

Industry Concerns with Health Canada Licensing – Patient Management Software

**CESO – ITAC Health
March 8, 2010**

ITAC Health

- **A division of the Information Technology Association of Canada**
- **Represents 350 companies, of which 130 provides ICT products and services to the health sector**
- **Services include advocacy, education and networking**

ITAC Health Position

- **ITAC Health recognizes the need for vendors to demonstrate to the public and to health care providers that ICT products and services are safe, effective, will address privacy and security concerns and will interoperate with an integrated health care delivery system.**
- **ITAC Health supports licensing and certification programs that:**
 - **Provide real value to patients, users and vendors**
 - **Are technically feasible and economically viable**
 - **Are coordinated with other certification programs**

Federal Budget – March 4, 2010

- **The Economic Action Plan provided \$500 million to Canada Health Infoway to support the goal of having 50 per cent of Canadians with an electronic health record by 2010 and to speed up the implementation of electronic medical record systems for physicians.**
- **This \$500 million investment will both enhance the safety, quality and efficiency of the health care system, and create thousands of sustainable, knowledge-based jobs throughout Canada.**

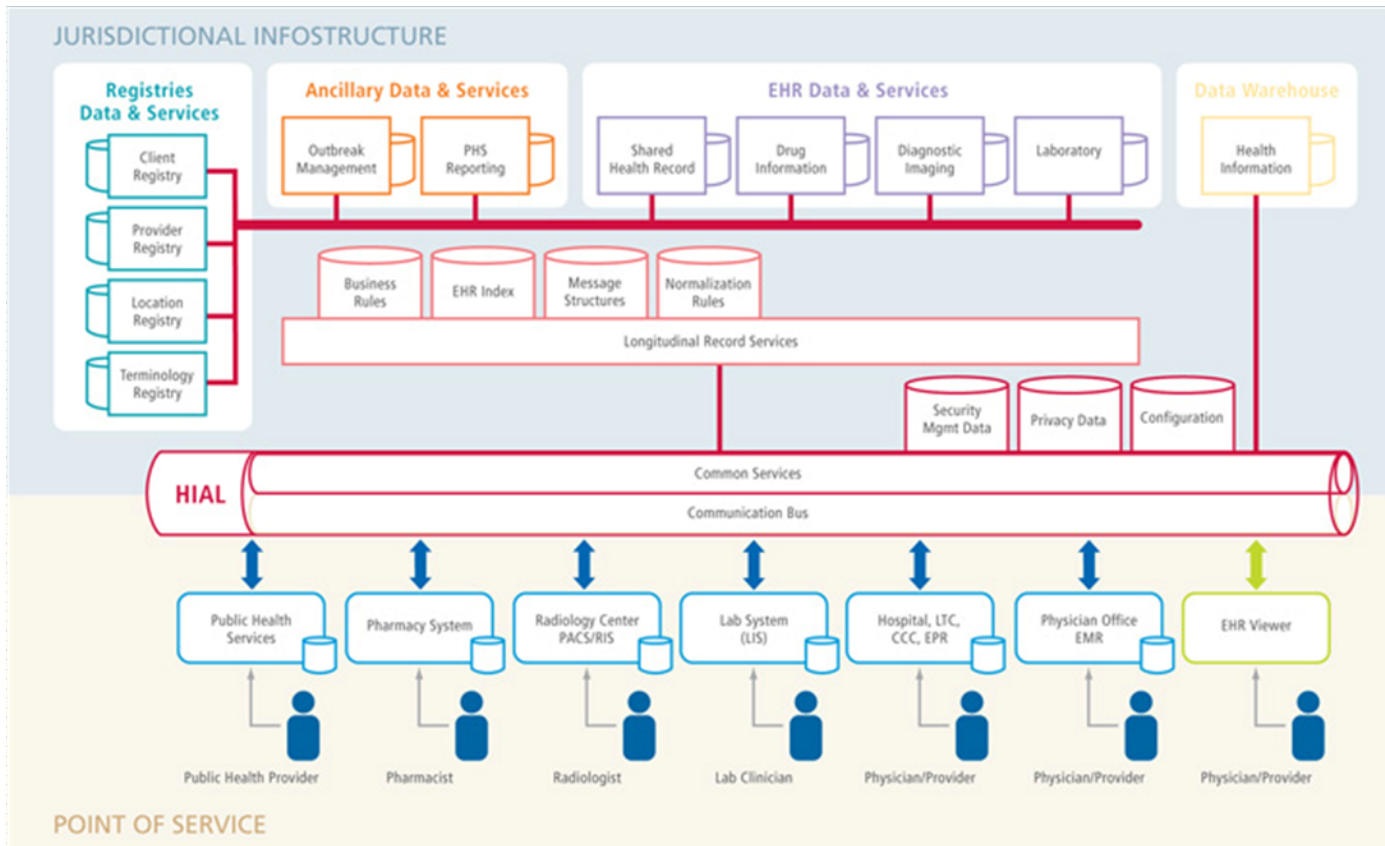
Issues

Who does this affect?

- **From HC Notice:**
 - **Manufacturers, importers and distributors of medical devices software**
 - **Facilities that purchase patient management software**
- **Others?**
 - **Ministries of health, health regions, districts and LHINs, professional associations and anyone else that develops, purchases and distributes patient management software**

Where's Waldo?

Can you spot the medical devices in this picture?



Complex Business Relationships

- Who is the “manufacturer” or “distributor”?
- Jurisdictions and regions that have already gone through procurement processes for EMRs and other software products
- Products built by the private sector under public sector direction
- Provincial and national registries
- Public/Private Partnerships (e.g. Ontario diabetes registry)
- Shared Services (e.g. SIMS)

Amnesty Period

- **Vast majority of patient management software products are not licensed today**
- **Unclear what the liabilities are for vendors and user organizations who sell and use unlicensed software products today**
- **Health Canada is considering an amnesty period**

Status of Legacy Systems

- **MDR applies to new systems sold and distributed in Canada**
- **What about:**
 - **Upgrades/new versions of software which may already have been “sold”**
 - **Patches/ bug fixes**
 - **Troubleshooting services that results in changes to software**
 - **Help desk support**

Application Service Provider Services

- **What is the status of application service provider services (ASP)?**
 - Many jurisdictions moving in this direction for physician EMRs
 - No software is “sold”
 - Services could be off-shore

Software Sold Offshore and Online

- **What is the status of software downloaded off the Internet that comes from another country?**
 - **Will definitely apply to consumer health applications and possibly to many other domains**
 - **Companies may have no operations or distributor in Canada**
 - **Support provided by call centres around the world**
 - **Is there any prohibition preventing the purchase of off-shore products?**

Multiple Certification Programs

- Many EMRs have already been certified/selected by provincial jurisdictions for use in their provinces
- Canada Health Infoway is rolling out its own certification program
- USA is implementing a certification regime under ARRA

What Standards Apply?

- Are there any standards other than ISO 13485 that apply for the development of patient management software to meet the safety and effectiveness requirements?

Everyone's an Expert

- There is an extreme lack of quality information about the Health Canada licensing program and its applicability to patient management software
- Consultants starting to fill in the void.
- Need for authoritative source of information

What ITAC Health is Doing

- Meeting with Health Canada to address issues of concern to members
- Preparing a white paper to provide guidance to vendors on licensing and certification
- Preparing a webinar to provide basic kick-start information to vendors
- Established a blog to keep members up-to-date
www.itachealth.blogspot.com

Contact Me

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