

HEALTH

HEALTH SYSTEMS BRANCH

CERTIFICATE OF NEED AND LICENSING DIVISION

CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE PROGRAM

Notice of Readoption

Manual of Standards for Licensing of Ambulatory Care Facilities

Readoption with Technical Changes: N.J.A.C. 8:43A

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

Authorized By: Judith M. Persichilli, RN, BSN, MA, Commissioner, Department of Health, with the approval of the Health Care Administration Board.

Effective Date: _____, 2021, Readoption;

_____ 2022, Technical Changes.

New Expiration Date: _____, 2028.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the Commissioner (Commissioner) of the Department of Health (Department) hereby readopts N.J.A.C. 8:43A, Manual of Standards for Licensing of Ambulatory Care Facilities.

In accordance with N.J.S.A. 52:14B-5.1(b), the rules were to expire on November 21, 2021. Pursuant to Executive Orders Nos. 127 (Governor Murphy, 2020) and 244 (Governor Murphy, 2021) and P.L. 2021, c. 103 (approved June 4, 2021), any chapter of the New Jersey Administrative Code that would otherwise have expired during the public health emergency, which was originally declared in Executive Order No. 103 (Governor Murphy, 2020), is extended through January 1, 2022. Therefore, this chapter

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has not yet expired and the 30-day filing date pursuant to N.J.S.A. 52:14B-5.1.c has not yet occurred, and this notice of readoption is timely filed.

N.J.A.C. 8:43A establishes licensure standards applicable to ambulatory care facilities that are subject to the Health Care Facilities Planning Act (Act), N.J.S.A. 26:2H-1, et seq. Subchapter 1, Definitions and Qualifications, establishes standards and general criteria for the licensure of an ambulatory care facility and the minimum qualifications of the various required professionals who work in ambulatory care facilities. Subchapter 2, Licensure Procedures, establishes applicable licensure procedures. Subchapter 3, General Requirements, establishes general requirements. Subchapter 4, Governing Authority, establishes the responsibilities of a facility's governing authority. Subchapter 5, Administration, establishes minimum requirements for facility administration including the requirement that a facility employs an administrator. Subchapter 6, Patient Care Policies and Services, establishes minimum standards for patient care policies and services. Subchapter 7, Medical Services, establishes requirements for the provision of medical services, including the requirement that facilities employ a medical director. Subchapter 8, Nursing Services, establishes requirements for the provision of nursing services, including the requirement that facilities employ a director of nursing. Subchapter 9, Pharmaceutical Services, establishes requirements for the provision of pharmaceutical services, including the requirement that facilities employ a pharmaceutical consultant, and the requirement that facilities develop and implement policies and procedures addressing medication administration and pharmaceutical control and reporting. Subchapter 10, Counseling Services, establishes requirements for the provision of counseling services, including

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social work and dietary counseling. Subchapter 11, Laboratory and Radiological Services, establishes requirements for the provision of laboratory and radiological services. Subchapter 12, Surgical and Anesthesia Services establishes requirements for the provision of surgical and anesthesia services. Subchapter 13, Medical Records, establishes requirements for the development and implementation of policies and procedures addressing the handling and maintenance of patients' medical records. Subchapter 14, Infection Prevention and Control Services, establishes requirements for the provision of infection prevention and control services. Subchapter 15, Emergency Services and Disaster Plans, establishes requirements for the development and implementation of policies and procedures addressing emergency services and disaster plans. Subchapter 16, Patient Rights, establishes requirements for the development and implementation of policies and procedures addressing patient rights. Subchapter 17, Housekeeping, Sanitation and Safety, establishes requirements for the provision of housekeeping, sanitation and safety issues. Subchapter 18, Quality Assurance Program, requires the establishment and implementation of a written plan for a quality improvement program. 19, Physical Plant and Functional Requirements establishes requirements governing physical plant and functional requirements. Subchapter 20, family Practice Services, establishes requirements for the provision of provides family practice services. Subchapter 21, Family Planning, Prenatal, Postpartum and Gynecological Services, establishes requirements for the provision of family planning, prenatal, postpartum and gynecological services. Subchapter 22, Pediatric Services, establishes requirements for the provision of pediatric services. Subchapter 23, Primary Care, establishes requirements for the provision of primary care services. Subchapter

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24, Renal Dialysis, establishes requirements for the provision of renal dialysis services. Subchapter 25, Computerized Tomography, Magnetic Resonance Imaging and Radiological Services, establishes requirements for the provision of computerized tomography, magnetic resonance imaging and radiological services. Subchapter 26, Drug Abuse Treatment Services, establishes requirements for the provision of drug abuse treatment services. Subchapter 27, Satellites of Licensed Ambulatory Care Facilities, establishes requirements applicable satellite facilities of ambulatory care facilities. Subchapter 28, Birth Centers, establishes requirements for the provision of birth services. Subchapter 29, Extracorporeal Shock Wave Lithotripsy Services, establishes requirements for the provision of extracorporeal shock wave lithotripsy. Subchapter 30, Radiation Oncology, establishes requirements for the provision of radiation oncology services. Subchapter 31, Water Supply and Laundry, establishes requirements governing potable water supplies and laundry services. Subchapter 32, Other Services, establishes requirements applicable to services that the chapter does not specifically address elsewhere in the chapter and provides procedures by which a license applicant must submit a waiver request. Subchapter 33, Programs of All-Inclusive Care for the Elderly (PACE) Organizations, establishes requirements applicable to PACE organizations a waiver request and provides procedures by which a license applicant must submit a waiver request.

The Department is making several technical changes upon readoption. The Department is correcting references throughout the chapter to the Department to reflect the change in the Department's name pursuant to N.J.S.A. 26:1A-2.

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The Department is correcting references to the names and contact information of units within the Department that have changed following Department reorganization.

The Department is correcting references to the Office of the Ombudsman for the Institutionalized Elderly to reflect the change in the name of that entity to the State Long-Term Care Ombudsman, pursuant to P.L. 2017, c. 131, § 202 (see N.J.S.A. 52:27G-1, et seq., particularly at 52:27G-3) and changes to that entity's contact information.

Throughout the chapter, the Department is updating mailing addresses and other contact information of entities to which the chapter refers. The Department is updating the names of organizations contained within the chapter, correcting internet links and updating documents referred to in N.J.A.C. 8:43A-14.4, the Sterilization of Patient Care Items.

Throughout the chapter, the Department is updating cross-references to laws, rules, and publications to which the chapter refers. The Department is deleting definitions of terms that the chapter does not use.

The Commissioner has reviewed N.J.A.C. 8:43A and has determined that, subject to the technical changes described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it, as amended and supplemented over time, and should be readopted.

Therefore, pursuant to N.J.S.A. 52:14B-5.1, N.J.A.C. 8:43A is readopted and shall continue in effect for seven years.

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Full text of the technical changes follows (additions indicated in boldface, thus; deletions indicated in brackets [thus]):

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:

...

“Addiction Professionals Certification Board of New Jersey, Inc.” means the entity by that name for which the contact information is Addiction Professionals Certification Board of New Jersey, Inc., [1200 Tices Lane, Suite 104, East Brunswick], **1164 Raritan Avenue, Highland Park**, NJ [08816 (732) 249-1991, telefacsimile (732) 249-1559, www.certbd.com] **08904**, <https://certbd.org>.

...

“American Board of Medical Physics” means the entity by that name for which the contact information is American Board of Medical Physics, [12100 Sunset Hills Road, Suite 130, Reston, VA 20190-5202, (703) 481-5001, telefacsimile (703) 435-4390, www.acmp.org/abmp] **Inc., PO Box 780518, San Antonio, TX 78278, (210) 901-9052, https://abmpexam.com.**

“American College of Radiation Oncology” means the entity by that name for which the contact information is American College of Radiation Oncology, [5272 River Road, Bethesda, MD 20816 (301) 718-6515, telefacsimile: (301) 656-0989, 2001 Sixth Ave, Suite 2700, Seattle, WA 98121] **319 South Glen Arven Avenue, Temple Terrace, FL 33617; (206) 956-3642; https://www.acro.org.**

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...

“American Osteopathic Board of Radiology” means the entity by that name for which the contact information is American Osteopathic Board of Radiology, [119 East Second Street, Milan, MO 63556-1331, 800-258-AOCR (2627) or (660) 265-4011] **142 East Ontario Street, Chicago, IL 60611-2864, (888) 626-9262 or (312) 202-8072**, telefacsimile [(660) 265-3494, <http://www.aocr.org/certification/index.asp>] **(312) 202-8372**, <https://certification.osteopathic.org/radiology>.

“Association for the Advancement of Medical Instrumentation” means the entity by that name for which the contact information is Association for the Advancement of Medical Instrumentation, [PO Box 1211, Annapolis Junction, MD 20701-0211, (800) 877-249-8226 or 240-646-7031] **901 North Glebe Road, Suite 300, Arlington, VA 22203, (703) 525-4890**, telefacsimile [(301) 206-9789] **(703) 525-1424**, <https://www.aami.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: <http://www.nj.gov/health/forms>.

“Certification Board of Infection Control and Epidemiology, Inc. (CBIC)” is an entity for which the contact information is 555 East Wells Street, Suite 1100, Milwaukee, WI 53202, (414) 918-9796; <https://www.cbic.org>.

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...

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

“Commission on Dietetic Registration“ means the entity by that name for which the contact information is Commission on Dietetic Registration, 120 South Riverside Plaza, Suite [2000] **2190**, Chicago, IL 60606[-6995], (312) 899-0040 extension 5500 or toll-free (800) 877-1600 extension 5500[, telefacsimile (312) 899-4772],

<https://www.cdrnet.org>.

...

“Construction guidelines“ means the **Facility Guidelines Institute**, Guidelines for Design and Construction of [Health Care] **Outpatient** Facilities, [2006] **2018** edition, incorporated herein by reference, as amended and supplemented, [published by] **available from** the [American Institute of Architects, for which the contact information is the American Institute of Architects, 1735 New York Avenue NW, Washington DC 20006-5292, (800) 242-3837 or (202) 626-7541, telefacsimile [(202) 626-7519],

www.aia.org] **Facility Guidelines Institute, 9750 Fall Ridge Trail, Saint Louis, MO 63127, telephone (800) 798-9296, website www.fgiguilines.org.**

...

“Controlled Dangerous Substances Acts“ means the Comprehensive Drug Abuse Prevention and [Controlled Substances] **Control** Act of 1970 (Title II, Public Law 91-513) and the New Jersey Controlled Dangerous Substances Act [of 1970], N.J.S.A. 24:21-1, et seq.

...

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“Division of Certificate of Need and Licensing” means a unit within the Department, which can be contacted at PO Box 358, Trenton, NJ 08625-0358; (609) 292-6552.

“Division of Child Protection and Permanency” means a unit within the New Jersey Department of Children and Families for which the contact information is PO Box 729, Trenton, NJ 08625-0729, (609) 292-0617.

“Division of Health Facility Survey and Field Operations” means a unit within the Department for which the contact information is PO Box 358, Trenton, New Jersey 08625-0358, (800) 792-9770.

...

“Health Care Plan Review Unit” means a unit within the Division of Codes and Standards of the New Jersey Department of Community Affairs, which can be contacted at PO Box 817, Trenton, NJ 08625-0817, (609) 633-8151.

...

8:43A-1.14 Qualifications of the medical director

The medical director shall be a physician who has successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in a medical specialty related to services provided by the facility, or who is a diplomate of one of the certifying boards approved by the American Board of Medical Specialties or one of the certifying boards of the American Osteopathic Association in a medical specialty related to

services provided by the facility. If the facility provides chronic dialysis services, the
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medical director shall be a nephrologist, in accordance with N.J.A.C. 8:43A-
[24.4(a)]**24.5**.

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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing**.

(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 the [Office] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing** to schedule an appointment to conduct a functional review of the application to review the conditions for licensure and operation, which request the [Office] **Division** 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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing** prior to providing the additional service.

1.-2. (No change.)

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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 **Care** Plan Review [Program of the Department of Community Affairs] **Unit** for review and approval or, in cases of existing construction where no Department of Community Affairs review is required, to the [Office] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing** 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) The licensure application for a newly constructed or expanded facility shall include a copy of the Certificate of Occupancy, Certificate of Continuing Occupancy or a Certificate of Approval issued by the municipality in which the facility has been constructed in accordance with the construction plan approval by[:] **the Health Care Plan Review**

[Division of Codes and Standards

Department of Community Affairs

PO Box 815

Trenton, New Jersey 08625-0815

Telephone: (609) 633-8151] **Unit.**

(c) Representatives of the [Office of Acute Care Assessment and Survey] **Division of 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 approved plans. The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

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 of Acute Care and Survey] **Division of 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 of Acute Care Assessment and Survey] **Division of Health Facility Survey and Field Operations** of the Department when the deficiencies, if any, have been corrected, [and the Office of Acute Care Assessment and Survey] **which** 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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing** and representatives of the facility, during which the Department will advise the facility representatives that the purpose of the

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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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing**.

(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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing** 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] **Division** of Certificate of Need and [Healthcare Facility Licensure] **Licensing**.

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

8:43A-3.3 Ownership

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(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] **Division** of Certificate of Need and [Healthcare Facility] Licensing 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] **Division** of Certificate of Need and [Healthcare Facility] Licensing.

(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.)

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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 of [Youth and Family Services] **Child Protection and Permanency** in the medical record, and serving as a liaison between the facility and the Division of [Youth and Family Services] **Child Protection and Permanency**;

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] **Child Protection and Permanency**.

(b) (No change.)

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8:43A-3.8 Reportable events

(a) The facility shall report to the Department by telephone at [(609) 588-7725 or at (609) 392-2020 after business hours] **(800) 792-9770**, the resignation or termination of employment of the administrator, and the name and qualifications of the administrator's replacement within seven days of the resignation or termination.

8:43A-9.3 Policies and procedures

(a) (No change.)

(b) The facility's policies and procedures for the administration, control, and storage of medications shall include, but not be limited to, policies and procedures for the following;

1.-10. (No change.)

11. Up-to-date pharmaceutical reference materials to be provided at locations specified in the facility's policies and procedures and made available to medical and nursing staff.

i. The telephone number of the designated Statewide or regional New Jersey Poison Information and Education System (1-800-[962-1253]**222-1222**) shall be provided at locations specified in the facility's policies and procedures.

ii.– iii. (No change.)

8:43A-12.2 Definitions

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

“Minor surgery“ means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intraoperative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve intensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple [ophthalmologic] **ophthalmologic** surgical procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as “major surgery“ within the meaning of N.J.A.C. 13:35-4.1.

...

8:43A-12.3 Surgical staff; qualifications

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(a) There shall be a physician director who is clinically responsible for the surgical service and is also board certified by the American Board of Medical [Specialists]

Specialties.

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

8:43A-12.7 Anesthesia continuous quality improvement

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

(c) The facility shall notify the [New Jersey Department of Health and Senior Services,] Inspections, Compliance and Complaints Program **of the Department**, by telephone at [(609) 292-9900 or] (800) 792-9770 or by fax at (609) 943-[3013]**4977** 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 [of Health and Senior Services] and shall include;

i.-ii. (No change.)

8:43A-12.10 Anesthesia supplies and equipment; safety systems

(a)–(b) (No change.)

(c) All medical gas hoses and adapters shall be color-coded [and labeled] **with clear labeling** according to current national standards, that is, the Compressed Gas

Association[: Standard color marking for compressed gas containers intended for
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medical use], **Standard Color Marking of Compressed Gas Containers for Medical Use**, [as well as clear labeling.] Publication [(C-9)] ([ed 3] **Edition 6**), [Arlington, VA 1988] **September 2019**, incorporated herein by reference, as amended and supplemented. That publication may be obtained [by telephoning] **from** the Compressed Gas Association at **8484 Westpark Drive, Suite 220, McLean, VA 22102 (703) [412-0900] 788-2700, <https://www.cganet.com>**.

(d)-(j) (No change.)

8:43A-14.1. Administrator's responsibilities

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

(c) The infection control professional shall have education or training in surveillance, prevention, and control of nosocomial infections. The infection control professional shall be certified in infection control within five years of beginning practice of infection control and shall maintain certification through the Certification Board of Infection Control **and Epidemiology, Inc. (CBIC)**.

8:43A-14.2. Infection control policies and procedures

(a) (No change.)

(b) The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1.-9. (No change.)

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NOTE: Centers for Disease Control publications can be obtained at

<https://www.cdc.gov/publications> and from:

National Technical Information Service

U.S. Department of Commerce

[5285 Port Royal] **5301 Shawnee** Road

[Springfield] **Alexandria**, VA [22161] **22312**

or

Superintendent of Documents

U.S. Government [Printing] **Publishing** Office

732 N. Capitol Street NW

Washington, [D.C. 20402] **DC 20401**

(866) 512-1800

Copies of the OSHA rule 29 CFR Part 1910.1030, which was published in the Federal Register on December 6, 1991, can be obtained at

<https://www.ecfr.gov/current/title-29/subtitle-A/part-29> and from:

OSHA Office of Publications

U.S. Department of Labor

Room N3101

200 Constitution Ave., NW

Washington, DC 20210

8:43A-14.3 Infection prevention measures

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(a) Infection prevention activities shall be based on the Centers for Disease Control and Prevention Guidelines, and [Hospital] **Healthcare** Infection Control Practices Advisory Committee (that is, HICPAC) recommendations listed below, incorporated herein by reference, as amended and supplemented;

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections ([1981]**2009**);

2.-3 (No change.)

4. Guidelines for Preventing Health-Care-Associated Pneumonia, 2003: Recommendation of CDC and the Healthcare Infection Control Practices Advisory Committee, published in the Morbidity and Mortality Weekly Report at MMWR 2004; 53 (No. RR-3), published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5303.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm>;

5.– 9. (No change.)

(b) The guidelines listed in (a) above are available at

<https://www.cdc.gov/infectioncontrol/guidelines/index.html> and from the National Technical Information Service (NTIS) [by calling 1-800-553-6847 or writing the NTIS, 5285 Port Royal Road, Springfield, Virginia 22161], **5301 Shawnee Road, Alexandria, VA 22312, (800) 363-2068**. [The complete set of the seven Guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention National Center of Infectious Diseases website at:

<http://www.cdc.gov/ncidod/hip/>.] The HICPAC Recommendations for Preventing the The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

Spread of Vancomycin Resistance is available on the CDC website at

[<http://www.cdc.gov/ncidod/vancom.htm>]

<https://www.cdc.gov/mmwr/preview/mmwrhtml/00039349.htm>. CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: [<http://www.cdc.gov/ncidod/hip/aresist/mrsahcw.htm>]
<https://www.cdc.gov/mrsa/healthcare/index.html>.

(c) (No change.)

8:43A-14.4. Sterilization of patient care items

(a) Methods for processing reusable medical devices shall conform with the following or revised or later editions, if in effect, incorporated herein by reference;

1. The Association for the Advancement of Medical Instrumentation (AAMI)

[requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46], ***Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ST 79;***

[2. The Association for the Advancement of Medical Instrumentation (AAMI)

requirements, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use," ST 37;

3. The Association for the Advancement of Medical Instrumentation (AAMI)

requirements, "Safe Use and Handling of Glutaraldehyde-based Products in Health Care Facilities," ST 58;

4. The Association for the Advancement of Medical Instrumentation (AAMI)

requirements, "Guidelines for the Selection and use of Reusable Rigid Container

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Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities,” ST 33;

5. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, “Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-Based, Ambulatory Care, Medical, Surgical and Dental Facilities,” January 1998; ST-42R;

6. The Association for the Advancement of Medical Instrumentation (AAMI) requirements], “Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings,” ST 35;

[7. The Association for the Advancement of Medical Instrumentation (AAMI) requirements], “Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness,” [October 1998, ST 41R] **2008, ST 41**; and

[8.] **4.** Society of Gastroenterology Nurses and Associates (SGNA), “Standards of Infection Control in Reprocessing [of] Flexible Gastrointestinal Endoscopes,” ([2000] **2018**).

(b) The documents referenced in (a) above are reviewed and/or revised every five years or more frequently as needed; the most current document is to be used. The AAMI requirements can be obtained from: The Association for the Advancement of Medical Instrumentation, [3330 Washington Building, Suite 400] **901 N. Glebe Road, Suite 300**, Arlington, VA [22209 or at the AAMI website at] **22203**, <https://www.aami.org>. SGNA’s Standards and Guidelines are available from the Society of Gastroenterology Nurses and Associates, Inc., [401 North Michigan Ave.] **330 N. Wabash Avenue, Suite 2000**, Chicago, [IL] **60611-4267**, or at **2000**, <https://www.sgna.org>.

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

8:43A-15.2 Drills, tests, and inspections

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

(c) Fire extinguishers shall be examined annually and maintained in accordance with manufacturers' requirements, National Fire Protection Association (N.F.P.A.) 10, as amended and supplemented, and N.J.A.C. [5:18] **5:70**, the New Jersey Uniform Fire Code.

(d)-(j) (No change.)

8:43A-16.3 Notice

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

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

8:43A-17.5 Regulated medical waste and solid waste management

(a) (No change.)

(b) The facility shall comply with the provisions of N.J.S.A. 13:1E-48.1, et seq., the Comprehensive Regulated Medical Waste Management Act, and [all rules promulgated

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pursuant to the aforementioned act] **the Regulated Medical Waste rules at N.J.A.C.**

7:26-3A.

(c) (No change.)

8:43A-19.3 Plan submission; payment of review fees

(a) Prior to any construction, plans shall be submitted for review and approval, in accordance with the provisions of this chapter, to the [Healthcare] **Health Care** Plan Review Unit.

(b) (No change.)

8:43A-24.4. Renal dialysis policies and procedures

(a) (No change.)

(b) The renal dialysis service shall have written infection control policies and procedures specific to the renal dialysis unit that include standard industry precautions. The written policies and procedures shall be in accordance with the Centers for Disease Control and Prevention (CDC) publication "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," MMWR, Vol. 50, No. RR-5, April 27, 2001, as amended and supplemented, available from the CDC, **1600 Clifton Road,** Atlanta, Georgia 30333 **and at**

<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm>, incorporated herein by reference.

8:43A-24.9. Reuse of dialyzers

The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

(a) If dialyzers are reused, reuse shall conform with the guidelines in the Association for the Advancement of Medical Instrumentation (AAMI) publications, “Hemodialyzers,” 2nd Edition and Amendment, RD16:1996 and A1:2002, “Hemodialyzer blood tubing,” 2nd Edition and Amendment, RD17:1994 and A1:2002, and “Reuse of hemodialyzers,” 3rd Edition and Amendment, RD47:2002 and A1:2003, incorporated herein by reference as amended and supplemented.

1. AAMI publications can be obtained from;

Association for the Advancement of Medical Instrumentation

[Suite 602

1901 North Fort Meyer Drive]

901 N. Glebe Road, Suite 300

Arlington, VA [22209] **22203**

or at the AAMI website at <https://www.aami.org>.

(b)-(e) (No change.)

8:43A-24.10 Water treatment and dialysate

(a) Water treatment equipment, water, and dialysate shall satisfy the requirements

specified in the Association for the Advancement of Medical Instrumentation

publications entitled, “Water treatment equipment for hemodialysis applications,”

RD62:2006, [“Dialysate for hemodialysis,” RD52:2004] **Preparation and quality**

management of fluids for haemodialysis and related therapies – Part 5: Quality of

dialysis fluid for haemodialysis and related therapies,” ISO 23500-5:2019,

“Hemodialysis systems,” [RD5:2003] **RD5:2008**, and [“Concentrates for hemodialysis”

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RD61:2000] “**Dialysis Fluid Chemical Composition,**” **AAMI TIR72:2017**, incorporated herein by reference, as amended and supplemented.

1. Samples shall be taken at the first and last station and at least 10 percent of the stations on a rotating basis within the distribution system to [insure] **ensure** each station is tested semi-annually. A calibrated loop may not be used in microbiological testing of water samples.

2.-4. (No change.)

5. Preparation of dialysate onsite requires the facility to establish policies and procedures to [assure] **ensure** the safety and efficacy of the dialysate solution. A record of preparation of the dialysate shall be maintained.

6.-9. (No change.)

8:43A-24.17. Requirements for pediatric dialysis services

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

(d) The pediatric care plan shall be established as follows;

1. The pediatric care plan shall be developed by a multidisciplinary team as set forth in N.J.A.C. 8:43G-[30.12]**30.7**.

i.– ii. (No change.)

(e) (No change.)

8:43A-24.18. Renal dialysis quality assurance plan

(a)–(b) (No change.)

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(c) At a minimum, the quality assurance plan shall analyze those indicators required by the Trans-Atlantic Renal Council (109 South Main Street, **Suite 21**, Cranbury, [New Jersey] **NJ** 08512, <https://www.tarcweb.org>). These indicators can be found in the Medicare ESRD Network Organizations Manual (Revision 2, September 12, 2003), incorporated herein by reference, as amended and supplemented, which is available for download from the Centers for Medicare and Medicaid Services website at [\www.cms.hhs.gov/esrd/2.asp and upon request to the Department by telephoning (609) 292-5960] <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2ESRD.pdf> and <https://www.cms.gov>.

(d) (No change.)

8:43A-26.2 Smoking in facility

(a) The facility shall [become] **be** smoke-free [within three months of the effective date of this section]. “Smoke-free“ means a total ban on smoking in the facility by employees and visitors. [Prior to the time at which the facility becomes smoke-free, the policy of the facility regarding smoking in the facility shall be in accordance with N.J.S.A. 26:3D-1, et seq.

1. If the facility permits patients to smoke after the facility becomes smoke-free, smoking] **Smoking** by patients shall only be permitted in accordance with N.J.S.A. 26:3D-[1]55, et seq., and in a designated area with outside ventilation. The ventilation system shall prevent contaminated air from recirculating through the facility and shall prevent backstreaming of smoke into nonsmoking areas of the facility.

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8:43A-26.7 Medical records

The complete medical record for patients receiving drug abuse treatment services shall include, but not be limited to, a copy of the Alcohol and Drug Abuse Data System (ADADS) form (See Appendix A) or other management information system form approved by the [Division of Alcoholism, Drug Abuse and Addiction Services of the] Department, incorporated herein by reference.

8:43A-27.2 On-site inspection

An on-site inspection of the construction of the physical plant shall be made by representatives of **the** Health [Facilities Construction Services] **Care Plan Review Unit** to verify that the building has been constructed in accordance with the architectural plans approved by the Department. The Department may choose to accept an equivalent inspection by a local agency in lieu of an inspection by representatives of **the** Health [Facilities Construction Services] **Care Plan Review Unit**.

8:43A-29.1 Scope

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

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

8:43A-29.13 Data collection and reporting for performance improvement

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

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(c) Licensees shall report to the Department, by telephone at [(609) 588-7725 or at (609) 392-2020 after hours] **(800) 792-9770**, incidents in which a medical device is connected with the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990, 21 U.S.C. § 360.

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

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

(c) Copies of American College of Radiology or the American College of Radiation Oncology accreditation 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-30.8 Megavoltage radiation oncology program utilization

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

(c) Megavoltage radiation oncology facilities providing potentially curative treatment to children under 13 years of age shall be accredited for participation in protocols of a national multi-institutional pediatric oncology group such as [Children's Cancer Group (CCG) or Pediatric Oncology Group (POG)] **Children's Oncology Group (COG)**.

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

Megavoltage radiation oncology facilities shall submit such utilization, performance and outcome data as the Department may request. Data shall include, but

not be limited to, staff qualifications, verification of equipment calibration, program

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accreditation status and program utilization by service category, on reporting forms developed and annually submitted to the Department [of Health and Senior Services] on or before March 31.

8:43A-31.1 Water supply

(a) The water supply used for drinking or culinary purposes shall be adequate in quantity, of a safe and sanitary quality, and from a water system which shall be constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1, et seq., N.J.A.C. 7:10, and local laws, ordinances, and regulations. There shall be no back siphonage conditions present.

Copies of the Safe Drinking Water Act can be obtained from the New Jersey Department of Environmental Protection, [Bureau of Potable Water] **Division of Water Quality**, PO Box 209, Trenton, [New Jersey] **NJ** 08625-0209.

(b) (No change.)

8:43A-32.3 Waiver requests

(a) (No change.)

(b) Waiver forms are available from the [Office of Certificate of Need and Healthcare Facility Licensure] **Division of Certificate of Need and Licensing**.

8:43A-33.1 Scope

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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) (No change.)

(b) Waiver requests shall follow the process outlined at N.J.A.C. 8:43A-2.9.

[(c) Waiver application forms are available at the Department's Forms page at <http://web.doh.state.nj.us/forms>] or from:

Director

Office of Certificate of Need and Healthcare Facility Licensure

Division of Health Facilities Evaluation and Licensing

New Jersey Department of Health and Senior Services

PO Box 358

Trenton, NJ 08625-0358.]

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