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Australian Clinic Moves Early on AI Regulation with TGA Submission of ROSE Clinical Support System

Botaniqal Clinics Australia has formally submitted its AI-enabled Clinical Decision Support Software (CDSS), **ROSE**, to the Therapeutic Goods Administration (TGA) for registration as Software as a Medical Device (SaMD) (Submission Reference: ANON-EH3X-D4JK-5).

The submission represents an early regulatory engagement approach as healthcare providers begin integrating structured AI-enabled systems into clinical workflows.

ROSE operates within Botaniqal Clinics and is **designed and delivered by Dr Sophia AI**, an enterprise clinical intelligence platform developed to support healthcare providers seeking structured digital infrastructure within regulated environments.

The platform is designed to organise digital patient onboarding, structure medical questionnaires, and generate consultation-ready documentation prior to a telehealth appointment with an AHPRA-registered practitioner.

While all medical decisions remain practitioner-led, ROSE assists in organising patient-submitted information and presenting a complete transcript to the consulting doctor ahead of consultation.

For healthcare providers, this type of structured clinical infrastructure may help address a growing operational challenge across healthcare systems — the increasing administrative burden placed on clinicians.

“The challenge healthcare systems face today isn’t a lack of intelligence — it’s the administrative burden surrounding clinical care,” said Dwayne Boyes CEO of Dr Sophia AI.

“ROSE was designed to help organise the information clinicians already work with every day, before the consultation even begins. By structuring patient intake and documentation, the goal is to allow doctors to spend less time navigating administrative workflows and more time focusing on patient engagement and clinical judgement.”

Importantly, the system does **not diagnose, prescribe, or replace professional medical judgement**. It operates strictly as clinician-support infrastructure within a human-in-the-loop governance framework.

Beyond patient intake and documentation structuring, the platform integrates administrative workflows including:

- structured digital intake
- electronic Health Record (EHR) generation
- payment verification and Medicare validation
- appointment scheduling

The result is a consultation environment where relevant patient information can be reviewed in advance, helping clinicians enter appointments with structured documentation already prepared.

The company has also engaged the TGA on two emerging regulatory considerations related to clinical AI deployment:

- whether multilingual translation functionality within CDSS systems constitutes a regulated feature
- how future AI-assisted synchronous consultation environments may be classified under current regulatory frameworks

Security architecture has also been a key focus of development. ROSE applies **256-bit AES encryption**, stores and processes health data within Australia, and maintains strict control of Private Health Information (PHI).

The regulatory submission signals a broader shift in the healthcare AI sector toward **governance-first deployment models**, where systems are introduced within defined regulatory frameworks rather than launched ahead of oversight.

“The real test for AI in healthcare isn’t technical capability — it’s whether the systems can operate safely within clinical governance frameworks,” says Mr Boyes.

“That’s why we engaged regulators early in the process.”

Healthcare organisations evaluating digital infrastructure to support clinician workflows — including **insurers, hospital networks, multi-site clinics, workers compensation insurers, and government health agencies** — may increasingly seek structured systems that operate within these governance boundaries.

Organisations interested in enterprise demonstrations or technical briefings can contact:

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