Registered Surgical Practice Training

What You Need to Do to Get Licensed
Welcome

Introduction to the Law

The Licensing Process

The Survey Process

Question and Answers
Welcome

If you’d like an electronic copy of this presentation, please send an email to regulations.cnl@doh.nj.gov
Introduction to the Law

- Amendments to **N.J.S.A. 26:2H-12** signed into law on January 16, 2018

- Requires all surgical practices to apply for licensure by January 15, 2019 (**N.J.S.A. 26:2H-12g(4)**)

- Provides for physical plant “grandfathering” for CMS certified or accredited ambulatory care facilities (**N.J.S.A. 26:2H-12g(4)**)

- Need to be accredited as an ambulatory surgery facility upon your first license renewal – one year (**N.J.S.A. 26:2H-12h**)

NJ Health
cNew Jersey Department of Health
Introduction to the Law

- Provides for an exemption from initial and renewal licensing fees (N.J.S.A. 26:2H-12b(1))

- Report changes in Medical Director, Director of Nursing and Director of Anesthesia Services within 30 days (N.J.S.A. 26:2H-12k(2))

- Can expand scope of services, i.e. conscious sedation to general anesthesia
  1. Receive initial licensure as an ASC, then
  2. Apply and receive approval prior to expanding scope of services
Introduction to the Law

• Surgical practices cannot relocate as a surgical practice
  • Need to be licensed prior to reopening (N.J.S.A. 26:2H-12i(7)(c)
  • New location needs to meet all current physical plant standards
Introduction to the Law

Required to comply with all applicable Departmental regulations, including:

- **N.J.A.C. 8:43A** - MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES (Except for certain physical plant requirements)
- **N.J.A.C. 8:43E** - GENERAL LICENSURE PROCEDURES AND STANDARDS APPLICABLE TO ALL LICENSED FACILITIES
- **N.J.A.C. 8:30** - RULES IMPLEMENTING THE HEALTH CARE PROFESSIONAL RESPONSIBILITY AND REPORTING ENHANCEMENT ACT
- **N.J.A.C. 8:56** - HEALTH CARE FACILITY INFECTION REPORTING
Exempt from Ambulatory Care Assessment (N.J.S.A. 26:2H-12g(4))

However, if you add an additional operating room(s), you will be subject to the assessment.
THANK YOU

michael.kennedy@doh.nj.gov
eugene.brenycz@doh.nj.gov
Licensing

• Application form is the CN-7 which is available on the DOH website at:

• There are a number of items that you will have to submit with the CN-7
Licensing

Project Narrative

• Description of the facility such as, freestanding or part of an office and floor)

• Your surgical practice registration number

• Types of surgeries to be provided

• Anesthesia types to be used
A listing of your facility staff:

1. Administrator (N.J.A.C. 8:43A-5.1);

2. Medical Director (N.J.A.C. 8:43A-7.2);

3. Director of Nursing (N.J.A.C. 8:43A-8.2); and

4. Director of Anesthesia, if required by N.J.A.C. 8:43A-12.4
Licensing

• A physical plant drawing which labels all rooms with their dimensions in square feet, along with corridor widths. Include all handwashing sinks and toilets

• Ownership List identifying 100% of the ownership
Licensing

• Track Record Review – Do owners of the new ASC have any ownership interest (including percent ownership) in all other types of licensed ambulatory care facilities in NJ or any other state (N.J.A.C. 8:33-4.10(d))

• Type of ambulatory care facilities include, but are not limited to ASCs, ACFs, diagnostic imaging, and dialysis facilities

• If there is an ownership interest of 10% or more, you will need to submit track records with your applications
Licensing

Inspection fee (N.J.A.C. 8:43A-2.2(m))

• $2,000

• Due every other year with renewal
Licensing

- If in the review of your licensing application staff notices that you have missed something or that something is not clear, you will receive written questions from staff asking for clarification.

- If you already submitted a licensing application, you will have to resubmit them and address all that has been discussed today.

- Once approved, you will be advised to contact survey to schedule an inspection.
Licensing

Renewal

• Renewal application (which includes the DOH record of current services, site address, ownership and the like) will be sent about 45-60 days before the annual license renewal date (N.J.A.C. 8:43A-2.6)

• This is for renewal only – do not make any other changes such as transfers of ownership
Licensing

Waivers

• The licensing requirements for ASCs do include a waiver provision (N.J.A.C. 8:43A-2.9)

• CN-28 is the waiver form

• One form per waiver request. Cite the rule from which you are requesting the waiver and provide a clear justification and rationale for it. Indicate how what you propose meets the intent of the requirement if not its “letter.”
Licensing

Transfer/Changes in Ownership

• Any changes to your license, including ownership, must be made on the CN-7 form. Please plan for a 90-120 day review period (N.J.A.C. 8:43A-3.3)

• A change in existing owners without a change resulting in someone achieving a 10% or more ownership interest requires notice within 30 days of the change (N.J.S.A. 26:2H-12k(1))
Licensing

• Your point of contact for your application is the analyst assigned to the county your surgical practice is located in

• Phone Numbers:
  (609) 292-6552
  (609) 292-7228
THANK YOU

john.calabria@doh.nj.gov
ASCs are licensed in accordance with **N.J.A.C. 8:43A**

State licensed facilities must also be in compliance with **N.J.A.C. 8:43 E**
Types of Surveys

- State Licensure Approval Surveys
- State Re-licensure Surveys
- Complaint Investigations
SURVEY PROCESS: Survey Team

- Usually two nurse surveyors
- One pharmacist
- One sanitarian/nurse
- One building inspector
- May have new staff on site
SURVEY PROCESS: Length of Survey

• Typically staff are on site one day for a State survey.

• Depends on the number of surveyors.

• Pharmacist or Building Inspector may survey after the team

• Approval surveys are announced, facility will select the date of inspection
Survey staff will interview DON or Administrator and ask for:

- Policies and procedures, infection control program, and QA information
- A blank medical record
- Employee files including health information and in-service records
- Facility will receive a helpful checklist when approval survey is scheduled
SURVEY PROCESS: Physician/Employee Files

We will review:

- Staff education/orientation/competencies
- Credentials/Privileges
- Licenses
- Health information
We will review:

- Review of bylaws/meeting minutes
- Appointment of privileges
- Appointment of Administrator/Alternate
- Appointment of Medical Director/Alternate
- Designation of Director of Nursing/Alternate
SURVEY PROCESS: Contracted Services

If not provided directly, must contract for:

- Dietary Services
- Social Work Services
- Lab
- Radiology
SURVEY PROCESS: Tour of Facility

Infection Control:

- Review processing of instrumentation
- Review storage/handling of instrumentation
- Review Manufacturer’s Instruction for Use
- CDC/AAMI guidelines
Infection Control:

- Infection control professional
- Day to day person for infection control
- Interview certified tech or tech who will be certified
Physical Environment:

• Assess environment for functionality vs. Facility Guidelines Institute (FGI) guidelines

• Cleanliness of environment

• Review of housekeeping policies/procedures
SURVEY PROCESS: Tour of Facility

Pharmacy:

• CDS/DEA

• Ability to respond to malignant hyperthermia

• Do not use single dose vials multiple times

• Drug accountability

• Contract with consultant pharmacist
Emergency Services:

- Able to respond to medical emergencies
- Drills and tests in accordance with subchapter 15
- RN in PACU must be ACLS
- One RN present when patient is in PACU and a second health care staff member immediately available
N.J.A.C. 8:43E/8:30

- Human Trafficking
- Pain Management
- Reportable Events and Patient Safety
- Universal Transfer Form
- N.J.A.C. 8:30 - Health Care Professional Responsibility and Reporting Enhancement Act
The ASC Survey Process

THANK YOU

stefanie.mozgai@doh.nj.gov
louise.steska@doh.nj.gov
Question and Answers

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