

*House Concurrent Resolution 70 of the 2019 Regular Legislative Session
Potential Licensure of Endovascular Suites*

Prepared by:

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Introduction / Executive Summary: House Concurrent Resolution (HCR) Seventy (70):

Potential Licensure of Endovascular Suites

Introduction

As required by House Concurrent Resolution (HCR) Seventy (70) of the 2019 Regular Legislative Session (HCR 70) urge and request the Louisiana Department of Health (LDH) to coordinate a study concerning the feasibility and desirability of potential state licensure of Endovascular Suites, and to report findings of the study to the Legislative Committees on Health and Welfare. An Endovascular Suite(s) is a room in which procedures are performed as a form of treatment on diseases of the vascular system. Currently Louisiana does not require state licensing of endovascular suites either as stand-alone facilities or as a module of the Ambulatory Surgical Center (ASC) license provided for in R.S. 40:2131 et seq. The Louisiana Department of Health through its Health Standards Section, protects public health and safety by licensing and oversight of regulations of various types of healthcare facilities, pursuant to the authority provided in Chapter Eleven (11) of Title Forty (40) of the Louisiana Revised Statutes, thereby, called by Louisiana Legislature to study and report concerning potential licensure of endovascular suites in order to inform its consideration of whether laws to provide for such licensure would serve the public interest.

Requirements of the Resolution

Endovascular Suite is a specialized room which offers the imaging capabilities of a catheterization laboratory, melded with an operating room that provides a hybrid approach to the diagnosis and treatment of vascular diseases. Endovascular Suites are comprised of both state-of-the-art surgical and advanced imaging equipment, which allows specialized physicians, such as, Interventional Radiologists, Interventional Cardiologists, Vascular Surgeons and General surgeons, to perform traditional, open surgery, and minimally-invasive, simultaneously image-guided percutaneous intervention for arterial, venous and dialysis – related procedures.

The LDH Deputy Assistant Secretary, Legal Counsel and Endovascular Suite Workgroup conducted their first meeting on September 3, 2019 with Laurie Brown, BSN, RN, and Chief Compliance Officer for Vascular Access Centers, Philadelphia, PA and Dr. Stephen Ferrara, Interventional Radiologist. Cecile Castello BSN, RN, LDH/DAS and Director for the Health Standards Section (HSS) and the HSS endovascular team continued to have ongoing meetings and conference calls to obtain information from Vascular Access Centers, as well as, consulted with stakeholder's organizations including, without limitation, Dr. Culotta from the Louisiana State Board of Medical Examiners (LSBME), the Louisiana Hospital Association (LHA), Cardiovascular Institute of the South Administration and several other Subject Matter Experts (SMEs).

Summary of Endovascular Suite Team Meetings

The Endovascular Team researched how other states are utilizing Endovascular Suites and revealed that the majority of the Endovascular Suites in some other states, are licensed as a module under the Ambulatory Surgical Center licensure versus a stand-alone licensure as its own entity. LDH/HSS Team and Vascular Access Centers (VAC) Administration had engaging discussions regarding the pros and cons of Endovascular Suite procedures as a module under an ASC versus performing endovascular procedures in the hospital setting. Summary of discussion with SME's are as follows:

Vascular Access Centers (VAC), currently operates multiple office based labs in multiple states and a licensed Ambulatory Surgery Facility (ASF) in the Commonwealth of Pennsylvania. VAC's office based labs and ASF are accredited by the Joint Commission under the system accreditation for Ambulatory Health Care since 2010. VAC discussed how they experienced several challenges when patients were admitted to a hospital to have an urgent Endovascular procedure. Often times, they found there was a delay scheduling a patient timely in the hospital operating room (OR), either because of lack of OR availability with proper imaging, inpatients taking precedence or lack of allowable OR time slots that coordinated with the Physician that was performing the endovascular procedure. Another issue that VAC mentioned, was when a patient was admitted to a hospital that does not administer hemodialysis after their endovascular procedure; thereby, causing further delay in treatment for a patient that is in renal failure. Lastly, VAC also explained that they often found that hospitalized patients had an increased risk of developing an infection, which increased their length of stay (LOS), as opposed to patients having endovascular procedures in an ASC.

Cardiovascular Institute of the South (CIS), one of the largest cardiovascular institutions in Louisiana, perform endovascular procedures in an office based Lab/Imaging setting and are credentialed and approved by a nationally recognized accrediting/credentialing organization; such as, Accreditation Council for Graduate Medical Education (ACGME). ACGME is responsible for accrediting all medical training programs for physician practitioners, board certification, board eligibility, and/or completion of a training program in a field of specialization recognized by the ACGME for the expertise and proficiency in that specialized field or demonstration of current competency for the specific procedures. CIS Physicians attest that having procedures in an office based endovascular lab setting increases their productivity by limiting waiting for the hospital procedure room to be available, allowing physicians to see other patients between cases, and no travel time required to and from the hospital. CIS Physicians and staff feels that they can continue the continuity of care by spending more time with patients before and after the procedures, and staff know their patients. The physicians have increased control over the patients' environment, the procedure room, and the physician's schedule is more accommodating and flexible to schedule the procedure when it is convenient for the patient. CIS states that when appropriately screened, almost all peripheral interventions can be performed in an office based lab with minimal complications, patients are prescheduled, and procedures are not typically performed the same day as an office visit.

Reimbursement comparison on Peripheral Vascular Disease (PVD) by New Cardiovascular Horizons (NCVH), is an educational nonprofit foundation focused on multidisciplinary accredited conferences to advance the field of cardiovascular care using endovascular technologies, pharmacotherapy treatments, and peripheral interventions to empower healthcare providers with knowledge of head-to-toe vascular treatments. Covidien Vascular Therapies published that Physicians performing endovascular procedures under an ASC module are reimbursed at higher rates than in the hospital setting. Hospitals will receive reimbursement for hospital rates, cost of supplies, anesthesia fee, and the physician receives a professional fee which is about fifteen percent (15%) of the hospitals reimbursement. The hospital will receive an additional amount of payment based on Medicare Severity Diagnosis Related Group (MS-DRG) reimbursement, if the patient is admitted to the hospital. When a physician performs an endovascular procedure in an ASC, they receive endovascular per diem and reimbursement for supplies and anesthesia. With endovascular procedures performed in an office based endovascular lab, the physician will receive the allowable amount for the endovascular procedure.

Program Status and Continuing Activities

Levels I-III Office Based Endovascular Procedures refers to the complexity of surgeries used by the State Board of Medical Examiners. Class A-C refers to the level of anesthesia provided as described by the American College of Surgeons in the "Guidelines for Optimal Ambulatory Surgical Care and Office based Surgery"

Levels of Surgeries:

Level I - Minor surgical procedures performed under topical, local or infiltration block anesthesia not involving drug-induced alteration of consciousness, other than minimal sedation utilizing preoperative oral anxiolytic (Ativan, Zanax) medication.

Level II - Minor or major surgical procedures in which peri-operative medication and sedation are used by any means altering the level of consciousness, thus making intra and post-operative monitoring necessary.

Level III - Procedures that require the use of deep sedation/analgesia, general anesthesia, or major conduction blockade. Offices must maintain full emergency equipment and medications, as well as, an established emergency transfer plan, peer review and performance improvement program.

Classification of Anesthesia used for endovascular procedures:

Class A - Provides for minor surgical procedures performed under topical and local infiltration blocks with or without oral or intramuscular preoperative sedation. Excluded are: spinal, epidural, axillary, stellate ganglion block, regional blocks (such as interscalene), supraclavicular, infra clavicular, and intravenous regional block.

Class B – Provides for minor or major surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs.

Class C: Provides for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions. General anesthesia is a drug-induced loss of consciousness during which patients cannot be aroused, even by painful stimulation.

Vascular Access Centers offer a variety of Endovascular Procedures in an ASC Outpatient Interventional Radiology Suite for diseases and treatments (not all inclusive).

1. **Deep Vein Thrombosis:** Mechanical treatment, Mechanical Thrombectomy, Angioplastasty
2. **Peripheral Arterial Disease:** Thrombolysis, Thrombectomy, Angioplasty, Atherectomy, Arterial stenting either with bare metal stents or drug eluting stents, Endovenous laser ablation treatment, Radiofrequency Ablation, Non-thermal treatments, Sclerotherapy
3. **Hypertension and Kidney Failure Disease:** Renal Artery Stenting, Percutaneous nephrostomy tube, ureteral stent, Fistulagram procedure, Thrombectomy, Hemodialysis Catheter, Peritoneal Dialysis Catheter insertion, change and removal, vessel mapping, Percutaneous AV Fistula Creation
4. **Female Procedures;** Ovarian vein embolization and Fallopian tube recanalization, Uterine Fibroid embolization
5. **Male Procedures:** Prostatic artery embolization, Varicocele embolization

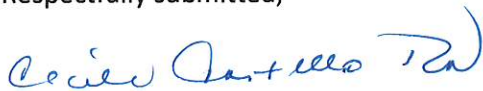
6. **Catheter Placements:** Peripherally Inserted Central Catheters, Port-a-Cath insertion
7. **Biopsies:** Bone, Breast, Thyroid, Liver, Kidney, Subcutaneous, Lymph Nodes
8. **Pain Management:** Epidural Steroid injection, Facet Infiltration (lumbar, thoracic or cervical), sympathetic Block, Trigger Point Injection, Tranforaminal Epidural, Intradiscal Electrothermal Therapy, Disc Decompression, Intercostal Nerve block
9. **IVC Filter:** Placement and removal

Conclusion

The Louisiana Department of Health Deputy Assistant Secretary, Director of Health Standards Section, and Endovascular Workgroup Team, including subject matter experts; (LSBME, LHA, VAC, and CIS) have met multiple times discussing the Endovascular Suites in a hospital, ASC and office based settings. Should it be determined that the department license centers to perform endovascular procedures, then the ASC statute would need to be revised to require endovascular procedures to be performed in a licensed ASC. LDH/HSS Team has concerns that opening the ASC statute for such would likely result in opposition from the Louisiana State Medical Society (LSMS), Dialysis Providers and CIS, as this would then require all endovascular procedures to be performed in a licensed /certified ASC.

The LSBME currently has under review their credentialing process for approvals for office based procedures. This process would likely incorporate those who perform office based endovascular procedures, thus allowing data to be available as who is performing these procedures and where such procedures are being performed. Therefore, the recommendation is that these Endovascular Office Based procedures may best be served as part of the LSBME self-attestation process. The LSBME is currently updating this self-attestation process and could provide what collected information LSBME may have of Endovascular procedures performed in office based labs.

Respectfully submitted,



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Cc: The Honorable Members of the Senate Health and Welfare Committee for Louisiana State Senate
The Honorable Members of the House Health and Welfare Committee for Louisiana State House of Representatives

The Executive Director of the Louisiana State Board of Medical Examiners

The Executive Director of the Louisiana State Board of Nursing

The President of Louisiana Hospital Association

The Executive Director of the Louisiana Ambulatory Surgery Center Association

The President of the Cardiovascular Institute of the South

The Chief Executive Officer of Vascular Access Centers, LLC.

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