Explanatory Note

This document states that, at the date of the brief, one of the key issues was that patient information was protected under the Privacy Act 1988 and that the matter had been referred to the Office of the Australian Information Commissioner (OAIC) for inquiry.

Since this brief was prepared, the OAIC has published its decision, finding that preliminary enquiries were sufficient to satisfy the Commissioner that the patient data disclosed in this instance had been sufficiently de-identified and was therefore not personal information for the purposes of the Privacy Act 1988. Accordingly, the Commissioner decided not to pursue regulatory action.

The decision can be viewed at this link: https://www.oaic.gov.au/privacy/privacy-assessments-and-decisions/privacy-decisions/Investigation-inquiry-reports/report-into-preliminary-inquiries-of-i-med

Australian Government

Department of Health and Aged Care

Information Brief
MB24-002936
Version (1)
Date sent to MO: 12/11/2024

To: **Minister Butler**

Subject: **DEPT INIT INFO BRIEF - UNAUTHORISED USE OF PATIENT INFORMATION TO TRAIN ARTIFICIAL INTELLIGENCE (AI)**

Comments:			
Contact Officer:	*John Jamieson*	*Assistant Secretary, Medical Devices Authorisation Branch, Medical Devices and Product Quality Division*	Ph: s22 Mobile: s22
Clearance Officer:	*Tracey Duffy*	*First Assistant Secretary, Medical Devices & Product Quality Division Health Products Regulation Group*	Ph: s22 Mobile: s22

Key Issues:

- Recent media (Crikey article, "Emergency room patient's scans used to train AI without their knowledge, documents suggest" 7 October 2024, Attachment A) has reported on the use of patient data being used to train AI tools used in health care, without the knowledge or consent of the patients.

- The AI software referenced in the article is Harrison.ai's chest x-ray AI analysis tool, Annalise.ai. Harrison.ai acquired chest x-ray images to train their tool from I-MED, a privately owned (by Permira a global investment firm) radiology network operating in Australia. Harrison.ai also used data from other sources to train and test the Annalise.ai model (Attachment B).

- The article raises concerns around the privacy of patient information that was provided to Harrison.ai, but raises no compliance concerns relating to the supply of the Annalise.ai medical device. Annalise.ai has been included in the Australian Register of Therapeutic Goods for supply in Australia since September 2020.

- Patient information is protected under the *Privacy Act 1988*, administered by the Office of the Australian Information Commissioner. The article states that the matter has been referred to the Office of the Australian Information Commissioner for inquiry.

Background:

Medical Device Regulatory Framework

Advances in computing technology and software production (including AI technologies) have led to a large increase in the number of software-based medical devices available on the market.

Following consultation with stakeholders including with global medical device regulators in 2019 and 2020, the *Therapeutic Goods (Medical Devices) Regulations 2002* were amended by the government to clarify some existing requirements and to introduce new requirements for software-based medical devices to ensure patient safety.

The changes commenced February 2021, and include**:**

- clarifying the boundary of regulated software products (including 'carve outs')
- introducing new classification rules to consider the potential for software products to cause harm to patients.
- clarifying the requirements for software-based medical devices in the Essential Principles.

Transition provisions were put in place to allow suppliers of existing products to comply with new requirements.

The reforms included amendments to the Essential Principles (EPs), which set out the expectations relating to the safety and performance characteristics of medical devices. Essential Principle 12.1 was amended to clarify requirements around data integrity and quality. This includes that the privacy and data of information must be maintained where it is relevant to the safety and performance of the device:

> **12.1 Programmed or programmable medical device or software that is a medical device**
>
> Paragraph (1) (g) …software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that…if relevant, the privacy of the data or information is maintained.

Australian Therapeutic Goods legislation does not currently include requirements relating to how data is sourced, shared or otherwise used, as these aspects are regarded as falling within clinical/health practice and privacy law.

Patient information is protected under the *Privacy Act 1988*, administered by the Office of the Australian Information Commissioner (OAIC).

The Office of the Australian Information Commissioner's website provides information about how the Privacy Act should be applied by health practitioners in healthcare settings. This includes legally binding guidelines, issued by the National Health and Medical Research Council (NHMRC).

The TGA will update guidance to clarify privacy requirements for medical devices, including how we interface with the OAIC to refer issues where appropriate.

AI Review

In the 2024-25 federal Budget, the Australian Government provided $39.9 million over five years for the development of policy and capability across government to support the adoption and use of AI technology in a safe and responsible manner.

Through the budget measure for Safe and Responsible AI, the government is aiming to ensure the design, development and deployment of AI systems in Australia in high-risk settings, is safe and can be relied upon, while ensuring the use of AI in low-risk settings can continue to flourish largely unimpeded.

The measure includes clarifying and strengthening existing laws to address risks and harms from AI, through an immediate review of the priority areas of health and aged care sector regulation, the Australian Consumer Law and copyright law.

The TGA has consulted on proposals identified for mitigating risks and leveraging opportunities associated with the use of AI models and systems across our regulated environment. This complements the Department of Health and Aged Care's broader review of the health and aged care regulation and legislation.

Feedback from the consultation activities is currently being analysed and will inform recommendations to Government, including possible changes to the regulatory framework.

Consultations: Health Products Regulatory Group

Attachments:
A: "Emergency room patient's scans used to train AI without their knowledge, documents suggest", Published 07 October 2024
www.crikey.com.au/2024/09/19/patient-scan-data-train-artificial-intelligence-consent/

B: "Effect of a comprehensive deep-learning model on the accuracy of chest x-ray interpretation by radiologists: a retrospective, multireader multicase study" Lancet Digit Health 2021; 3: e496–506 Published Online 01 July 2021
doi.org/10.1016/S2589-7500(21)00106-0

Minister	**Minister Butler**
PDR Number	**MB24-002936**
Subject	**Dept Init Info Brief - Unauthorised use of patient information to train Artificial Intelligence (AI)**
Contact Officer	John Jamieson s22
Clearance Officer	Tracey Duffy s22
Division/Branch	|Health Products Regulation| Medical Devices & Product Quality
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐