ClinicaL PRIVILEGE WHITE PAPER

Cardiac pacing and arrhythmia management

Background

Cardiac pacing and arrhythmia management involves the use of an implantable device to regulate the heartbeat of a patient whose heart beats abnormally or irregularly. According to the American Heart Association (AHA), a heartbeat of less than 60 beats per minute is called bradycardia; a heartbeat of more than 100 beats per minute is called tachycardia. People with uncontrolled arrhythmias are far more likely to suffer heart attacks than people with regular heartbeats. There are several mechanical devices that can be implanted into the patient’s chest to control irregular heartbeats and/or to stimulate the heart muscle to pump.

A pacemaker is a small, battery-operated mechanism about the size of a matchbox. It is implanted under the skin of the chest, usually near the collarbone. One or two leads run into the heart through the pacemaker and send electrical impulses into the heart muscle. Pacemakers do not operate continuously; they sense when the heartbeat is irregular and send electrical current that resets the heart to a normal rhythm. Pacemaker implantation is typically done under local anesthesia, and the procedure lasts from one to two hours. Most pacemaker batteries last 5–8 years; when the battery runs down, it must be replaced surgically.

Unlike a pacemaker, an implantable cardiac defibrillator (ICD) operates continuously. An ICD is about the size of a cell phone and is implanted just beneath the skin, either near the collarbone or at the waistline. When the heart is beating too slowly, the ICD acts as a pacemaker and sends a current to the heart to speed up its rhythm. When the heartbeat is too fast or the heart is beating chaotically, the ICD sends a shock to the heart, just an external defibrillator does. This shock can reset the heart to a more normal rhythm. ICD implantation surgery is done under general anesthesia.

Involved specialties

Electrophysiologists, cardiologists, cardiothoracic surgeons, vascular surgeons, critical care physicians, and emergency medicine physicians
Positions of specialty boards

ABIM

The American Board of Internal Medicine (ABIM) offers a subspecialty certificate in cardiovascular disease. To be eligible for this certification, candidates must hold a valid, unrestricted license to practice medicine; be board certified in internal medicine; demonstrate clinical competence and professional ethics; and complete a 36-month cardiology training program, which includes 24 months of clinical rotations in which the physician must perform the following procedures:

➤ Advanced cardiac life support, including cardioversion
➤ Electrocardiography, including ambulatory monitoring and exercise testing
➤ Echocardiography
➤ Arterial catheter insertion
➤ Right-heart catheterization, including insertion and management of temporary pacemakers
➤ Left-heart catheterization and diagnostic coronary angiography

The ABIM also offers a certification exam in the subspecialty of clinical cardiac electrophysiology. Physicians must already be board certified in cardiovascular disease.

Candidates applying for clinical cardiac electrophysiology certification in and after 1998 should follow the Formal Training Pathway, which requires:

➤ Successful completion of a three-year cardiovascular disease fellowship training program (24 months must be spent in clinical training in an Accreditation Council for Graduate Medical Education [ACGME]-accredited program)
➤ One year of training in clinical cardiac physiology completed after July 1, 1992
➤ After training, candidates must spend at minimum 50% of their time practicing clinical cardiac electrophysiology in various settings, such as the electrophysiology laboratory (performing as the primary operator or assistant), emergency department, coronary care unit, OR, or follow-up clinic
➤ Twelve months of training in electrophysiological studies, including the following experiences:
  − Catheter and intraoperative
  − Catheter-based and other ablation procedures
  − Implant pacemakers and cardioverter-defibrillators (a minimum of 150 intracardiac procedures in at least 75 patients, of which 75 are catheter-based ablation procedures, including post-diagnostic testing, and 25 are initial implantable cardioverter-defibrillator procedures, including programming)

Candidates may count procedures performed during training in cardiovascular disease toward fulfilling these requirements. A candidate will be awarded a certificate in electrophysiology if he or she has met the training requirements, can supply a letter of recommendation from his or her program director testifying to the candidate’s competence in the required procedures, holds a valid license to
practice medicine, and has passed the ABIM’s Clinical Cardiac Electrophysiology Certification Examination.

**AOBIM**

The American Osteopathic Board of Internal Medicine (AOBIM) offers a certificate in cardiology. Applicants must be board certified in internal medicine and must have completed a three-year training program in cardiology. The certification exam in cardiology covers diagnosis, pharmacology, electrocardiography, echocardiography, doppler echocardiography, chest x-ray interpretation, cardiac catheterization data interpretation, hypertensive heart disease, valvular heart disease, ischemic heart disease, congenital heart disease, cardiomyopathies, infectious heart disease, pericardial disease, pulmonary hypertension, cardiovascular surgery, and peripheral arterial disease.

The AOBIM also offers a certificate of added qualification in clinical cardiac electrophysiology. Eligible candidates must be board certified in cardiology and have completed one of the following training pathways:

➤ Three years of American Osteopathic Association (AOA)–approved subspecialty training in cardiology followed by one year of training in clinical cardiac electrophysiology

➤ Two years of subspecialty training in cardiology completed prior to September 1, 1993, followed by one year of subspecialty training in clinical cardiac electrophysiology

**IBHRE**

The International Board of Heart Rhythm Examiners (IBHRE), an independent affiliate of the Heart Rhythm Society (HRS), offers competency examinations to physicians and allied health personnel. The examination is open to both fellowship-trained physicians and experienced physicians who have not had fellowship training in clinical cardiac electrophysiology, but have experience in the field and wish to gain privileges to implant cardiac devices.

Applicants for the IBHRE Cardiac Rhythm Device Therapy Examination for Physicians must have done one of the following:

➤ Completed a fellowship in cardiology (adult or pediatric).

➤ Completed a fellowship in clinical cardiac electrophysiology.

➤ Demonstrated one year of direct, substantial involvement in the care of cardiac rhythm device patients, including a minimum of 100 device interrogations with reprogramming as needed. The devices must include pacemakers, implantable defibrillators, cardiac resynchronization devices, and implantable loop recorders/cardiac monitors.

Physician applicants must document their medical training and experience, and have a valid, unchallenged license to practice medicine in the United States.
Positions of societies, academies, colleges, and associations

ACC/AHA/HRS

The American College of Cardiology (ACC) and the AHA address training requirements and guidelines for pacemaker and ICD implantation in the report Task Force 6: Training in Specialized Electrophysiology, Cardiac Pacing and Arrhythmia Management. The HRS endorses the report. The report describes three levels of training for cardiac pacing, arrhythmia management, and specialized electrophysiology. This report was most recently revised in 2008. The basic premise of the report is that implantable devices are now so sophisticated that managing patients with the devices has become its own subspecialty; although all cardiologists are trained in the basics of pacemaker operation and management of patients with implantable devices, the implantation and primary follow-up should be performed by a physician with specialized training in clinical cardiac electrophysiology.

Levels 1 and 2 are basic cardiology training in which the physician acquires knowledge and experience in the diagnosis and management of bradyarrhythmias and tachyarrhythmias (Level 1) and noninvasive arrhythmia management techniques to develop competence and proficiency in the diagnosis, treatment, and long-term care of patients with complex arrhythmias (Level 2). These basic levels of training include programming and follow-up management of all types of bradycardia pacing, biventricular pacing, and ICD systems.

At Level 2, trainees must function as the primary programming operators who interrogate, interpret, prescribe, and reprogram devices in at least 100 patients. Although Level 2 trainees must have significant exposure to invasive electrophysiology, ICDs, and the surgical aspects of arrhythmia control device implantation, Level 2 training by itself does not qualify the trainee to perform these invasive procedures. Another six months is required for pacemaker implantation training for a total of one year of advanced training beyond the cardiology core of Level 1. The training may be obtained within a three-year cardiology program if one of the three years is dedicated to acquiring pacemaker implantation and related management and follow-up skills.

Level 3 training is for specialization in clinical cardiac electrophysiology. After the requirements of Level 1 and Level 2 are fully met, a total of one year beyond the three-year cardiology training program is required. Level 2 and Level 3 trainees may choose to receive additional training in the surgical aspects of device implantation; this may be obtained concurrently or sequentially with Level 2 or Level 3 training, respectively. For cardiology trainees who elect to obtain proficiency in the surgical aspects of transvenous bradycardia device (i.e., pacemaker) implantation, previous or concurrent Level 2 training is required.
The pacemaker implantation training must include development of expertise in:
➤ Permanent atrial right and left ventricular lead and ICD lead placement
➤ Threshold testing and programming of devices
➤ Principles of surgical asepsis
➤ Surgical techniques of implantation
➤ Management of implant-related complications

Individuals receiving qualifying training in pacemaker implantation must participate as the primary operator—under direct supervision—in at least 50 primary implantations of transvenous pacemakers and 20 pacemaker system revisions or replacements. At least half of the implantations should involve dual-chamber pacemakers. The trainee must also participate in the follow-up of at least 100 pacemaker patient visits and acquire proficiency in advanced pacemaker electrocardiography, interrogation, and programming of complex pacemakers.

Level 2 training (six months) with the option of training in pacemaker implantation (six months) requires a total of one year of advanced training beyond the cardiology core of Level 1. This may be obtained within a three-year cardiology program if one of the three years is dedicated to acquiring pacemaker implantation and related management and follow-up skills.

The trainee pursuing a career in CCEP also has the option of obtaining expertise in the surgical aspects of pacemaker or transvenous ICD implantation, or both. The same amount of surgical experience with bradycardia pacemaker implantation is required and may be supplemented with surgical training for ICD implantation. If the Level 3 trainee chooses this option, he or she must participate as the primary implanter—under direct supervision—in at least 25 ICD system implantations and possess the appropriate skills in management and follow-up.

**HRS**

The HRS published the *HRS Policy Statement Clinical Cardiac Electrophysiology Fellowship Curriculum: Update 2011*.

Although the HRS states that the curriculum do not replace the standards set by the ACGME and ABIM, the document outlines the skills a practicing electrophysiologist needs to care for a patient. Fellows should receive education on the following:
➤ Normal physiology
  – Anatomic structures, anatomic relationships, and vascular supply
  – Resting membrane potential, action potential, and passive membrane properties
  – Determination of normal conduction
  – Cellular basis for the inscription of the electrocardiogram (ECG)
  – Ion channels
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➤ Genetic basis of arrhythmia
- The spectrum of heritable arrhythmia syndrome/cardiac channelopathies
- The pathogenetic basis for the cardiac channelopathies
- Genotype–phenotype relationships and risk stratification for each channelopathy
- The state of genetic testing for each cardiac channelopathy
- Indications for pharmacotherapy, left cardiac sympathetic denervation therapy, and device therapy for the cardiac channelopathies

➤ Diagnosis of arrhythmia
- Surface ECG and ambulatory monitoring
- Invasive electrophysiological evaluation
- Laboratory safety

➤ Treatment of arrhythmia
- Basic pharmacokinetics and pharmacodynamics
- New technology/ablation physics
- Imaging technology
- Ablation of supraventricular tachycardias (SVT)

➤ Atrial fibrillation and flutter
- For atrial fibrillation: mechanisms, epidemiology, and risks of atrial fibrillation; prevention of thromboembolism in atrial fibrillation; drug therapy for atrial fibrillation; cardioversion of atrial fibrillation; nonpharmacologic therapy; risk of atrial fibrillation ablation; and diagnosis, evaluation, and management of post-ablation atrial tachycardia
- For atrial flutter: Classification of atrial flutter, risks of atrial flutter; prevention of thromboembolism in atrial flutter; drug therapy for atrial flutter; nonpharmacologic therapy

➤ Ablation of ventricular tachycardia (VT)
- Idiopathic VT
- Catheter ablation for non-ischemic cardiomyopathy
- Catheter ablation of post-infarction VT
- Catheter ablation of frequent PVCs in patients with cardiomyopathy and PVC-induced ventricular fibrillation for polymorphic VT

➤ Pacemakers
- Pathophysiology of various bradyarrhythmias, and their etiology and natural history
- Effects of pharmacologic ablation and radiation therapy on sinus nodal, AV nodal, and His Purkinje system function
- Physiologic pacing
- Understanding pacing system technology
- Temporary pacing
- Permanent pacemaker indication
- Permanent pacemaker implantation
- Radiology
- Immediate post-procedure care; recognition and management of complications
- Permanent pacemaker follow-up and troubleshooting
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Procedure 50

- Lead extraction
- Device-device, device-drug, and device-environmental interactions
- Management in patients with terminal illness

➤ Implantable cardioverter-defibrillator and CRT
- Technologic principles
- Indications for the ICD/CRT system and appropriate integration of results of prospective trials into clinical decision-making
- Guidelines for implantation of ICD/CRT systems
- Implantation techniques and testing of ICD/CRT system function at implantation
- Indication and implantation of coronary sinus leads to enable biventricular pacing
- Drug-ICD interaction
- Implant procedure complications
- Follow up and troubleshooting
- Recommendations for driving for the patient
- Cost-effectiveness of the ICD/CRT system
- Quality of life and psychosocial impact of the ICD/CRT system

➤ Special conditions
- Syncope
- Sudden cardiac death

Additionally, the HRS published the clinical competency statement Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices. In the statement, the HRS addressed training requirements for physicians who were already experienced in pacemaker implantation but had not completed a fellowship in CCEP. This document set forward the requirements for an alternate training pathway for such physicians. However, the alternate training pathway expired in 2008. A letter from the board of directors of the HRS, dated October 2008, “strongly recommends” that all credentialing bodies follow the recommendations as set forth in Task Force 6: Training in Specialized Electrophysiology, Cardiac Pacing and Arrhythmia Management.

There may be some experienced cardiologists who have not completed a fellowship in electrophysiology and were not able to meet the requirements of the alternate pathway before it expired, but who wish to implant pacemakers and ICDs regardless. For such physicians, the HRS recommends taking a competency examination, and it suggests that the exam offered by the IBHRE is an acceptable alternative for those physicians who do not qualify to sit for the ABIM exam.

For all cardiologists seeking privileges to implant pacemakers and ICDs, the HRS recommends the following minimum number of procedures performed:

➢ 10 temporary pacemakers
➢ 10 cardioversions
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- 75 cardiovascular implantable electronic device (CIED) implantations (25 single chamber, 25 double chamber, 25 CRT)
- 30 CIED revisions/replacements
- 200 CIED interrogations/programming

To maintain competence, the HRS suggests a minimum of 35 CIED implantations per year. To maintain competence in ICD, the physician must perform 10 ICD implantations per year and follow up on at least 20 patients per year.

The HRS also publishes several clinical guidelines regarding the management of patients with CIEDs. Visit the organization’s website for more information (www.hrsonline.org/ClinicalGuidance).

ACGME

The ACGME has established training standards for resident physicians. The ACGME requires that physicians complete training in the subspecialty of cardiovascular disease as a prerequisite to electrophysiology training. The cardiovascular disease training program is three years in duration. This must include the following:

- Four months in a cardiac catheterization laboratory
- Six months of noninvasive cardiac evaluations, which must include three months of echocardiography and Doppler, two months of nuclear cardiology, and one month of other noninvasive cardiac evaluations
- Two months of electrophysiology, pacemaker follow-up, and ICDs
- At least nine months of non-laboratory clinical practice activities

Clinical training must provide fellows with formal instruction and an opportunity to gain experience. Fellows must demonstrate competence in the prevention, evaluation, and management of inpatients and outpatients with the following conditions:

- Chronic coronary heart disease
- Congestive heart failure
- Arrhythmias
- Acute myocardial infarction and other acute ischemic syndromes
- Lipid disorders
- Hypertension
- Cardiomyopathy
- Valvular heart disease
- Pulmonary heart disease and pulmonary embolism
- Peripheral vascular disease
- Infections and inflammatory heart disease
- Cardiovascular rehabilitation

Fellows also must have formal instruction and clinical experience in prevention, evaluation, and management of patients with adult congenital heart disease,
pericardial disease, and cardiovascular trauma. In addition, fellows must demonstrate competence in performing:

- Elective cardioversion
- Insertion and management of temporary pacemakers, including transvenous and transcutaneous
- Programming and follow-up surveillance of permanent pacemakers
- Bedside right-heart catheterization
- Right- and left-heart catheterizations including coronary arteriography (at least 100 procedures)
- Exercise stress testing (at least 50)
- Echocardiography (perform at least 75, interpret a minimum of 150)
- Intracardiac electrophysiology studies
- Intra-aortic balloon counterpulsation
- Percutaneous transluminal coronary angioplasty
- Programming and follow-up surveillance of ICDs
- Pericardiocentesis

Fellows must have formal instruction, clinical experience, and demonstrated competence in interpreting:

- Chest x-rays
- ECGs (minimum of 3500)
- Ambulatory ECG recordings (minimum of 150)
- Radionuclide studies of myocardial function and perfusion

After successfully completing the three-year cardiovascular disease fellowship, the resident may apply for an additional fellowship year with a concentration in electrophysiology. The program must provide formal instruction in:

- Basic cardiac electrophysiology, including normal and abnormal autonomic responses, electrophysiologic responses, autonomic influences, effects of ischemia, drugs, and other interventions
- Clinical cardiac electrophysiology
- Arrhythmia control device management
- Genetic basis of pathological arrhythmias
- Clinical trials of arrhythmia management

Electrophysiology fellows must have formal instruction, clinical training, and demonstrated competence in preventing, evaluating, and managing both inpatients and outpatients with the following cardiac rhythm disorders:

- Sinus node dysfunction
- Atrioventricular and intraventricular blocks
- Supraventricular and ventricular tachyarrhythmias
- Unexplained syncope
- Aborted sudden cardiac death
- Palpitations
- Wolff-Parkinson-White syndrome
- Prolonged QT syndrome
Fellows also must have formal instruction, clinical experience, and ability to competently perform the following skills:

➤ Noninvasive testing relevant to arrhythmia diagnosis and treatment
➤ Invasive electrophysiologic testing (an average of three or more per week, a minimum of 150 intracardiac procedures performed, and at least 75 studies related to supraventricular arrhythmia)
➤ Electrode catheter introduction and positioning
➤ Stimulating and recording techniques
➤ Measurement and interpretation of data
➤ Therapeutic catheter ablation procedures (minimum of 75 including post-diagnostic testing; must be a mix of AV nodal reentrant tachycardia and accessory pathway modification, atrial tachycardia and atrial flutter, AV junctional ablation and modification, and ventricular tachycardia ablation)
➤ Implantation of cardioverter-defibrillators and pacemakers (minimum of 25 initial ICD and 50 pacemaker procedures)
➤ Device programming (minimum 100 interrogations)
➤ Noninvasive programmed stimulation for arrhythmia induction
➤ Defibrillation threshold testing
➤ Final prescription of anti-tachycardia pacing and defibrillation therapies

Electrophysiology fellows also must have formal instruction, clinical experience, and demonstrated competence in interpreting:

➤ Activation sequence mapping recordings
➤ Invasive intracardiac electrophysiologic studies, including endocardial electrogram recording
➤ Relevant imaging studies, including chest radiography
➤ Tilt testing
➤ ECGs and ambulatory ECG recordings
➤ Continuous in-hospital ECG recording
➤ Advanced electrocardiographic methods of risk stratification
➤ Stress test ECG recordings
➤ Transtelephonic ECG recordings

**AOA**

The AOA oversees a fellowship program in osteopathic electrocardiology. Applicants first must complete fellowship training in cardiology, a two-year program of study that includes learning activities in preventive cardiology, risk factor reduction, management of lipid disorders, and cardiac rehabilitation. Cardiology rotations include:

➤ Nine months of hospital-based general cardiology experience
➤ Three months of hospital-based general cardiology experience in the ICU/critical care unit
➤ Four months of cardiac catheterization experience
➤ Three months of echocardiographic experience
➤ Four months of nuclear medicine
Two months of electrophysiology
One month of vascular medicine

The general cardiology fellowship also requires the fellow to obtain knowledge, skill, and experience in the following tests and procedures:

- Electrophysiologic evaluations (150)
- Ablations, non-atrial fibrillations (interpret/participate in 75)
- Atrial fibrillation ablations (interpret/participate in 35)
- ICD implantations (interpret/participate in 25)
- CRT (biventricular pacing) (25)
- Dual-chamber pacemakers (25)
- Pacemaker/device revisions (30)
- Pacemaker/device interrogations (20)
- Electrocardiographic interpretations (3500)
- Ambulatory ECG monitor recording interpretations (150)
- Exercise test interpretations (200, including 100 pharmacologic [dipyridamole, adenosine, and dobutamine] tests)
- Diagnostic cardiac catheterizations (100)
- Complete (M-mode, 2-D, and Doppler) echocardiographic examination interpretations (150)
- Transesophageal echocardiographic intubations (25)
- Interpretation of complete (myocardial perfusion, function, and viability) cardiac nuclear imaging studies (100)
- Insertion of temporary pacemakers (10)
- Cardioversions (10)
- Functioning as the primary programming operator who interrogates, interprets, prescribes, and reprograms devices (in at least 100 patients)
- Participation in permanent pacemaker insertions (50)
- Interpretation of cardiac magnetic resonance studies (25)
- Interpretation of cardiac CT studies (50)
- Insertion of intra-aortic balloon assist devices, with subsequent clinical management and removal of the device (10)

The AOA’s subspecialty training in electrocardiology requires an additional year of specialized study. During the fellowship, the physician must have training and experience in:

- Catheter and intraoperative mapping procedures
- Catheter and surgical ablations
- Trans-septal perforation techniques
- Insertion of single- and dual-chamber pacemakers and implantable defibrillators
- External cardioversion and defibrillation
- Diagnostic electrophysiology studies
- Implantation of biventricular pacing devices
- Cardiopulmonary resuscitation
- Outpatient monitoring of pacemakers, implantable defibrillators, and patients with chronic arrhythmias
The fellow also must perform the following exams and procedures (procedures performed during the general cardiology fellowship do not count toward this number):

- Electrophysiologic evaluations (150)
- Ablations, non-atrial fibrillations (75)
- Atrial fibrillation ablations (35)
- ICD implantations (25)
- CRT (biventricular pacing) (25)
- Dual-chamber pacemakers (25)
- Pacemaker/device revisions (30)
- Pacemaker/device interrogations (20)

Positions of subject matter experts

**Adam Zivin, MD**

Adam Zivin, MD, is the director of cardiovascular electrophysiology at the Swedish Medical Center’s Heart and Vascular Institute in Seattle. He points out that device implantation is no longer a standard part of cardiology fellowship training. Although there are many practicing cardiologists who were trained in pacemaker implantation, the rapid growth in the technological sophistication of the devices has made device implantation the realm of the subspecialist.

“The reality is that who implants devices (pacemakers, ICDs, CRT) is changing,” says Zivin. “Certainly ICDs should only be implanted by cardiologists with specialized electrophysiology training. There is ample data out there showing better outcomes when ICDs are implanted by electrophysiology-trained cardiologists, and given the adequate supply of EP docs, there really is no reason for general cardiologists to be implanting ICDs anymore.”

**John M. Miller, MD**

John M. Miller, MD, is associated with the Krannert Institute of Cardiology and oversees the electrophysiology fellowship program at the Indiana University School of Medicine in Indianapolis. Miller notes that although general cardiologists are trained to interrogate pacemakers, they are no longer trained to implant them, and the alternate training pathway for cardiologists to learn to implant them has closed. He explains that “many ‘grandfathered’ cardiologists implant pacemakers but should not be doing ICDs without the additional training of an EP fellowship. Intensivists and ER physicians can implant temporary transvenous pacemakers but not the permanent ones (there is no temporary transvenous ICD).”

Miller points out that the ABIM requires 25 ICD implantations to establish competency but has no minimum number of pacemaker implantation procedures. “It is assumed if you can implant an ICD you can implant a pacemaker,” he says. Miller’s institution requires physicians seeking privileges in implanting ICDs to
do 12 procedures per year. “It’s not very many, but if you have done a good number in the past, this is more than adequate to maintain skills.”

**Positions of accreditation bodies**

**CMS**

CMS has no formal position concerning the delineation of privileges for cardiac pacing and arrhythmia management. However, the CMS *Conditions of Participation (CoP)* define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS
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recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for cardiac pacing and arrhythmia management. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
- A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff.
- Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested.
- A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested.
- Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism.
- A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9).
- A process to determine whether there is sufficient clinical performance information to make a decision related to privileges.
- A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws.
- Information regarding any changes to practitioners’ clinical privileges, updated as they occur.

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments.
and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for cardiac pacing and arrhythmia management. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for cardiac pacing and arrhythmia management. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”
The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined. DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

**Minimum threshold criteria for requesting privileges in cardiac pacing and arrhythmia management**

**Basic education:** MD or DO.

**Minimal formal training:** Successful completion of an ACGME-/AOA-accredited residency program in internal medicine followed by successful completion of an accredited fellowship in cardiovascular disease (cardiology) and clinical cardiac electrophysiology (to implant ICDs).

**Note:** Critical care and emergency medicine physicians may implant temporary ICDs.

**Required current experience:** Demonstrated current competence and evidence of the performance of 12 CIED procedures in the past 12 months or completion of training in the past 12 months.
References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Demonstrated current competence and evidence of the implantation of at least 24 CIEDs in the past 24 months based on results of ongoing professional practice evaluation and outcomes.

In addition, continuing education related to cardiac pacing and arrhythmia management should be required.

For more information

Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654
Telephone: 312/755-5000
Fax: 312/755-7498
Website: www.acgme.org

American Board of Internal Medicine
510 Walnut Street, Suite 1700
Philadelphia, PA 19106-3699
Telephone: 800/441-ABIM
Fax: 215/446-3590
Website: www.abim.org

American College of Cardiology
Heart House
2400 N Street
Washington, DC 20037
Telephone: 202/375-6000
Fax: 202/375-7000
Website: www.cardiosource.org
American Heart Association
7272 Greenville Avenue
Dallas, TX 75231
Telephone: 800/242-8721
Website: www.heart.org

American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611
Telephone: 312/202-8000
Fax: 312/202-8200
Website: www.osteopathic.org

American Osteopathic Board of Internal Medicine
1111 W. 17th Street
Tulsa, OK 74107
Website: www.aobim.org

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Telephone: 877/267-2323
Website: www.cms.hhs.gov

DNV Healthcare, Inc.
400 Techne Center Drive, Suite 350
Milford, OH 45150-3710
Telephone: 513/947-8343
Fax: 513/927-1250
Website: www.dnvaccreditation.com

Healthcare Facilities Accreditation Program
142 E. Ontario Street
Chicago, IL 60611
Telephone: 312/202-8258
Website: www.hfap.org

International Board of Heart Rhythm Examiners
1400 K Street NW, Suite 500
Washington, DC 20005
Telephone: 202/464-3400
Fax: 202/464-3401
Website: www.ibhre.org
Cardiac pacing and arrhythmia management

Krannert Institute of Cardiology
1801 Senate Boulevard, Suite 4000
Indianapolis, IN 46202
Telephone: 317/962-0500
Website: www.medicine.iupui.edu/krannert

Swedish Medical Center Heart and Vascular Institute
550 17th Avenue, Suite 680
Seattle, WA 98122
Telephone: 206/215-4545
Fax: 206/215-4550
Website: www.swedish.org

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