State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

MIKIE SHERRILL
Governor

DR. DALE G. CALDWELL
Lt. Governor

DR. RAYNARD E. WASHINGTON
Commissioner

In Re Licensure Violation:

Advanced Surgical Institute

(NJ Facility ID# NJ24201)

NOTICE OF ASSESSMENT OF PENALTIES

TO: Lisa McNulla
LMcNulla@virtua.org
Advanced Surgical Institute
556 Egg Harbor Road, Suite B
Sewell, NJ 08080

The Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) (the Act) provides a statutory scheme designed to ensure that all health care facilities are of the highest quality. Pursuant to the Act and N.J.A.C. 8:43E-1.1 et seq., General Licensure Procedures and Standards Applicable to All Licensed Facilities, the Commissioner of the Department of Health (the "Department") is authorized to inspect all health care facilities and to enforce the Standards for Licensing Ambulatory Care Facilities set forth at N.J.A.C. 8:43A-1.1 et seq.

LICENSURE VIOLATIONS & MONETARY PENALTIES

Staff from the Department's Health Facility Survey and Field Operations visited Advanced Surgical Institute (hereinafter "Advanced Surgical") on December 2, 2024, for the purpose of conducting a complaint survey. The report of this visit is incorporated herein by reference.

The survey substantiated that the facility was in violation of N.J.A.C. 8:43A-7.4(a)(2), N.J.A.C. 8:43A-9.4(a), and N.J.A.C. 8:43A-14.4(g), which require licensed health care facilities to maintain written medical policies and medical staff bylaws that include mechanisms for credentials review, delineation of qualifications, medical staff appointments and reappointments, evaluation of medical care, and the granting, denial, suspension, or revocation of medical staff privileges; to ensure that all medications administered are prescribed in writing with each order specifying the drug name, dose, frequency, route of administration, and the prescriber's signature and date; and to ensure that manufacturer's instructions for the cleaning, testing, disassembly, and sterilization of patient care equipment are readily available and consistently followed by staff.

Based on observation, staff interview, and review of medical records, credentialing files, and facility documentation, Advanced Surgical failed to ensure effective medical staff oversight, safe medication administration practices, and adherence to infection prevention and control standards, resulting in systemic breakdowns that placed patients at risk for harm.

Review of medical staff credentialing files revealed that the facility failed to ensure that all members of the medical staff were granted clinical privileges in writing by the governing body, with clear delineation of the

procedures they were authorized to perform. On November 25 and November 26, 2024, review of credentialing files for Staff #4 (Registered Nurse First Assistant), Staff #10 (Certified Registered Nurse Anesthetist), and Staff #12 (Anesthesiologist) identified delineation of privilege forms that were incomplete and lacked documentation of approval or denial for requested procedures. Although reappointment letters indicated that privileges were granted in accordance with delineation of privileges, the corresponding forms failed to reflect governing body approval, were unsigned and undated, and did not specify which procedures were authorized. Facility leadership and the Medical Director asserted that the providers were qualified and approved; however, the absence of complete and accurate documentation demonstrated a failure to implement the facility's own medical staff bylaws and credentialing processes, limiting the facility's ability to ensure accountability, oversight, and patient safety.

Further review identified significant failures in medication administration practices related to controlled dangerous substances (CDS). On November 26 and December 2, 2024, review of multiple patient medical records revealed that nursing staff administered CDSs to patients without a complete, written physician order. Specifically, patients P28, P29, P31, P34, and P35 received medications including Percocet and Fentanyl based on non-specific statements such as "medications as ordered by anesthesia," without corresponding physician or anesthesia orders specifying the drug, dose, route, frequency, signature, and date. Controlled Substance Count Sheets and Post-Anesthesia Care Unit records confirmed administration of these medications despite the absence of valid orders. Interviews with nursing staff and the Director of Nursing confirmed that the expectation was to have a physician's order for each medication administered, yet staff were unable to explain why medications were given without such orders. These failures represented a breakdown in nursing oversight, physician accountability, and adherence to facility policy, placing patients at risk for medication errors, adverse drug events, and compromised post-operative care.

In addition, the facility failed to ensure compliance with infection prevention and control requirements related to the sterilization and processing of patient care equipment. During a tour of the Sterile Processing area on November 25, 2024, a handheld canless air system ("Hurricane") was observed being used to dry cannulated instruments. Staff interviews confirmed that the device was routinely used to dry ophthalmology cannulas and suction instruments following washing. Despite multiple requests, staff were unable to produce the manufacturer's instructions for use (MIFU) for the Hurricane device. While MIFUs for the instruments being dried were available and specified the use of micro-filtered, pressurized medical-grade air, the facility could not demonstrate that the Hurricane device met these specifications or was intended for use on medical devices. The absence of the MIFU prevented verification that equipment was used safely and in accordance with manufacturer requirements, increasing the risk of inadequate drying, contamination, and compromised instrument sterility.

Collectively, these findings demonstrated systemic failures in governance, clinical oversight, and regulatory compliance. The facility failed to comply with N.J.A.C. 8:43A-7.4(a)(2) by not ensuring medical staff privileges were properly delineated, approved, and documented; N.J.A.C. 8:43A-9.4(a) by administering controlled dangerous substances without complete, written physician orders; and N.J.A.C. 8:43A-14.4(g) by failing to maintain and follow manufacturer instructions for equipment used in the cleaning and sterilization process. These deficiencies placed surgical patients at continued risk for unauthorized clinical practice, medication errors, infection transmission, and compromised surgical and post-operative care, reflecting failure to adhere to regulatory requirements, facility policies, and accepted standards of professional practice.

In accordance with N.J.A.C. 8:43E-3.4(a)(10), a penalty of $2,500 per violation is assessed due to the violation of N.J.A.C. 8:43A-9.4(a), which resulted in an immediate and serious risk of harm to patients. The penalty is assessed from November 25, 2024, the date Survey identified that Controlled Dangerous Substances were administered to patients P28, P29, P31, P34, and P35 without complete, written physician orders, to December 2, 2024, the date the facility completed staff re-education, observation, and documentation to ensure compliance with medication administration policies. During this period, the facility failed to ensure that all medications were administered in accordance with physician orders, placing patients at risk for medication errors, adverse drug events, and compromised post-operative care. The penalty is assessed for 5 affected patients at $2,500 per patient, resulting in a total penalty of $12,500.

In accordance with N.J.A.C. 8:43E-3.4(a)(8), a penalty of $1,000 per day is assessed due to the violation of N.J.A.C. 8:43A-14.4(g), which represented a deficiency posing a direct risk to patient safety. The penalty is assessed from November 25, 2024, the date Survey observed the Hurricane canless air system being used to dry cannulated instruments without manufacturer's instructions for use, to November 26, 2024, the date the device was removed from service and correction was verified through direct observation, documentation, and staff interview. During this period, the facility failed to ensure that sterilization and processing of patient care equipment adhered to manufacturer guidelines, increasing the risk of contamination and compromised instrument sterility. The penalty is assessed for a total of 2 days at $1,000 per day, resulting in a total penalty of $2,000.

In accordance with N.J.A.C. 8:43E-3.4(a)(10), a penalty of $2,500 per violation is assessed due to the violation of N.J.A.C. 8:43A-7.4(a)(2), which resulted in an immediate and serious risk of harm to patients. The facility failed to maintain documentation demonstrating governing body approval and delineation of clinical privileges for three medical staff members. Because the facility could not verify which procedures these practitioners were authorized to perform, the Department could not ensure that surgical and anesthesia services were provided only by appropriately privileged individuals. The penalty is assessed for three affected practitioners at $2,500 per violation, resulting in a total penalty of $7,500.

Thus, the total penalty imposed for these violations is $22,000.

The total amount of this penalty is required to be paid within 30 days of receipt of this letter by certified check or money order made payable to the "Treasurer of the State of New Jersey" and forwarded to Office of Program Compliance, New Jersey Department of Health, P.O. Box 358, Trenton, New Jersey 08625-0358, Attention: Lisa King. **On all future correspondence related to this Notice, please refer to Control AX25001.**

INFORMAL DISPUTE RESOLUTION (IDR)

N.J.A.C. 8:43E-2.3 provides facilities with the option to challenge factual survey findings by requesting Informal Dispute Resolution with Department representatives. Facilities wishing to challenge only the assessment of penalties are not entitled to IDR review, but such facilities may request a formal hearing at the Office of Administrative Law as set forth herein below. Please note that the facility's rights to IDR and administrative hearings are not mutually exclusive and both may be invoked simultaneously. IDR requests must be made in writing within ten (10) business days from receipt of this letter and must state whether the facility opts for a telephone conference or review of facility documentation only. The request must include an original and ten (10) copies of the following:

1. The written survey findings;

2. A list of each specific deficiency the facility is contesting;

3. A specific explanation of why each contested deficiency should be removed; and

4. Any relevant supporting documentation.

Any supporting documentation or other papers submitted later than 10 business days prior to the scheduled IDR may not be considered at the discretion of the IDR panel. Send the above-referenced information to:

Nadine Jackman, Office of Program Compliance
New Jersey Department of Health
P.O. Box 358
Trenton, New Jersey 08625-0358

The IDR review will be conducted by professional Department staff who do not participate in the survey process. Requesting IDR does not delay the imposition of any enforcement remedies.

FORMAL HEARING:

Advanced Surgical is entitled to challenge the assessment of penalties pursuant to N.J.S.A. 26:2H-13, by requesting a formal hearing at the Office of Administrative Law (OAL). The facility may request a hearing to challenge any or all of the following: the factual survey findings and/or the assessed penalties. Advanced Surgical must advise this Department within 30 days of the date of this letter if it requests an OAL hearing.

Please forward your OAL hearing request to:

Attention: OAL Hearing Requests
Office of Legal and Regulatory Compliance, New Jersey Department of Health
P.O. Box 360
Trenton, New Jersey 08625-0360

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if Advanced Surgical is owned by a corporation, representation by counsel is required.

In the event of an OAL hearing regarding the penalty, Advanced Surgical is further required to submit a written response to each, and every charge as specified in this notice, which shall accompany its written request for a hearing.

Failure to submit a written request for a hearing within 30 days from the date of this notice will render this a final agency decision. The final agency order shall thereafter have the same effect as a judgment of the court. The Department also reserves the right to pursue all other remedies available by law.

Thank you for your attention to this important matter and for your anticipated cooperation. Should you have any questions concerning this notice, please contact Lisa King, Office of Program Compliance at Lisa.King@doh.nj.gov.

Sincerely,

Gene Rosenblum

Gene Rosenblum, Director
Office of Program Compliance
Division of Certificate of Need and Licensing

GR:LK:jc:nj
DATE: June 12, 2026
REGULAR AND CERTIFIED MAIL, RETURN RECEIPT REQUESTED
Control# AX25001