

Joint Best Practices Recommendation for Clinical Health Care Industry Representative Credentialing

The undersigned organizations propose that the following credentialing criteria for the Clinical Health Care Industry Representative (Clinical HCIR) be considered as a national standard to provide the appropriate balance among the goals of patient safety, patient and HCIR privacy, high quality care, immediate access to clinical technology, efficient communication of product information and education (provided by the HCIR) and efficient use of resources by provider institutions and vendors. The credentialing criteria detailed herein do not apply to HCIRs that should not be classified as a Clinical HCIR.

Background

- Presently, no national standard exists for HCIR credentialing.
- Although all stakeholders share the common goals of patient safety and quality care, the current environment subjects HCIRs to widely varying credentialing requirements, resulting in increased costs and administrative burdens which can also impede access to technology, technical support, and educational resources.
- Some existing HCIR credentialing policies impose standards and credentialing requirements that: (i) are duplicative of existing controls, training and screening processes; (ii) are not reasonably related to the duties performed by HCIRs; (iii) compromise the privacy rights of HCIRs and/or are implemented without assurances that sufficient safeguards, per state and/or federal privacy regulations, are in place; (iv) are inconsistent with existing contractual obligations; and/or (v) are inconsistent with FDA adverse event reporting requirements.

As of June 2, 2009, the attached criteria for Clinical HCIR Credentialing represent the joint best practices recommendation of the following organizations:

Advanced Medical Technology Association (AdvaMed)

American Association of Critical-Care Nurses (AACN)

Association of peri-Operative Registered Nurses (AORN)

Healthcare Industry Supply Chain Institute (HISCI)

Health Industry Distributors Association (HIDA)

Health Industry Group Purchasing Association (HIGPA)

Health Industry Representatives Association (HIRA)

Healthcare Manufacturers Management Council (HMMC)

Independent Medical Manufacturer Distributors Association (IMDA)

Industry Partners for Patient Safety (IPPS)

Innovative Healthcare Access Coalition (IHAC)

Medical Device Manufacturers Association (MDMA)

Feedback concerning this proposal is welcome to advance the dialogue concerning HCIR credentialing and enhance best practices and may be submitted to any of the above associations. Alternatively, comments may be emailed to fperner@aorn.org or tchang@advamed.org.

March 9, 2009 – Recommended Clinical HCIR Credentialing Criteria

After a thorough review of numerous current hospital Health Care Industry Representative (HCIR) credentialing requirements, and, in conjunction with the objective of creating realistic, meaningful and comprehensive HCIR credentialing requirements, the following credentialing elements are recommended for the Clinical HCIR (individuals who represent a company or companies in the immediate vicinity of patient care, such as a surgical procedure or cardiac catheterization).

- **Health Vaccinations** - Statement from the HCIR's employer (hereinafter, "Company") or HCIR attesting: performance of TB test (annually); that the Hepatitis B vaccine was offered per OSHA standard; Mumps, Measles, Rubella (MMR) immunity or documentation of 2 doses of the MMR vaccine and evidence of varicella immunity or 2 doses of the adult varicella vaccine. Privacy concerns dictate that these records should be handled and maintained by the Company and/or HCIR.
- **Product and/or General Liability Insurance** - Company policy for HCIR coverage—statement of liability insurance letter - OR - certificate of liability insurance. This includes limits of liability coverage and dates of coverage. No personal liability coverage, liability waiver or personal indemnity should be sought by the hospital/health system.
- **Background Verification** - Letter from Company attesting that background verification was performed for each representative upon hire*. Typically this includes: criminal background check; healthcare sanctions (OIG exclusion, FDA and GSA debarment); Prohibited parties (SDN); sex offender registry; and Drug screen per state regulations* (*various state laws prohibit drug screens in certain instances). Privacy concerns dictate that these records should be handled and maintained by the Company and/or HCIR.
- **Hospital Unit Orientation/Policies and Procedures** – If appropriate, unit orientation with procedural area should be conducted and documented by the hospital (e.g., if appropriate, OR protocol, Procedure Suite protocol, ED protocol, and/or ICU protocol). If there are hospital rules and policies related to appointments, check-in processes and/or other requirements (e.g., knowledge of emergency procedures), these policies and procedures should be communicated and observed.
- **Training Documentation** – Letter from the company verifying that training was successfully completed by the HCIR in the following areas:
 - (1) Device/Procedure-Specific Training;
 - (2) HIPAA / Patient Confidentiality & Privacy training;
 - (3) Conduct Policies and Procedures- - letter from Company verifying training and/or stating that Company requires a HCIR to be trained on policies and procedures consistent with a nationally recognized applicable industry code of ethics such as the AdvaMed Code of Ethics;
 - (4) OSHA/Blood Borne Pathogens;and if appropriate:
 - Sterile/Aseptic Control; and/or
 - Radiation safety.

In our experience, the interests of patients are not advanced by the types of credentialing policies that request HCIR Personal Identification Information: social security, driver's license, passport number, job performance reviews, credit checks and resumes. This is an inefficient and ineffective way to protect patient safety and it unnecessarily invades the privacy of HCIRs. A coordinated credentialing process, which takes place in advance of a HCIR visit and encourages hospitals to institute a policy of reciprocity, saves resources throughout the health care system.