



24 June 2015

PCEHR/HI Discussion Paper Feedback
Department of Health
MDP 1003
GPO Box 9848
Canberra ACT 2601

RE: Submission to the Electronic Health Records and Healthcare Identifiers Legislation Discussion Paper

Thank you for the opportunity to comment on this important discussion paper.

Our response is limited to matters of relevance to us as Australia's peak standards development body and the Australian member of two of the three International standards setting bodies.

Key Points

- Adoption of International Standards should continue to be a first consideration in Australia;
- International, Regional and Private Standards should be properly defined;
- Proper consultation and engagement is essential;
- We look forward to discussions with the Australian Commission for Electronic Health.

Adoption of International Standards should continue to be a first consideration in Australia

Standards Australia has long supported, and continues to support, the participation in and adoption of International Standards in the health informatics sector.

Standards Australia's MOU with the Commonwealth government, for very good reason, provides that:

6.6 When preparing Australian Standards, Standards Australia will, in accordance with Articles 3 and 4 of the WTO TBT Agreement, utilize accepted international standards to the maximum extent possible and will only depart from this practice where there are compelling reasons to do so.

Standards Australia acknowledges that there are a broad range of standards development organisations and consortia engaged in this sector internationally.

We believe that the participation in, and adoption of International Standards (and other standards developed overseas) should continue to be a focus in this area, and that adequate representation of Australian stakeholders be maintained at the various standards development fora related to e-health.

We also believe that to the extent that Australia seeks to adopt standards, consideration should be given to active Australian participation in the development process. This consideration should extend beyond Australians being present at meetings, to a process whereby Australian requirements are identified, consulted on and agreed, and taken to relevant fora.

International, National, Regional and Private Standards should be properly defined

International Standards are documents developed through the processes of the:

- International Organization for Standardization (ISO);
- International Electrotechnical Commission (IEC); and
- International Telecommunication Union (ITU).

Separately assessing International Standards from other 'standards' is important because Article 2.5 of the WTO Agreement (of which Australia is a signatory) provides:

*2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.
(Emphasis added)*

The rebuttable presumption does not apply to regional (for example, CEN Standards), national (Standards developed by national standards bodies (for example Australian Standards), or private standards (developed by organisations, companies, and consortia outside of the International and national standards setting process).

Proper consultation and engagement is essential

The Commonwealth government has a very clear set of criteria on which it assesses the development and implementation of regulation in *The Australian Government Guide to Regulation*.

This is in addition to the COAG *Guide for Ministerial Councils and National Standards Setting Bodies*.

Standards Australia supports the implementation of the principles contained in these Guides across all sector of the Australian economy.

We look forward to discussions with the Australian Commission for Electronic Health

Standards Australia welcomes the establishment of the Australian Commission for Electronic Health. Given our continuing role in this important area, we look forward to discussions with the Commission once established.

Should you require further information, please do not hesitate to contact Bronwyn Walker, Bronwyn.Walker@standards.org.au or by telephone on (02) 9237 6011.

Yours sincerely



Bronwyn Walker
National Sector Manager, Health and ICT