



White Paper on Vendor Credentialing

A Collaborative Industry Study

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Executive Summary

Vendor Credentialing (VC) is the process of establishing the qualifications of vendors and assessing their background and legitimacy. Healthcare providers may utilize VC as a primary criterion in Vendor Access Management - this means managing the access of vendors to the hospital in general, and / or to certain clinical areas.

The practice of VC in healthcare is well established in the United States but is only recently becoming an established practice in Canada. As a result of the challenges and inefficiencies being experienced in the US, the Healthcare Supply Chain Network (HSCN), representing the Canadian industry, would like to influence the development of Vendor Credentialing in Canada and steer its growth towards value while minimizing cost to the industry.

Through a process of literature review and interviews with healthcare supply chain professionals, HSCN has developed industry statements on 7 important elements of Vendor Credentialing. Those statements are as follows:

1. **Financial Impact of Vendor Credentialing** – Providers and suppliers must work together to limit the financial and bureaucratic impact of introducing more robust and / or third party vendor credentialing systems into the Canadian healthcare landscape. Specifically:
 - a) Providers and suppliers should work to create nationally acceptable credentialing standards that could be used either internally or through third party Vendor Credentialing Companies (VCCs);
 - b) Providers should accept a single credentialing approach, meaning that each VCC would be recognized by all as a valid credentialing body, allowing access to any hospital or clinic for those completing the credentialing. If a supplier's sales representatives are credentialed by a different third party VCC than the VCC the provider has contracted with, then this credentialing is seen to be acceptable and no new credentialing is required;
 - c) In order to minimize the financial burden on the healthcare system of vendor credentialing, the cost of the annual renewal fee for a supplier sales rep should more closely reflect the true cost of renewal.
2. **Levels of Vendor Credentialing** - Two levels of vendor credentialing should be implemented, with the differentiation being those supplier representatives entering clinical areas, such as the OR, and those entering other patient care areas. Supplier representatives only accessing those areas where any member of the general public has access, including, but not limited to, common areas, the corporate office or loading dock, should not be required to be individually credentialed.
3. **Immunizations** - Recognizing that it is an individual's right to receive or decline immunizations, the credentialing record of each supplier sales representative should

indicate all current immunizations that this representative has received. Individual hospitals would have access to this record and may restrict access based on a bona fide occupational requirement given clinical circumstances and risks of having non-immunized individuals in specific areas of the healthcare facility. *

4. **Background Checks** - Including criminal record checks (CRC) as part of vendor credentialing should be done with caution as it may impinge provincial or federal rights and laws. If a healthcare provider deems that a CRC is a bona fide occupational requirement in order for a vendor representative to provide services in a specific area of a healthcare facility, the initial requirement and subsequent renewal of the CRC should only be done as required to support the original rationale for a CRC. Again, if a CRC is deemed to be required, the arrangements to provide a CRC can be made directly with the vendor representative, or the representative's employer can attest to the check on behalf of their employee and provide this information either directly to the provider or through the VCC. *
5. **Hospital Policy Reviews** - Credentialing requirements for policy reviews should focus only on patient privacy and confidentiality and a Vendor Code of Conduct.
6. **Education Courses** - HCSN believes suppliers are providing sufficient education to their sales representatives and that should any specific training be required as part of a credentialing process, in-house training provided by suppliers is sufficient.
7. **Secure Canadian Data Storage** - All data collected by third party Vendor Credentialing Companies must be stored in Canada by a Canadian based data storage company. Further, all VCCs should follow the Canadian Standards Association's *Model Code for the Protection of Personal Information*, ensure they are in compliance with PIPEDA (Personal Information Protection and Electronic Documents Act (Canada) and comply with all applicable provincial and federal privacy laws.

* HSCN encourages readers to seek their own legal advice when considering implementing policies relative to Immunizations or Background Checks.

Through this paper, HSCN has undertaken a review of the concerns of both healthcare providers and suppliers and reached an agreed upon, collaborative statement on critical elements of Vendor Credentialing. It is the intent of this paper to guide and influence how Vendor Credentialing takes form in Canada and to encourage a national approach that ensures added value and is conscious of added costs. In the months ahead, HSCN will continue to facilitate an efficient, sustainable approach to Vendor Credentialing in the Canadian Healthcare industry.

Introduction

This paper is a collaborative effort of member healthcare providers and suppliers of the Healthcare Supply Chain Network, encompassing joint industry statements on 7 important elements of Vendor Credentialing. Information gathered for these statements comes from research of existing literature as well as interviews conducted in February 2012, with supplier and provider members of HSCN.

At the time of writing, very little Canadian based information was available. As such, most of the data and background information provided is American based.

Research of the US experience as well as answers to the questions posed to the HSCN members interviewed indicate that the concepts of Vendor Access Management and the act of Vendor Credentialing are blurred. In fact, vendor credentialing is being confused and / or used as a way to manage vendor access, so definitions are useful here:

Vendor Access Management (VAM) means managing the access of vendors to the hospital in general, and / or to certain clinical areas. The need to implement more controlled and formal access policies can be due not only to quality of care and patient safety issues, but also the potential financial impact of unrestricted contact between clinicians and vendors. In this process vendors may be required to check in with Materials Management, have a confirmed appointment, wear a specific badge at all times, use certain routes only to certain areas of the hospital, etc. Vendor Access Management only involves vendor credentialing as far as the vendor's documentation and credentials may be checked prior to being given access to all or certain areas of a facility.¹

Vendor Credentialing (VC) is the process of establishing the qualifications of vendors and assessing their background and legitimacy. Many health care facilities and provider networks conduct their own credentialing, either in-house or through a contracted service, sometimes with review by a medical staff or credentialing committee. The process is generally an objective evaluation of a vendor representative's credentials for providing a particular service, their training or experience, competence, and compliance with health and safety requirements. Vendor Credentialing often also includes documentation of immunizations, drug-of-abuse testing and criminal background checks which may be as stringent as what is imposed upon full-time hospital employees. These credentials determine the level of access as well as whether and how vendors are present during direct patient care, such as in the Operating Room. Credentialing of vendors or other organizations may begin prior to the purchasing process and be repeated regularly.²

¹ Implementing Vendor Access Policies and Procedures, by Eileen McGinnity;
http://findarticles.com/p/articles/mi_m0BPC/is_11_29/ai_n15860302/

² <http://en.wikipedia.org/wiki/Credentialing>

The concept of Vendor Access Management, while an important one, is not examined in great detail in this paper. It is interesting to note, however, that both providers and suppliers who were interviewed brought up this concept. One SSO provider commented: “The issue (of credentialing) is in large part access management – when we were in the hospital all vendors had to check with materials management. Today we are not in the hospital, so vendors have open access.” A supplier stated: “I believe that we are confusing credentialing with vendor access. I don’t have a problem to wear a badge and abide by the hospital’s policies, but I do have a problem with providing information about my employees to a third party data collection agency and am deeply concerned about the amount of time and money this will cost.”

It is also important to differentiate the concept of VC wherein each individual representative of a supplier must be credentialed versus the due diligence done during contract negotiations between providers and suppliers of the credentials of the supplier company as a whole. This latter form of credentialing is not discussed here.

Historical Background

Vendor credentialing can occur within the hospital or by a third party company. Until recently there were no vendor credentialing companies (VCC) operating in Canada. In 2010, VCCs established in the US started offering services in Canada. There were, at one point, two VCCs operating in Canada, but currently only one Canadian service provider is in operation and actively marketing and signing up healthcare providers.^{3, 4, 5}

As noted in the introduction, information on the internet directly related to the issues surrounding vendor credentialing in Canada was very limited. However there is significant information in regards to the US where due to “increasing pressure to comply with [several federal agency] guidelines and regulations ... many [hospitals have] looked to third-party Credential Verification Organizations to alleviate some of their administrative burden.”⁶ This began a few years ago.

Once this happened, several third party VCCs entered the health care industry and since that time, a number of concerns have arisen. These include cost and added bureaucracy related to the credentialing process in general:

³ <https://www.status-blue.ca/Hospital-Vendor-Compliance-News-and-Events-Status-Blue.aspx>

⁴ <http://www.prnewswire.com/news-releases/intellicentrics-inc-acquires-hospital-vendor-credentialing-solution-status-blue-llc-119924074.html>: IntelliCentrics, Inc., owner and operator of both Reptrax and VendorClear, announced today the acquisition of Status Blue, LLC, a leading vendor compliance solution.

⁵ <http://www.newswire.ca/en/story/917555/joseph-brant-memorial-hospital-awards-vendor-credentialing-and-compliance-contract-to-vendor-credentialing-services-canada>

⁶ http://www.imda.org/documents/Statement_of_Issue.pdf

*"... these requirements represent a patchwork of repetitive formalities and intrusive questionnaires, topped off by burdensome fees."*⁷

and to the number of VCCs in the industry:

*"... these Credential Verification Organizations are populating the healthcare landscape at an alarming rate, with disparate and inconsistent policies for Health Care Industry Representatives and hospital access procedures."*⁸

The cost can be substantial. A group of US Manufacturers calculated:

Let's say that there are 10,000 Medical Device Reps in the United States (to be conservative, the number is probably closer to 100,000). If each rep had to pay \$100 (again, conservative) to go into each hospital, and each rep had 20 hospitals as part of their territory. Here is how the math would break-down.....

10,000 Reps X 20 Hospitals @ \$100 each

Total Cost would be..... \$20,000,000.00

*This is merely an ENTRY into the hospital. This is NO guarantee of business.*⁹

For all these reasons, several large and influential US organizations have proposed the need for national standards, or an ability to be credentialed only by one VCC rather than being forced to be credentialed by several, due to the fact that different providers are working with different VCCs.

In August 2008, the Independent Medical Distributors Association (IMDA), after conferring with its own members and other interested organizations including AdvaMed (the Advanced Medical Technology Association), MDMA (the Medical Device Manufacturer's Association), HMMC (the Healthcare Manufacturer's Management Council), HIRA (the Health Industry Representatives Association) and HIDA (the Health Industry Distributors Association) issued three documents on the topic:

- **["Statement of issue"](#)**. In the format of a "To Whom It May Concern" letter, President Shawn Walker laid out the key issues of vendor credentialing, including the dire economic consequences vendor credentialing can have on suppliers if certain measures are not taken.
- **[Suggested attributes of vendor credential organizations](#)** also called "third-party credentialing organizations." In this document, IMDA lists the 11 most important

⁷ <http://www.hisci-net.org/Portals/0/Press%20Room/CurtisRooney-JHC-MarApr08.pdf>; written by *Curtis Rooney, at the time the President of the Healthcare Industry Supply Chain Institute*

⁸ http://www.imda.org/documents/Statement_of_Issue.pdf

⁹ <http://www.truthaboutvendorcredentialing.com/financials-of-vcs.html>

attributes of a vendor credential organization. It is hoped that hospitals, GPOs and other entities will give these attributes careful consideration before contracting with or endorsing a third-party credentialing firm.

- [Recommendations regarding vendor credentialing requirements](#). In order to bring some uniformity to the vendor credentialing process, IMDA recommends that healthcare providers focus on just four [SIC] credentialing requirements for clinical sales reps (that is, those who require regular access to patient care areas and/or provide assistance to or consult with patient care staff while in the immediate vicinity of patients).¹⁰

In March 2009, IMDA and a number of other supplier and provider organizations developed and sent to the Joint Commission the **Joint Best Practices Recommendation for Clinical HCIR [Health Care Industry Reps] Credentialing**. The recommended standards address credentialing criteria for clinical sales reps, that is, those who find themselves in the immediate vicinity of patient care, such as the OR or cath lab. This was updated in June 2009, [Updated Joint Best Practices Recommendation - HCIR Credentialing](#)¹¹, and can be found in Appendix One.

There was hope that the Joint Commission would develop national credentialing standards, but this has not occurred. According to the Joint Commission, this is due to the fact that there are no accepted national standards on competence for the tasks performed by these health care industry/vendor representatives. Currently, there is also no specific licensure, certification, or registration for health care industry/vendor representatives who are involved in care, treatment, and services provided by professional staff in accredited health care organizations.¹²

¹⁰ <http://www.imda.org/vendorcredential.htm>

¹¹ <http://www.imda.org/vendorcredential.htm>

¹² There are several Joint Commission standards that are relevant to any individual that enters a health care organization who directly impacts the quality and safety of patient care. In order to protect patient safety, accredited health care organizations need to be aware of who is entering their organization and what these individuals are doing in their organization (EC.02.01.01). Accredited health care organizations need to take steps to ensure patient rights are respected (RI.01.01.01), and that infection control precautions (IC.02.01.01) and other organization-specific policies and procedures are followed. Additionally, The Joint Commission has several standards related to anyone who can impact the quality and safety of patient care; many of which are located in the Leadership chapter. Some of the requirements located in the Leadership chapter are LD.03.06.01 EP4 (competence of anyone who works in the organization), LD.04.01.05 EPs 1 and 3 (leaders oversee operations, and administrative and clinical direction responsibilities are defined), and LD.04.04.05 EPs 1, 3, and 4 (the development and implementation of a patient safety program).

http://www.jointcommission.org/mobile/standards_information/icfaqdetails.aspx?StandardsFAQId=92&StandardsFAQChapterId=66

Financial Impact of Vendor Credentialing

Statement:

Providers and suppliers must work together to limit the financial and bureaucratic impact of introducing more robust and / or third party vendor credentialing systems into the Canadian healthcare landscape. Specifically:

1. Providers and suppliers should work to create nationally acceptable credentialing standards that could be used either internally or through third party Vendor Credentialing Companies (VCCs);
2. Providers should accept a single credentialing approach, meaning that each VCC would be recognized by all as a valid credentialing body, allowing access to any hospital or clinic for those completing the credentialing. If a supplier's sales representatives are credentialed by a different third party VCC than the VCC the provider has contracted with, then this credentialing is seen to be acceptable and no new credentialing is required;
3. In order to minimize the financial burden on the healthcare system of vendor credentialing, the cost of the annual renewal fee for a supplier sales rep should more closely reflect the true cost of renewal.

Supporting Information

National Standards

One need only look across the border to see the problems and issues a lack of national standards has had on the industry. IMDA has concluded that a price per hospital per vendor business model would cost the US healthcare industry over \$1.7 billion annually.¹³ The numerous organizations calling for national standards have stated "Without a move towards standards, managing the multiple requirements from various hospitals could cause delays to providing technology or technical support, as well as add to the cost of care without offering anything in exchange."¹⁴

One provider interviewed felt they have the purchasing power to negate a possible cost increase, while another felt that the additional cost was worth the reduction in liability exposure, although they did comment that at least for some of the smaller companies there may be issues in terms of cost. The third provider believed the cost would be passed on and that "if hospitals were asked to pay for this service upfront, many would say that they did not require it." All three suppliers interviewed were concerned about the cost impact on their companies and two felt that these increased costs would be passed, either directly or indirectly, through to hospitals. It did not appear that any of the interviewees really knew

¹³ http://www.imda.org/documents/CVO_Attributes.pdf

¹⁴ <http://www.medicaldevicestoday.com/2009/03/advamed-leads-multigroup-endorsement-of-vendor-credentialing-standards-.html>

how much this could cost the industry. Based on the American example above, at 10% of the population, this could possible amount to 170 *million* dollars annually.

Many of those interviewed commented that we need national standards. One provider stated “this should become part of the accreditation process or we should have a national non-profit organization run this process.” There is a strong feeling in the US that standardization is possible. Said one provider, “Yes, hospitals will always have unique requirements. But perhaps as much as 80 percent of the credentialing process could be standardized industry wide.”¹⁵

Late last year MEDEC, the national organization representing the medical technology industry in Canada, came out with a position statement on credentialing. While recognizing the need for credentialing they called for a common standard noting:

*Credentialing policies impose standards and credentialing requirements, including those that: (i) are duplicative of existing controls, training and screening processes; (ii) are not reasonably related to the duties performed by MTIRs; (iii) compromise the privacy rights of MTIRs and/or (iv) are inconsistent with existing contractual obligations; and/or (v) increase the costs of providing medical technology products and services.*¹⁶

As Canada is at the beginning of the movement towards third party VCCs, now is the opportune time to get national standards on the table. There has been significant work done in the United States to develop standards that could be adapted for the Canadian marketplace. AdvaMed, the world's largest trade association representing medical device manufacturers, has proposed a set of national standards to minimize redundancy, reduce information costs, and avoid unnecessary administrative burdens while still protecting patients' interests.¹⁷ IMDA has also come out with suggested credentials, the American College of Surgeons has developed a *Statement on Health Care Industry Representatives in the Operating Room*,¹⁸ and the Association of Peri-Operative Registered Nurses (AORN) has written *The Role of the Health Care Industry Representative in the Perioperative/Invasive Procedure Setting*.¹⁹

Additionally, organizations such as MEDEC, and international suppliers who have been exposed to the problems in the US could be brought to the table. All interviewees felt that it would be possible to standardize at least some parts of the credentialing process, including

¹⁵ Vendor Credentialing Still a Thorny Issues: <http://www.repertoiremag.com/Article.asp?Id=3612>

¹⁶ http://www.medec.org/webfm_send/1362

¹⁷ From AdvaMed's letter to the Joint Commission September, 2007. To view a copy: <http://www.advamed.org/NR/rdonlyres/D13CA862-1836-45DF-891F-CC009B5EAC99/0/AdvaMedcommentsonHCIRCredentialing0926074.pdf>

¹⁸ http://www.facs.org/fellows_info/statements/st-33.html

¹⁹ <http://www.aorn.org/PracticeResources/AORNPositionStatements/>

the different levels of vendors to be credentialed, a national background check, recommended immunizations and basic policies.

A Single Credentialing Approach

The cost to the health care system of credentialing could be substantial, if supplier companies must register with multiple VCCs to service all their clients. In the summer of 2011, the US Healthcare Industry Supply Chain Institute issued a report on the impact of vendor credentialing on vendors. Vendors who participated in the survey reported dealing with *four or more* vendor credentialing companies. “They report that many [credentialing companies] require the same information but require the vendor to use their services for verification/validation,” according to the study.²⁰

If we can assume that other hospitals that have contracted with a VCC have done their due diligence on what the credentialing elements will be, there is no reason to force suppliers to get re-credentialed by the VCC a different provider may choose to work with.

Alternatively, as has been suggested in the US, a central repository for credentials could be created, similar to how physician credentials are accessed in the US. A central repository would serve several functions: it would house the credentials of all necessary sales reps and other personnel; VCCs could access the credentialing data for all personnel; hospitals would have the ability to track who they are dealing with; and it would provide security to vendor reps that their information is safe and not being misused.²¹

Renewal Fees Controlled

While many professional organizations require their members to renew their credentials every one to three to five years, none charge the same price to renew as to register. However, research indicates that VCCs will charge representatives the same rate to renew each year as it costs to register initially. If a sales representative is renewing their credentialing with no changes except immunization updates, why do suppliers need to pay the same price at renewal every year? With the exception of immunization updates (annual TB testing for example), the remainder of the information on that particular sales rep likely has not changed.

Levels of Vendor Credentialing

Statement:

Two levels of vendor credentialing should be implemented, with the differentiation being those supplier representatives entering clinical areas, such as the OR, and those entering

²⁰ <http://www.hisci-net.org/Portals/0/Press%20Room/JHC.HISCI%20Article%20December%202010.pdf>

²¹ <http://www.beckershospitalreview.com/hospital-management-administration/3-issues-hospitals-and-vendors-face-regarding-vendor-credentialing.html>

other patient care areas. Supplier representatives only accessing those areas where any member of the general public has access, including, but not limited to, common areas, the corporate office or loading dock, should not be required to be individually credentialed.

Supporting Information:

For economic and social reasons, it makes sense to limit the extent of the credentialing elements required for various suppliers and/or supplier representatives. Only a proportion of supplier representatives access clinical areas, while others, including trainers, consultants, delivery drivers and garbage haulers never access these parts of the hospital.

Vendor Credentialing companies in both Canada and the US offer different categories at varying prices. Some VCCs offer deep discounts for representatives who only visit general areas of the hospital and higher rates for those visiting areas of higher risk such as the Operating Room or other patient care areas. It was noted with one VCC, representatives from the following two categories pay the same rate:

Level 1 (\$249):

Pharmaceutical and some bioscience reps whose responsibilities require working and meeting with pharmacists, physicians, & hospital staff in the pharmacy, hospital common areas, clinics or offices.

Level 2 (\$249):

Reps that are needed or technically support surgeries or mini-invasive areas with medical devices and products. Areas include operating room, Interventional Radiology and catheterization lab.

One can presume that the rates in the US are more competitive based on the number of VCCs operating there and perhaps due to the pressure that GPOs and organizations such as IMDA and AdvaMed have exerted on the VCCs to create different levels and different pricing.

All interviewees thought it made sense to have difference levels of vendor credentialing, as not everyone is required to go into clinical areas. Not all, however, felt that everyone should be credentialed; one commented: “Does this mean we ask Staples or FedEx to get their drivers credentialed to solely walk up to the front desk of the hospital?” A provider commented : “Those that we see once or twice per year, for example a consultant doing a project, they should not need to be credentialed personally; we ensure at the RFP process that their firm is insured, etc.” Interviewees were also divided on the number of levels of credentialing – either two or three.

Elements of Vendor Credentialing

VCCs in the United States tend to credential in the following areas:

1. Immunizations – most commonly requested are MMR, HepB, and TB test
2. Background checks, including drug screens (as applicable), criminal background checks, sexual offender registry, and sanction screens
3. Hospitals policies and procedures; possibly hospital orientation
4. Education and Training — product competency, HIPAA policies, Code of conduct/ethics, OSHA/Bloodborne pathogens
5. Statement of Insurance Liability letter²²

It is the first four areas that have been examined in this research.

Immunizations

Statement:

Recognizing that it is an individual’s right to receive or decline immunizations, the credentialing record of each supplier sales representative should indicate all current immunizations that this representative has received. Individual hospitals would have access to this record and may restrict access based on a bona fide occupational requirement²³ given clinical circumstances and risks of having non-immunized individuals in specific areas of the healthcare facility²⁴.

Supporting Information:

Few issues generate such impassioned debate as mandatory vaccination policies. Advocates say vaccines are safe and exemptions should be minimal. Opponents counter that vaccines are hazardous to health and that any limitation on exemptions is a violation of constitutional rights.²⁵

It is understood that supplier representatives may be in patient care areas. Studies have shown that “(flu) vaccination of health care personnel reduces transmission of influenza in health-care settings, staff illness and absenteeism, and influenza-related morbidity and mortality among persons at increased risk for severe influenza illness.²⁶ However it is questionable whether any health care facility can demand compulsory immunizations for all supplier representatives unless all individuals entering a hospital, including visitors, were required to show proof of vaccinations. Any mandatory requirement by a hospital could end

²² <http://vendorcompliance.vendormate.com/category/immunization-requirements/>

²³ A bona fide occupational requirement must meet the following criteria: (a) it must have a rational connection to the performance of the job; (b) it must have been adopted in reasonable and good faith belief that it was necessary to accomplish a legitimate work-related purpose and (c) it must be reasonably necessary to accomplish that work-related purpose. For an employer to show that a standard is reasonable necessary, it must be prepared to show that it is impossible to accommodate employees who do not meet the standard without suffering undue hardship. The definition of “employer” in human rights legislation is very broad and can include third parties such as a hospital or VCC.

²⁴ HSCN encourages readers to seek their own legal advice when considering implementing policies relative to Immunizations.

²⁵ Mandatory Vaccinations, No Middle Ground: by Erin Walkinshaw *CMAJ* November 8, 2011 vol. 183 no.

<http://www.cmaj.ca/content/183/16/1830.full?sid=23fb0ea1-4398-43ef-b71d-87ae335b5a32>

²⁶ <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>

in a legal challenge under the Charter of Rights and Freedoms. Even healthcare workers cannot be forced to be immunized.²⁷ In fact, unions for health-care workers have strenuously resisted efforts to make flu shots mandatory, and, in interviews, several union and employee organizations said they would be prepared to go to court to battle such an order.²⁸

Several cases have gone to labour arbitration in this regard with varying results. The Charney arbitration decision concerning St Peter's Hospital in Ontario stated that "enforced medical treatment is an assault and suspending employees who refuse to undergo medical treatment violates their security of the person's interests."²⁹ A relatively recent arbitration board case of Health Employers Assn. of BC v. BC Nurses Union (2006) decided for the hospital based on authority in the collective agreement and the finding that the policy itself was reasonable. The Board found that s. 7 of the Charter had not been violated, due to the nature of the choice to pursue other employment or to suffer minor economic loss. Section 7 of the Charter does not protect economic rights, and does not extend to the right to exercise a chosen profession or employment.³⁰

In many instances, individual work place policies do require health care workers to be immunized against specific diseases as a condition of employment at the facility.³¹ For example, the Vancouver Coastal Health Authority requires that all staff be immunized (for the flu), regardless of whether they have direct patient contact. In practice, the best it can do is threaten to send workers home without pay if they are assigned to work where there is a flu outbreak and they refuse to be immunized. It rarely comes to that – most are reassigned to another work area for the duration of an outbreak.³² Courts have demonstrated that any employee who cannot receive a particular vaccination due to an allergy, medical condition or religious observance will have to be accommodated unless it can be shown that having the vaccination in question constitutes a bona fide occupational requirement.

While it is unlikely suppliers would take their own customers to court, they themselves could be taken to court by their employees. Suppliers interviewed are concerned about the legal issues that could arise if their employees were required to be immunized. In fact, the majority of individuals interviewed, both providers and suppliers, did not believe this could become mandatory. Providers acknowledged that their own staff cannot be forced to get

²⁷ <http://www.thefreelibrary.com/Influenza+vaccination+for+health+care+workers%3A+towards+a+workable+and...-a0229302915>

²⁸ Mass health-worker absenteeism feared: by Patrick Brethour, Justine Hunter and Katherine O'Neill, *Globe and Mail* Feb 2009; <http://www.theglobeandmail.com/news/national/mass-health-worker-absenteeism-feared/article1225296/>

²⁹ Ibid: See Background for additional information

³⁰ Influenza vaccination for health care workers: towards a workable and effective standard. <http://www.thefreelibrary.com/Influenza+vaccination+for+health+care+workers%3A+towards+a+workable+and...-a0229302915>

³¹ Mandatory vaccinations: The Canadian Picture; by Erin Walkinshaw; *CMAJ* November 8, 2011 vol. 183 <http://www.cmaj.ca/content/183/16/E1165.short>

³² Mass health-worker absenteeism feared: by Patrick Brethour, Justine Hunter and Katherine O'Neill, *Globe and Mail* Feb 2009; <http://www.theglobeandmail.com/news/national/mass-health-worker-absenteeism-feared/article1225296>

immunized. “We can encourage it and we can recommend it but we cannot force it” said one.

It would be extremely difficult, if not impossible, to require all vendor representatives to be vaccinated, particularly those representatives accessing only common areas of the hospitals. Neither visitors nor patients are required to have all immunizations prior to entering a hospital, so suppliers only accessing the same areas as a visitor could not be treated differently under the law. However, it is not a constitutional right of a vendor representative to have access to restricted patient care areas of the hospital. Facilities could require reps to be vaccinated to attain access to these areas. By having access to their immunization records, hospitals could restrict access to certain clinical areas (such as the OR).

Background Checks

Statement:

Including criminal record checks (CRC) as part of vendor credentialing should be done with caution as it may impinge provincial or federal rights and laws. If a healthcare provider deems that a CRC is a bona fide occupational requirement in order for a vendor representative to provide services in a specific area of a healthcare facility, the initial requirement and subsequent renewal of the CRC should only be done as required to support the original rationale for a CRC. Again, if a CRC is deemed to be required, the arrangements to provide a CRC can be made directly with the vendor representative, or the representative’s employer can attest to the check on behalf of their employee and provide this information either directly to the provider or through the VCC.³³

Supporting Information:

In Canada, criminal records are stored in Criminal Records Information Management Services, a centralized database operated by the RCMP under the Canadian Police Information Centre (CPIC). The database includes all convictions for which a pardon has not been granted, all charges regardless of disposition, outstanding warrants and charges, all judicial orders and other information that might be of interest to police investigations.³⁴

It is debatable whether all supplier sales representatives require criminal records checks (CRC), particularly those working in non-clinical areas. The Canadian Charter of Rights and Freedoms, the Human Rights Code, and Supreme Court of Canada decisions impose strict limits on how an employer uses information from these records. A CRC must relate to the

³³ HSCN encourages readers to seek their own legal advice when considering implementing policies relative to Background Checks.

³⁴ http://en.wikipedia.org/wiki/Criminal_record#Canada

requirements of the position.³⁵ In fact, several provinces prohibit the refusal to hire someone on the basis of a criminal conviction unless the employer can show that the offense is directly related to the position. The information requested must be “necessary”. In most provinces employers are not permitted to discriminate on the basis of criminal offences in respect of which a pardon has been granted unless they can show that it is a bona fide occupational requirement. Background searches are often conducted by third party service providers, but employers remain responsible (and potentially liable) for the collection.³⁶

While this paper often references the employee-employer relationship, we need to keep in mind the definition of “employer” in human rights legislation is very broad and could include third parties such as a healthcare provider organization or VCC who may have the ability to affect a vendor representative’s ability to earn a living.

Interviewees were divided on whether CRC could be made mandatory, especially for supplier representatives not operating in clinical areas. Two of the three providers stated they perform CRC on their employees as did one supplier. However, one supplier mentioned that vulnerable sector checks, which is likely what one wants to screen for here, could not be included in a third party VCC background check and based on the research, this appears to be the case.

A "vulnerable sector" check identifies whether an individual has been granted a pardon for certain specified sexual offences, but is only available to organizations hiring individuals to care for children and vulnerable persons based on restrictions in the *Criminal Records Act*. Specifically, vulnerable sector is defined as a minor (less than 18 years of age) and persons who, because of their age, a disability or other circumstances, whether temporary or permanent (a) are in a position of dependence on others; or (b) are otherwise at a greater risk than the general population of being harmed by persons in a position of authority or trust relative to them.³⁷

The RCMP direction on vulnerable sector checks specifies that these checks must not be provided through commercial services providers. The results can only be first released to the applicant by the police and the police agency may only release the information to the organization with the prior written consent by that individual.³⁸

Some provinces require high-risk professions to be screened to ensure public safety. For example, the BC Ministry Public Safety and Solicitor General requires all healthcare professionals, practicum students in healthcare, childcare facilities staff and volunteers,

³⁵ http://www.bcpublicserviceagency.gov.bc.ca/policy/HR_policy/14_Security_Screening.htm

³⁶ A Routine Background Check in Canada? There's No Such Thing. <http://blogs.hrhero.com/northernexposure/2009/01/13/a-routine-background-check-in-canada-2/>

³⁷ http://en.wikipedia.org/wiki/Criminal_record#Canada

³⁸ <http://www.slaw.ca/2010/01/27/new-rcmp-commitment-to-enforcement-of-background-check-policies-squeezing-canadian-employers/>

school and hospital staff regardless of position to undergo a CRC via the Criminal Records Review Program³⁹, but not until after the employee is offered the job.⁴⁰

Many Canadian universities require a Criminal Records Check or other screening procedure (e.g. Child Abuse Registry Check, Vulnerable Sector Screen) as a condition of admission into its programs.⁴¹ To obtain and maintain a nursing license in Canada, a criminal records check is required.⁴²

In VC circles in the US, questions around background checks have been raised. Says one supplier: "Is a Class A misdemeanour enough to keep a rep out? And what is the definition of "misdemeanour" anyway? It varies from state to state. Everyone agrees that a felon should not be in the hospital. But should a person convicted of a DUI be denied access? And how long ago? A year ago? Five years ago?"⁴³ Tricky questions requiring thoughtful answers.

One supplier, who did not believe that CRC were required, commented: "Our sales people are not unescorted, standing next to a patient by themselves. They are surrounded by physicians and nurses, as they are there to do training. Visitors have more open access."

Suppliers also raised the concern of privacy around using a third party (the VCC) to perform the CRC. This is partly due to liability; as mentioned above employers remain responsible (and potentially liable) for the collection of background information including criminal records checks.⁴⁴ If CRCs are already being performed by the supplier company, there is no reason to have it done a second time. Additionally, if an employee would rather have their employer request the CRC for privacy reasons, this should be allowed.

Hospital Policy Reviews

Statement:

Credentialing requirements for policy reviews should focus only on patient privacy and confidentiality and a Vendor Code of Conduct.

Supporting Information:

³⁹ http://en.wikipedia.org/wiki/Criminal_record#Canada

⁴⁰ <http://www.bccla.org/privacy/privacy5-5.html>

⁴¹ http://en.wikipedia.org/wiki/Criminal_record#Canada

⁴² http://www.registered-nurse-canada.com/criminal_record_background_search.html

⁴³ Vendor Credentialing Still a Thorny Issues: <http://www.repertoiremag.com/Article.asp?Id=3612>

⁴⁴ A Routine Background Check in Canada? There's No Such Thing. <http://blogs.hrhero.com/northernexposure/2009/01/13/a-routine-background-check-in-canada-2/>

One of the results of the VC issue in the US to avoid in Canada is the move by hospitals to arbitrarily include “multiple policies – some as many as 25 – in their vendor credentialing processes.”⁴⁵ Commented a US supplier, “I understand there are certain things hospitals want reps to know. But some are redundant. Don’t ask me for proof of knowledge of OR protocol and aseptic technique, then put 15 different hand washing policies in there.”⁴⁶

Individuals interviewed felt that vendors do review policies, that in general it is important and that certain policies (privacy and confidentiality, business ethics, code of conduct) could certainly become standardized. A couple of suppliers commented that some providers demanded policy sign off but could not provide the policies in an efficient and timely manner or that these policies were aimed at staff, not third parties representatives. One supplier commented that while they expected to sign off on privacy and business ethics policies, how would they have the time to sign off every single hospital’s fire and safety policy? Some providers echoed this concern, feeling that privacy and business ethics could be made national, but specific OR policies would need to be reviewed on-site, assuming that was a hospital requirement.

Several hospitals have created supplier policy booklets right on their website for review, such as that provided by St Michael’s Hospital in Toronto (see: http://www.stmichaelshospital.com/pdf/business/vendor_handbook.pdf); or the Vendor Guide to Doing Business with Alberta Health Services at <http://www.albertahealthservices.ca/org/cpsm-guid-doing-business-with-ahs.pdf>. There are also several examples in the US.

Education Courses

Statement:

HCSN believes suppliers are providing sufficient education to their sales representatives and that should any specific training be required as part of a credentialing process, in-house training provided by suppliers is sufficient.

Supporting Information:

Both providers and suppliers felt that the level of training and education already provided to vendor representatives is quite high. Said one provider: “A lot of vendors hire people with clinical backgrounds; we are very comfortable with the majority of companies and find they have a profound amount of expertise.” Another commented that “many vendors spend

⁴⁵ Vendor Credentialing Still a Thorny Issue, December 2010; <http://www.repertoiremag.com/Article.asp?id=3612>

⁴⁶ Ibid

money on training their reps, so should only have to upload proof that this has occurred if an external vendor credentialing firm is being used”.

Suppliers strongly believe that they provide far more detailed and in-depth training than a VCC would offer. One supplier commented “in our company, product training is huge. Depending upon the equipment they are representing, they could be sent to the US for a 2 week course that includes one full week in a hospital. We also access MEDEC courses, use OR Nurses to train about the OR, train on infection control, privacy, legal compliance and many others.” Another stated: “every year our reps do training, but there is not always a certification of that training – we would love to see something like that where we train in-house and a third party exam and certification is offered, such as through a College or Healthcare Association.”

There was little to be found on the internet in regards to training as it relates to vendor credentialing. Interestingly, two of the larger credentialing organizations in the US have partnered, in the last couple of years, with on-line healthcare education training companies and charge additional fees to suppliers for many of the training courses offered.

The concept of annual review was raised in the interviews. One VCC’s guide states that “appropriate privacy training ... expires annually” as does training on blood borne pathogens. One wonders if hospitals require their own staff to take privacy training every single year of employment.

Secure Canadian Data Storage

Statement:

All data collected by third party Vendor Credentialing Companies must be stored in Canada by a Canadian based data storage company. Further, all VCCs should follow the Canadian Standards Association’s Model *Code for the Protection of Personal Information, ensure they* are in compliance with PIPEDA (Personal Information Protection and Electronic Documents Act (Canada) and comply with all applicable provincial and federal privacy laws.

Supporting Information:

The *USA PATRIOT Act* was introduced in the United States in October 2001 as an anti-terrorism measure. The issue of concern is that the Act permits U.S. law enforcement officials, for the purpose of an anti-terrorism investigation, to seek a court order that allows access to the personal records of any person without that person's knowledge. Under the Act, U.S. officials could access information about citizens of other countries, including Canada, if that information is physically within the United States or accessible electronically.⁴⁷

⁴⁷ From the Treasury Board of Canada website http://www.tbs-sct.gc.ca/pubs_pol/gospubs/TBM_128/usapa/faq-eng.asp#Q1

After the introduction of the Act, Canadian provinces and the federal government took steps to protect Canadian information. In BC for example, the government introduced a law that requires that all personal information be stored in Canada and that access to personal information take place only within Canadian boundaries. As a result, a service provider located outside Canada can no longer store or access personal information unless it establishes facilities within Canada for this purpose.⁴⁸

The Canadian Standards Association is a not-for-profit association working to develop standards that address real needs, such as enhancing public safety and health. The *Model Code for the Protection of Personal Information* sets out ten principles that balance the privacy rights of individuals and the information requirements of private organizations. In Canada, the key elements of the Privacy Code are now incorporated into the *Personal Information Protection and Electronic Documents Act* (PIPEDA). All organizations that comply with the CSA standard can be confident that they meet the federal requirements of PIPEDA.⁴⁹

An individual issue around data storage and protection of privacy is data encryption. In the US, IMDA has stated that any VCC “should offer SAS70 LEVEL II or its equivalent around its database and servers.”⁵⁰ In addition, the VCC should have a clearly defined privacy policy to address the misuse or potential sale of information it collects for itself or on behalf of its clients.

Perhaps understandably, the suppliers interviewed expressed more concern about the issue of data storage than the providers, although one provider did comment that it is “a big concern – releasing information is already an issue – we need a records retention schedule, destruction dates, etc.” It is important to recognize that suppliers can be held legally liable by their employees for any issues with inappropriate data storage, even if that data storage is through a third party company such as a VCC.

⁴⁸ British Columbia's Privacy Laws Amended In Response to the *USA Patriot Act*<http://www.cwilson.com/services/18-resource-centre/190-british-columbias-privacy-laws-amended-in-response-to-the-usa-patriot-act.html>

⁴⁹ <http://www.csa.ca/cm/ca/en/about-csa>

⁵⁰ http://www.imda.org/documents/CVO_Attributes.pdf

Appendix One

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 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.