Credentialing of CRNAs—Time for a new look

Key words: Allied health provider, clinical privileges, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), medical staff, primary source verification.

Attitudes toward hospital medical staff credentialing have changed rapidly in the past few decades. Prior to 1975, hospital leaders, attorneys, third-party payers, the medical legal environment and regulatory agencies, such as the Joint Commission on Accreditation of Hospitals (JCAHO), then known as the Joint Commission on Accreditation of Hospitals, were barely concerned with the issue of medical staff credentialing. In contrast, today’s hospital medical staffs find themselves involved in increasing numbers of interdepartmental credentialing issues for a number of reasons: the medical legal environment has become far more invasive, the JCAHO has featured the issue of hospital credentialing prominently in the results of its surveys, and the National Committee for Quality Assurance which accredits HMOs has required an active credentialing process as a prerequisite of accreditation. Additionally, examples of improper or ineffectual credentialing are often discussed in professional circles and sensationalized in the lay media.

As a result of these changes, hospital leaders are challenged to establish corporate policies and procedures that assure objectivity, consistency, and clinical competence throughout the appointment, privileges delineation, and reappointment process. Hospitals may accomplish this through medical staff bylaws, governing board bylaws and/or departmental rules and regulations.

James W. Saxton, Esquire, speaking at the 6th Annual Symposium of Healthcare Attorneys and Risk Managers, February 1997, Dallas, Texas, commented that the “opportunities for hospitals, healthcare systems and physician group practices to maintain quality of care and patient satisfaction while at the same time increasing the level of service and reducing costs can be maximized by utilizing four types of midlevel practitioners (MLPs): midwives, Certified Nurse Practitioners, Certified Registered Nurse Anesthetists (CRNAs) and Physician Assistants.” In addition, market forces continue to change our healthcare delivery systems shifting services to outpatient clinics and offices with increased emphasis on primary care physicians and allied health providers. Allied health providers (AHPs), also called midlevel practitioners, are becoming more prevalent in managed care systems. MLPs can help accomplish the goals of the new healthcare environment: to deliver health services differently, using less resources yet maintaining quality outcome and customer satisfaction.
Risk management perspectives

The increased use of MLPs creates many political, legal, and practical questions. Which allied health providers may have access to the facility? Will there be a different process for employed providers and contracted providers? What is the process for initial credentialing and the process for ongoing monitoring or renewal of privileges? The governing body must approve the categories of allied health providers who are permitted access to the facility and must define the method of evaluating current competency. Whether or not an allied health provider has access to a hospital or other healthcare facility depends upon two factors: (1) state law, including the state's licensing act, and (2) the facility's governing body bylaws, rules, and regulations.

Hospital or healthcare facility bylaws also may define whether the midlevel practitioners will be providing services independently to hospital clients or whether there will be collaboration with a member of the medical staff. Fay A. Rozovsky, JD, MPH, vice president and director of Risk Management, The Reciprocal Group, Richmond, Virginia, observed that the terminology “licensed independent practitioner” obscures an important aspect of the healthcare delivery system. Practitioners cannot be divided into two camps in which some function independently and others must always be under close supervision. Ms. Rozovsky states that “In reality, the level of independence of individuals who deliver care, diagnostics, and supportive healthcare services is a continuum...”1

“In the midrange of the continuum are well-trained individuals who are expected to exercise some independent judgment. These are typically individuals with advanced degrees or training. Although technically at law unable to function ‘independently’, in reality the degree of control or supervision exerted by others may be quite limited. Growing emphasis on cost containment and with utilization management in the healthcare delivery system is propelling more of these professionals to higher levels of independent judgment and decreasing levels of supervision. In this group are physician assistants, advance practice nurses, nurse practitioners, certified nurse midwives, clinical nurse specialists, and certified registered nurse anesthetists.”1

Implications for CRNAs

Currently, a multiplicity of approaches to credentialing CRNAs exists. When CRNAs are contracted by the hospital to provide services independently, they are generally required to apply and be credentialed as an allied health provider but may be processed through regular medical staff credentialing channels. When CRNAs are hospital employees, their initial verification of credentials and experiences is documented by human resources and the anesthesia department manager. Individual clinical privileges should be delineated regardless of the contractual or employment relationship that exists within the practice setting. CRNAs are responsible for seeking clinical privileges that reflect their educational preparation, clinical experience, and level of professional competence. To establish privileges for employees, the hospital should establish an appropriate interface between the credentialing office and human resources. In the absence of a specific privileging process, the CRNA will practice according to department policy, or frequently, according to determinations made on a case-by-case basis by an anesthesiologist providing medical direction.

When the CRNA is an employee of a physician group with privileges to provide anesthesia care in the hospital, there has been more uncertainty on whether to credential the CRNAs as allied health providers. Many facilities have left the responsibility of initial and ongoing credentialing to the physician group and required only evidence of current licenses, certification, and professional liability to be given to the hospital. Concerns by hospitals about credentialing liability may change this process. Traditionally, hospitals were not held accountable for the errors and omissions of credentialed members of the medical staff. They were viewed as independent contractors to patients, using the hospital premises. This assumption has changed as courts have recognized how much authority healthcare entities exert in the selection and retention of members of the medical staff. Thus, liability has been imposed in situations where a healthcare entity knew or should have known that a clinician was likely to cause injury to patients. This direct corporate liability for the selection and credentialing of medical staff/allied health providers is different from situations in which the hospital is held vicariously liable for the negligence of medical staff members. Mr. Saxton is of the opinion that “JCAHO requirements as well as hospital corporate negligence concerns, where applicable, force the undeniable conclusion that MLPs must be credentialed.”

A healthcare facility must also decide how to provide due process if MLPs are denied access to the hospital or subjected to disciplinary action. JCAHO does not require hospitals to afford allied healthcare providers the same due process as physicians. JCAHO does, however, allow hospitals to offer CRNAs membership on the medical staff with
the same due process rights. An argument can be made that MLPs who are now performing many of the same procedures should have the same due process as other medical staff. An appropriate credentialing process may help protect the hospitals from claims of corporate negligence. The ability of hospitals and healthcare facilities to indicate that they have adequate processes for hiring, credentialing, monitoring, and supervising of MLPs may reduce claims that a hospital did not fulfill its oversight duty. This may be true whether the MLP is employed, contracted, or employed through a physicians group.

The hospitals may open themselves to antitrust claims if the credentialing criteria developed are so restrictive that they exclude midlevel practitioners from the hospital. Written credentialing policies stating the criteria on which privilege decisions will be made should be applied equally to all applicants.

**Initial credentialing**

The credentialing process, while striving to meet the same goals, may differ from one facility to another (Figure 1). In fact, key points in JCAHO recommendations for credentialing state: "The organization establishes hospital specific mechanisms and appointment of medical staff/allied medical staff members, and for granting and renewing or revising specific clinical privileges. These mechanisms may differ for medical staff members and other individuals." The procedures for credentialing AHPs frequently follow the procedures for medical staff membership or reappointment. This is appropriate, but the process should include an application that is specifically tailored to reflect the qualifications of an AHP and the standards applicable to the respective practice.

The American Association of Nurse Anesthetists (AANA) has developed a document titled "Guidelines for Clinical Privileges" (revised 1996). This document continues to be a valuable guide to hospitals establishing allied medical staff privileges for CRNAs as it includes a CRNA specific application form and a listing of specific anesthesia privileges. It is included in the Professional Practice Manual for the Certified Registered Nurse Anesthetist. Accomplishing an effective privileges delineation system involves classifying all major diagnostic and treatment procedures the hospital or healthcare organization permits within its walls or renders its auspices into meaningful categories—what the JCAHO calls "accurate, detailed, and specific" categories (MS 5.14, intent). The privileging of physicians in hospitals is relatively standardized, however, the privileging of AHPs or MLPs is far from standardized. Although healthcare organizations have the advantage of having more leeway in privileging AHPs/MLPs compared to privileging physicians, they also have the disadvantage of having little guidance or tradition. Members of the profession are most knowledgeable of the educational requirements and clinical practices of their profession and should develop the training and experience requirements and definitions of privileges for their particular professions.

Privileges should be appropriate to the scope
and complexity of care provided by CRNAs and should not be overly specific or restrictive. Clinical privileging should be so defined as to permit the CRNA to provide selected procedures under specific conditions with or without supervision. The clinical privileging process includes:

1. The qualifications of the provider.
2. The actual practice privileges requested and granted.
3. The conditions or limits of practice.
4. The process for evaluation and renewal of privileges.

**Primary source verification**

The medical staff credentialing and privileging path is more complex and includes requirements that are not in the human resources path. An example is that the medical staff standards require primary source verification of education and training “for initial granting of clinical privileges, the hospital verifies information about the applicants’ licenses, specific training, experience, and current competence . . . with information from the primary source(s) when feasible.” Primary sources are the organizations which issue the credentials (i.e., anesthesia program, board of nursing) or, to verify experience, the hospital or facility in which you obtained experience. This requirement for primary source verification was instituted by JCAHO in 1988 and eliminated the physician or allied health provider as the intermediary to transmit the credentials, documents, or experience.

The purpose of primary source verification is to reduce the possibility of forgery or falsification of credentials. Hospitals cannot accept material in the possession of medical staff applicants as sufficient evidence of credentials. Thus, credentials committees will require original letters of reference, request transcripts directly from colleges, and call the state board of nursing instead of accepting photocopies. Hospitals may still request photocopies of licenses, diplomas, etc., as helpful in the credentialing verification process. In an effort to establish that they have used “due diligence” to verify an applicant’s experience, many hospitals contact all past employers and/or practice settings for the past 3 to 5 years. Because of this need for primary source verification, there are a number of things applicants can do to help the credentialing process go faster and smoother (Table I).

It is strongly recommended to query the National Practitioner Data Bank at the time privileges are granted and every 2 years thereafter. With the recent attention to credentialing and increased numbers of HMOs and hospital mergers, requirements of the credentialing process have put additional strain on medical staff coordinators and the physicians and allied health providers who must provide ever more information (Table II). A cooperative attitude is essential. Efforts in making the credentialing process go smoothly for the medical staff coordinator will most likely be rewarded by return cooperation received when you want assistance with policy changes or educational endeavors.

**Assessment of continued competency/recredentialing**

For the hospital employed CRNA, the human resources department and anesthesia department determines that initial requirements for education, licensing, certification, and experience have been met. The anesthesia department director establishes which competencies are necessary to meet the needs of their anesthesia department. These may include demonstrations of knowledge of cardiorespiratory resuscitation and other emergency procedures, use of anesthesia and emergency equipment, and review of specific skills, i.e., arterial line placement. Written evidence of continued competency for the employed CRNA will generally be summarized in an annual review completed by a hospital employed manager or for the physician group employed CRNA, by physicians in the group (Figure 3). Requests for renewal of specific anesthesia privileges should be based on the CRNA’s education, training, experience, demonstrated ability, and judgment.

For the contracted CRNA or physician group employed CRNA with allied health provider status at the hospital, written evidence of continued competency will usually be assessed every 2 years. This privilege reappointment process may ask two

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**Table I**

**Suggestions for facilitating the credentialing process**

<table>
<thead>
<tr>
<th>Suggestions</th>
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<tbody>
<tr>
<td>Provide complete addresses for all educational institutions and practice sites.</td>
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<tr>
<td>List a key contact person for each practice site (department manager or former colleague).</td>
</tr>
<tr>
<td>If your work at the hospital was arranged through an agency, provide the agency name, address, and telephone number.</td>
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<tr>
<td>Call the colleagues you list as references, and let them know a timely response will be appreciated.</td>
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<tr>
<td>Sending a structured reference letter may encourage a more rapid reply (Figure 2). Enclose a stamped, preaddressed letter to the medical staff coordinator at the facility where you are applying for privileges.</td>
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<tr>
<td>When selecting references, use people who are familiar with your skills and patient outcomes, such as CRNAs, anesthesiologists, surgeons, and administrators.</td>
</tr>
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Figure 2
Sample reference questions for credentialing or recredentialing

The following CRNA has applied for privileges with our hospital: ____________________________

Please complete the following questionnaire:

Do you have direct knowledge of this applicant’s current level of skill and knowledge? _____ yes _____ no

1. If so, for how long? From ___________________ to ___________________

Please comment: ________________________________________________________________

Dates of affiliation with ______________________________ Hospital: __________________ to __________________

2. In your opinion, is the applicant’s current and overall competence:
   _____ less than adequate _____ competent _____ above average

If less than adequate, please explain: _______________________________________________

3. Would you be willing to have this applicant participate in the clinical care and management of yourself or your family?
   _____ yes _____ no

4. Does the applicant have the ability to work cooperatively in a milieu setting with all members of the interdisciplinary
   team?
   _____ yes _____ no

5. Are the applicant’s ethical standards in conformance with the ethical standards maintained by the other members of
   your professional staff? _____ yes _____ no

6. If the answer to questions 3, 4, or 5 is no, please explain: ______________________________

7. Does the applicant have any mental or physical problems or disabilities that, to your knowledge, would prevent him or
   her from adequately performing clinical duties? _____ yes _____ no

8. Has the applicant ever been the subject of any disciplinary action to your knowledge? _____ yes _____ no

9. Has the applicant, to your knowledge, ever had his or her membership, status, and/or clinical privileges revoked,
   suspended, reduced, or not renewed in any facility? _____ yes _____ no

10. To your knowledge, has this applicant’s license and/or certification to practice in any jurisdiction ever been suspended
    or terminated? _____ yes _____ no

11. If the answer to question 7, 8, 9, or 10 is yes, please explain: ____________________________

Additional comments: ______________________________________________________________

Signature: ____________________________
Title: ________________________________
Address: ____________________________

or three colleagues familiar with the CRNA’s work to verify the CRNA’s continued qualifications for a specific list of privileges and attest to the CRNA’s continued competence by completing a letter of reference similar to Figure 2. JCAHO standards recommends quality improvement and risk management data to be considered as part of the reappointment process. Attendance at medical staff meetings may be reviewed. Many hospitals require a 50% or 60% attendance rate.

It is beyond the minimum requirements for credentialing and a mark of excellence to take an active part in identifying and maintaining the qualifications and competencies necessary to provide anesthesia care for your patient group, i.e., if the hospital adds trauma care, open heart surgery, pain management, or a labor epidural service, the professional CRNA should take an active role in establishing reliable competencies.

Credentials verification organizations

Although hospitals cannot accept evidence of credentials carried by applicants, they may rely on other organizations to conduct primary source verification. Credentials verification organizations acting as an “agent” have started up all over the country, many of them managed by hospital and physician associations. For example, the Michigan Professional Credential Verification Services, Inc. was started as a joint venture of the Michigan Hos-
Table II
What to maintain in your own credentials file
Nursing and anesthesia program addresses, transcripts, and diplomas
Resume (including employment/practice history with addresses)
Registered nurse licenses
Accreditation and recertification certificates
Specialty certification (if applicable in your state)
Basic cardiac life support/advanced cardiac life support documentation
Letters of reference from colleagues who practice with you
Transcript of continuing education hours
Immunization status: hepatitis B, measles-mumps-rubella
Tuberculosis test results
Professional liability insurance
List of appropriate clinical privileges

Figure 3
Recredentialing/continued competency

<table>
<thead>
<tr>
<th>Contracted CRNA or physician group employed CRNA</th>
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<tbody>
<tr>
<td>Recredentialing every 2 years</td>
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<tr>
<td>Current privileges sent to peers for comment</td>
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<tr>
<td>Submit continuing education credits</td>
</tr>
<tr>
<td>Current licenses and certifications</td>
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<tr>
<td>Current basic cardiac life support/advanced cardiac life support (BCLS/ACLS)</td>
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<table>
<thead>
<tr>
<th>Facility employed CRNA</th>
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<tbody>
<tr>
<td>Ongoing assessment of continued competency by the department manager</td>
</tr>
<tr>
<td>Job description</td>
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<tr>
<td>Skills review</td>
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<tr>
<td>Peer review</td>
</tr>
<tr>
<td>Current licenses and certifications</td>
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<tr>
<td>Current BCLS/ACLS</td>
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Hospital Association and the Michigan State Medical Society. Managed care organizations (MCOs) have contributed to the growth of credentials verification organizations (CVOs) because a typical MCO will enroll several hundred practitioners, and the burden of credentialing could be enormous. Once a CVO checks a practitioner's credentials, it does not need to check them again when another hospital requests credentialing (within a reasonable timeframe). This reduces the cost and time required for credentialing and reduces the number of inquiries that agencies issuing the credentials must handle. However, it ultimately remains the hospital's responsibility to credential competent AHPs.

Conclusions
1. The public expects (and increasingly demands through litigation) that the hospital/healthcare entity will have mechanisms in place to screen the providers who care for them.

2. The JCAHO, as an external regulatory agency, holds itself out to the public as the group that will assess whether hospitals have appropriate mechanisms to review the credentials of physicians, allied health providers, and employees. Approximately 5,200 hospitals report to their local communities that they are accountable to the public because they have met JCAHO recommendations assessed during an on-site visit (verified by phone, JCAHO Marketing Department, March 3, 1997).

3. Hospitals are increasingly using CVOs to provide primary source verification of data required to credential medical and allied medical staff. One factor spurring this change is the merger of many large hospitals and managed care systems which has necessitated the processing of large numbers of new medical staff simultaneously.

4. Although JCAHO requires physician members of the medical staff to be credentialled and privileged, hospitals may choose to verify the CRNA credentials through one of two mechanisms: the human resources department or allied medical staff credentialing. Employed CRNAs’ qualifications will be processed by human resources. In addition, there may be allied medical staff credentialing.

5. The process to award specific clinical privileges is always part of allied medical staff credentialing and may or may not be implemented for employed CRNAs. CRNAs should be granted clinical practice privileges in the same manner as other healthcare professional staff members who are permitted by law and the facility to provide patient care services. The credentialing and privileging process should provide an objective mechanism for initial application and renewal of clinical privileges based on education, experience, legal qualifications, and a practitioner's competence and abil-
ity to render quality care. There is substantial evidence that many CRNAs' privileges are restricted not by initial training or experience, but by medical staff bylaws or by the employing or supervising physician anesthesiologist group.

6. Healthcare attorneys and risk managers are encouraging hospitals to use the allied medical staff credentials verification process to credential all midlevel providers, i.e., advanced practice nurses, physician assistants, physical therapists, psychologists, podiatrists, and chiropractors. They recommend that hospitals may gain some legal protection by: (1) regular recredentialing of providers who exercise a high level of independent decision making in the provision of patient care and (2) providing similar due process rights as are customarily afforded medical staff.

7. All CRNAs should be prepared for the potential changes to the allied medical staff credentialing and clinical privileges process by maintaining their own credential file.

REFERENCES
(2) Vanaman v Milford Memorial Hosp., 2272 A.2d 71 (Del. 1970); Dickenson v. Maillaird, 175 N.W.2d 388 (Iowa 1970); and Rosane v. Senger, 149 P.2d 372 (Colo. 1944).
(3) Moore v. Board of Trustees of Carson-Tahoe Hospital, 495 P.2d 605, 608 (1972).

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ACKNOWLEDGEMENT
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SHORT-TERM I.V. THERAPY FOR HYPERTENSION IN N.P.O. PATIENTS

PRECISE CONTROL THAT PRESERVES CARDIAC FUNCTION

Prompt and potent blood pressure control
- Significant decreases in systemic vascular resistance (SVR) reduce afterload with no effect on preload

Preserves cardiac function
- No change in LVEDP* or conductance
- No direct effect on myocardial contractility
- Increases ejection fraction and cardiac output

One of the most selective calcium channel blockers
- More vascular selective than other calcium antagonists (nifedipine, diltiazem, and verapamil)
- Also dilates coronary arteries, improving perfusion

Linear pharmacokinetics
- Quick, dose-dependent onset and offset
- Can be used in the elderly without dosage adjustments
- Dosage independent of patient weight

* Left ventricular end diastolic pressure

Observe caution in patients with severe left ventricular dysfunction due to possible negative inotropic effect.

Cardene I.V. is indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their clinical condition permits.

Please see adjacent page for Brief Summary of Prescribing Information.

CARDENE® I.V.
(nicardipine HCl) 2.5 mg/mL
ARTERIAL SELECTIVE VASODILATOR
CARDENE® I.V. (nicardipine hydrochloride)
Brief Summary of Prescribing Information

INDICATION AND USAGE: For the short-term treatment of hypertension when oral therapy is not feasible or desirable. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their clinical condition permits.

CONTRAINDICATIONS: In patients with known hypersensitivity to Cardene I.V. is also contraindicated in patients with advanced aortic stenosis because part of Cardene I.V. is not removed by renal excretion. Reduction of diastolic blood pressure in these patients may worsen rather than improve myocardial oxygen balance.

WARNINGS: Beta-Blocker Withdrawal: Nicardipine is not a beta-blocker and provides no protection against the dangers of abrupt betablocker withdrawal; any such withdrawal should be by gradual reduction in dose of beta-blockers.

Rapid Decrease in Blood Pressure: No clinical events have been reported suggestive of a too rapid decrease in blood pressure with Cardene I.V. However, in some hypertensive patients, blood pressure lowering should be accomplished over a long time as is compatible with patient’s clinical status.

Use in Patients with Atrialectomy: Intra-arterial or intravenous administration of Cardene I.V. is contraindicated in patients with atrialectomy.

Use in Patients with Congestive Heart Failure (CHF): Cardene I.V. reduced afterload without impairing myocardial contractility in preliminary hemodynamic studies of CHF patients. However, in some patients, a negative inotropic effect has been observed. Exercise caution when using Cardene I.V., particularly in combination with a beta-blocker, in patients with CHF or significant left ventricular dysfunction.

Use in Patients with Pseudohypertension: Limited clinical experience exists in these patients; therefore, exercise caution when administering Cardene I.V. Use Covariance IP with caution in patients with pseudo-hypertension.

Use in Patients with Impaired Hepatic Function: Nicardipine is metabolized in the liver; exercise caution in patients with impaired liver function or reduced hepatic blood flow. Consider use of lower doses. Intravenous nicardipine may increase hepatic venous pressure gradient by 4-8 mmHg in patients with high doses (IV, IM). Use Cardene I.V. with caution in patients with portal hypertension.

Use in Patients with Impaired Renal Function: When Cardene I.V. was given to mild to moderate hypotensive patients with moderate renal impairment, a significantly lower systemic clearance and higher AUC were observed. These results are consistent with those seen after oral administration of nicardipine. Close dose titration is advised when treating renally impaired patients.

Drug Interactions: Since Cardene I.V. may be administered to patients already being treated with other medications, including other antihypertensive agents, careful monitoring of these patients is necessary to detect and promptly treat any undesired effects from concomitant administration.

Beta-blockers in most patients Cardene I.V. can be safely used with beta-blockers. However, exercise caution when using the combination in CHF patients. (See WARNINGS.)

Observe caution in patients with severe left ventricular dysfunction due to possible negative inotropic effect.

Cardene I.V. is contraindicated in patients with known hypersensitivity to the drug, and those with advanced aortic stenosis. Caution is advised when administering Cardene I.V. in patients with impaired renal or hepatic function or in combination with a beta-blocker in CHF patients. Cardene I.V. gives no protection against the dangers of abrupt beta-blocker withdrawal. Beta-blocker dosage should be gradually reduced. Most common side effects of Cardene I.V. are hypotension, headache, tachycardia, and nausea/vomiting. Less frequent adverse effects include ECG abnormalities, postural hypotension, and ventricular extrasystoles.

CARDENE® I.V. (nicardipine HCl) 2.5 mg/mL
ARTERIAL SELECTIVE VASODILATOR

ADVERSE EXPERIENCES: 244 patients participated in two multicenter double-blind, placebo-controlled trials of Cardene I.V. Adverse effects were generally not serious and most were expected effects of vasodilators. Some adverse effects required dosage adjustment. Therapy was discontinued in 12% of patients due to hypertensive or bradycardic responses. The following numbers represent percentage of patients with adverse experiences during the double-blind portion of controlled trials with Cardene I.V. I.V. (n=144) versus Placebo (n=100), respectively.

<table>
<thead>
<tr>
<th>Percent of Patients with Adverse Experiences</th>
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<tbody>
<tr>
<td>Hypertension</td>
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<tr>
<td>56%</td>
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<tr>
<td>Tachycardia</td>
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<td>14%</td>
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<tr>
<td>ECG abnormality</td>
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<tr>
<td>14%</td>
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<tr>
<td>Cardiac arrest</td>
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<tr>
<td>7%</td>
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<tr>
<td>Nausea/vomiting</td>
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<tr>
<td>7%</td>
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<tr>
<td>Syncope</td>
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<tr>
<td>7%</td>
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<tr>
<td>Vasoconstriction</td>
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<tr>
<td>7%</td>
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<tr>
<td>Ventricular tachycardia</td>
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<td>7%</td>
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<tr>
<td>Digestive</td>
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<tr>
<td>4%</td>
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<tr>
<td>Injection Site reaction</td>
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<tr>
<td>Metabolic and Nutritional</td>
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<tr>
<td>Hypokalemia</td>
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<tr>
<td>1%</td>
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<td>Nervous</td>
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<td>Diarrhea</td>
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<td>1%</td>
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<tr>
<td>Intraocular hemorrhage</td>
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<tr>
<td>Hypersalivation</td>
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<tr>
<td>Respiratory</td>
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<td>Uremia</td>
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<td>Sweating</td>
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RARE EVENTS: The following events have been reported in clinical trials or in the postmarketing experience with nicardipine: Cardiac: ventricular extrasystoles, atioventricular block, vasodilator reactions, angina, chest pain, bradycardia, cardiac arrest, cardiac failure, pancreatitis, hypotension, syncope, vasodilator reactions. Neurological: peripheral neuropathy, gait disturbance, seizures, paresthesia, visual disturbance, cranial nerve palsies, anaphylactic reactions. Other: chest pain, back pain, rash, diarrhoea, fever, nasal congestion, pharyngitis. Intravenous Administration: Fever, chills, hypotension, tachycardia. Skin: rash, pruritus, urticaria. Eye: visual disturbance, retrobulbar neuritis. Other: cardiovascular: angina, back pain, chest pain, chest tightness. Gastrointestinal: nausea, vomiting, emesis. Nervous: back pain, chest pain, syncope. Respiratory: dyspnea, hyperventilation. Special Senses: conjunctivitis, visual disturbances. Dermatological: rash, urticaria. Genito-urinary: haematuria, renal failure. General: fever, chills, back pain. Overdosage: Symptoms following an overdose of nicardipine have included marked hypotension, bradycardia, chest pain, nausea, vomiting, confusion and slurred speech. Symptoms resolved without sequelae. Based on animal data, fatal outcomes may occur. Hypotension, edema, fluid overload, hypotension, bradycardia (following initial tachycardia) and progressive aorto-ventricular conductive block. Reversible hepatic function abnormalities and spastic facial hepatic reactivity were noted in some animal species receiving very large doses of nicardipine. Treatment with standard measures including intravenous and respiratory function monitoring and frequent blood pressure determinations. Position patient to avoid central hypoventilation. Tachycardia is not indicated for near-term treatment of hypertension. Intravenous clonidine may help reverse the effects of calcium entry

Dosage and Administration: Dosage must be individualized depending on severity of hypertension and patient response. Monitor blood pressure during and after the infusion, avoid rapid or excessive reductions in systolic or diastolic blood pressure.

WARNING: Ampuls Must Be Inoculated Before Infusion. Cardene I.V. is administered into a large vein via a central line with a CONCENTRATION OF 0.1 mg/mL (flush in each 25mg with 240 mL of sodium chloride, 120 mL of dextrose 5% in water, 0.1 mg/mL of sodium bicarbonate). DO NOT INJECT DIRECTLY. See special instructions. Cardene I.V. is NOT COMPATIBLE with Sodium Bicarbonate (5%) Injection, USP; or Lactated Ringer’s Injection, USP.

See package insert for full prescribing information.

This Brief Summary is based on the current direction sheet; G 41192-1 (2001) Philadelphia, PA, 19101.
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