# Request for Information

**2016**
**Issued by the Consortium for Universal Healthcare Credentialing (C4UHC):**

**FOREWORD**

**1.1 Objectives of the RFI**

The purpose of this request is to invite vendors to partner with the Consortium for Universal Healthcare Credentialing (C4UHC) to create a standardized, open, and interoperable individual and company credentialing solution. The ultimate goal of this project is to solidify written and data standards for credentialing and create an interoperable process to communicate those standards to meet the needs for both suppliers and health care providers.

This Request for Information (RFI) provides potential vendors with a basic background and understanding of C4UHC and this project. This information enables vendors to respond in a format that promotes a fair comparison and ensures that the proposed solution meets requirements. Information obtained during this process will be used to refine the scope of the project and requirements to create an RFP for a solution or solutions to be piloted in 2017. At that time, a more detailed technical specifications document will be provided. This is an opportunity for vendors to educate the Consortium on technology solutions that are available.

***Please note***: Proposed solutions must allow for all stakeholders to be able to use the C4UHC standards so as to not create proprietary solutions.

**1.2 Confidentiality**

This RFI and all materials submitted by the Consortium are to be treated as strictly confidential. You should not disclose this information to any third party or use this information for any other purpose, other than to present a proposal to C4UHC. C4UHC will require a non-disclosure agreement prior to engaging any vendor in product strategic discussions. In the event that it is determined that a vendor disclosed information, they will automatically be disqualified from the RFI and may be subject to legal action.

**2.1 RFI Process**

Vendors interested in participating in the RFI process will have until November 28, 2016 to complete the questions outlined in section 4.1 regarding its capabilities and project cost estimates. On Monday, November 21st C4UHC will make our full team available to each vendor to answer questions, if desired. After review of the responses, C4UHC may invite a vendor or vendors to present to the full board of directors on Thursday, December 08, 2016.

During this RFI process, questions can be directed to Dede Godstrey at Dede.Godstrey@dbr.com at any time.

### 2.2 Critical Dates

- **Monday, November 14th** - RFI sent to vendors
- **Monday, November 21st** - C4UHC available to answer questions
- **Monday, November 28th** - Answers to RFI due back to C4UHC:
- **Thursday, December 08th** - Up to three vendors may be invited to present to C4UHC.

### 2.3 Method of Response/Requests for Clarification

Please contact Dede Godstrey at C4UHC:

Dede Godstrey
C4UHC Secretariat
Email: Dede.Godstrey@dbr.com
Phone: (202) 230-5607

### 2.4 Right of Rejection

C4UHC reserves the right to accept or reject any or all responses to this RFI.

## Background Information

### 3.1 C4UHC Fact Sheet

**About C4UHC**

- The mission of the Consortium for Universal Healthcare Credentialing (C4UHC) is to streamline the health care industry representative credentialing process in a manner that will protect patient safety and confidentiality, eliminate duplicative efforts and costs, and meet the needs for both suppliers and health care providers. The Consortium looks to accomplish this goal by solidifying written and data standards for credentialing, promoting adoption of such standards, and creating an interoperable process to communicate those standards.
- C4UHC currently has 11 companies as members representing approximately 20,000 employees impacted by vendor credentialing. C4UHC is supported through a Secretariat staffed from the law firm Drinker Biddle & Reath, LLP.
- C4UHC Membership includes:
    - Abbott Laboratories
    - Abiomed, Inc
    - Cardinal Health, Inc.
    - Cook Medical
    - GE Healthcare
    - Johnson & Johnson
    - Philips
    - Siemens Medical Solutions USA, Inc./Siemens Healthcare Diagnostics, Inc.
    - STERIS Corporation
    - Teva Pharmaceuticals USA, Inc.
    - W.L. Gore & Associates, Inc.

### 3.2 Solution Background

In order to comply with healthcare providers' requirements and applicable regulatory requirements, C4UHC must collect and publish to a registry/cloud/database all required attributes for representative and company credentialing as outlined in the Best Practices (Appendix 1) and list of data elements (Appendix 2). Currently there is no standard process used amongst the approximately 80,000 suppliers and 5,000 acute care hospitals to create maintain and publish all the data required. C4UHC seeks to implement a solution to capture, validate, store and publish US representative and company attributes through a secure and accessible platform.

### 3.3 Project Details

The project timeline is as follows:

| Phase | Estimated Timeframe |
|---|---|
| RFI process and solution/vendor selection. Engagement kick-off. | November 14, 2016 – March 31, 2017 |
| **C4UHC Pilot Implementation** | **Q2 2017** |
| Phased scale up of solution to additional suppliers and providers | January 2018 – forward (or earlier) |

### 3.4 Services Requested

This RFI seeks a vendor to supply a solution with any or all of the following functions:

a. Aggregate required documentation, validate if necessary.
b. Receive validated data elements and publish to the solution platform.
c. Convert documentation in to the standard data elements for each requirement (Appendix 2)
d. Publish data elements to the solution platform
e. Restrict access to authenticated/validated users
f. Create a solution platform to house the data that meets the performance and security specifications (Appendix 3 will be provided in RFP in 2017)
g.
h. Host and maintain the solution platform and the contained data.
i. Create reporting functionality for appropriate users
j. Ability to interface with other systems that utilize industry standards
k. Provide interfaces at provider site utilizing new or existing processes that provides mechanism for displaying compliance to the standards (Badge/app/scan)

**Out of Scope:**

- Assistance with the phased migration of data into the solution
- Publishing the data collected in this solution to any other target except platform solution pools (e.g. some C4UHC members may like to use data to populate other tools/systems).

### 3.5 Challenges

The following may be potential challenges to implementing a C4UHC solution:

1. C4UHC has member companies which include lines of business in pharmaceuticals, nutrition, devices and diagnostics. Many of these member companies are in varying stages of integration. They are highly autonomous and typically collaborate where there is a clear benefit. As a result, variations in availability and quality of data/resources available for C4UHC compliance are common.
2. The volume of data may expand.

3. Enterprise implementations are often complex, especially with aggressive deployment schedule such as the Q2 2017 implementation timeline for this pilot project.

**4.1 RFI Questions - Firm Information, Capabilities, Proposal and Project Cost Estimate**

**Please respond to C4UHC with the following**:

1. Which of the following services are you able to provide? Please provide a very brief explanation. If you do not currently have that capability, please provide a date for if/when you will have that capability.
    a. Aggregation of required documentation.
        i. Hard copy documents
        ii. Electronic files
    b. Validation of documentation.
    c. Convert documentation in to the standard data elements for each requirement (Appendix 2)
    d. Publish data elements to the solution platform.
    e. Create a solution platform that meets the performance and security specifications (Appendix 3 will be provided in RFP in 2017)
    f. Ability to interface with other systems that utilize industry standards
    g. Host and maintain the solution platform.
    h. Create reporting functionality for appropriate users of the solution platform.
    i. Provide interfaces at provider site utilizing new or existing processes that provides mechanism for displaying compliance to the standards (Badge/app/scan)

2. Please explain why you are uniquely qualified to develop and deliver this C4UHC solution.

3. Describe your experience and capabilities in implementing similar standardized and interoperable initiatives for large/diverse companies.

4. Identify whether you have worked with any C4UHC Members, if so provide a business owner (name) contact information for other C4UHC member organizations you have worked with over the past two years.

5. Describe your ability to support the proposed project with the adequate number of consultants or other personnel.

6. Provide a general schedule of fees (rates by level) for your services in developing the proposed solution.

7. Architecture/Technical Overview
    - Describe key aspects of your proposed infrastructure architecture. Include a high-level infrastructure architecture diagram that depicts the requirements.
    - Provide your software licensing model (ex: licensing by user/site/enterprise) including software maintenance fees.
    - Does your solution use centralized authentication and authorization?
    - Do you develop and deliver application security updates?
    - What is the estimated throughput or data volume for interfaces used in your solution? Is there an anticipated change in network traffic?
    - Do you have an application strategy/roadmap defined for your proposed solution? (What are your plans for enhancements/changes to your application/service offering over the next year or two?)

8. Is your company classified as small, small disadvantaged, minority, women-owned, veteran, disabled veteran, or a Hub Zone business?

Appendix 1

Best Practices

# Joint Recommendation *for* Healthcare Industry Representative (HCIR) Credentialing Best Practices

**Version 1**
**August 2016**

**Consortium for Universal Healthcare Credentialing**

## Section 1. Title

This document may be cited as the "Joint Recommendation for Healthcare Industry Representative (HCIR) Credentialing Best Practices."

## Section 2. Summary

(1) The primary objective of this document is to articulate credentialing recommendations for healthcare industry representatives entering healthcare facilities for the purpose of conducting business.
(2) Health and safety are the primary focus of these recommendations, which may include education on policies, processes and procedures specific to a healthcare organization (HCO).
(3) 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.

## Section 3. Definitions

***[Commonly used terms and definitions to come (e.g., HCOs]***

## Section 4. Background

(1) As of the date of this publication, no national standard exists for HCIR credentialing.
(2) Although all stakeholders share the common goals of patient safety and quality care, inconsistencies in the current environment result in widely varying credentialing requirements for HCIRs. Variations in requirements in-part result from differing organizational cultures, history and interpretation of The Joint Commission ("TJC") guidelines.
(3) Some existing HCIR credentialing policies impose standards and credentialing requirements that:
    a. Are duplicative of existing controls, training and screening processes;
    b. Are not necessary or reasonably related to the duties performed by HCIRs;
    c. Compromise the privacy laws and/or are implemented without assurances that sufficient safeguards, per state and/or federal privacy regulations, are in place;
    d. Create inconsistencies within established contractual obligations;
    e. Are inconsistent with Food and Drug Administration (FDA) adverse event reporting requirements;
    f. Create non-value add work for the healthcare organization (HCO) staff; and/or
    g. Are not reviewed and assessed by a governing or standards setting body or adhere to best practices.

## Section 5. Common Goals

(1) HCO credentialing requirements are intended to promote patient health, safety, confidentiality, and conformance to regulatory guidelines.
(2) 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:
    a. Require completion of the majority of criteria and training that meet credentialing requirements before the HCIR is hired or permitted to enter the HCO; and/or
    b. Require ongoing criteria and training equivalent to, or that go beyond the scope of, credentialing elements (e.g., training regarding the technology).

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

## Section 6. Relevance

(1) Diverse and onerous requirements can create delays in HCIR access to patient care areas. (e.g., Social Services coordination, durable medical equipment (DME) services), which have the potential to negatively impact patient care.
(2) 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.
(3) 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 a lack of consistency and standardization.
(4) Inconsistency in requirements, such as safety codes and operating room (OR) process, can create confusion leading to errors.

## Section 7. Healthcare Industry Representative Categorizations

(1) In general, HCIR is defined as an individual seeking access to an HCO and who 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:

*Table 1*

| | | |
|---|---|---|
| Clinical education specialist | Mortician | Supplier executive |
| Home care provider | Construction worker | Hospice staff |
| Social Services | Delivery personnel | Durable medical equipment (DME) staff |
| Supplier sales representative | Non-employee maintenance | |
| Bio-medical technician | Contract labor | |

1

(2) Category levels:
   a. **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. Clinical partners are generally accredited by an accreditation or standards organization. All non-clinical contract labor also falls within this category.
      i. **Examples** - Patient care personnel can include, but are not limited to, nursing, therapy, pharmacy, dietary, activities staff, drug and alcohol counselors, and nursing assistant/aids.
      ii. **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 and the proposed

recommendations outlined herein. Any 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.

iii. **Limitations** - This category is not within the scope of this document and the proposed recommendations outlined herein, however it should be considered and addressed by HCOs in their efforts to assure a safe environment.

b. **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.

i. **Examples** – May include, but are not limited to 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.

ii. **Requirements -** In general, these individuals are required to meet specific requirements within their organizations equivalent to credentialing requirements. 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 of the HCIR's employer.

iii. **Limitations -** This category is not within the scope of the recommendations however should be considered and addressed by HCOs in their efforts to assure a safe environment.

c. **Level I - HCIR Guests** – Defined as individuals who 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.

i. **Examples** - Level I 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, but are not limited to, morticians, delivery vendors, construction labor, non-clinical contract vendor, and vendor's management or implementation specialists.

ii. **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.

1. 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.

d. **Level II - Tech Support and Sales HCIRs** – *(Access to patient care environments <u>excluding</u> sterile or restricted areas)* Defined as individuals who 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.

i. **Examples** – Level II may include, but is not limited to, durable medical equipment (DME) providers, medical device sales and pharmacy

representatives, representatives calling on departments such as laboratory and radiology, as well as diagnostic representatives.

ii. **Requirements -** *See Figures 1 thru 3*

e. **Level III – Clinical Support and Sales HCIRs** – *(Access to patient care environment <u>including</u> sterile or restricted areas)* Defined as individuals who 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 the medical equipment.

i. **Examples** - A small percentage of these HCIRs contract with hospitals to calibrate implantable cardiac devices or other implanted pumps and/or devices.

1. 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 the respective equipment functions safely.

ii. **Requirements -** *See Figures 1 thru 3*

## Section 8. Credentialing Requirements Managed within Supplier Representative Registration System *(Outlined in Figure 1 below. Excluded activities managed with HCO's Security and HR systems)*

(1) **Administrative Credentials**

a. HCIR's Company Name Tag

i. Description - Includes the name of the company and the name of the individual, photo ID is required.

ii. Application - Levels I, II, and III

iii. Rationale - Any individual entering an HCO for purposes of conducting business should be easily identifiable.

b. HCO's Name Tag

i. Description - A name tag is produced by an automated vendor credentialing system or the HCO.

ii. Application - Levels II and III

iii. Rationale - The name tag is required to help the HCO assure compliance with all credentialing expectations.

c. Employment Verification

i. Description - A memo or letter on the supplier's letterhead will serve as acceptable documentation of employment.

ii. Application - Levels I, II and III

iii. Rationale – Documentation of employment is a good practice to reduce fraud and abuse.

d. Proof of Liability Insurance

i. Description - 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.

ii. Application - Levels II and III

iii. Rationale - 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. Application of this requirement for independent representatives, for the purposes of this document, is under review.

e. Proof of Criminal Background Check/Drug Screen

i. Description - 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 a background check that meets the recommendation herein *(Reference 2)*, a background check conducted by a recognized third party such as a VCO is acceptable.

ii. Application - Levels II and III

iii. Rationale - For companies that currently perform a background check at least as comprehensive as recommended can attest to verification*. (Reference 2)* While documentation to ensure 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. Application of this requirement for independent representatives, for the purposes of this document, is under review.

(2) **Training Credentials** – With regard to the training requirements outlined here, a letter from the HCIR's employer or a recognized third party verifying that training was successfully completed by the HCIR will suffice as proof of training for credentialing purposes

a. Bloodborne Pathogens Training, per the Occupational Safety and Health Administration (OSHA) Standards

i. Application - Levels II and III

ii. Rationale - 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 and care should not be required to have operating room (OR) protocol training.

b. Operating Room Protocols (Sterile /Aseptic Controls), per the American College of Surgeons (ACS) and Association of Perioperative Registered Nurses (AORN) Guidelines

i. Application - Level III only

ii. Rationale - 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 and care should not be required to have operating room (OR) protocol training.

c. HIPAA Training

i. Application - Levels I, II and III

ii. Rationale - 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.

d. Product Training / Competency Verifications (as applicable), per Manufacturer's Process
    i. Application - Levels II and III
    ii. Rationale - All employers should be able to provide documentation as to competency training in the form of a memo or other documents. *(Reference 4)*
e. Product Complaints & Medical Device Reporting (MDR) Requirements Training (as applicable), per Food and Drug Administration (FDA) Guidelines
    i. Application - Levels II and III
    ii. Rationale - This training is generally an industry standard and an FDA requirement, however it may not apply to all HCIRs.
f. Ethics/Conduct Policies and Procedures
    i. Application - Levels II and III
    ii. Note - 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.
    iii. Rationale - A manager's contact information or email should be provided by the HCIR to the HCO or the VCO managing the requirements. The manager or employer should be afforded the opportunity to remedy an issue should the HCIR violate policies and procedures or engage in non-compliant conduct. The HCIR's employer should provide an escalation process for corrective action.
g. HCO-specific Policies
    i. Application - Levels II and III
    ii. Note - HCO-specific policies that are relevant to all HCIRs may be placed in the certification system (of either the HCO or VCO) 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 the 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.
    iii. Rationale - Policies and requirements unique to the HCO should be provided directly to the individual HCIR and not the employer. HCO-specific policies should allow the employer the opportunity to remedy any situations, such as a violation or non-compliant conduct, with their HCIRs. A credentialing document may only impact a contractual agreement between the HCO and employer if it is a specific addendum to the original contract.

(3) **Immunization Credentials** - In general, with regard to 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 Centers for Disease Control and Prevention (CDC) guidelines for low risk individuals and as required by HCOs. Privacy concerns dictate that these records should be handled and maintained by the HCIR's employer or the individual.
    a. Tuberculosis Testing, per CDC Guidelines (Specific to HCO's Policy)
        i. Application - Levels II and III
        ii. Rationale - May be necessary for 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.
    b. Influenza Immunization, Seasonal Requirement (Specific to HCO's Policy)
        i. Application - Levels II and III

ii. Rationale - May be necessary for 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.

c. MMR – Measles, Mumps, and Rubella
   i. Application - Level III only
   ii. Rationale – This may be required if it is also a requirement of the HCO's employees in the same setting. HCIR employers will recommend these for employees that access sterile or restricted areas and are recommended to incorporate into new hire processes.

d. Varicella or Chicken Pox
   i. Application - Level III only
   ii. Rationale - This may be required if it is also a requirement of the HCO's employees in the same setting. HCIR employers will recommend these for employees that access sterile or restricted areas and are recommended to incorporate into new hire processes.

e. TDaP – Tetanus, Diphtheria, and Pertussis
   i. Application -Level III only
   ii. Rationale - This may be required if it is also a requirement of the HCO's employees in the same setting. HCIR employers will recommend these for employees that access sterile or restricted areas and are recommended to incorporate into new hire processes.

f. Hepatitis B or Declination
   i. Application - Level III only
   ii. Rationale - This may be required if it is also a requirement of the HCO's employees in the same setting. HCIR employers will recommend these for employees that access sterile or restricted areas and are recommended to incorporate into new hire processes.

*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<br>Includes the name of the company and the name of the individual, photo ID is required. | ✓ | ✓ | ✓ | Any individual entering an HCO for purposes of conducting business should be easily identifiable |
| HCO's Name Tag<br>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<br>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<br>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. |

| Credentialing Requirements Managed within Supplier Representative Registration System<br>*(excluded activities managed with HCO's Security and HR systems)* | | | | |
|---|---|---|---|---|
| **Administrative Credentials** | **Levels** | | | **Rationale** |
| | **III** | **II** | **I** | |
| Proof of Criminal Background Check<br>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 best practice, 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. |

*Figure 2*

| Credentialing Requirements Managed within Supplier Representative Registration System<br>*(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.* | | | | |
| Bloodborne Pathogens Training, per OSHA standards | ✓ | ✓ | | 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), per ACS and AORN guidelines | ✓ | | | |
| 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), per Manufacturer's Process | ✓ | ✓ | | All employers should be able to provide documentation as to competency training in the form of a memo or other documents. (see reference 4) |
| Product Complaints & Medical Device Reporting (MDR) Requirements Training (as applicable), per FDA Guidelines | ✓ | ✓ | | Industry standard and a FDA requirement, however may not apply to all HCIRs. |
| Ethics/Conduct Policies and Procedures<br>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<br>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 | ✓ | ✓ | | 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 |

| Credentialing Requirements Managed within Supplier Representative Registration System<br>*(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.* | | | | |
| 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.*** | | | | addendum to the original contract language. *as an example. The HCO may have a policy related to patient consent for HCIR presence in the OR and documentation in the medical record. The HCIR would be expected to follow the HCO policy |

*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.<br>Privacy concerns dictate that these records should be handled and maintained by the HCIR's employer or the individual. | | | | |
| Tuberculosis Testing per CDC guidelines<br>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)<br>Specific to HCO's Policy | ✓ | ✓ | | |
| MMR – Measles, Mumps, and Rubella | ✓ | | | These may be required if there is a requirement of the HCO's 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 | ✓ | | | |
| TDaP – Tetanus, Diphtheria, Pertussis | ✓ | | | |
| Hepatitis B or Declination | ✓ | | | |

## Section 9. Limitations and Exclusions

(1) As a result of the thorough review of HCIR credentialing requirements conducted in preparation of this document, it is the recommendation herein that some criteria are limited or excluded from HCIR credentialing processes. *(Figure 4)*

(2) In general, these requirements do not contribute materially to patient safety and confidentiality. In addition, current inconsistencies and variations amongst the following requirements may actually increase risk to HCOs, HCIRs, and/or HCIR employers. The following recommendations explicitly exclude acceptance of business items that would be considered general contract terms and conditions that are a prerequisite for HCIR credentialing.

a. Confidentiality Declaration - Contained in the Code of Conduct (*Reference 3)*
b. Conflict of Interest Document - Contained in the Code of Conduct.
c. False Claims - Contained in the Code of Conduct and in most cases does not apply to HCIRs unless they are directly involved in reimbursement assistance.
d. Non-exclusion Documentation (OIG) - Performed via the HCIR employer or VCO.
e. Office of Medicaid Inspector General (OMIG) - A state-specific requirement only.
f. Business Associate Agreement (BAA) - BAA should only be required if the HCIR or the employer meets the definition of a BA. An HCIR is not authorized to sign a BAA agreement on behalf of the employer.
g. Substance Abuse Testing - Only the Substance Abuse and Mental Health Services Administration ("SAMHSA") five panel drug screen should 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.

h. Electrical Safety Training – Should not be required for HCIRs as they are not employees of the HCO and there is some liability if the HCIR were to act.
i. Fire Safety Training - General awareness of fire safety is recommended, however HCIRs should not be required to train on each HCO's fire safety protocol. There is not consistency from HCO-to-HCO or state-to-state and confusion could result. In general the HCIR should follow the lead of the HCO.
j. National Patient Safety Goals - These are intended for healthcare professionals who are direct caregivers not for HCIRs.
k. Professional Certification/State Licensure - Only relevant for those practicing medicine and/or it is covered in the Contracted Clinical HCIR definition.
l. Tissue/Bone Rep FDA Registration/Approval - Is appropriate for very specific HCIRs only.
m. Business or Contract Related Terms - Should be negotiated at the time of business agreement.

*Figure 4*

| **Requirements to be Limited or NOT Included in General HCIR Credentialing** | **Rationale** |
|---|---|
| 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 |
| Drug Screen (Substance Abuse Testing*)<br><br>*The coalition is currently discussing the drug screening requirements as many HCOs are requiring different panels | Only the 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 and confusion could result. In general the HCIR should follow the lead of the HCO. |
| 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 |

## Section 10. Enforcement

(1) The HCO, the HCIR and their employer have a responsibility to enforce requirements 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 corrective 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.

(2) A corrective escalation process for non-compliance with the HCO's credentialing requirements could adhere to a process as follows:

   a. **Type 1 Infraction** - Non-compliance with requirement or violation of a requirement.
      i. **Action:** Direct communication with the HCIR and written or email notification to their manager.
   b. **Type 2 Infraction or Notice** - Non-compliance or violation has not been resolved, an additional violation has occurred; or patient safety and/or confidentiality have been compromised.
      i. **Action:** Written or email notification to the HCIR and their manager, as well as potential suspension dependent on the nature and seriousness of the violation or non-compliance.
   c. **Type 3 Infraction or Notice** - Situation has not been rectified, there has been a repeated violation subsequent to a second notice; or patient safety and/or confidentiality have been severely compromised.
      i. **Action:** Written or email notice to the HCIR, their manager and the employer that the HCIR is suspended from access to the facility until appropriate resolution of the infraction(s) or the HCIR's employer and the HCO can come to a resolution of the situation.
   d. Dependent on the severity of non-compliance, an organization may move directly to actions outlined in the Type 3 Infraction/Notice.

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

(4) In all instances the HCIR employer should take responsibility for assuring continuity and quality of service and patient care safety in the event an HCIR is unable to perform their duties.

## Reference Information – 2015 updates

*Reference 1*

**$1.5 Billion – Cost to the industry considering 60% utilization**

Assumptions:

(1) 90+% of HCOs apply credentialing requirements
(2) 5,754 hospitals, American Hospital Association statistic
(3) Estimated 500,000 - HCIRs in Vendor Credentialing Systems nation-wide
(4) 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

(5) $- is the average annual expense per HCIR in fees and medical testing
(6) Bureau of Labor Statistics job codes
   a. 41-4011 fully burdened salary
   b. 13-1023 fully burdened salary
(7) Cost estimates do not include staff training, system implementations, or administrative overhead

*Reference 2*

**Background Check/Drug Screen should include**

- Social Security Number Trace/Validation
- Five (5) year state and federal felony and misdemeanor background check
- 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*

- Drug Screen/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

**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

***Reference 3 Recommendations for medical requirements***

| | |
|---|---|
| MMR – Measles, Mumps, and Rubella | Titer showing immunity or 2-shot series |
| Varicella or Chicken Pox | Titer showing immunity or 2-shot series |
| TDaP – Tetanus, Diphtheria, and Pertussis | TDaP - Combo of T, D, and P |
| Hepatitis B or Declination | Titer showing immunity or 3-shot series |

***[Reference 5 Recommendations for training and competency assessments- to come]***

This documentation should include the most recent completion date or evaluation date as training and competency assessments are ongoing.

Appendix 2

Data Elements

| | | Data Definition | Sample Data | Data Format |
|---|---|---|---|---|
| Individual Requirements | Administrative Requirements | **Employee Unique ID** | | **Text** |
| | | **Report Generated Date** | Date | Date |
| | | **PreferredName** | | Text |
| | | **FirstName** | | Text |
| | | **LastName** | | Text |
| | | **MiddleName** | | Text |
| | | **Suffix** | | Text |
| | | **Employer Company** | | |
| | | **Employee Photo** | | BLOb |
| | | **Job Title** | | Text |
| | | **Function Performed/Job Description** | | Text |
| | | **Email** | | Text |
| | | **Office Phone** | | Text |
| | | **Manager First Name** | | Text |
| | | **Manager Last Name** | | |
| | | **Division Name** | | Text |
| | | **Manager/Division Email** | | Text |
| | | **Employer GLN** | | |
| | | **Product Type** | | Text |
| | | **Proficiency Date** | | Date |
| | | **Request Created Date** | Date | Date |
| | | **Credentialing no longer required** | Date | Date |
| | | **Request Modified Date** | Date | Date |
| | | **Status of the Request** | | |
| | Training Verification | **Aseptic Training** | 8/15/2011 | *1/0 (1 if date entered, 0 if not)* |
| | | **Blood Borne Pathogen Training** | 12/22/2011 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | **HIPAA Training** | 7/15/2015 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | **OR Protocol** | 7/1/2016 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | **National Patient Safety Goals** | 7/1/2016 | *1/0 (1 if date entered, 0 if not)* |
| | | **Electrical Safety** | 8/9/2011 | *1/0 (1 if date entered, 0 if not)* |
| | | **Radiation Safety** | 7/1/2016 | *1/0 (1 if date entered, 0 if not)* |
| | | **Fire Safety** | 8/2/2013 | *1/0 (1 if date entered, 0 if not)* |
| | | **Employment Background Check** | 4/2/1990 | *1/0 (1 if date entered, 0 if not)* |
| | | **Commitment to Confidentiality** | 7/1/2016 | *1/0 (1 if date entered, 0 if not)* |
| | | **Adverse events reporting** | 2/3/2014 | *1/0 (1 if date entered, 0 if not)* |
| | | **DRA Requirements Certification** | NO | *1/0 (1 if YES, 0 if NO)* |
| | | **Educational Material Restrictions** | YES | *1/0 (1 if YES, 0 if NO)* |
| | | **Gift Restrictions** | YES | *1/0 (1 if YES, 0 if NO)* |
| | Hosp Req | **Best Practice Code of Conduct** | NO | *1/0 (1 if YES, 0 if NO)* |
| | | **Best Practice Orientation** | YES | *1/0 (1 if YES, 0 if NO)* |
| | Medical Requirement | **TB (Blood test or PPD Skin test Annuall** | 5/6/2009 | *1/0 (1 if date entered, 0 if not)* |
| | | **Influenza Seasonal Vaccination (Annual** | 5/6/2013 | *1/0 (1 if date entered, 0 if not)* |
| | | **Hep A** | 9/2/2013 | *1/0 (1 if date entered, 0 if not)* |
| | | **TDaP/Tetanus, Diphtheria and Pertussis** | 7/5/2015 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | **Varicella/Chicken Pox Titer blood test o** | 8/9/2012 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | **Hepatitis B Titer blood test or 3-shot va** | YES | *1/0 (1 if YES, 0 if NO)* |
| | | **10 Panel drug Screen** | NO | *1/0 (1 if YES, 0 if NO)* |
| | Background | **Employment Background Check** | 4/2/1990 | *1/0 (1 if date entered, 0 if not)* |
| | | **Refresh Background Check**<br>**Criminal Databases**<br>**Sanctions and Exclusions DB**<br>**Sex Offenders** | 8/27/1927 | *1/0 (1 if entered & valid, 0 if entered and expired)* |
| | | | | |
| Company Data | | **Parent GLN** | | Numeric |
| | | **Child GLN 1** | | |
| | | **Child GLN 2** | | |
| | | **Child GLN 3** | | |
| | | **Child GLN 4** | | |
| | | **Child GLN 5** | | |
| | | **Child GLN 6** | | |
| | | **Child GLN 7** | | |
| | | **Child GLN 8** | | |
| | | **Child GLN 9** | | |
| | | **GRIN (GSRN)** | Rep ID number | Text |
| | | | | |
| | | **Physical Business Address** | | Text |
| | | **Federal Reporting Tax Identification Number (TIN)** | | Text |
| | | **Contact** | | Text |
| | | **Are you a Publically Traded Company?** | Yes | Y/N |
| | | **Stock Ticker Symbol** | | Text |
| | | **Company Name** | | Text |
| | | **DBA/Disregarded Entity Name** | | Text |
| | | **Federal Tax Classification** | | Text |
| | | **State of Incorporation** | | Text |
| | | **Type of Business (Drop Down)** | | Text |
| | | **Business Category (Drop Down)** | | Text |
| | | **Business Sub Category (Drop Down)** | | Text |
| | | **W9** | | Document |
| | | **Year Established** | | Text |
| | | **Company Web Address** | | Text |
| | | **Small, minority, woman, disabled, veteran owned?** | No | Y/N |
| | | **Is your business Non-Profit?** | No | Y/N |
| | | **Remit to address** | | Text |
| | | **I-9** | YES | *1/0 (1 if YES, 0 if NO)* |
| | | **MOI** | 7/5/2015 | *1/0 (1 if entered & valid, 0 if entered and expired)* |