

PHILIP D. MURPHY Governor

TAHESHA L. WAY

PO BOX 358 TRENTON, N.J. 08625-0358

www.nj.gov/health

JEFFREY A. BROWN Acting Commissioner

TO: Registered Surgical Practices Required to Apply for Licensure and Ambulatory

Surgery Centers

FROM: Michael J. Kennedy, J.D.

Executive Director, Division of Certificate of Need and Licensing

NOV

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RE: Responses to Frequently Asked Questions to Registered Surgical Practices

This document is designed to answer some frequently asked questions (FAQ) regarding registered surgical practices (RSP), which are statutorily required to apply for licensure as ambulatory surgery centers (ASC) and to summarize various aspects of compliance, from operational standards to reporting obligations.

1. What is the role of the Department of Health (Department) in regulating registered surgical practices?

RSPs are one-room surgical facilities owned and operated by private physicians for use in their private practices. Originally, those private practices were only subject to regulation by the Board of Medical Examiners (BME). Statutory authority for the Department to regulate RSPs is contained in *N.J.S.A.* 26:2H-12. With multiple amendments to the statute dating back to 2009, the legislature has determined that Registered Surgical Practices were required to apply for licensure as an ASC, which is a type of ambulatory care facility, by January 15, 2019.

2. With which Department regulations should administrators of registered surgical practices required to apply for licensure by the Department as an ambulatory care facility be familiar?

RSPs requiring licensure are subject to regulation under the New Jersey Administrative Code (*N.J.A.C.*). Chapter 43A Manual of Standards for Licensing Ambulatory Care Facilities, Chapter 8:43E General Licensure Procedures and Standards Applicable to All Licensed Facilities and Chapter 8:30 Rules Implementing the Health Care Professional Responsibility and Reporting Enhancement Act.

3. What are the characteristics of a surgical practice that required registration?

A surgical practice required to register was characterized by having no more than one operating room, which is specifically equipped to perform surgical procedures and designed to accommodate invasive diagnostic and surgical procedures. It may include one or more post-anesthesia recovery units or a designated recovery area. These surgical practices were established in a practice form that was specified by the BME. Acceptable practice forms included a private physician, a professional association of physicians, or other professional entity. A surgical practice was and is intended solely for the private medical practice of the organizing entity or individual. (See *N.J.S.A.* 26:2H-12g(5)).

4. Which physician-owned surgical practices did not need to register with the Department of Health?

Physician-owned surgical practices that have a procedure room used for endoscopies, hysteroscopies, and cystoscopies that have a sink in the room did not need to register since the room cannot be used for surgery due to sterility issues. Physician-owned surgical practices that have a single room only used for pain management also did not need to register.

5. If an RSP is not licensed with the Department as an ASC, what does it need to do?

RSPs were required by P.L. 2017, c.283 to apply for licensure with the Department by January 15, 2019. It is the facility's responsibility to ensure that this license has been obtained. Any questions regarding the licensing process can be directed to CNandLicensingRequests@doh.ni.gov.

6. Can an RSP that failed to apply to the Department by January 15, 2019, be licensed as an ASC?

No. The statute is clear that RSPs were required to apply for licensure within one year of the date of enactment of the statute, which was January 15, 2019. (See *N.J.S.A.* 26:2H-12g(4)).

7. Can a new ASC be established?

Beginning on March 21, 2009, in accordance with P.L.2009, c.24, and as provided in P.L.2017, c.283, the Department will not issue a new license to an ambulatory surgery center unless: it is a transfer of ownership of an existing facility that the Department must approve, the entity is a registered surgical practice required to be licensed by the Department, the entity has filed its plans, specifications, and required documents with the Health Care Plan Review Unit of the Department of Community Affairs or the municipality in which the surgical practice or facility will be located, as applicable, on or before September 17, 2009, the facility is owned jointly by a general hospital in this State, the

facility is owned by a hospital or medical school in this State, or the facility is a newly licensed ambulatory surgical facility that was created by combining two or more registered surgical practices, provided that the number of operating rooms at the newly licensed facility is not greater than the total number of operating rooms prior to the establishment of the newly licensed facility.

8. Are RSPs required to apply for licensure by the Department as an ambulatory care facility exempt from the physical plant and functional review requirements specified in *N.J.A.C.* 8:43A-19.1 et seq.?

N.J.A.C. 8:43A-19.1 et seq. contains physical plant and functional requirements. In accordance with *N.J.S.A.* 26:2H-12g(4), an RSP that is certified by the Centers for Medicare and Medicaid Services (CMS) is not be required to meet the physical plant and functional requirements specified in *N.J.A.C.* 8:43A-19.1 et seq. An RSP that is not Medicare certified, either by CMS or by any deeming authority recognized by CMS, but which has obtained accreditation from the American Association of Ambulatory Surgery Facilities or any accrediting body recognized by CMS and is in operation on January 16, 2018, is not be required to meet the physical plant and functional requirements specified in *N.J.A.C.* 8:43A-19.1 et seq.

9. Can a registered surgical practice that does not meet the certain limited circumstances exemption contained in the statute apply for a waiver of the physical plant requirements?

N.J.A.C. 8:43A has a waiver provision to allow for some flexibility in meeting the regulatory standards. RSPs required to apply for licensure by the Department as an ambulatory care facility that do not meet the requirements contained in *N.J.S.A.* 26:2H-12g(4) may apply for a waiver from physical plant requirements under *N.J.A.C.* 8:43A-19.1 et seq. An application for a waiver form (CN-28) is available on the Department's Forms webpage at https://healthapps.nj.gov/forms/subforms.aspx?pro=healthfacilities. All waivers are subject to review and are granted only if it is determined that the facility can ensure the continued health and safety of patients and the public.

10. Can a registered surgical practice relocate to another location?

Once licensed by the Department as an ambulatory care facility, an RSP may relocate within 20 miles of its current location or into a Health Enterprise Zone. To relocate, a facility must request review and approval of the proposed relocation before obtaining a license at the new location. The relocation of a facility must be preapproved by the Department. (See *N.J.S.A.* 26:2H-12(i)(2)).

11. Once an RSP is licensed by the Department under the provisions of *N.J.A.C.* 8:43A as an ASC, is it still exempt from the ambulatory care assessment?

The Healthcare Finance Enhancement Act, P.L. 2025, c.70 amended N.J.S.A. 26:2H-12

to remove the RSP exemption from the ambulatory care assessment. Therefore, all ASCs, are required to report their revenue beginning in the current fiscal year 2026 and to pay the ambulatory care assessment starting in fiscal year 2027. Information regarding the ambulatory care assessment can be found at the Department's Health Care Financing webpage at https://www.nj.gov/health/hcf/assessments/.

12. What fees are an RSP required to apply for licensure by the Department as an ambulatory care facility still exempt from paying?

RSPs required to apply for licensure by the department as an ambulatory care facility are exempted by *N.J.S.A.* 26:2H-12b(1) from DOH application and license renewal fees. This exemption expires if the RSP chooses to expand the scope of its practice by adding additional operating rooms.

13. What fees is an RSP required to apply for licensure by the department as an ambulatory care facility required to pay?

While RSPs required to apply for licensure by the department as an ambulatory care facility are exempt from paying a license renewal fee, *N.J.A.C.* 43A requires that ambulatory surgery centers pay a biennial inspection fee. This fee, listed in *N.J.A.C.* 8:43A-2.2, is \$ 2,000.

14. What is the licensure process for an RSP to expand the scope of service from conscious sedation to general anesthesia?

To expand services from conscious sedation to general anesthesia, a practice must first obtain licensure as an ambulatory care facility and then seek approval from the Department.

15. What are the accreditation requirements for an ambulatory surgery center?

An ambulatory care facility licensed to provide surgical services is required to obtain ambulatory care accreditation from an accrediting body recognized by the Centers for Medicare and Medicaid Services. Accreditation was mandatory for licensed ASCs, with a one-year timeframe following the effective date of P.L. 2009, c.24. Newly licensed ASCs must achieve accreditation upon the first license renewal, ensuring adherence to quality standards. (See *N.J.S.A.* 26:2H-12h).

16. What changes must be reported to the Department of Health?

The Department requires ASCs to report the name of the facility's medical director, physician director, and physician director of anesthesia, as applicable, and the director of nursing services annually and within 30 days of any change in a director, pursuant to *N.J.S.A.* 26:2H-12(k). This obligation is critical to maintaining transparency and compliance with state regulations and safeguarding the integrity of healthcare operations.

17. When is a Transfer of Ownership (TOO) application required?

A TOO application is required when a new individual or entity will own 10 percent or more of the licensed operator, or when an existing owner increases their ownership from less than 10 percent to more than 10 percent.

18. When is the process when the changes in ownership structure do not exceed 10 percent?

Notification, submitted in writing within 30 days, is required when a new owner will hold less than 10 percent of the licensed operator, when an existing owner with 10 percent or more changes their ownership percentage, or when an existing owner with less than 10 percent changes their ownership but remains below the 10 percent threshold.