Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

National e-Health Transition Authority (NeHTA)

Budget Estimates 2011-12, Supplementary Estimates

Question: 2

OUTCOME 10.2: e-Health

Topic: PCEHR

Senator Boyce asked:

If there are no such documents does that mean key issues relating to clinical safety and the implementation processes are not resolved and not completed?

Answer:

Testing of PCEHR Release 1a (software developers) is still underway at this stage. Ongoing identification and analysis of clinical hazards will continue until it informs the go-live decision for PCEHR Release 1b, and importantly, post deployment into the live clinical environment.

The process for reviewing clinical safety continues to be documented as per NEHTAs Sentry system as outlined above.

Clinical safety at NEHTA is managed within the broader process of quality management. At NEHTA, each program is required to drive their own quality processes for the products that they develop (e.g. Healthcare Identifiers, Referral, secure messaging, etc.). While there are differences in the details of these processes based on the nature of the product being developed, there is a common underlying product development life cycle with embedded quality checkpoints.

The CSU is responsible for identifying clinical hazards introduced through the design and development of NEHTA products and assessing how these may contribute to clinical harm. The CSU works with product teams during the development phases to recommend mitigating controls and the product team is responsible for deciding how best to implement the proposed controls and communicate their approach to stakeholders.

The review process goes through a number of cycles during product development and where risks are identified, mitigation strategies put in place to ensure the risks are as low as possible.