Appendix A

Joint Commission on the Accreditation of Healthcare Organizations
Lung Volume Reduction Surgery Certification –
October 25, 2004 Requirements Packet

The chart below contains existing Disease-Specific Care standards and the elements of performance used to evaluate compliance with those standards. Any program applying for Disease-Specific Certification must meet all the applicable standards in the program. There are eight elements of performance that have requirements specific to certification for Lung Volume Reduction Programs.

Standard	**Element of Performance / *Requirement Specific to LVRS certification***
DF.1 Practitioners are qualified and competent.	Practitioners have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives. *Members of the team exhibit expertise in pulmonary medicine, especially as it related to end-stage emphysema, functional and exercise testing, pulmonary rehabilitation, thoracic surgery, anesthesia, and pulmonary radiology assessment as appropriate.* *Providers must include a board certified adult pulmonary specialist AND a board certified thoracic surgeon with experience performing LVRS.* *Providers must have clinical expertise treating emphysema patients and have a firm understanding of pulmonary medicine, pulmonary physiology and pulmonary rehabilitation.* *Prior to joining the program, the surgeon must have performed a minimum of 8 of each type of LVRS surgery the surgeon will perform (either as attending surgeon or surgeon) or 20 surgeries as first* assist during an accredited cardiothoracic fellowship *The surgeon's thoracic procedures privilege list specifically indicates privilege to perform LVRS*
	Core criteria for hiring practitioners in the program include, at a minimum, current licensure, relevant education, training and experience, and current competence.
	Criteria for evaluating practitioners in the program include, at a minimum, current licensure and current competence.
	Current licensure is verified from primary sources.
	Orientation provides information and necessary training appropriate to program responsibilities.

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	The competence of all practitioners is assessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the program.
	Ongoing in-service and other education and training activities are relevant to the program's needs
	Practice, care, and/or services are analyzed for negative patterns and trends to provide feedback to practitioners and to identify and respond to their learning needs.
DF.2 A standardized process originating in clinical practice guidelines or evidence-based practice is used to deliver or facilitate the delivery of clinical care.	The CPGs used are based on evidence that has been evaluated as current by the clinical leaders.
	The CPGs used have been evaluated as appropriate for the target population.
	When the CPGs are selected by a sponsoring organization (for example, a disease management.
	Assessment activities are consistent with CPGs • *Patients must be assessed for, and meet all criteria to be eligible for the procedure (note – exclusion criteria are listed at the end of this document)* • *History and physical examination* • *Consistent with emphysema* • *Stable with ≤20 mg prednisone (or equivalent) q day* • *Radiographic* • *HRCT scan evidence of bilateral emphysema* • *Pulmonary function (pre-surgical)* • *FEV_1, ≤ 45% predicted (≥ 15% predicted if age ≥70 years)* • *TLC, ≥100% predicted post-bronchodilator* • *RV, ≥150% predicted post bronchodilator* • *Arterial blood gas level (pre-surgical)* • *PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if one mile above sea level)* • *PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 30 mm Hg if one mile above sea level)* • *Cardiac assessment* • *Approval for surgery by cardiologist if any of the following are present: unstable angina; LVEF cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> 5 PVCs per minute; cardiac rhythm other than sinus; PACs on EKG at rest)* • *Surgical assessment* • *Pre surgical approval for surgery by pulmonary physician,*

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	and thoracic surgeon post-rehabilitation • *Exercise* • *Presurgical post rehabilitation 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test* • *Smoking* • *Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products)* • *Nonsmoking for 4 months prior to initial interview and throughout screening* • *Rehabilitation/ adherence* • *Must complete pre- rehabilitation assessments* *Exclusion Criteria - The presence of any one criterion makes the patient ineligible for the procedure* *Cardiovascular* • *Dysrhythmia that might pose a risk during exercise or training* • *Resting bradycardia (< 50 beats/min); frequent multifocal PVCs; complex ventricular arrhythmia; sustained SVT* • *History of exercise-related syncope* • *MI within 6 months and LVEF < 45%* • *Congestive heart failure within 6 months and LVEF < 45%* • *Uncontrolled hypertension (systolic, > 200 mm; diastolic, > 110 mm)* *Pulmonary* • *History of recurrent infections with clinically significant sputum production* • *Pleural or interstitial disease that precludes surgery* • *Clinically significant bronchiectasis* • *Pulmonary hypertension: peak systolic PPA, ≥ 45 mm Hg (Denver criterion: ≥ 50 mm Hg) or mean PPA, ≥ 35 mm Hg (Denver criterion: ≥ 38 mm Hg). (Note: Right heart catheter is required to rule out pulmonary hypertension if peak systolic PPA on echocardiogram is ≥ 45 mm Hg)* • *Requirement for > 6 L O_2 to keep saturation ≥ 90% with exercise* *General* • *Any concurrently occurring or co morbid condition that excludes the patient from being a viable candidate.* • *Unplanned weight loss of > 10% usual weight in 90 d prior to enrollment*

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	• *Evidence of systemic disease or neoplasia expected to compromise survival during 5-yr period* • *6-min walk distance ≤140 m after rehabilitation* • *Any disease or condition that interferes with completion of initial assessment*
	Intervention activities are consistent with CPGs *The program where the surgery takes place coordinates and monitors the performance of all services.* *All participants are actively involved in a preoperative rehabilitation program or have completed a complementary program.* *The focus of the rehabilitation program is to:* • *Optimize exercise capacity* • *Achieve physical fitness to affect early postoperative mobilization* *Specific components of the pulmonary rehabilitation program include:* • *Comprehensive evaluation of medical, psychosocial and nutritional needs* • *Setting of goals for education and exercise training* • *Exercise training (lower extremity, flexibility, strengthening,*

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	and upper extremity) • *Education about emphysema and medical treatments* • *Psychosocial counseling* • *Nutritional counseling* *Postoperatively, participants' participate in at least six sessions within 9 weeks of the LVRS.* *Operative procedures performed are either unilateral or bilateral excision of damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.*
	Adapted or adopted CPGs are reviewed annually or when significant changes in the field occur, to ensure their appropriateness for the program.
	Modifications made to CPGs are implemented.
	Appropriate leaders and practitioners in the program review and approve CPGs selected for implementation.
	Practitioners have been educated about CPGs and their use
DF.3 The standardized process is tailored to meet the participant's needs.	The program defines the patient assessment process
	An assessment is completed for all participants within the time frame determined by the program.
	The assessment is used to develop a plan of care.
	An explicit method of stratification exists
	Stratification methods direct interventions. *The program has a process to obtain concurrent, objective evaluations for both LVRS and lung transplant when the patient meets lung transplant eligibility requirements*
	The standardized method or process is tailored to meet the targeted population's age and developmental needs
	The plan of care is updated to meet the participant's ongoing needs. *The plan of care is consistent with the care plan developed by the treating physician*
DF.4 Concurrently occurring conditions are managed, or the information necessary for their management is	Care is coordinated for participants with multiple diseases and/or whom multiple disease-specific care programs manage.
	When concurrently occurring conditions are identified, important information is communicated to the appropriate practitioners treating or managing the condition(s).

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communicated to the appropriate practitioner(s).	When a concurrently occurring condition needs medical intervention, the patient is either treated by the practitioners in the program or referred to an appropriate practitioner.
	The program has a mechanism for managing urgent health issues
DF.5 The standardized process is revised or improved through the ongoing collection and evaluation of data regarding variance from the clinical practice guideline.	Variances are tracked at the individual participant level
	Use of the CPGs is modified based on the analysis of outcomes
	Information related to the changes made within the standardized process is communicated to all appropriate individuals.
	Changes in the standardized process are evaluated
PM.1 The program has an organized, comprehensive approach to performance improvement.	The PI program is well designed and planned.
	The PI program collects relevant data.
	The PI program analyzes current performance.
	The PI improvement program improves and sustains performance.
	PI activities are planned across practitioners, disciplines, and/or settings.
	PI activities include input from participants.
PM.2 The program uses measurement data to evaluate process and outcomes.	The program selects performance measures that are the following: • Based on the clinical practice guideline or other evidence • Relevant to the management of the disease • Valid • Reliable *The program provides data including;* • *Post operative length of stay (acute care and rehab facility LOS)* • *surgical and medical complication rates and* • *Mortality <u>< 90</u> days*.
	Data related to processes and/or outcomes of care are collected at the level of the individual participant.
	The program reports data aggregated at the program level to the Joint Commission on Accreditation of Healthcare Organizations at the defined intervals.
	Measurement data are analyzed.
	Measurement data are used to improve processes and outcomes.
PM.3 Participant perception of care quality is evaluated.	The program evaluates participant perception of care quality
	The program makes improvements based on the analysis of the feedback from participants about the perception of care quality.

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PM.4 Data quality and integrity are maintained.	Minimum data sets, data definitions, codes, classifications, and terminology are standardized throughout the program.
	Data collection is timely, accurate, complete, and sufficiently discriminating for its intended use throughout the program
	The program monitors data reliability (including accuracy and completeness) and validity on an ongoing basis and verifies that data bias is minimized.
	Sampling methodology is based on measurement principles
	Appropriate data analysis tools are used.
	Factors (participant and/or practitioner) that might affect the outcome(s) of the process (es) being measured have been evaluated.
SE.1 The program involves participants in making decisions about managing their disease or condition	Participants are involved in decisions about their clinical care
	Participants and practitioners mutually agree upon goals
	Participants are informed of their responsibilities to provide information to facilitate treatment and cooperate with health care practitioners.
	Participants are informed about potential consequences of not complying with a recommended treatment.
	The patient's readiness, willingness, and ability to provide or support self-management activities are assessed
	As appropriate, the family's readiness, willingness and ability to provide or support self-management activities are assessed
SE.2 The program addresses life-style changes that support self-management regimens	Life-style changes that support self-management regimens are promoted as necessary
	Support structures (family and community) are involved as necessary
	Barriers to change are evaluated as necessary
	The participant's response to making the recommended life-style changes is assessed and documented.
	The effectiveness of efforts to help the participant in making life-style changes is assessed.
SE.3 The program addresses participants' education needs.	Materials comply with generally recommended elements of intervention in the literature or promoted through the CPGs
	Content is presented in an understandable and culturally sensitive manner.
	The participant's comprehension is assessed initially and on an ongoing basis.
	Education needs related to life-style changes that support self-management regimens are addressed

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	Education needs related to health promotion and disease prevention are addressed
	Education needs related to information about the participant's illnesses and treatments are addressed.
	When appropriate, participants are notified about screening recommendations or lifestyle changes related to preventing the disease for their family members, that the participant could then present to the family member
PR.1 Leadership roles in the program are clearly defined.	The leaders involved in program development and oversight have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives
	The leaders' accountability is clearly defined
	The leaders' participate in designing, implementing, and evaluating care treatment and services.
	The leaders provide for the uniform performance of patient care treatment and services
	The leaders confirm that practitioners practice only within their licensure, training, and current competency.
	The leaders set expectations, develop plans, and manage processes to measure, assess, and improve the quality of their leadership and the program's management, clinical, and support activities.
PR.2. The program is relevant for the targeted population and/or health care service areas.	The program's mission and scope of services are defined in writing and approved by the appropriate leaders.
	The program identifies their target population
	The program ensures that the services available are relevant for its targeted population *The program can perform and interpret pulmonary function studies and pulmonary and diaphragm mechanics, including:* • *flow-volume loops,* • *static lung volumes by body plethysmogrophy.* • *diffusing capacity* *The program can perform cardiopulmonary exercise testing including;* • *measurements of maximum workload,* • *maximum ventilation,* • *maximum volume at rest* • *Maximum volume with exercise (>30% FIO_2)* *The program can assess patients for;*

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	• *evidence of coronary heart disease,* • *right and left heart function and* • *pulmonary artery pressures.* *The program can demonstrate proficiency in the measurement of Arterial Blood Gases.* *The program can perform detailed radiological assessment of the lung* *The program must be capable of supporting the clinical needs of the patient. This includes the capacity and staffing of* • *operating rooms,* • *recovery rooms,* • *post-operative care facilities,* • *pulmonary rehabilitation and other physical therapy facilities,* • *pulmonary function laboratories, and* • *radiological facilities.* *Please note – under this requirement the program will be asked to furnish the reviewer with a written description of the types or equipment within the pulmonary function laboratory and the pulmonary rehabilitation clinic as well as a detailed description of the laboratory and clinical facilities available at the program.*
PR. 3 The scope and level of care and/or services offered by the program are provided to participants	Care and/or services offered are provided to the participants as planned and in a timely manner.
	Participants are informed of how to access care and services, including after hours (if applicable).
	Adequate numbers and types of practitioners are available to deliver or facilitate the delivery of care treatment and services.
	The program evaluates services provided through contractual arrangement to ensure that the scope and level of care and/or services are consistently provided
	Documented policies, processes and procedures support the care treatment and services provided.
PR.4 Eligible patients have	Enrollment and/or participation requirements are well defined

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access to the care and services provided by the program.	For programs that do not rely solely on direct referrals, a systematic method based on perceived need is used to identify potential participants.
	For programs that do not rely solely on direct referrals, individuals are given multiple opportunities to participate in the program.
PR. 5 The scope and level of care and/or services provided are comparable for individuals with the same acuity and type of condition	Individuals have access to an adequate level of resources required to meet the health. care needs for the disease(s) being managed
PR.6. The program's leaders and, as appropriate, participants, practitioners, and community leaders collaborate to design, implement, and evaluate services.	All relevant individuals and/or disciplines participate in designing the program
	All relevant individuals and/or disciplines participate in implementing the program
	All relevant individuals and/or disciplines participate in evaluating the program
PR.7 The program complies with applicable law and regulation	The program complies with applicable laws and regulations.
PR.8 The program follows a code of ethics.	The program protects the integrity of clinical decision-making, regardless of how the program compensates or shares financial risk with its leaders, managers, and practitioners
	The program respects the participant's right to decline participation in the program.
	The program provides for receiving and resolving complaints and grievances in a timely way
PR.9 Facilities where individuals receive care are safe and physically accessible.	The program has evaluated security and implemented strategies to minimize security risks
	The program has developed an emergency plan and implemented strategies to minimize the risk of disruption of care due to an environmentally related emergency
	The program has evaluated risk points in fire safety and implemented strategies to minimize the risk of fire and fire-safety-related issues
	The program has developed and implemented a medical equipment management plan
	The program has evaluated risk points in power, gas, and

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	communication services and implemented strategies to minimize those risks
	Staff has learned environment of care risk-reduction strategies
	The program tracks incidents related to the environment of care and makes changes accordingly
PR.10 The program has reference and resource materials readily available.	The program has reference materials (hard copy or electronic) that are easily accessible to practitioners
	The resources are authoritative and current
PR.11 The process for identifying, reporting, managing, and tracking sentinel events is defined and implemented.	A process exists for identifying these events if and when they occur.
	A process exists for internally tracking these events if and when they occur.
	The program has a process for internally tracking these events if and when they occur.
	A process exists for analyzing these events if and when they occur.
	Changes are made accordingly.
CT.1 The confidentiality and security of participant information are preserved.	Participant confidentiality is preserved.
	Records and information are safeguarded against loss, destruction, tampering, and unauthorized access or use.
	Participants and practitioners about whom data and information may be collected are made aware of how the information will be used.
	Methods for adding comments in the form of statements or addenda into the formal records are defined.
	Individuals and/or positions that have access to information and measures compliance with access limitations are defined.
	How and when consent for release of information is required and defined.
	Process followed when confidentiality and security are violated is defined.
CT.2 The program gathers information about the participant's disease or condition from practitioners and settings across the continuum of care.	The program gathers information directly from the participant and/or family
	Information is gathered from all relevant practitioners or health care organizations.
CT.3 The program shares	The program shares information directly with the participant

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information about the participant's disease or condition across the entire continuum of care to any relevant setting or practitioner.	and/or family
	The program shares information with other relevant practitioners or health care organizations as needed *The program must provide a plan for rehabilitation maintenance and education*
CT.4 Information management processes meet the program's internal and external information needs.	Data are easily retrieved in a timely manner without compromising security and confidentiality.
	The program has determined how long health records and other data and information are retained in accordance with applicable law and patient need.
	The program defines, captures, analyzes, transmits, and reports aggregate data and information that supports managerial decisions, operations, PI activities, and participant care
CT.5 The program initiates, maintains, and makes accessible a health or medical record for every participant.	Practitioners have access to all needed participant information as necessary.
	The record contains sufficient information to identify the patient or the participant (if other than the patient); support the diagnosis; justify care, treatment, and services; and document the course and results of care, treatment, and services.
	The record contains sufficient information to track the patient's movement through the care system and facilitate continuity of care both internally and externally to the program.
	Records are periodically reviewed for completeness, accuracy, and timely completion of all necessary information.