Standardizing Credentialing Requirements for Healthcare Industry Representatives

June 1, 2012

Mayo Clinic Supply Chain Management
A Review for Consideration & Implementation

The document that follows recommends National Healthcare Industry Representative (HCIR) Standards to ensure a healthy and safe environment for patients, employees and guests while in healthcare facilities. Contained within the Standards are primary categories of HCIRs and business partners including articulation of the credentialing requirements for each. To clarify, there are additional business partners, e.g. contract labor, agencies providing post-acute care, etc. that do not fall within the Joint Commission definition of an HCIR and whose access may not be actively managed within the HCOs oversight processes. The following recommendations reflect the April 2012 Joint Commission publication providing clarification on the definition of an HCIR. It is this author's recommendation that HCOs also create processes to address all groups in order to help assure a safe environment. The Level I, II, and III HCIR recommendations in this review are the product of a collaboration of the Indiana Hospital Association, industry representatives, hospital CEOs, Risk Managers, Supply Chain Managers, and AdvaMed. Participation included a wide range of clinical, business and legal scholars from across the industry as well as inclusion of state and national regulatory agencies expectations. Mayo Clinic Supply Chain Management was an ad hoc participant in these discussions. The Standards provide a clear and defined framework for HCIR credentialing that may allow healthcare providers, vendors and service providers to redirect resources to higher value activities. The Standards employ the premise that healthcare organizations can secure welfare and safety through utilization of documentation that articulates professional qualifications and immunization status; and that educational tools are utilized to communicate expectations of business terms/conditions in lieu of requiring HCIRs agreement or acceptance of those terms as a prerequisite for credentialing. Several proposed Standards exceed the Mayo Clinic HCIR previous requirements including fire protection training, proof of liability insurance, and authentication of employment. They do however suggest less cumbersome, alternative identification tag options for Level I HCIRs. Endorsement and implementation of these Standards for Mayo Clinic resulted in minimal changes to existing policy and practice, yet provide substantive simplification and broader coverage of HCIR activities within its facilities. It is recommended that the industry both endorse and implement the standards as articulated in the proposed Standards for Healthcare Industry Representative Requirements. The standards recommended in this document were incorporated into Mayo Clinic Supplier Credentialing policies effective May 1, 2012.

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Mayo Clinic provides care to 1,113,000 patients each year through an integrated clinical practice, education and research model. Mayo consists of 22 acute care facilities, 59,000 employees and 3,800 physicians, scientists and researchers.

Proposal for Healthcare Industry Representative (HCIR) and Business Partner Credentialing Standards

The following requirements were developed through a collaborative initiated by Indiana Hospital Association and AdvaMed.

This document serves as a review by Mayo Clinic of the work performed in association with the Indiana Hospital Association, AdvaMed and various industry participants. The primary objective was to determine the relevance of these standards to Mayo Clinic and the appropriateness of not only adoption but endorsement in an effort to improve environmental safety but reduce costs at the industry level.

Introduction

The Indiana Hospital Association (IHA) and the Indiana life-science industry participants developed a collaborative process that arrived at a mutually agreeable solution to establishing universal vendor standards. The IHA and a task force of representative hospital CEOs, along with a task-force of Indiana-based life-science executives participated in a process that focused on identifying the issues and the impact to each respective organization. An additional meeting was held with the Risk Managers and Materials Managers of member hospitals. The process included surveying member organizations of both the IHA and the life-science industry and then sharing the information in several in-person meetings which focused on open and transparent dialogue. The in-person meetings allowed for the identification of current regulatory requirements along with the ability to outline issues and recommend possible solutions. There were additional meetings that contributed to the creation of the proposed standards, the two most relevant collaboratives were the AdvaMed Pilot Group and a Credentialing Summit held in Chicago in July 2011.

Background

As of the date of this publication, 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 be passed on to Health Care Organizations ("HCOs"). These variations in requirements in-part result from differing organizational cultures, history and interpretation of The Joint Commission ("TJC") guidelines.

Some existing HCIR credentialing policies impose standards and credentialing requirements that: (i) are duplicative of existing controls, training and screening processes; (ii) are not necessary or reasonably related to the duties performed by HCIRs; (iii) compromise the privacy laws and/or are implemented without assurances that sufficient safeguards, per state and/or federal privacy regulations, are in place; (iv) create inconsistencies within established contractual obligations; and/or (v) are inconsistent with FDA adverse event reporting requirements (vi) create non-value added work for HCO staff.

Common Goals

The bases for the requirements are patient health, safety, confidentiality, and conformance to regulatory guidelines and other requirements.

Industry, like HCOs, holds patient safety and quality care as essential goals that are embedded in its rigorous HCIR recruiting, hiring criteria and training programs. Traditionally, the companies employing or contracting with the HCIR, (i) require HCIR completion of the majority of credentialing requirements before the HCIR is hired or permitted to enter the hospital, and/or (ii) require ongoing credentialing elements (e.g., training regarding the technology).

HCOs and vendors seek consistent standards to address all industry representatives including but not limited to supplier and/or vendor representatives that may operate within the healthcare environment.

Relevance

Diverse and onerous requirements can create delays in HCIR access to patient care areas. (i.e., Social Services coordination, DME services), which have the potential to negatively impact patient care.

Normal business process flow can be disrupted due to service personnel being denied access as a result of inconsistencies between the HCO and the HCIR employer's requirements/limitations.

Increased Costs - Credentialing is adding to increased costs and is estimated to add close to $1 Billion per year in health care costs. *Reference 1*

- Much of the cost is attributed to labor, spent in an effort to assure compliance by both the HCO and the HCIR employer due to lack of consistency and standardization.

Increased Liability – Inconsistency in requirements such as Safety Code's and OR process can create confusion leading to errors or omission.

Healthcare Industry Representative Categorizations

For the purpose of this discussion, the author will utilize a broader definition than TJC; an HCIR is defined as an individual seeking access to a HCO that is employed by a third party or is an independent contractor. These individuals may or may not be seeking access to patient care and/or procedural areas within the organization. Examples of HCIRs include, however are not limited to:

- Clinical Education Specialist
- Home Care Providers
- Social Services
- Supplier Sales Reps
- Bio-medical Technician
- Mortician
- Construction workers
- Delivery personnel
- Non-employee Maintenance
- Contract labor
- Supplier Executives
- Hospice staff
- DME staff

The category levels are:

Contracted Labor, Clinical and Collaborative Partners – Described as contract employees/vendors that may provide direct patient care and/or services on behalf of an organization; typically a contractual relationship exists between the HCO and the vendor/service provider.

Patient care personnel can include but are not limited to nursing, therapy, pharmacy, dietary, activities staff, drug and alcohol counselors, and nursing assistant/aids. Clinical partners are accredited by an accrediting or standards organization.

All non-clinical contract labor also falls within the category.

Requirements: In general, credentialing for these individuals, as with all contracted vendors, should be addressed in the HCO's human resource processes and are not within the scope of this document. Credentialing required should be addressed within the terms of the supplier's contract with the HCO. Requirements are very similar if not identical to that of an HCO's employees.

Referrals or Care Continuum HCIRs - Defined as individuals who primarily serve in a clinical support role and most often receive patients or provide equipment for patient use in the next site of care. Their role requires them to often work in patient care areas, and/or provide assistance to or consult with patient care staff.

Examples include: assisted living, hospice, rehabilitation facilities staff, home care representatives, long-term care staff, etc. These individuals are employed by healthcare organizations that would require immunizations and mandatory in-services.

Requirements: In general, these individuals are required to meet individual credentialing requirements within their organizations. This information should be made available to the

HCOs upon request by the employer. At a minimum these HCIRs would be required to wear a name tag identifying their company and personal name. Proof of credentialing and immunizations should be made available to the HCO upon request by the HCIR's employer.

The two mentioned categories were not within the scope of the original recommendations drafted by the Indiana Hospital Association/AdvaMed collaborative. However subsequent to this review, it is recommended that these two categories should be considered and addressed by each HCO in their efforts to assure a safe environment.

Level I - HCIR Guests – These individuals may seek access to an HCO's facility, however do not have access to clinical areas, do not provide technical assistance, do not operate equipment, do not enter patient care areas and do not provide assistance or consult with patient care staff or clinicians.

This may include company representatives that visit the HCO less than three times per year, are accompanied by a credentialed HCIR and are NOT entering a patient care area. Examples may include morticians, delivery vendors, construction labor, non-clinical contract vendor, vendor's management or implementation specialists etc.

Requirements: In general, these individuals are not required to provide any credentials or documentation, however would be required to wear a name tag identifying their company and personal name. If an HCIR guest is a frequent visitor to the HCO and is NOT a contracted HCIR or a referral HCIR they should be elevated to a Level II.

Level II - Tech Support and Sales HCIRs – *(Access to patient care environments excluding sterile or restricted areas)* these individuals serve primarily in a technical support role or product and service sales role. They may provide technical assistance, may occasionally assist with operation of equipment and be in a patient care environment that is not defined as a restricted or sterile procedure area. Their role requires them to often work in patient care areas where other visitors may be present and/or provide assistance to or consult with patient care staff.

This also includes vendor and supplier sales representatives that interact with care providers for the purpose of sales, education and technical support. Examples may include: DME providers, medical device sales and pharmacy reps, representatives calling on departments such as laboratory and radiology, as well as diagnostic representatives.

Requirements: *See Figures 1 thru 3*

Level III – Clinical Support and Sales HCIRs – *(Access to patient care environment including sterile or restricted areas)* These individuals serve primarily in a clinical support or product sales/service role while attending or observing patient procedures. They often provide technical information and serve as a resource for the medical professional, by responding to questions regarding the appropriate operation of their medical equipment; a small percentage of these HCIRs contract with hospitals to calibrate implantable devices/pumps.

These Representatives may not: scrub in on a procedure; "lay hands on" a patient; or operate, control, or touch any equipment being used on a patient, except that, at the request of the attending physician and for the sole purpose of ensuring patient safety, they may troubleshoot, offer technical assistance, calibrate or program equipment, and provide other technical support needed to ensure that their respective equipment functions safely.

Requirements: *See Figures 1 thru 3*

Figure 1

Credentialing Requirements Managed within Supplier Representative Registration System *(excluded activities managed with HCO's Security and HR systems)*				
Administrative Credentials	**Levels**			**Rationale**
	III	**II**	**I**	
HCIR's Company Name Tag Includes the name of the company and the name of the individual, photo ID is preferred but not required.	✓	✓	✓	Any individual entering an HCO for purposes of conducting business should be easily identifiable
HCO's Name Tag Name tag is produced by an automated vendor credentialing system or the HCO.	✓	✓		Required to help HCO assure compliance with all credentialing expectations
Employment Verification A memo or letter on the supplier's letterhead will serve as acceptable documentation	✓	✓		Good practice to reduce fraud and abuse
Proof of Liability Insurance Individuals or the employer or principal shall provide proof of general liability insurance coverage in the form of either a certificate of insurance or a memorandum, or other written documents confirming the existence of insurance coverage through either a third party insurer or a self-insurance program. A general release shall not be a conditional requirement of credentialing	✓	✓		Company level insurance should be provided within the credentialing documentation for general liability coverage. Limits vary by state and company. HCIRs are not authorized to sign a general release of liability.
Proof of Criminal Background Check A letter from the employer attesting that background verification was performed for each representative upon hire and that action would be taken subsequently, if warranted. Privacy concerns dictate that these records should be handled and maintained by the employer. The scope of the background check should be provided as an attachment. Alternately, if the HCIR's employer does not perform the background check that meets the standard, the background check conducted by a recognized third party such as a VCO is acceptable.	✓	✓		For companies that currently perform a background check at least as comprehensive as outlined can attest to verification. *Reference 2* While documentation to protect patient safety is required, all efforts should be made to minimize the opportunity for personal information to be compromised including unnecessary transmission of background information. Background check should be no older than 5 years.

✓ *Indicates requirement must be met*

Figure 2

Credentialing Requirements Managed within Supplier Representative Registration System *(excluded activities managed with HCO's Security and HR systems)*				
Training Credentials	**Levels**			**Rationale**
	III	**II**	**I**	
With regard to the requirements below, a letter from the employer or a recognized third party verifier that training was successfully completed by the HCIR will suffice as proof of training for credentialing purposes.				
Blood Born Pathogen Training	✓	✓		HCIRs in a sterile or restricted area should be required to meet these standards. General patient care areas where other visitors are present or the HCIR is not in close physical proximity to direct patient procedure/care should not be required to have OR protocol training.
Operating Room Protocols (Sterile /Aseptic Controls)	✓			
HIPAA Training	✓	✓		HCIRs in these areas may have incidental exposure to protected health information and should be trained on HIPAA guidelines. This training does not infer that the HCIR is a HIPAA Business Associate.
Product Training / competency Verifications as applicable	✓	✓		All employers should be able to provide documentation as to competency training in the form of a memo or other documents.
Product Compliance & Medical Device Reporting (MDR) requirements training as applicable	✓	✓		Industry standard and a FDA requirement, however may not apply to all HCIRs.
Ethics/Conduct Policies and Procedures A letter from the employer verifying training and/or stating that the employer requires the 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 or the PhRMA Code of Ethics is acceptable for certification.	✓	✓		A manager's contact information or email should be provided by the HCIR. The manager/employer should be afforded the opportunity to remedy an issue. The HCIR's employer should provide an easy mechanism for escalation.
HCO Specific Policies HCO specific policy that are relevant to all HCIRs may be placed in the certification system for HCIRs to indicate they have read the documents, however this should not be construed as acceptance of the document nor does it override any contract terms and conditions between two parties. **A brief summary of key information relevant to the HCIR and their company is recommended rather than complete policies that are intended for HCO employees.**	✓	✓		These requirements should be directed specific to the individual HCIR and not the employer and should allow the employer the opportunity to remedy any situations with their HCIRs. For a credentialing document to impact a contractual agreement it would need to be a specific addendum to the original contract language.

✓ *Indicates requirement must be met*

Figure 3

Immunization Credentials	Levels			Rationale
	III	II	I	
Health Vaccinations – a statement from the HCIR's employer, the HCIR, or recognized third party attesting: performance of TB test and influenza vaccination consistent with CDC guidelines for low risk individuals and as required by organizations. Privacy concerns dictate that these records should be handled and maintained by the HCIR's employer or the individual.				
Tuberculosis Testing Specific to HCO's Policy	✓	✓		Highly communicable in-patient care areas, individual healthcare personnel will assess their level of risk. No other health requirements needed unless required by the HCO of their own employees in the same clinical setting.
Influenza Immunization (seasonal requirement) Specific to HCO's Policy	✓	✓		
MMR	✓			These may be required if a requirement of the hospital employees in the same setting. HCIR employers will recommend these for employees that access sterile or restricted areas and incorporate into their new hire process.
Varicella or Chicken Pox	✓			
Tetanus/TDaP	✓			
Hepatitis B or Declination	✓			

During the review of credentialing requirements a number of recommendations were excluded. *(see Figure 4)* In general, they did not contribute materially to patient safety and confidentiality. In addition due to the number of variations the requirements below may actually increase risk to the organizations.

Figure 4

What Should NOT be Included in General HCIR Credentialing	Rational
Confidentiality Declaration	Contained in the Code of Conduct *Reference 3*
Conflict of Interest Document	Contained in the Code of Conduct
False Claims	Contained in the Code of Conduct. In most cases does not apply to HCIRs unless they are directly involved in reimbursement assistance.
Non-exclusion Documentation (OIG)	Performed via HCIR employer or VCO
Office of Medicaid Inspector General (OMIG)	Specific State requirement only
Business Associate Agreement	BAA only required if the HCIR or the employer meets the definition of a BA. A HCIR is not authorized to sign a BAA agreement on behalf of the employer
Substance Abuse Testing	Only the Substance Abuse and Mental Health Services Administration (SAMHSA) five panel drug screen may be required and only at the time of hire unless prohibited by law. If there is cause for additional drug screening, the HCIR employer will follow their drug screening process for cause.
Electrical Safety Training	Not required for HCIRs as they are not employees of the HCO and there is some liability if the HCIR were to act
Fire Safety Training	General awareness of Fire Safety is recommended however HCIRs should not be required to train on each HCO Fire Safety protocol. There is not consistency from HCO-to-HCO or state-to-state. The HCIR should follow the hospital employee's lead.
National Patient Safety Goals	These are intended for healthcare professionals that are direct caregivers not for HCIRs.
Professional Certification/State Licensure	Only relevant for those practicing medicine and/or it is covered in the Contracted Clinical HCIR definition.
Tissue/Bone Rep FDA Registration/Approval	Is appropriate for very specific HCIRs only
Business or Contract Related Terms	Should be negotiated at the time of business agreement

Enforcement

The HCO, the HCIR and their employer have a responsibility to enforce standards and practices that are in the best interest of the patient. HCIR credentialing is intended to help ensure the HCO is providing a safe environment for all of their patients, guests and employees. To that end, clear and effective communication and escalation processes should be articulated within the HCO and the HCIR's employer to facilitate rapid resolution of any violations or issues that may need to be addressed by any of the parties.

While specific enforcement actions were not included in the original standard reviewed by the author, in the spirit of open communication and collaboration, an escalation process for non-compliance with the HCO's credentialing requirements could adhere to a process as follows:

- **Type 1 Infraction or Notice** – Non-compliance with requirement or violation of a requirement
  Action: Direct communication with the HCIR and written/email notification to their manager
- **Type 2 Infraction or Notice** – Non-compliance or violation has not been resolved, an additional violation has occurred, or patient safety/ confidentiality has been compromised
  Action: Written/email notification to the HCIR and their manager and potential suspension dependent on the nature and seriousness of the violation or non-compliance.
- **Type 3 Infraction or Notice** – Situation has not been rectified, there has been a repeated violation subsequent to a second notice, or patient safety/confidentiality has been severely compromised
  Action: Written/email notice to the HCIR, their manager and the company that the HCIR is suspended from access to the facility until appropriate resolution of the infraction (s) or a meeting between the HCIR's employer and the HCO can come to a resolution of the situation.

Dependent on the severity of non-compliance, an organization may move directly to actions outlined in the Type 3 Infraction/Notice.

When addressing non-compliance issues stakeholders should handle with dignity and respect that an organization affords its own employees during a corrective action process. While HCOs are not legally required to use formal notification and escalation process to permanently suspend an HCIR, it is recommended.

In all instances the vendor should take responsibility for assuring continuity and quality of service and patient care safety in the even an HCIR is unable to perform their duties.

Summary

The primary objective of this document is to articulate what credentialing should be required for Healthcare Industry Representatives entering healthcare facilities for the purpose of conducting business.

Health and safety are the primary focus of these recommendations, which may include education on policies, processes and procedures specific to a healthcare organization. The guidelines explicitly exclude acceptance of business items that would be considered general contract terms and conditions that are a prerequisite for HCIR credentialing.

If the industry can coalesce around the categorization and associated credentialing requirements articulated above, the level of complexity and labor required to assure a disciplined and safe environment for all parties would be significantly reduced.

Reference Information

Reference 1

$800,000,000+ – Cost to the industry considering 60% utilization

Assumptions:

- 60% of HCOs apply credentialing requirements through a third party vendor
- 5,754 hospitals - American Hospital Association statistic
- Estimated 350,000 - HCIRs in Vendor Credentialing Systems nation-wide
- Estimated labor efforts
  - 240 hours per hospital/campus/year to manage a compliant program
  - 40 hours per year – average time HCIR spends on credentialing based on industry surveys
- $751.00 - is the average annual expense per HCIR in fees and medical testing
- Bureau of Labor Statistics job codes
  - 41-4011 fully burdened salary (30%)
  - 13-1023 fully burdened salary (40%)
- Cost estimates do not include staff training, system implementations, or administrative overhead

Reference 2

Background Check should include

- Social Security Number Verification
- Five (5) year state and federal felony and misdemeanor background check
- Substance Abuse and Mental Health Services Administration (SAMHSA) Five Panel
  - Amphetamines Urinalysis Drug Screen upon hire which includes (inclusive of Methamphetamine)
  - Cocaine
  - Cannabinoids such as marijuana and THC
  - Phencyclidine (PCP)
  - Opiates such as Heroin, Codeine, Vicodin, Morphine, Oxycodone, etc.
  - Additional drug testing for cause
- DOJ National Sex Offender Public Registry check
- HHS OIG Exclusion List check
- GSA Excluded Parties List check
- FDA Debarment List check
- Global sanction search (U.S. Office of Foreign Asset Controlled Specially Designated Nationals List (SDN) and World Bank checks

Reference 3

Recommendations for HCIR's Employer Code of Conduct

- Honest and Ethical conduct
  - Conflict of interest, gifts, meals and entertainment per the PhRMA and AdvaMed guidelines
  - Accuracy and integrity of books records and accounts
  - Protection of confidential information
- Full, Fair, Accurate, Timely and Understandable Disclosures
- Compliance with Applicable laws
- Compliance with Company Standards Policies and Procedures
- Protection of Employees and Resources
  - Protection of Company's Assets
  - Protection of Company's Confidential Information
  - Employee Health and Safety
  - Electronic Media Usage

About the Author

As Vice Chair of Supply Chain Operations, Bruce Mairose has oversight for teams responsible for procurement, movement and payments of more than $2 billion in products. The Mayo Supply Chain transacts $3.0 billion in payment, processing over 1 million invoices across 400,000 unique payees. Mayo Clinic Supply Chain Management has been recognized by Gartner/AMR as a Top 5 Life Sciences and Healthcare supply chain operation and has been recognized with numerous national awards for innovation. Mr. Mairose began work as a Registered Respiratory Practitioner, earned his Bachelor in Business Administration in 1990 from the University of North Dakota, and holds a Masters in Healthcare Administration in 1995 from Cardinal Stritch University in Milwaukee, Wisconsin.