.C. 8:43A-3.6 to delete references to, and the mailing address of, the Division of Youth and Family Services, and to add in place thereof, references to the Department of Children and Families, and its website, to reflect the reorganization that the Department of Children and Families Act, N.J.S.A. 9:3A-1 et seq. Likewise, the Department proposes to amend N.J.A.C. 8:43G-2.13 to delete references to the Division of Child Protection and Permanency as being within the Department of Human Services and to replace these with references to the Department of Children and Families.

The Department proposes to repeal and replace N.J.A.C. 8:43G-7A Appendix, Stroke Centers, which is the form that hospitals having designation as primary stroke centers are to use to report patient-level data to the New Jersey Acute Stroke Registry pursuant to N.J.A.C. 8:43G-7A.6(b) with an updated version of the form. The

Department proposes new N.J.A.C. 8:43G-7A.6(e) to indicate the form's availability from the Department's forms webpage.

The Department proposes to amend N.J.A.C. 8:43A-30.10 and 8:43G-28.24, which are identical to each other, to reorganize these provisions to correct syntax errors.

Because the Division has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendments to N.J.A.C. 8:43A-30.7 and 8:43G-28.19 would have a beneficial social impact on ambulatory care facilities and hospitals licensed in New Jersey. The Department believes that by allowing an additional accreditation agency, the proposed amendments would provide more options for providers and may result in a more competitive environment among the various accreditation agencies. In addition, the proposed amendments would help to ensure the continuing availability of appropriately accredited radiology programs and services at hospitals and ambulatory care facilities in New Jersey.

The balance of the proposed amendments, repeal, and new rule would be informational or technical and would have no social impact.

Economic Impact

The proposed amendments to N.J.A.C. 8:43A-30.7 and 8:43G-28.19 would recognize an additional accrediting body from which ambulatory care facilities and hospitals could obtain the mandatory accreditation of their radiation oncology programs

and services. They might have a positive economic impact on ambulatory care facilities and hospitals by increasing their options in selection of accreditation service providers, thereby potentially enhancing competition among radiation oncology accreditation service providers, which might lower their fees in response.

The proposed amendments to N.J.A.C. 8:43A-30.7 and 8:43G-28.19 might have a beneficial economic impact on the patients of hospitals and ambulatory care facilities and the public, if the enhanced competition, described above, lowers the cost of accredited radiation oncology services, and if the providers of those services pass those cost savings onto consumers.

The balance of the proposed amendments, repeal, and new rule would be informational or technical and would have no economic impact and would impose no new fees on members of the regulated community.

Federal Standards Statement

42 CFR Part 416 establishes standards applicable to ambulatory care facilities in New Jersey. 42 CFR 416.40 requires ambulatory surgical centers to comply with State licensure requirements.

The Social Security Act, at 42 U.S.C. §§ 1396(a)(29) and 1396(g), and its implementing regulations at 42 CFR Parts 431, 482, and 483, establish standards applicable to hospitals in New Jersey. 43 CFR 482.11(b) requires hospitals to be licensed or approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

A Federal standards analysis is not required because the proposed amendments, repeal, and new rule are consistent with, but do not exceed, these

applicable Federal standards.

Jobs Impact

The proposed amendments, repeal, and new rule would not result in the generation or loss of jobs in New Jersey.

Agriculture Industry Impact

The proposed amendments, repeal, and new rule would not have an impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed amendments to N.J.A.C. 8:43A would establish standards applicable to ambulatory care facilities that are subject to licensure thereunder. As of December 2018, approximately 1,065 ambulatory care facilities were subject to licensure pursuant to N.J.A.C. 8:43A. Most of the 1,065 facilities employ fewer than 100 persons and approximately 21 provide radiation oncology services, and, therefore, could be considered small businesses under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.

N.J.A.C. 8:43A-30.7 requires ambulatory care facilities that provide radiation oncology services to retain the professional services of one of the accrediting agencies listed in the rule. The proposed amendment would not change this requirement but would enhance facilities' options in their selection of a radiation oncology accreditation services provider. The Economic Impact describes the costs to comply with the proposed amendments. The proposed amendment would establish no reporting or recordkeeping requirements and would impose no new costs on members of the

regulated community.

The Department has determined that the proposed amendments would establish the minimum standards necessary to ensure quality, uniformity, and professionalism in the provision and oversight of ambulatory care facilities in New Jersey, particularly with respect to those that provide radiation oncology programs and services. Therefore, the Department proposes no lesser or differing standards for ambulatory care facilities that are small businesses.

The proposed amendments, repeal, and new rule at N.J.A.C. 8:43G are applicable only to hospitals, which are not small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 54:14B-16 et seq., because all employ greater than 100 people full-time. Therefore, a regulatory flexibility analysis is not required with respect to the proposed amendments to N.J.A.C. 8:43G.

Housing Affordability Impact Analysis

The proposed amendments, repeal, and new rule would neither have an impact on the affordability of housing in New Jersey nor evoke a change in the average costs associated with housing because the proposed amendments, repeal, and new rule would establish licensure standards applicable to hospitals and ambulatory care facilities and would have no bearing on housing.

Smart Growth Development Impact Analysis

The proposed amendments, repeal, and new rule would neither have an impact on the achievement of smart growth nor evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey, because the proposed amendments, repeal, and

new rule would establish licensure standards applicable to hospitals and ambulatory care facilities and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the rule proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:43G-7A Appendix.

Full text of the proposed amendments and new rule follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES
SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

8:43A-1.3 Definitions

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

...

“American Society for Radiation Oncology” means the entity for which the contact information is American Society for Radiation Oncology, 251 18th Street South, 8th Floor, Arlington, VA 22202, (703) 502-1550, <https://www.astro.org>.

...

“Certificate of Need and Healthcare Facility Licensure Program” means the health care facility licensing unit within the Division of Certificate of Need and Licensing of the Health Systems Branch of the Department, for which the contact information is Certificate of Need and Healthcare Facility Licensure Program, Division of Certificate of Need and Licensing, NJ Department of Health, PO Box 358, Trenton, NJ 08625-0358, (609) 292-5960, website address for forms: www.nj.gov/health/forms.

...

“Commissioner” means the Commissioner of Health [and Senior Services].

...

“Department” means the Department of Health [and Senior Services].

...

“Division of Health Facility Survey and Field Operations” means the division of the Health Systems Branch of the Department, for which the contact information is Division of Health Facility Survey and Field Operations, NJ Department of Health, PO Box 367, Trenton, NJ 08625-0367, (609) 292-9900.

...

“Hospital” means a [health care] facility as [defined in the] N.J.A.C. 8:43G, Hospital Licensing Standards [for Hospitals, N.J.A.C. 8:43G], defines that term.

...

[“Office of Acute Care Assessment and Survey” means the survey and inspections unit for acute care services within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department, for

which the contact information is Office of Acute Care Assessment and Survey, Division of Health Facilities Evaluation and Licensing Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358, (609) 292-9900.

“Office of Certificate of Need and Healthcare Facility Licensure” means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department, for which the contact information is Office of Certificate of Need and Healthcare Facility Licensure, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358, (609) 292-5960, website address for forms: www.nj.gov/health/forms.

“Office of the Ombudsman for the Institutionalized Elderly” means the unit of the same name within the Division of Elder Advocacy of the Department of the Public Advocate that investigates and responds to complaints of abuse, neglect and exploitation of individuals 60 years of age and older, who reside in licensed facilities within the State, both public and private, for which the contacted information is Office of the Ombudsman for the Institutionalized Elderly, Division of Elder Advocacy, Department of the Public Advocate, PO Box 852, Trenton, NJ 08625-0852, (877) 582-6995.]

...

“State Long-Term Care Ombudsman” or “Ombudsman” means the entity by that name established pursuant to N.J.S.A. 52:27G-1 et seq., particularly at 52:27G-3, for which the contact information is New Jersey Long-Term Care Ombudsman, PO Box 852, Trenton, NJ 08625-0852, toll-free telephone intake line

1-877-582-6995, telefacsimile (609) 943-3479, email ombudsman@ltco.nj.gov,
website <https://www.nj.gov/ltco>.

...

“Tuberculosis **Control** Program” means the Tuberculosis **Control** Program within the [Communicable Disease] **Division of HIV, STD, and TB Services** of the Public Health Services Branch of the Department, for which the contact information is Tuberculosis **Control** Program, [Communicable Disease] **Division of HIV, STD, and TB Services**, [Public Health Services Branch,] **NJ Department of Health [and Senior Services]**, PO Box [369] **363**, Trenton, NJ [08625-0369] **08625-0363**, telephone (609) [588-7522] **826-4878**, telefacsimile (609) **826-4879**, website <https://www.nj.gov/health/hivstdtb/tb/>.

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43A-2.2 Application for licensure

(a) Any person, organization, or corporation desiring to operate an ambulatory care facility shall make application to the Commissioner for a license on forms prescribed by the Department, which are available from the [Office of] Certificate of Need and Healthcare Facility Licensure **Program**.

(b)-(j) (No change.)

(k) Each applicant for a license to operate a facility shall complete all information requested on the licensure application and may request **that** the [Office of] Certificate of Need and Healthcare Facility Licensure [to] **Program** schedule an appointment to

conduct a functional review of the application to review the conditions for licensure and operation, which request the [Office] **Program** shall grant.

(l)-(m) (No change.)

8:43A-2.3 Types of services requiring a license

(a)-(d) (No change.)

(e) If a facility wishes to add any health care service during the annual licensure period, including any health care service not identified in (a) above, the facility shall obtain the authorization of the [Office of] Certificate of Need and Healthcare Facility Licensure **Program** prior to providing the additional service.

1.-2. (No change.)

8:43A-2.4 Newly constructed or expanded facilities

(a) Any ambulatory care facility that intends to undertake any alteration, renovation, or new construction of the physical plant, whether a Certificate of Need is required or not, shall submit plans to the Health Plan Review [Program] **Unit** of the Department of Community Affairs for review and approval or, in cases of existing construction where no Department of Community Affairs review is required, to the [Office of] Certificate of Need and Healthcare Facility Licensure **Program** for review to verify that the facility's physical plant is consistent with the licensure standards prior to the initiation of any work, in accordance with N.J.A.C. 8:43A-19.

(b) (No change.)

(c) Representatives of the [Office] **Division** of [Acute Care Assessment and] **Health Facility Survey and Field Operations** shall conduct an on-site inspection of the construction of the physical plant to verify that the building has been constructed in accordance with the architectural plans approved by the Department of Community Affairs or, in cases of existing construction where no Department of Community Affairs review is required, to verify that the facility's physical plant is consistent with the licensure standards at N.J.A.C. 8:43A-19.

8:43A-2.5 Surveys and full or temporary license

(a) When the written application for licensure is approved and the building is ready for occupancy, representatives of the [Office] **Division** of [Acute Care and] **Health Facility Survey and Field Operations** shall conduct a survey of the facility to determine if the facility complies with the rules in this chapter.

1. (No change.)

2. The facility shall notify the [Office] **Division** of [Acute Care Assessment and] **Health Facility Survey** [of the Department] **and Field Operations** when the deficiencies, if any, have been corrected, and [the Office of Acute Care Assessment and Survey] **that division** will schedule one or more resurveys of the facility prior to occupancy.

(b) The Department may issue full or temporary licensure to a facility when the following conditions are met:

1. A functional review (see N.J.A.C. 8:43A-2.2(k)) for review of the conditions for licensure and operation, unless the Department determines functional review to be

unnecessary, has taken place between the [Office of] Certificate of Need and Healthcare Facility Licensure **Program** and representatives of the facility, during which the Department will advise the facility representatives that the purpose of the temporary license is to allow the Department to determine the facility's compliance with N.J.S.A. 26:2H-1 et seq., and this chapter;

2.-4. (No change.)

(c) No facility shall admit patients to the facility until the facility has the written approval and/or license issued by the [Office of] Certificate of Need and Healthcare Facility Licensure **Program**.

(d)-(g) (No change.)

8:43A-2.8 Surrender of license

The facility shall notify each patient, each patient's physician, and any guarantors of payment at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of a license and shall return the license to the [Office of] Certificate of Need and Healthcare Facility Licensure **Program** within seven working days after the voluntary surrender, revocation, non-renewal, or suspension of the license.

8:43A-2.9 Waiver

(a) (No change.)

(b) A facility seeking a waiver of these rules shall apply in writing to the Director of the [Office of] Certificate of Need and Healthcare Facility Licensure **Program**.

(c)-(d) (No change.)

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:43A-3.3 Ownership

(a) The licensee shall disclose the ownership of the facility and the property on which it is located to the Department, shall make proof of this ownership available in the facility or at a designated location, and shall report any proposed change in ownership to the Director of the [Office of] Certificate of Need and Healthcare Facility Licensing **Program** in writing at least 30 days prior to the change and in conformance with requirements for Certificate of Need applications.

1.-3. (No change.)

(b) (No change.)

8:43A-3.4 Submission of documents and data

(a) Upon the Department's request, a facility shall submit in writing any documents that this chapter requires to the Director of the [Office of] Certificate of Need and Healthcare Facility Licensing **Program**.

(b) (No change.)

8:43A-3.6 Policy and procedure manual

(a) A policy and procedure manual(s) for the organization and operation of the facility shall be developed, implemented, and reviewed at intervals specified in the manual(s). Each review of the manual(s) shall be documented, and the manual(s) shall be

available in the facility to representatives of the Department at all times. The manual(s) shall include at least the following:

1.-7. (No change.)

8. Policies and procedures for complying with applicable statutes and protocols to report child abuse and/or neglect, abuse or mistreatment of elderly or disabled adults, sexual abuse, specified communicable disease, rabies, poisonings, and unattended or suspicious deaths. These policies and procedures shall include, but not be limited to, the following:

i. The designation of a staff member(s) to be responsible for coordinating the reporting of diagnosed and/or suspected cases of child abuse and/or neglect in compliance with N.J.S.A. 9:6-1 et seq., recording the notification to the [Division] **Department** of [Youth] **Children** and [Family Services] **Families** in the medical record, and serving as a liaison between the facility and the [Division] **Department** of [Youth] **Children** and [Family Services] **Families**;

ii. The notification of any suspected case of patient abuse or exploitation to the State [of New Jersey Office of the] **Long-Term Care** Ombudsman [for the Institutionalized Elderly], pursuant to N.J.S.A. 52:27G-7.1 et seq., if the patient is 60 years of age or older;

iii.-iv. (No change.)

Note: [Copies of] N.J.S.A. 9:6-1 et seq., [can be obtained from the local district office of the Division of Youth and Family Services (DYFS) or from the Office of Program Support, Division of Youth and Family Services, New Jersey State Department

of Human Services, PO Box 717, Trenton, New Jersey 08625-0717] is available at <https://www.nj.gov/dcf/reporting/links>.

(b) (No change.)

8:43A-3.7 Employee health

(a)-(c) (No change.)

(d) The facility shall establish policies and procedures for the detection and control of the transmission of *Mycobacterium tuberculosis* that include, but are not limited to, developing a Tuberculosis Exposure Control Plan (TB plan), according to the guidelines set forth in "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005," incorporated herein by reference, as amended and supplemented, published in the Morbidity and Mortality Weekly Report, at MMWR 2005; 54 (No. RR-17) (December 30, 2005) published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>, pursuant to the Occupational Safety and Health Act of 1970 Public Law 91-596, incorporated herein by reference, as amended and supplemented.

1.-2. (No change.)

3. Questions regarding tuberculosis control may be directed to[:] the Tuberculosis **Control** Program.

(e) (No change.)

SUBCHAPTER 12. SURGICAL AND ANESTHESIA SERVICES

8:43A-12.7 Anesthesia continuous quality improvement

(a)-(b) (No change.)

(c) The facility shall notify the [New Jersey Department] **Division of Health Facility Survey** and [Senior Services, Inspections, Compliance and Complaints Program] **Field Operations**, by telephone at (609) 292-9900 or (800) 792-9770 or by fax at (609) 943-3013 within 24 hours, and in writing within 30 days, of all deaths in anesthetizing locations and unexpected events or outcomes related to anesthesia, except those in which the patient expired prior to the administration of anesthesia.

1. The written report shall be submitted on the form entitled "Confidential Report of Anesthesia-Related Incident" (HFE-5), available from the [New Jersey Department] **Division of Health Facility Survey** and [Senior Services] **Field Operations** and shall include:

i.-ii. (No change.)

SUBCHAPTER 16. PATIENT RIGHTS

8:43A-16.3 Notice

(a) The administrator shall provide all patients and/or their families upon request the names, addresses, and telephone numbers of the following offices with which complaints may be lodged: the [Office] **Division of [Acute Care Assessment and] Health Facility Survey and Field Operations** and the [Office of the] **State Long-Term Care Ombudsman [for the Institutionalized Elderly]**.

(b)-(c) (No change.)

SUBCHAPTER 23. PRIMARY CARE

8:43A-23.3 Mobile vans

(a) If a facility wishes to provide services through use of one or more mobile vans, the facility shall obtain the prior authorization of the **Certificate of Need and Healthcare Facility** Licensing[, Certification and Standards] Program [of the Department]. Such authorization may be contingent upon an on-site inspection by representatives of the Department.

(b) (No change.)

SUBCHAPTER 28. BIRTH CENTERS

8:43A-28.3 Structural organization

(a) The birth center shall be a formal member of a Maternal and Child Health Consortium and shall have been designated as a community perinatal center-birthing center by the Department [of Health], in accordance with N.J.A.C. 8:33C.

(b) (No change.)

8:43A-28.7 Additional policies and procedures

(a)-(c) (No change.)

(d) The birth center shall have a written protocol to be followed in completing and reporting all newborn screening tests to the Department [of Health].

(e)-(f) (No change.)

SUBCHAPTER 29. EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES

8:43A-29.1 Scope

(a) All lithotripsy providers shall be licensed by the Department [of Health and Senior Services] and shall comply with the rules in this subchapter and all applicable requirements of this chapter[, as well as all applicable requirements in N.J.A.C. 8:43A-1 through 19].

(b)-(c) (No change.)

(d) The rules in this subchapter, **which the Department shall enforce as a condition of licensure**, apply to all lithotripsy services [and shall be enforced as a condition of licensure by the Department of Health and Senior Services].

SUBCHAPTER 30. RADIATION ONCOLOGY

8:43A-30.7 Radiation oncology services quality improvement methods

(a) (No change.)

(b) New and existing radiation oncology facilities shall [have]:

1. Have and maintain accreditation by the American College of Radiology [or], the American College of Radiation Oncology[.], **or the American Society for Radiation Oncology; and**

[(c)] **2. [Copies] Within 45 days of receiving a certificate** of [American College of Radiology or the American College of Radiation Oncology] accreditation **from one of the entities in (b)1 above, submit a copy of the** certificate [shall be sent] to the [New Jersey] Department [of Health and Senior Services] as part of State licensure [within 45 days of receiving the certificate].

8:43A-30.10 Data to be maintained and reported

Megavoltage radiation oncology facilities **annually** shall submit [such], **on or before March 31 of each year**, utilization, performance, and outcome data [as] **that** the Department may request[. Data shall include] **including**, but not [be] limited to, staff qualifications, verification of equipment calibration, program accreditation status, and program utilization by service category, on reporting forms [developed and annually submitted to] **that** the Department [of Health and Senior Services on or before March 31] **establishes**.

SUBCHAPTER 33. PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS

8:43A-33.1 Scope

All PACE organizations as defined at 42 CFR § 460.6, incorporated herein by reference, as amended and supplemented, shall be licensed by the Department [of Health and Senior Services].

8:43A-33.4 Waiver requests

(a)-(b) (No change.)

(c) Waiver application forms are available at the Department's Forms page at

[<http://web.doh.state.nj.us/forms>] <https://www.nj.gov/health/forms> or from[:

Director

Office of] **the Certificate of Need and Healthcare Facility Licensure Program**.

[Division of Health Facilities Evaluation and Licensing
New Jersey Department of Health and Senior Services
PO Box 358
Trenton, NJ 08625-0358]

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

SUBCHAPTER 2. LICENSURE PROCEDURE

8:43G-2.13 Child abuse and neglect and substance-affected infants

(a) (No change.)

(b) The facility shall have in effect written policies and procedures reviewed by the Department and revised as required by the Department to include, but not be limited to, the following:

1. The designation of a staff member(s) to be responsible for coordinating the reporting of diagnosed and/or suspected cases of child abuse and/or neglect on a 24-hour basis, recording the notification to the Division of Child Protection and Permanency of the Department of [Human Services] **Children and Families** on the medical record, and serving as a liaison between the facility and the Division of Child Protection and Permanency of the Department of [Human Services] **Children and Families**;

2.-3. (No change.)

SUBCHAPTER 5. HOSPITAL ADMINISTRATION AND GENERAL HOSPITAL-WIDE
POLICIES

8:43G-5.16 Disaster planning

(a) The hospital shall have a written, comprehensive disaster plan. The disaster plan, and any updates or changes to it, shall be submitted to the Inspection Service Program within the [New Jersey State] Department [of Health] and shall include the following:

1.-9. (No change.)

(b)-(k) (No change.)

SUBCHAPTER 7. CARDIAC

8:43G-7.23 Requirements for licensure

(a) Initial licenses granted to pilot catheterization program facilities shall be valid for a period not to exceed 30 months from the month in which the facility initiates low risk invasive cardiac diagnostic services under the program and shall expire automatically without the need for further notification or other action by the Department [of Health and Senior Services].

(b) (No change.)

8:43G-7.28 Percutaneous transluminal coronary angioplasty policies and procedures

(a) Elective percutaneous transluminal coronary angioplasty (PTCA) or percutaneous coronary interventions (PCI) shall be performed only in cardiac surgical centers approved by the [New Jersey State] Department [of Health and Senior Services] unless a certificate of need has been granted in accordance with N.J.A.C. 8:33-3.11.

(b)-(c) (No change.)

SUBCHAPTER 7A. STROKE CENTERS

8:43G-7A.6 Primary stroke center continuous quality improvement

(a)-(c) (No change.)

(d) The patient-level data submitted pursuant to this section [contains] **contain** medical information related to patients evaluated for stroke and patients receiving stroke interventional therapy and shall not be considered “government records” subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., and shall be deemed information relating to medical history, diagnosis, treatment, or evaluation within the meaning of Executive Order No. 26, § 4(b)1 (McGreevey, [August 13,] 2002).

(e) The form at N.J.A.C. 8:43G-7A Appendix is available from the Department’s forms page at <https://www.nj.gov/health/forms>.

Appendix

New Jersey Department of Health ACUTE STROKE REGISTRY (NJASR) VERSION 2.1

A. DEMOGRAPHIC DATA

*Hospital Type (1): 1=Primary 2=Comprehensive 3=Other _____
*Hospital Code (2): _____ *Hospital Transferred From Code (3): _____ *Medical Record # (4): _____
*Patient: Last Name (5): _____ *First Name (6): _____ *MI (7): _____
Date of Birth (8): (mm/dd/yyyy) ___/___/___ *SS# (9): _____ *Zip Code (10): _____
Gender (11): 1=Male 2=Female 3=Other/Unknown _____
Race (Check all that apply)
(12a) White (12b) Black or African American (12c) Asian (12d) American Indian or Alaskan Native
(12e) Native Hawaiian or Pacific Islander (12f) Unknown or Unable to Determine (UTD) _____
Hispanic or Latino Ethnicity (13): 1=Yes 0= No/UTD _____
Health Insurance Status (14): 1=Blue Cross/Blue Shield 2=Commercial 3=HMO 4=Medicaid 5=Medicare
6=Self-pay 7=Tricare (Champus) 8=Uninsured/Indigent 9=Other _____

B. PRE-HOSPITAL/EMERGENCY MEDICAL SYSTEM (EMS) DATA

Where was the patient when stroke was detected or when symptoms were discovered (15)?
1=Not in a health care setting 4=Stroke occurred after hospital arrival (in ED/obs/inpatient)
2=Another acute care facility 5=Outpatient health care setting
3=Chronic health care facility 9=ND or Cannot be determined _____
If answer is 1, 2, 3, 5 or 9 on #15:
How did the patient get to your hospital for treatment of his/her stroke (16)?
1=EMS from home or scene 3=Transferred from another hospital
2=Private transportation/taxi other 9=ND or unknown _____
If patient arrived by EMS, then complete questions 17 through 21:
Date and time call received by EMS:
Date (17): (mm/dd/yyyy) ___/___/___ Date Not Documented (18): 1=Yes 2=No _____
Time (19): (hh:mm) ___:___ Time Not Documented (20): 1=Yes 2=No _____
Was there EMS pre-notification to your hospital (21)? 1=Yes 0=No/ND _____

C. HOSPITALIZATION

Date of arrival to Hospital/ED (22): (mm/dd/yyyy) ___/___/___
Time of arrival to Hospital/ED (23): (hh:mm) ___:___
Hospital Admission Date (24): (mm/dd/yyyy) ___/___/___
In what area of the hospital was the patient first evaluated (25)?
1=Emergency Department/Urgent Care
2=Direct Admit (DA) or Direct to Floor, not through ED
3=Imaging suite prior to ED arrival or DA
9=Cannot be determined _____

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

Was the patient admitted to your hospital (26)? 1=Yes 0=No, Not Admitted _____

If patient was Not Admitted to your hospital, select the reason why the patient was not admitted (27)?

1=Patient was transferred from your ED to another acute care hospital
2=Patient was discharged directly from ED to home or other location other than an acute care hospital
3=Patient left ED AMA
4=Patient died while in ED
5=Patient discharged from observation status without being admitted to the hospital
6=Other _____

What was the presumptive hospital admission diagnosis at the time of admission (28)? (select only one)

1=intracerebral Hemorrhage 3=Subarachnoid Hemorrhage 5=Ischemic Stroke
2=Transient Ischemic Attack 4=Stroke not otherwise specified 6=No stroke related diagnosis _____

Did symptoms completely resolve prior to presentation (29)? 1=Yes 0=No 9=ND _____

Initial Findings:

Weakness or Paresis (30) 1=Yes 0=No/ND _____

Altered Level of Consciousness (31) 1=Yes 0=No/ND _____

Aphasia (32) 1=Yes 0=No/ND _____

Initial Blood Pressure:

If patient received IV tPA, what was the first systolic blood pressure? (33) (mmHg) _____

If patient received IV tPA, what was the first diastolic blood pressure? (34) (mmHg) _____

Initial Glucose:

If patient received IV tPA, what was the first blood glucose? (35) (mg/dL) _____

Prescribed medications currently taking prior to admission:

Antiplatelet medication (36) 1=Yes 0=No/ND _____

Anticoagulation medication (37) 1=Yes 0=No/ND _____

Antihypertensive medication (38) 1=Yes 0=No/ND _____

Cholesterol reducing medication (39) 1=Yes 0=No/ND _____

Diabetic medication (40) 1=Yes 0=No/ND _____

Was patient ambulatory prior to the current stroke/TIA (41)?

1=Able to ambulate independently (no help from another person) w/ or w/o device
2=With assistance from another person
3=Unable to ambulate
9=Not documented _____

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

D. IMAGING

Was brain imaging performed at your hospital after arrival as part of the initial evaluation for this episode of care or this event (42)?

1=Yes 0=No/ND 2=NC-if outside imaging prior to transfer or patient is DNR/CMO

If yes,

Date of initial brain imaging: (43) (mm/dd/yyyy) / /

Date not documented or unknown: (44) 1=Yes 0-No

Time of initial brain imaging: (45) (hh:mm) :

Time not documented or unknown: (46) 1=Yes 0-No

Initial brain image findings (47) 1=Hemorrhagic 0=No hemorrhage 9=N/D or Not available

Date of initial brain image findings: (48) (mm/dd/yyyy) / /

Date of initial brain image findings not documented or unknown: (49) 1=Yes 0-No

Time of initial brain image findings: (50) (hh:mm) :

Time of initial brain image findings not documented or unknown: (51) 1=Yes 0-No

E. SYMPTOM TIMELINE

When was the patient last known to be well (i.e., in their usual state of health or at their baseline), prior to the beginning of the current stroke or stroke-like symptoms? (To within 15 minutes of exact time is acceptable)

Date: (52) (mm/dd/yyyy) / /

Date last known well is unknown/not documented/UTD: (53) 1=Yes 0-No

Time: (54) (hh:mm) :

Time last known well is unknown/not documented/UTD: (55) 1=Yes 0-No

When was the patient first discovered to have the current stroke or stroke-like symptoms?

Date: (56) (mm/dd/yyyy) / /

Date patient discovered with symptoms unknown/not documented: (57) 1=Yes 0-No

Time: (58) (hh:mm) : (May record within 15 minutes of exact time).

Discovery time unknown/not documented: (59) 1=Yes 0-No

Was NIH Stroke Scale (NIHSS) score performed as part of the initial evaluation of the patient (60)?

1=Yes 0=No/ND

If performed, what is the first NIHSS total score recorded by hospital personnel (61)? (00-42)

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

F. THROMBOLYTIC TREATMENT

Was IV tPA initiated for this patient at this hospital (62)?

1=Yes 0=No

If IV tPA was initiated at this hospital or ED, please complete this section:

Date: (63) (mm/dd/yyyy) ___/___/___

Date not documented or unknown: (64) 1=Yes 0=No

Time: (65) (hh:mm) ___:___

Time not documented or unknown: (66) 1=Yes 0=No

IV tPA at an outside hospital (67): 1=Yes 0=No

IA catheter-based reperfusion at this hospital (68):

1=Yes 0=No 2=Attempted but unable to access target occlusion

If yes, record date and time:

Date: (69) (mm/dd/yyyy) ___/___/___

Date not documented or unknown: (70) 1=Yes 0=No

Time: (71) (hh:mm) ___:___

Time not documented or unknown: (72) 1=Yes 0=No

IA catheter-based reperfusion at outside hospital (73): 1=Yes 0=No

Investigational or experimental protocol for thrombolysis (74): 1=Yes 0=No

If yes, specify: (75): _____

*Other investigative therapy for ischemic or hemorrhagic stroke (76): 1=Yes 0=No

Complications of thrombolytic therapy (77):

- 0=None
- 1=Symptomatic intracranial hemorrhage <36 hours of tPA
- 2=Life threatening, serious systemic hemorrhage <36 hours of tPA
- 3=Other serious complications
- 9=Unknown/unable to determine

Were there bleeding complications in a patient transferred after IV tPA (78)?

- 1=Yes and detected prior to transfer
- 2=Yes but detected after transfer
- 3=UTD
- 9=Not applicable

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

G. NON-TREATMENT WITH THROMBOLYTICS

Documented Exclusions (Contraindications) or Relative Exclusions (Warnings) for not initiating IV Thrombolytic in the 0-3 hour treatment window (79):

1=Yes 0-No If yes: select from 0 - 3 hour listed items. _____

Documented Exclusions (Contraindications) or Relative Exclusions (Warnings) for not initiating IV Thrombolytic in the 3-4.5 hour treatment window (80):

1=Yes 0-No If yes: select from 3 - 4.5 hour listed items. _____

Were one or more of the following reasons for not administering IV thrombolytic therapy at this hospital explicitly documented by a physician, advanced practice nurse, or physician assistant's notes in the patient's chart?
(Check all that apply)

	0 – 3 Hours (Check all that apply)	3 – 4.5 Hours (Check all that apply)
Documented Exclusions (Contraindications) for not initiating IV thrombolytic treatment:		
Active internal bleeding (81)		
CT demonstrates multilobar infarction (hypodensity) > 1/3 cerebral hemisphere (82)		
History of intracranial hemorrhage, intracranial neoplasm, arteriovenous malformation or aneurysm (83)		
Acute bleeding diathesis (low platelet count, increased PTT, INR ≥ 1.7 or use of NOAC. This includes: Platelet count <100 000/mm ³ ; Heparin received within 48 hours resulting in abnormally elevated aPTT greater than the limit or normal; current use of anticoagulant with INR >1.7 or PT >15 seconds; current use of direct thrombin inhibitors or direct factor Xa inhibitors with elevated sensitive laboratory tests (such as aPTT, INR, platelet count, and ECT; TT; or appropriate factor Xa activity assays) (84)		
Recent intracranial or spinal surgery, significant head trauma or stroke in previous 3 months (85)		
Elevated blood pressure (systolic >185 mmHg or diastolic >110 mmHg) despite treatment (87)		
Symptoms may suggest subarachnoid hemorrhage (89)		
Arterial puncture at noncompressible site in previous 7 days (89a)		
Blood Glucose concentration <50 mg/dL (2.7 mmol/L) (92)		
Relative Exclusions (Warnings) (conditions that might lead to unfavorable outcomes):		
Care-team unable to determine eligibility (91)		
IV or IA thrombolysis/thrombectomy at an outside hospital prior to arrival (94)		
Life expectancy <1 year or severe co-morbid illness or CMO on admission (96)		
Recent acute myocardial infarction (within previous 3 months) (97)		
Pregnancy (98)		
Patient/family refused (99)		
Stroke severity too mild (100)		
Rapid improvement (102)		
Seizure at onset with postictal residual neurological impairments (88)		
Major surgery or serious trauma within previous 14 days (86)		
Recent gastrointestinal or urinary tract hemorrhage (within previous 21 days) (102a)		

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

	0 – 3 Hours <i>(Check all that apply)</i>	3 – 4.5 Hours <i>(Check all that apply)</i>
Hospital-Related or Other Factors:		
Delay in patient arrival (103)		
Delay in stroke diagnosis (104)		
In-hospital time delay (105)		
No IV access (106)		
Other (Specify) (107):		

H. MEDICAL HISTORY

Documented past medical history:	Check all that apply
Atrial Fib/Flutter (108)	
Myocardial Infarction (MI) or coronary artery disease (CAD) (109)	
Carotid stenosis (110)	
Did this event occur during pregnancy or within 6 weeks after delivery or termination of pregnancy (111)?	
Diabetes Mellitus (112)	
Drugs or alcohol abuse (113)	
Dyslipidemia (114)	
Family history of stroke (115)	
Heart failure (116)	
Hormone replacement therapy (HRT) (117)	
Hypertension (118)	
Migraine (119)	
Obesity (120)	
Prior Stroke (121)	
History of Transient Ischemic Attack (TIA) or Vertebral-Basilar Insufficiency (VBI) (122)	
Peripheral Vascular Disease (PVD) (123)	
Heart valve prosthesis (124)	
Chronic renal insufficiency (serum creatinine >2.0) (125)	
Sickle cell disease (sickle cell anemia) (126)	
Smoking (at least one cigarette during the year prior to hospital arrival) (127)	
None of the above (128)	

Record patient's height (129): _____ cms.

Record patient's weight (130): _____ kgs.

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

I. IN-HOSPITAL PROCEDURES AND TREATMENT

Where was patient cared for and by whom?

Neuro Admit (131)	1=Yes	0=No	_____
Other Service Admit (132)	1=Yes	0=No	_____
Stroke Consult (133)	1=Yes	0=No	_____
No Stroke Consult (134)	1=Yes	0=No	_____
In Stroke Unit (135)	1=Yes	0=No	_____
Not in Stroke Unit (136)	1=Yes	0=No	_____

When is the earliest time that the physician, advanced practice nurse, or PA documented that patient was on comfort measures (137)?

1=Day of arrival or first day after arrival
 2=2nd day after arrival or later
 3=Timing unclear
 4=ND/UTD _____

Was antithrombotic therapy received by the end of hospital day 2 (138)?

1=Yes 0=No/Not documented 2= NC _____

Was the patient ambulatory at the end of hospital day two (139)?

1=Yes 0=No 2=Not documented _____

VTE Prophylaxis (select all that apply):

VTE Prophylaxis	Check all that apply
Low dose unfractionated heparin (LDUH) (140)	_____
Low molecular weight heparin (LMWH) (141)	_____
Intermittent pneumatic compression devices (IPC) (142)	_____
Graduated compression stockings (GCS) (143)	_____
Factor Xa Inhibitor (144)	_____
Warfarin (145)	_____
Venous foot pumps (VFP) (146)	_____
Oral Factor Xa Inhibitor (147)	_____
Not documented or none of the above (148)	_____

What date was the initial VTE prophylaxis administered after hospital admission (149)?

(mm/dd/yyyy) ____/____/____ Check if date is unknown (150)

If not documented or none of the above types of prophylaxis apply, is there documentation why VTE prophylaxis was not administered at hospital admission (151)?

1=Yes 0=No _____

Is there a documented reason for using Oral Factor Xa Inhibitor for VTE (152)?

1=Yes 0=No _____

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

Other Therapeutic Anticoagulation (153): (Select One)

- 1=Unfractionated Heparin IV
- 2=Dabigatran (Pradaxa)
- 3=Argatroban
- 4=Desirudin (Iprivask)
- 5=Rivaroxaban (Xarelto)
- 6=Lepirudin (Refludan)
- 8=Apixaban (Eliquis)
- 9=Other Anticoagulant

Was the patient NPO throughout the entire hospital stay (154)? (i.e., this patient never received food, fluids, or medication by mouth at any time)

- 1=Yes
- 0=No or Not documented

Was patient screened for dysphagia prior to any oral intake, including food, fluids or medications (155)?

- 1=Yes
- 0=No or Not documented
- 2= NC-A documented reason for not screening exists in the medical record

*IV therapeutic heparin administered (156)?

- 1=Yes
- 0=No

*Was the patient's cardiac rhythm monitored continuously (157)?

- 1=Yes
- 0=No

J. OTHER IN-HOSPITAL COMPLICATIONS

Did patient experience a DVT or pulmonary embolus (PE) during this admission (158)?

- 1=Yes
- 0=No/ND

Was there documentation that the patient was treated for pneumonia during this admission (159)?

- 1=Yes
- 0=No/ND
- 9=NC

Was patient treated for a urinary tract infection (UTI) during this admission (160)?

- 1=Yes
- 0=No/ND

If patient was treated for a UTI, did the patient have a Foley catheter during this admission (161)?

- 1=Yes, and patient had catheter in place on arrival
- 2=Yes, but only after admission
- 0=No
- 9=Unable to determine

K. DISCHARGE DATA

Date of discharge from hospital (162) (mm/dd/yyyy) _____

ICD discharge diagnosis related to stroke (163): _____

Principal discharge ICD diagnosis (164): _____

Clinical hospital diagnosis related to stroke that was ultimately responsible for this admission (Select one) (165):

- 1=Subarachnoid hemorrhage
- 2=Intracerebral hemorrhage
- 3=Ischemic stroke
- 4=Transient ischemic attack
- 5=Stroke not otherwise specified
- 6=No stroke related diagnosis
- 8=Elective carotid intervention only

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

What was the patient's discharge disposition on the day of discharge (Select only one) (166):

- 1=Home
- 2=Hospice - Home
- 3=Hospice – Health Care Facility
- 4=Acute Care Facility
- 5=Other Health Care Facility
- 6=Expired
- 7=Left against medical advice/AMA
- 8=Not Documented or Unable to Determine (UTD)

If discharged to another healthcare facility, what type of facility was it (167)?

- 1=Skilled nursing facility
- 2=Inpatient rehabilitation
- 3=Long-term acute care facility or hospital
- 4=Intermediate care facility
- 5=Other

Ambulation status at Discharge (168):

- 1 = Able to ambulate independently (no help from another person) w/or w/o device
- 2 = With assistance from another person
- 3 = Unable to ambulate
- 9 = Not documented

If past medical history of smoking is checked as yes on #127, was the adult patient or their care giver given smoking cessation advice or counseling during the hospital stay (169)?

- 1=Yes
- 0=No or not documented in the medical record
- 2=NC– A documented reason exists for not performing counseling

***Record lipid levels in the first 48 hours or within 30 days prior to admission:**

Total Cholesterol (3-digits) (170)	_____ mg/dl	} Lipids: ND (174) Lipids: NC (175)
Triglycerides (4-digits) (171)	_____ mg/dl	
HDL (3-digits) (172)	_____ mg/dl	
LDL (3-digits) (173)	_____ mg/dl	

Glycosylated Hb (HbA1C) (176): _____ % ND (177)

Cholesterol-reducing treatment prescribed at discharge: (178) (Check all that apply)

- 1=None-prescribed N/D
- 2=None-contraindicated
- 3=Statin
- 4=Fibrate
- 6=Other med
- 7=Niacin
- 8=Absorption inhibitor

If statin was not prescribed, was there a documented reason for not prescribing a statin medication (179)?:

- 1=Yes
- 0=No

Is there documentation that antihypertensive medication was prescribed at discharge (180)?

- 1=Yes
- 0=No/ND
- 2=NC

ACUTE STROKE REGISTRY (NJASR) VERSION 2.1
(Continued)

Was antithrombotic (antiplatelet or anticoagulant) medication that is approved for stroke prescribed at discharge (181)?

1=Yes 0=No/ND 2=NC

Was an antithrombotic medication not on the Antithrombotic Therapy Approved in Stroke inclusion list (an alternate antithrombotic medication) prescribed at discharge (181a)?

1=Yes 0=No/ND

If patient was discharged on an antithrombotic medication, was it an antiplatelet (182)? 1=Yes 0=No/ND

If patient was discharged on an antithrombotic medication, was it an anticoagulant (183)? 1=Yes 0=No/ND

Was atrial fibrillation/flutter or paroxysmal atrial fibrillation (PAF) documented during this episode of care (184)?

1=Yes 0=No/ND

If a history of atrial fibrillation/flutter or PAF is documented in the medical history of the patient or if the patient experienced atrial fibrillation/flutter or PAF during this episode of care, was patient prescribed anticoagulation medication upon discharge (185)?

1=Yes 0=No/ND 2=Contraindicated (NC)

Was there documentation that the patient and/or caregiver received education and/or resource materials regarding any of the following?

Personal modifiable risk factors for stroke (186) 1=Yes 0=No/Not documented

Stroke warning signs (187) 1=Yes 0=No/Not documented

How to activate EMS (188) 1=Yes 0=No/Not documented

Need for follow-up after discharge (189) 1=Yes 0=No/Not documented

Their prescribed medications (190) 1=Yes 0=No/Not documented

Is there documentation in the record that the patient was assessed for or received rehabilitation services (191)?

1=Yes 0=No/Not documented

If patient was assessed for rehabilitation services or received rehabilitation services, check all rehabilitation services that the patient received or was assessed for in the list below:	Check all that apply
Did patient receive rehabilitation services during hospitalization (192)?	
Was patient transferred to a rehabilitation facility (193)?	
Was patient referred to rehabilitation services following discharge (194)?	
Was patient ineligible to receive rehabilitation services because symptoms resolved (195)?	
Was patient ineligible to receive rehabilitation services due to impairment (i.e., poor prognosis or patient being unable to tolerate rehabilitation therapeutic regimen) (196)?	

Was Modified Rankin Scale done at discharge (197)? 1=Yes 0=No/ND

If Modified Rankin Scale was done at discharge, what was the Modified Rankin Score (198)?

0=No symptoms at all

1=No significant disability despite symptoms; able to carry out all usual duties and activities

2=Slight disability; unable to carry out previous activities, but able to look after own affairs without assistance

3=Moderate disability; requiring some help, but able to walk without assistance

4=Moderately severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance

5=Severe disability; bedridden, incontinent and requiring constant nursing care and attention

6=Dead

Possible Comprehensive Stroke Questions:

*Reserved field 1 (199): _____ *Reserved field 2 (200): _____ *Reserved field 3 (201): _____

*Reserved field 4 (202): _____ *Reserved field 5 (203): _____ *Reserved field 6 (204): _____

*Reserved field 7 (205): _____ *Reserved field 8 (206): _____ *Reserved field 9 (207): _____

*Reserved field 10 (208): _____ *Reserved field 11 (209): _____ *Reserved field 12 (210): _____

*Reserved field 13 (211): _____ *Reserved field 14 (212): _____ *Reserved field 15 (213): _____

NOTE: * = State Added Item

SUBCHAPTER 12. EMERGENCY DEPARTMENT AND TRAUMA SERVICES

8:43G-12.12 Trauma services; scope and purpose

(a) The requirements of N.J.A.C. 8:43G-[12.12]**12.13** through 12.23 [shall] **and this section** apply to all hospitals [designated by] **that** the Department [of Health] **designates** as Level I or Level II trauma centers, pursuant to Certificate of Need designation criteria at N.J.A.C. [8:33P] **8:33**.

(b) (No change.)

SUBCHAPTER 15. MEDICAL RECORDS

8:43G-15.1 Medical records structural organization

(a)-(b) (No change.)

(c) If the hospital ceases to operate, at least 14 days before cessation of operation **the hospital shall notify** the [State] Department [of Health shall be notified] in writing [about] how and where medical records will be stored.

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

SUBCHAPTER 16. MEDICAL STAFF

8:43G-16.1 Medical staff structural organization

(a)-(k) (No change.)

(l) [Notifications required by] **The hospital shall submit the notification that** (k) above [shall be provided] **requires to the Department** within seven days of the [reported]

occurrence of the reportable event [and shall be submitted] on forms [approved by] **that** the Department [of Health] **approves** for that purpose.

(m)-(o) (No change.)

SUBCHAPTER 23. PHARMACY

8:43G-23.6 Pharmacy patient services

(a) (No change.)

(b) The hospital shall have in effect a unit dose drug distribution system with individual cassettes or containers [which] **that** bear the patient's identification. The system shall cover at least the medical/surgical, obstetric, pediatric, and psychiatric units and include scheduled cart exchanges at least every 24 hours, including weekends and holidays.

1. [An] **The hospital may substitute an** alternative method of distributing drugs [approved by the Department of Health may be substituted] for the unit dose drug distribution system if the **hospital demonstrates to the Department that the** method [has been demonstrated to the Department to have] **has** at least equivalent clinical effectiveness **and the Department approves the use of the alternative method.**

(c)-(m) (No change.)

SUBCHAPTER 28. RADIOLOGY AND RADIATION ONCOLOGY

8:43G-28.19 Radiation therapy continuous quality improvement methods

(a) (No change.)

(b) New [or] **and** existing radiation oncology facilities shall [be fully accredited]:

1. Have and maintain accreditation by the American College of Radiology [or], the American College of Radiation Oncology [by December 20, 2002 and continuously maintained thereafter.], **or the American Society for Radiation Oncology; and**

[(c)] **2. [Copies] Within 45 days of receiving a certificate** of [the American College of Radiology or the American College of Radiation Oncology] accreditation **from one of the entities in (b)1 above, submit a copy of the** certificate [shall be sent] to the [New Jersey] Department [of Health and Senior Services] as a condition of licensure [within 45 days of receipt of the certificate].

8:43G-28.24 Data to be maintained and reported

Megavoltage radiation oncology facilities **annually** shall submit [such], **on or before March 31 of each year**, utilization, performance, and outcome data [as] **that** the Department may request[. Data shall include] **including**, but not [be] limited to, staff qualifications, verification of equipment calibration, program accreditation status, and program utilization by service category, on reporting forms [developed and annually submitted to] **that** the Department [of Health and Senior Services on or before March 31] **establishes**.

SUBCHAPTER 32. SAME-DAY STAY

8:43G-32.23 Observation service space and environment

(a) Prior to implementation, the hospital shall inform the Department [of Health and Senior Services] in writing of the location and the number of spaces in the service.

(b)-(c) (No change.)