Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October

Question: E11-465

OUTCOME 10: Health System Capacity and Quality

Topic: eHEALTH - LEGISLATION & STANDARDS

Written Question on Notice

Senator Boyce asked:

Nicola Roxon has recently been attacking privacy advocates and their concerns about the security of the proposed PCEHR. But its Draft Legislation has just been released before the standards and technical specifications that form the basis of its function have been finalised. In the PCEHR, which is the core reason for NEHTA's existence, there are 60 key technical standards and NEHTA has not completed them as yet, and we're told is miles from doing so.

(a) Would you agree if NEHTA doesn't get this right, patients safety will be placed at great risk?
(b) What detailed clinical testing has been conducted?
(c) What were the results of those tests?
(d) How many of the 60 key technical standards have been fully completed and fully tested?

Answer:

(a) (b) and (c)
Each stage of the development process for the PCEHR technical specifications require clinical governance and safety processes to be followed. NEHTA's Clinical Safety Unit (CSU) is fully embedded into all areas of NEHTA's product development and oversees clinical governance at NEHTA. The CSU is supplemented through NEHTA's Clinical Leads. NEHTA's CSU:

- identify circumstances related to eHealth that put patients at risk of harm;
- being actively involved in reviews (from a safety perspective) of all specifications/products released using the Clinical Safety Management System (CSMS) defined processes;
- document the evidence, where possible in a safety case; and
- maintain the safety cases for the operational life of the product/system.

The CSU addresses safety by working across the work programs in NEHTA to provide certainty to medical software developers, end-users and policy makers. It is a legitimate expectation of vendors that products developed by NEHTA are safe and have Clinical Utility.

The CSU activities involve clinicians, with health IT knowledge experience, system safety engineering and risk management as well as a:

- Biomedical engineer
- Biomedical scientist

- System Safety engineer
- Test Engineer
- Program Coordinator and Projects Coordinator/Manager
- Program support officer

Any clinical safety findings as a result of reviews of specifications and standards are included in the overall review outcomes and mitigations are recommended for inclusion as part of any proposed drafting changes in the specifications, or in the form of implementation guidance to mitigate the risks.

(d) NEHTA advises that 23 bundles of specifications are needed, 11 of which will become standards over time. As at 31 January 2012, 16 areas of specifications are complete and have been tested. These are available on the NEHTA site for vendors, along with guidance material on how to implement the specifications. Through a quality assurance process an issue was identified with the guidance material for 5 of the specification bundles. This guidance material has been removed and is currently being updated.