CLINICAL PRIVILEGE WHITE PAPER

Implantable nerve stimulators

Background

According to the National Pain Foundation (NPF), neuromodulation is the medical specialty in which small, implantable nerve stimulators are used to electrically stimulate a peripheral nerve, the spinal cord, or the brain to treat pain or other disorders of the central nervous system.

Several types of procedures rely on these small systems (the generators are typically about the size of a tape measure), which are typically used for patients who do not respond to medication or other medical means. The most common types of neuromodulation procedures include sacral nerve, vagus nerve, and spinal cord stimulation.

Sacral nerve stimulation (SNS): A generator/stimulator is placed behind the pelvis and connected via a thin lead wire to an electrode placed near the sacral nerve, in the lower spine, which controls urinary function. The stimulator then sends small electrical impulses continuously to the nerve. The impulses act as a bladder pacemaker, reducing or eliminating urge incontinence in a high percentage of patients, according to the Mayo Clinic based in Rochester, MN. Patients can adjust the level of stimulation and turn the SNS system on and off with a handheld device.

Vagus nerve stimulation (VNS): This type of procedure involves stimulating the vagus nerve (one of 12 pairs of cranial nerves) in the back of the neck to curb epileptic seizures. The vagus nerve has motor functions in the larynx, diaphragm, stomach, and heart, and sensory functions in the ears and tongue. It also has motor and sensory functions in the pharynx (sinuses) and the esophagus. VNS involves implanting the generator in the chest while the patient is under general anesthesia. That generator is then linked to three small lead wires equipped with similar electrodes, which are then attached to the left vagus nerve in the neck, according to *neurologychannel.com*. The generator is programmed to stimulate the vagus nerve at regular intervals at a frequency determined by the physician. If a seizure begins during those intervals, the device can also be triggered by a small handheld magnet.

Intermittent electrical stimulation of the left vagus nerve has been shown to cause widespread and bilateral effects in those areas where seizures take place. According to the University of Maryland Medical Center in Baltimore, although VNS completely eliminates seizures in some patients, most report that the therapy cuts the occurrence of their seizures in half and reduces the intensity of the seizures.

Spinal cord stimulation (SCS): According to the NPF, SCS (also called dorsal column stimulation) involves sending electrical charges to the spinal cord, which blocks some, but not all, types of pain. Stimulators can be external or implanted.

With implantable SCS systems, the power source and leads are implanted in the patient. According to St. Jude Medical, a device manufacturer in St. Paul, MN, SCS systems consist of three components: leads, a generator/receiver, and a programmer/transmitter. Leads are placed in the epidural space, or the area above the spinal column, and are connected to the generator/receiver, which is placed in the abdomen. When the generator/receiver is turned on, the electrical energy is sent through the leads to electrodes that stimulate nerve fibers with a mild shock, which interrupts the pain signal being sent to the brain. According to St. Jude, the stimulation effectively replaces pain messages with a more pleasant sensation (often characterized as tingling) called parethesia. Patients control the amplitude and length of stimulation with a handheld controller.

According to the NPF, SCS can treat only neuropathic pain and not that caused by surgery or tissue injury. SCS is also used to treat other painful disorders, such as peripheral vascular disease and pancreatitis.

Deep brain stimulation (DBS): According to the Cleveland Clinic, DBS is used to treat patients with Parkinson's disease, essential tremor, dystonia, and tremors due to multiple sclerosis. The therapy involves implanting a thin lead connected to four electrode contacts into a specific area in the brain. The lead is connected to the generator, which is placed in the chest cavity. Use of DBS in treating depression is an area under research. However, the FDA has not yet approved its use for this purpose.

Uses for implantable nerve stimulators continue to grow and develop. Functional electrical stimulation is one such new technique still being developed that implants microstimulators next to nerves to help muscles used in breathing, movement, and urination in people with spinal cord injury.

Healthcare industry representatives (HCIR) play a significant role in the process of implanting nerve stimulators because they offer support and guidance on many technological innovations. Hospitals should define duties and responsibilities of HCIRs as a part of the credentialing process. Examples of these duties and responsibilities may include participation of HCIRs in a timeout process, validating availability of specialized equipment, or in performing on-site calibration of any equipment to include the nerve stimulator, etc.

For information on the credentialing of HCIRs, please see HCPro Inc.'s *Clinical Privilege White Paper* "HCIRs in the operating room and other invasive and special procedure sites—Special Report 1010."

The **Credentialing Resource Center (CRC)** recommends that hospital leaders have a defined process for approval and reapproval of HCIRs in their facility.

Involved specialties SCS: Interventional pain management specialists, orthopedic surgeons, neurosurgeons, anesthesiologists

SNS: Urologists and urogynecologists

VNS: Epileptologists, neurologists, and neurosurgeons

DBS: Neurosurgeons and neurologists

Positions of societies and academies

AAPM

Founded in 1983 as the American Academy of Algology, the American Academy of Pain Medicine (AAPM) is the primary organization for physicians practicing the specialty of pain medicine in the United States.

According to the AAPM, SCS is a treatment that has been used for more than 30 years, but only in the previous five years has it met with widespread acceptance and recognition by the medical community.

In its *Chronic Pain Medical Treatment Guidelines,* published in August, 2007, the AAPM states that in the past decade, there has been growing awareness that SCS is a reasonably effective therapy for many patients who suffer from neuropathic pain, for which there is no alternative remedy. There are several reasons for this development, the academy states, but the main reason is that indications are now more clearly defined. The enhanced design of electrodes, leads, and receivers/generators has substantially increased the incidence of reoperations for device failure. These implantable devices have a very high initial cost in relation to the cost of conventional medical management. However, SCS may lead to a cost savings over time for the patient, as well as better results compared with other remedies.

Epilepsy Foundation

The Epilepsy Foundation is a nonprofit organization dedicated to improving the lives of the more than 3 million epilepsy patients and their families in the United States.

Although the foundation does not publish guidelines for the delineation of clinical privileges for implantable nerve stimulator procedures, it states that recent advances in technology have opened the door to new lines of research. "Research in genetics, new drug development, surgery, and technology hold the key to controlling and preventing seizures," the foundation states on its Web site. In addition, the organization states that new technologies have created opportunities for advancement

in areas including treatment delivery devices, which presumably includes implantable nerve stimulators used to treat epilepsy with VNS.

NASS The North American Spine Society (NASS) is a multidisciplinary medical organization that fosters evidence-based, ethical, and spine care of the highest quality by promoting education, research, and advocacy. The organization is comprised of more than 4,400 members from disciplines including orthopedic surgery, neurosurgery, physiatry, radiology, anesthesiology, research, physical therapy, and other spine care professionals.

According to NASS, new drugs and devices are being introduced to the field of spine care at a rapid pace, making it essential for physicians to be educated on the indications, applications, techniques, and potential complications related to the new technology. As a result, NASS formed a task force on training recommendations for new technologies to address concerns about patient safety, education, resident and fellow activities, and clinical guidelines specific to each new technology being discussed.

With regard to privileges for new technologies, the society states that although it is frequently approached by hospitals requesting recommendations for the implementation of new technologies, "NASS cannot implement or enforce any physician training recommendations, nor does it attempt to do so … Implementation and enforcement of any recommendations are at the discretion of individual hospital or hospital system credentialing and privileging committees."

However, the society publishes recommendations about physician training and experience regarding new technologies.

According to NASS, use of new technology in the clinical setting requires defined and appropriate education of physicians. This education should include the following considerations:

- As a prerequisite, physicians should possess an in-depth knowledge (gained through formal training and clinical experience) of the relevant disease process and its management.
- Physicians should acquire the necessary technical skills and familiarity with indications through defined educational programs presenting balanced content in the technology. Qualifying programs must include didactic and practical elements that are successfully completed (not just attended)

and documented as part of fellowship training, a post-residency course of instruction, or an approved residency program.

- ➤ The physician must be qualified, experienced, and knowledgeable in managing the diseases for which the technology is applied.
- ➤ Many skills are highly specialized, and the mere acquisition of a skill is not the only criterion by which to measure qualifications.
- ➤ For spine care in general, patient selection is an essential element in the use of any treatment or technology. In addition, prompt recognition and management of complications can be achieved only when the physician is fully qualified in all aspects of treatment of the disease and equipped to make timely and appropriate referrals as needed.
- ➤ Physicians performing the procedure should be knowledgeable about appropriate treatment options should the procedure fail and be accomplished in the required revision techniques.
- ➤ Qualifications of the physician who will apply the new technology should be reviewed by a local credentialing body with members that have experience managing complex spine procedures. Mentoring and proctoring are also encouraged.

Other recommendations by NASS include educating physicians using a balanced presentation of the pros and cons of a new technology, comparing the new technology to existing treatments, and revealing content and funding sources for training presentations so attendees can determine any potential bias.

AUA

The American Urological Association (AUA) does not publish guidelines regarding the delineation of clinical privileges for implantable nerve stimulator procedures. The AUA states that urologists should have access to the technological support necessary to practice state-of-the-art care as defined in the specialty of urology.

Positions of other interested parties

ABNS

The American Board of Neurological Surgery (ABNS) was created to encourage the study, improve the practice, elevate the standards, and advance the science of neurological surgery. Its stated purpose is to certify candidates who meet the basic requirements and who pass its oral and written examinations. The board works with the residency review committee for neurological surgery of the Accreditation Council for Graduate Medical Education (ACGME) to improve the standards of training in neurosurgical residency programs.

To be eligible for board certification by the ABNS, each applicant must be a graduate of a medical school acceptable to the board. A candidate must have successfully completed an internship and neurosurgical residency training in an ACGME-accredited program.

In addition to passing the examination and successfully completing other steps necessary for applying for certification (e.g., requesting letters of recommendation and obtaining a valid license), the following training in neurological surgery is required:

- Fundamental skills: internship year (12 months)
  - Twelve months must be devoted to acquiring knowledge in fundamental clinical skills. This year of training is preferably taken prior to beginning neurosurgical residency and must be completed prior to beginning the third year of residency training.
- Neurological surgery residency: 60 months minimum
  - At least 36 months of that time must be devoted to core clinical neurosurgery with progressive responsibility culminating in 12 months as the seniormost resident. As senior resident, the trainee shall have major or primary responsibility for patient management and administrative duties as designated and deemed appropriate by the program director. Training in neurosurgery must be progressive and not obtained during repeated short periods in several institutions. At least 24 months must be spent in one institution.
  - A minimum of three months must be devoted to clinical neurology, although six months is preferred. This period must be taken as a full-time resident in a neurology residency program accredited by the ACGME.
  - The remaining 12–24 months must be devoted to aspects of the basic or clinical neurological sciences, which may include neuropathy, neuroradiology, and research.
  - An individual's training is not complete and a program director's endorsement cannot be provided until the primary examination has been passed for credit toward certification.

Modification of the above requirements to fulfill specific training goals may be formulated for an individual resident.

Prior to acceptance of a candidate for oral examination, the ABNS requires a statement from the candidate's program director that he or she has fulfilled the professional training requirements of the

board, performed satisfactorily in the program, and has passed the primary examination for credit.

ABSS The American Board of Spine Surgery (ABSS) grants certification in spine surgery. Applicants must meet the following minimum requirements:

- ➤ Certification by the ABNS or the American Board of Orthopedic Surgery (ABOS)
- ➤ Successful completion of a 12-month spine fellowship program approved by the ABSS, or resident training and experience deemed equivalent to a 12-month spine fellowship program approved by the ABSS
- ➤ Full and unrestricted licensure to practice medicine in the United States or Canada, or engagement in full-time practice in the U.S. government for which licensure is not required
- ➤ Successful completion of parts one (written) and two (oral) of the ABSS examination
- ➤ Submittal of two letters of recommendation regarding character, reputation, and practice ethics, written by the director of the applicant's residency program, the director of the applicant's spine fellowship program, or the chief of surgery or equivalent at a hospital where the applicant holds staff privileges

AOA The American Osteopathic Association (AOA) grants certification in neurology through the American Osteopathic Board of Surgery. To be eligible for certification, the applicant must:

- ➤ Graduate from an AOA-accredited college of osteopathic medicine
- ➤ Be a member in good standing of the AOA or its Canadian counterpart and hold a valid medical license
- ➤ Successfully complete an AOA-approved Osteopathic Graduate Medical Education (OGME)-1 internship
- ➤ Have evidence of satisfactory completion of previous years of an AOA-approved residency training program in the surgical specialties under the jurisdiction of the board
- ➤ Complete one year of training in general surgery followed by four years of training in neurological surgery
- ➤ Complete five years in neurological surgery

ABA The American Board of Anesthesiology (ABA) offers certification in anesthesiology. To be eligible for certification, the applicant must meet the minimum requirements and hold a valid medical license. Training requirements include:

- ➤ Satisfactory completion of four years of full-time training, including one year of clinical base training and three years of clinical anesthesiology training

- Possession of a certificate of clinical competence covering the final six months of clinical anesthesia training showing that the applicant met the training requirements

During the clinical base year, the physician must be enrolled and training as a resident in a transitional year or primary specialty training program in the United States or its territories that is accredited by the ACGME or approved by the AOA, or outside the United States and its territories in institutions affiliated with medical schools approved by the Liaison Committee on Medical Education from the date the training begins to the date it ends.

The ABA also offers certification in the subspecialty of pain medicine, an area of medicine that encompasses implantable nerve stimulators.

In addition to general requirements that include previous ABA certification, the ABA mandates the following:

- Completion of 12 months of full-time subspecialty training in a program accredited by the ACGME, which must follow the continuum of education for anesthesiology. The ABA will accept no more than two months of training in institutions not recognized by the ACGME as part of the accredited subspecialty program.
- Possession of Certificate of Clinical Competence for both six-month increments of subspecialty training (the ABA grants a fellow credit for subspecialty training in six-month increments).

ABOS

The ABOS grants certification to orthopedic physicians who qualify. Educational requirements include:

- Five years of ACGME-accredited postdoctoral residency
- One year in an accredited graduate medical education program in which the curriculum fulfills the content requirements for postgraduate year one (PGY-1) and is determined or approved by the director of an accredited orthopedic surgery program

PGY-1 must include:

- A minimum of six months of structured education in surgery, including multisystem trauma, plastic surgery/burn care, intensive care, and vascular surgery
- A minimum of one month of structured education in at least three of the following: emergency medicine, medical/cardiac intensive care, internal medicine, neurology, neurological

surgery, rheumatology, anesthesiology, musculoskeletal imaging, and rehabilitation
- ➤ A maximum of three months of orthopedic surgery

For orthopedic requirements beyond PGY-1, the minimum distribution of educational experience must include:
- ➤ 12 months of adult orthopedics
- ➤ 12 months of fractures/trauma
- ➤ Six months of children's orthopedics
- ➤ Six months of basic and/or clinical specialties

ABU The American Board of Urology (ABU) states that the purpose of awarding certification is to assure the public that the individual has received the appropriate training and has a level of urologic knowledge necessary to practice safe and effective urology.

Applicants accepted by the board to enter the certification process must complete a qualifying examination and, if successful, a subsequent examination. Assessment of clinical practice through review of practice logs and peer review will also be carried out prior to admission to the certifying (second) examination. Certification must be achieved within five years of the successful completion of residency training in an ACGME or Royal College of Physicians and Surgeons of Canada program.

AORN The Association of periOperative Registered Nurses (AORN) is a national association committed to improving patient safety in the surgical setting. Although AORN does not publish privileging guidelines related to implantable nerve stimulator procedures, the association does address the use of HCIRs in its *Statement on the Role of the Health Care Industry Representative in the Operating Room.* HCIRs promote, sell, give training, and advise on medical systems, devices, and procedures within hospital premises, such as the operating room (OR). The knowledge and expertise that these representatives provide about their products may make their presence in the hospital worthwhile because they are more familiar with their system, device, or procedure than the physician and the healthcare team, according to AORN. Although they most often provide services in the OR, it is also becoming common for HCIRs to practice in other hospital and ambulatory settings, including cardiac catheterization labs and special procedure rooms.

In the past, there have been cases in which HCIRs in the OR have been blamed for adverse events. As a result, groups, such as the

American College of Surgeons (ACS) and AORN, have developed and published statements that provide guidelines to hospital senior leadership, board and medical staff leadership, and other members of the hospital leadership team for governing the presence and use of sales representatives or other vendor representatives in the operating/surgical or other special procedures suites.

AORN further states that HCIRs, by virtue of their training, knowledge, and expertise, can provide technical assistance to the surgical team. This assistance can expedite the procedure and facilitate desired patient outcomes. However, HCIRs, like any visitor or observer to the OR, must obtain the permission of hospital leadership. They must also obtain informed consent from patients (i.e., patients must be told of the sales representatives' permitted level of involvement and role).

AORN states that the organization "recognizes the need for a structured system within the perioperative setting for education, training, and introduction of procedures, techniques, technology, and equipment to practicing healthcare professionals." AORN affirms the valuable role HCIRs play in the care of surgical patients and to assist the perioperative team in maintaining patients' safety, right to privacy, and confidentiality when an HCIR is present during a surgical procedure. An HCIR may be present during a surgical procedure under conditions prescribed by the facility. AORN recognizes that there is a wide range of regional variations regarding the activities of the HCIR in the OR. This statement provides general guidelines to assist facilities in developing policies best suited to their community standards.

Along with concerns pertinent to the facility, AORN recommends that the following precepts guide policy development:

- Policy should be developed in collaboration with the facility's risk management and/or legal counsel to ensure compliance with applicable laws.
- Each facility should develop a system that addresses informed patient consent regarding the presence and role of an HCIR in the OR during a surgical procedure in routine and emergency situations. This system should include documentation in medical records.
- As the patient's advocate, the RN responsible for the patient's care during the procedure is accountable for maintaining the patient's safety, privacy, dignity, and confidentiality. To achieve this, the RN should monitor the HCIR's activities whenever possible and facilitate the representative's service

to the patient and the perioperative team during the procedure. The RN should be informed of an HCIR's presence and his or her purpose for being there prior to the procedure.

- Perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment with which they are unfamiliar prior to their use in a surgical procedure. This instruction may be provided by the HCIR. The facility should maintain evidence of documented competencies for healthcare professionals, especially when introducing new procedures, techniques, technology, and equipment as required by The Joint Commission (formerly JCAHO).
- Each facility should develop a system that documents that the HCIR has completed instruction in the principles of asepsis, fire and safety protocols, infection control practices, bloodborne pathogens, and patients' rights. Based on community standards, this may range from maintaining up-to-date documentation provided by the HCIR's employing company to providing facility-specific instruction and training.
- The HCIR's presence and purpose should be prescheduled with the designated OR management authority and the surgeon in accordance with the facility's policy.
- The HCIR should wear identification while in the facility.
- Each facility should develop a system that clearly delineates limits on HCIR activities in the OR based on community standards. The HCIR should not scrub in.
- Medical equipment and other complex devices must be reviewed and approved prior to their use by the facility's service provider.
- A clearly defined mechanism should exist to address departures from established policy.

In its statement *The Role of the Health Care Industry Representative in the Perioperative/Invasive Procedure Setting*, AORN states that HCIRs:

- May be permitted in the perioperative setting to provide technical support in accordance with facility policies and local, state, and federal regulations.
- Should not provide direct patient care or be allowed in the sterile field. However, HCIRs with specialized training and facility approval may perform calibration/synchronization to adjust program devices (such as, but not limited to, implanted electronic devices, radio frequency devices, and lasers) under the supervision of the physician.

Note: For more information on this topic, please see HCPro Inc.'s *Clinical Privilege White Paper*, "HCIRs in the OR and other invasive and special procedure sites—Special Report 1010."

ACS Although the ACS does not publish privileging guidelines on implantable nerve stimulator procedures, it establishes guidelines for HCIRs with regard to their involvement in new technology in its *Statement on Health Care Industry Representatives in the Operating Room*. The following ACS statement outlines institutional policies and specific procedures relevant to HCIRs:

- The institution should designate an authority for approving an HCIR's presence in the OR. A time frame for securing this approval should be established. This authority should:
  - Supply a time-limited approval and appropriate identification (to be worn at all times) for the HCIR
  - Ensure that orientation to the facility is provided
  - Verify the documentation that certifies the HCIR has had education and training in: HIPAA compliance and all matters related to patients' rights and confidentiality; appropriate conduct and attire in the OR environment; aseptic principles and sterile techniques; infectious disease and bloodborne pathogens; occupational safety (e.g., biohazardous waste, fire, electrical, radiation, and other safety protocols); and other applicable practices that may be related to the operation
- The HCIR should be present at the request of the operating surgeon and should be introduced to the entire OR team, along with an explanation of the purpose of the visit. If the surgeon did not initiate the request, the surgeon should be notified and approve the visit prior to the operation.
- The patient should be informed of the presence and purpose of the HCIR in the OR and give written, informed consent. This should be documented within the medical records.

According to the ACS, the HCIR is present as an advisor to the perioperative team to ensure the safe and effective application of surgical devices and technologies. The presence of the HCIR in the OR is not an adequate substitute for preoperative training of the surgical team. The surgical team must have the theoretical understanding and knowledge, training, and skills necessary for the application of these surgical devices and technologies prior to surgery. In the role of educator and facilitator, the HCIR:

- Should not engage in the practice of surgery, nursing, or medical decision-making

- ➤Should not scrub or be involved in direct patient contact
- ➤May be involved in the remote calibration or adjustment of medical devices to the surgeons and manufacturers' specifications (e.g., pacemakers, radio frequency devices, and lasers)
- ➤Should have his or her activities monitored and supported by the surgeon (or at the surgeon's discretion) by the perioperative nurse responsible for the patient's care

Note: For more information on this topic, please see HCPro Inc.'s *Clinical Privilege White Paper*, "HCIRs in the OR and other invasive and special procedure sites—Special Report 1010."

Texas Back Institute–Plano

Ralph Rashbaum, MD, a board-certified orthopedic surgeon who specializes in spine surgery at the Texas Back Institute in Plano, regularly performs SCS procedures. He says SCS is by far the most prevalent form of neuromodulation, and physicians who perform SCS are typically neurosurgeons, orthopedic surgeons, anesthesiologists, and spine surgeons. In some cases, they may also be physiatrists, he says. However, most physicians who perform SCS have completed a residency program specializing in anesthesia, followed by a fellowship in interventional pain management within an orthopedic or neurosurgical spine service or department, he says. That fellowship would also include the diagnosis and application of neuromodulation devices. Such a fellowship would allow the physician the hands-on training he or she needs.

Rashbaum says device manufacturers provide weekend courses in SCS, although those cases are practiced on cadavers. Afterward, physicians are instructed to continue their education in SCS with proctors to achieve competency.

Note: For more information, please see HCPro Inc.'s *Clinical Privilege White Paper,* "Post-residency surgical education and training—Special Report 1007."

With the necessary training and education, implanting SCS systems is a relatively straightforward procedure and is merely one part of managing neuropathic pain, says Rashbaum. What is more important and more difficult, he says, is learning how to manage the overall process. "It's really more [about] the actual ability to diagnose and treat these [patients] on [an ongoing] process," he says. [SCS] is simply one tool in the treatment of chronic pain. It doesn't mean you put this in, and the patients go away."

To become competent in SCS, Rashbaum says physicians need to have completed 12–15 proctored cases, although there is no agreed-upon number. "It simply gives us an understanding that they understand the technicalities of it," he says.

Physicians would also need to perform six to 20 cases on their own. "That would qualify them," Rashbaum says, and indicate that the physicians had spent enough time studying SCS and that their proctors had deemed them competent. Physicians in fellowship programs may easily get that many, if not more, he says.

Rashbaum says competency guidelines for SCS are applicable to all neuromodulation procedures using implantable nerve stimulators, given that the biggest difference is the part of the body where the electrodes are placed. The devices used in procedures such as SCS, DBS, VNS, and SNS differ only slightly, he says.

Rashbaum also says the number of cases a physician must perform under a proctor's guidance, as well as on his or her own, is the same for all kinds of neurostimulation, namely those previously mentioned.

"The thing that [all of these devices] share is utilization of an implantable pulse generator that drives an electrical current to a neuroreceptor," Rashbaum says. "When I use those numbers, it's basically generically neuromodulation. Once you learn to do one, you can do them all."

North Shore University Hospital Manhasset, NY

Michael Schulder, MD, is vice chair of North Shore University Hospital's department of neurosurgery in Manhasset, NY. Schulder says procedures that entail implanting an electronic nerve stimulator are all different, except for the hardware itself. "The surgical procedures, the risks are very different. The thing that they have in common is … the hardware," he says, adding that most of the devices have a stimulating electrode connected to a stimulator. In addition to working in different parts of the body, the risks can also be very different, he says.

In the case of a peripheral nerve implant (which includes sacral and vagus nerve implants), Schulder says physicians simply look anatomically for the nerve and then put it in. Inclusion criteria for performing the procedure would be based on doing nerve blocks and ensuring that there is a clinical response before the procedure.

"You put a peripheral nerve stimulator in, you're exposing the nerve, you wrap the electrode around it, or lay it alongside it, whatever the technical demands are, and that's it. You're done. Unless you're grossly careless, or have grossly bad luck, then you won't injure a nerve or have bleeding," Schulder says. "When you're putting in a deep brain stimulator, you're relying on very carefully targeted small areas in the brain and guiding it with special stereotactic equipment to those areas with a concomitant risk of bleeding—that's the main acute risk of doing the procedure in the brain. The whole rhythm and procedure of doing it is very different."

"Hemorrhage in the brain after a deep-brain-stimulating electrode has a known percentage risk. It happens in, I guess, 2%–3% of the cases," Schulder says.

The processes for implanting spinal cord, peripheral, or deep brain stimulation devices "are completely, completely different," Schulder adds.

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 practice area.

Minimum threshold criteria for requesting core privileges in neuromodulation/ implantable nerve stimulators

Basic education: MD or DO
Minimum formal training: Applicants must have successfully completed an ACGME/AOA-accredited residency program followed by an approved fellowship program in neurology, neurosurgery, anesthesiology, physiatry, epileptology, interventional pain management, urology, orthopedic surgery, anesthesiology, or similar field, depending on what type of neuromodulation procedures the physicians seeks to perform.
Required previous experience: Applicants must be able to demonstrate that they have successfully implanted at least 12 neuromodulation devices in the previous 12 months in an accredited clinical fellowship program. If the applicant's fellowship program did not include experience in neuromodulation, he or she must have obtained the equivalent experience by completing an approved training course taught by a manufacturer of implantable nerve stimulators.

Note: For more information, please see HCPro Inc.'s *Clinical Privilege White Paper*, "Post-residency surgical education and training—Special Report 1007."

References A letter of reference should come from the director of the applicant's training program in his or her primary subspecialty. Alternatively, a letter of reference regarding competence may come from the director of the relevant department at the institution where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization's existing quality assurance mechanisms.

Applicants must be able to demonstrate competence by showing evidence that they have implanted at least 12 neuromodulation procedures annually during the reappointment cycle.

In addition, documentation of continuing education related to neuromodulation/implantable nerve stimulators should be required.

For more information

For more information regarding this practice area, contact:

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American Board of Anesthesiology
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Web site: *www.theaba.org*

American Board of Neurological Surgery
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Web site: *www.abns.org*

American Board of Orthopedic Surgery
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Web site: *www.abos.org*

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American Board of Spine Surgery
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Fax: 904/786-9939
Web site: *www.spinesurgboard.org*

American College of Surgeons
633 North Saint Clair Street
Chicago, IL 60611
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American Osteopathic Board of Surgery
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Telephone: 937/235-9786
Fax: 937/235-9788
Web site: *www.aobs.org*

American Urological Association
1000 Corporate Boulevard
Linthicum, MD 21090
Telephone: 410/689-3700
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Web site: *www.auanet.org*

Association of periOperative Registered Nurses
2170 South Parker Road, Suite 300
Denver, CO 80231
Telephone: 303/755-6304
Fax: 303/755-2676
Web site: *www.aorn.org*

Epilepsy Foundation
8301 Professional Place
Landover, MD 20785
Telephone: 800/332-1000
Web site: *www.epilepsyfoundation.org*

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432
Telephone: 763/514-4000
Fax: 763/514-4879
Web site: *www.medtronic.com*

National Pain Foundation
300 East Hampden Avenue, Suite 100
Englewood, CO 80113
Web site: *www.nationalpainfoundation.org*

North American Neuromodulation Society
4700 West Lake Avenue
Glenview, IL 60025
Telephone: 847/375-4714
Fax: 847/375-4714
Web site: *http://northamerica.neuromodulation.com/north-american-neuromodulation-society-home.htm*

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7075 Veterans Boulevard
Burr Ridge, IL 60527
Telephone: 630/230-3600
Fax: 630/230-3700
Web site: *www.spine.org*

St. Jude Medical
One Lillehei Plaza
St. Paul, MN 55117
Telephone: 651/483-2000
Fax: 651/482-8318
Web site: *www.sjm.com*

Texas Back Institute
6020 West Parker Road, Suite 200
Plano, TX 75093
Telephone: 972/608-5000
Web site: *www.texasback.com*

Privilege request form
Implantable nerve stimulators

To be eligible to request clinical privileges in neuromodulation/implantable nerve stimulators, an applicant must meet the following minimum threshold criteria:

➤Basic education: *MD or DO*

➤Minimum formal training: *Applicants must have successfully completed an ACGME-/AOA-accredited residency program followed by an approved fellowship program in neurology, neurosurgery, anesthesiology, physiatry, epileptology, interventional pain management, urology, orthopedic surgery, anesthesiology, or similar field, depending on what type of neuromodulation procedures the physicians seeks to perform.*

➤Required previous experience: *Applicants must be able to demonstrate that they have successfully implanted at least 12 neuromodulation devices in the previous 12 months in an accredited clinical fellowship program. If the applicant's fellowship program did not include experience in neuromodulation, he or she must have obtained the equivalent experience by completing an approved training course taught by a manufacturer of implantable nerve stimulators.*

Note: *For more information, please see HCPro Inc.'s Clinical Privilege White Paper, "Post-residency surgical education and training— Special Report 1007."*

➤ References*: A letter of reference should come from the director of the applicant's training program in his or her primary subspecialty. Alternatively, a letter of reference regarding competence may come from the director of the relevant department at the institution where the applicant most recently practiced.*

➤ Reappointment*: Reappointment should be based on unbiased, objective results of care according to the organization's existing quality assurance mechanisms.*

Applicants must be able to demonstrate that they have maintained competence by showing evidence that they have implanted at least 12 neuromodulation procedures annually during the reappointment cycle.

In addition, documentation of continuing education related to neuromodulation/implantable nerve stimulators should be required.

I understand that by making this request, I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician's signature: _____

Typed or printed name: _____

Date: _____