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SUBMISSION

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AMA submission to the Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review

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Introduction

The Australian Medical Association (AMA) welcomes ongoing consultation with the Department of Health and Aged Care regarding the review of legislative and regulatory frameworks on the safe and responsible use of Artificial Intelligence (AI).

The application of AI to healthcare is a relatively new but rapidly evolving field. While AI has the potential to benefit healthcare, the clinical and social implications of AI in the healthcare environment remain largely unknown and uncertain. In such a fluid and rapidly expanding environment, the development and implementation of AI technologies must be undertaken with appropriate consultation, transparency, accountability, and regular, ongoing review to determine its clinical and social impact and ensure it continues to benefit, and not harm, patients, healthcare professionals, and the wider community.

The AMA notes the broader government activities occurring across national, state and territory governments towards establishing a consistent regulatory framework for the application of AI across industry settings. This is an important step in responding to the many opportunities and attendant risks presented by AI across industries.

In our submissions to the Department of Industry, Science and Resources' proposed 'mandatory guardrails for safe and responsible AI' and the Therapeutic Goods Administration's (TGA) consultation on 'Clarifying and strengthening the regulation of Artificial Intelligence', the AMA argues:

- healthcare is a high-risk sector requiring tiered regulation based on risk associated with the specific application of AI
- a dedicated governance body consisting of practising clinicians, medical professionals, consumers and technology developers should be established to support regulation
- tailored AI regulation for healthcare should be integrated with existing clinical regulatory mechanisms and aligned with the emerging national AI regulatory framework.

The AMA advocates for a comprehensive, ethically grounded regulatory framework that enhances healthcare delivery while safeguarding patient rights. We recognise a balance in regulation must be struck to support the advancement of increasingly sophisticated and secure AI capabilities that will achieve the best health and efficiency outcomes.

Our response is directed by the principles for the safe application of AI we have already laid out in previous submissions to various consultations relating to the use of AI. In summary, regulation for healthcare and high-risk contexts must ensure:

- clinicians are meaningfully involved in governance of AI in healthcare at every level, including human intervention points during the decision-making process
- AI never compromises medical practitioners' clinical independence and is never used by non-medical individuals to second-guess.
- clearly established responsibility and accountability for any errors in diagnosis and treatment caused by AI products
- use of AI in healthcare protects the privacy and security of patient health information. Any data collected in using AI in healthcare must be subject to stringent data governance and security measures
- visibility of AI generated components of care and advice, treatment, or diagnostic procedure to be undertaken, with full disclosure and patient consent for the use of health data
- data undergirding machine learning algorithms for AI in healthcare is inclusive and representative to mitigate against bias
- AI systems are required to substantiate the information which supports decision making at any point in time.

A coordinated all-of-government initiative to integrate new AI regulation within existing frameworks is a positive step towards keeping pace with international standards and safeguards. However, the AMA views healthcare as a high-risk setting requiring a dedicated regulatory framework and clinical governing body. Significant existing regulation in healthcare provides a strong framework to embed new provisions for the challenges of AI in healthcare and ensure patient safety, privacy, and ethical standards.

The department has raised many relevant questions in relation to AI regulation in healthcare. We will structure the remainder of this submission to respond directly to these.

1. Approaches to regulating AI in healthcare

AI must be subject to the same regulation required for any technology involved in the diagnosis and treatment of patients. Healthcare requires a bespoke national regulatory framework for the implementation of AI. Regulation should build trust and confidence in the rapidly evolving digital health solutions using AI and their capacity to contribute to an interoperable health system.

The AMA supports a risk-based approach, which considers levels of risk and key characteristics, and balances preventative and remedial regulatory measures to mitigate against known risks. Regulation in healthcare should avoid misclassifying low-risk applications and be adaptable to technological advancements. Government regulation of AI in healthcare must place adequate protections around patients and consumers, as well as healthcare professionals, engendering trust in the system. Those protections must:

(a) support improved patient outcomes

(b) ensure the final clinical decision is made by the medical practitioner

(c) the treatment or diagnostic procedure undertaken is always agreed to by the patient

(d) guarantee patient and practitioner data are protected.

In our submission to the DISR consultation on proposed mandatory guardrails, the AMA recommended the government implement "framework legislation, with associated amendments to existing legislation", as a whole-of-government approach to supporting proactive, industry-specific regulation of AI. This approach acknowledges the effective regulatory structures already in place and focusses on establishing new, pre-market safeguards and risk-mitigation measures specific to AI application in healthcare.

A framework approach seeks harmonisation between sector-specific legislative instruments dealing with the management of AI risks to build national consistency, with standardised regulatory terminology and powers across jurisdictions and industries. This method:

- is congruent with existing regulation in various high-risk contexts across industries in Australia
- leverages familiarity with existing health regulatory regimes, making implementation smoother for medical practices and regulators
- promotes a consistent approach to AI reform across the economy by establishing a centralised source for AI-related concepts, aiding clarity and reducing regulatory burdens
- will facilitate the establishment of health-specific regulatory structures for the application of AI in clinical practice
- is most able to adapt and respond to clinical requirements, including alignment with international standards, helping Australian AI innovators integrate into global AI supply chains.

2. Healthcare is a high-risk setting

Regulating the application of AI in healthcare requires a tailored approach that allows for the adoption and integration of safe technologies while protecting practitioner and patient safety. The application of AI in healthcare must always be considered high-risk, primarily due to potential negative consequences that could arise from systemic errors, patient privacy issues, and algorithmic biases. AI associated errors can lead to significant harm, such as misdiagnosis or inappropriate treatment, with potentially irreversible impacts on patient health.

Evidence base and consultation: Medical practice is a high-risk environment governed by robust frameworks for clinical action founded on scientific evidence. A regulatory framework for AI in healthcare should be founded on solid evidence, incorporating insights from clinical studies, expert opinions, and data analytics. This approach helps ensure regulations are grounded in the realities of healthcare practice and patient safety. Evidence-based regulation must be maintained through ongoing collaboration with experts in AI, healthcare, ethics, and law to adapt to the evolving landscape of AI technology. We will take this up further under *3. AI health advisory body*.

Accountability and liability: AI regulation must be integrated with existing clinical standards mechanisms to ensure we can delineate responsibility for clinical errors or adverse outcomes stemming from AI applications. This is crucial for accountability, allocating liability, and enabling proper avenues for redress in cases of misdiagnosis or inappropriate treatment. It must be recognised medical practitioners are not technology experts and cannot be expected to bear full

knowledge of how an AI application operates. The AMA emphasises the importance of clarifying accountability and ensuring legal responsibility is demarcated clearly and appropriately between developers and deployers.

Application, tiered approach: The clinical space is complex. Regulations cannot be one-size-fits-all but must be adaptable to the specific risks associated with various AI applications. Governance structures tailored to different services and programs within healthcare should be developed. The AMA recommends a tiered, application approach to regulation that categorises risk levels based upon potential consequences and establishes corresponding governance structures to manage them. This structured approach is inspired by international examples, such as the European Union, which distinguishes risk levels associated both with the AI product itself and its use setting.

Technology developers and deployers: While the government carries the key responsibility for establishing and maintaining a regulatory framework, it is not the chief agent in the development of AI. This role lies with the technology developers and other stakeholders as active innovators in technology across the various spaces of industry. In earlier consultations the AMA has highlighted a key challenge to regulating AI in the healthcare sector is the central agency of technology deployers. It cannot be supposed that end users will be informed about how technology functions and the inherent risks to their use. Practice managers, medical practitioners, and a range of professionals in the health space have vastly differing degrees of knowledge regarding AI, which can present significant risks to sound clinical practice and patient outcomes. Regulation must provide consistent guidance and resourcing at the organisational and system level.

The AMA supports a regulatory structure which imposes accountability upon developers and deployers of technology to satisfy standards requirements and ongoing monitoring for safety and improvement to AI technologies. The DISR's proposed guardrails target these cohorts as key drivers of AI innovation. A regulatory approach to AI in healthcare should recognise the importance of resourcing and educating medical practitioners as active participants in clinical technology innovation.

Developers: Regulatory safeguards must require developers to be transparent regarding AI design and ensure its operation adheres to agreed ethical principles. This will involve regulating manufacturers of medical devices using AI to impose robust standards in quality management systems for generating, collating, assessing and maintaining evidence in conformity with the essential principles for safety and performance.

Measures should be implemented that enforce principles and standards for AI-based platforms to promote clinician awareness regarding how AI functions within clinical tools. For example, developers must build transparency in software regarding how an AI-generated output was calculated. This information is essential to support clinicians in reviewing output and applying it towards making clinical determinations.

Medical devices using AI in healthcare must support clinicians in recommending appropriate treatment to maximise health outcomes for the patient. Algorithms for generative AI in healthcare must never formulate treatment pathways based upon maximising billing or claiming. The TGA carries responsibility to adapt current regulatory frameworks for medical devices to accommodate new technologies using AI, without compromising patient outcomes. We will provide comment on the TGA's role under *7. TGA Regulation*.

Deployers: Healthcare providers must be educated, supported and held responsible for assessing where AI can be safely and effectively integrated into clinical workflows. Standards must ensure health outcomes analysis and risk assessment associated with AI application are integrated into clinical workflows. Clinical governance should be responsible for regularly reviewing and updating the standards to account for emerging trends and new capabilities. The AMA believes an Australian body specifically dedicated to overseeing AI in healthcare would provide the necessary oversight to support this (see *below*).

3. AI health advisory body

Since legislative requirements across jurisdictions in Australia differ, any legislative change will require strong engagement from jurisdictional stakeholders to identify potential issues and manage them accordingly. The AMA has consistently advocated for tailored regulation of AI in healthcare as a fundamentally high-risk application of technology and to ensure patient safety, privacy, and ethical standards.

Healthcare is already subject to multiple complex regulatory structures associated with medical risk management, clinical governance, and the control of medical products and treatments. Robust, principle-based standards, capable of keeping pace with AI developments, must be embedded in clinical practice. These measures need to integrate effectively with TGA regulation of medical devices and regulation of health practitioners provided by Aphra and the Medical Boards. The complexity of this system requires the expertise of a health-specific governing authority.

While the Australian Government's temporary artificial intelligence expert group will be of value in the early stages of regulatory implementation nationally, healthcare requires a permanent body capable of continuous review. The European Artificial Intelligence Board, which oversees implementation and regulation, provides a potential approach. The AMA calls for the establishment of a health sector regulatory advisory body, consisting of practising clinicians, medical professionals, consumers, and technology developers, for the active oversight of AI application in healthcare.

Ongoing collaboration with experts in AI, healthcare, ethics, and law is critical to developing effective regulations that adapt to the evolving landscape of AI technology. AI model and systems testing before deployment, and ongoing monitoring activities in the clinical context, must include interaction between model developers and upstream/downstream stakeholders. A health-specific governance body would be equipped to provide this mechanism. These subject-matter experts must be engaged in ongoing testing and evaluation of AI products. This measure should support transparency and open-source development of new AI applications so healthcare expertise is integrated into the design process.

4. Interoperability and data governance

Interoperability

The AMA supports a more connected and interoperable healthcare system that enables seamless communication between different healthcare settings and equitable access to medical care. Digital innovation in the health system should focus on interoperability with core clinical systems and assistive technologies within which machine learning (ML) and automatic decision making (ADM) operate. AI's capacity to enable more efficient data exchange and collection will improve accessibility of patient data for both patients and healthcare providers, with simplified storage and analysis.

Pursuing interoperability drives the digitisation of healthcare further. The means of significant and compounding efficiency gains is a vast complex of increasingly interconnected data. This carries significant risks to data privacy, health provider security, and platform accuracy across the myriad of AI-supported digital health solutions to come.

Data governance

AI capabilities are built upon the imperatives of accessible, quality data. The government must recognise the novel relationship between data and machine learning, and the importance of protecting sensitive data in the AI landscape. Without this, there is a serious risk of undermining the utility of information used by AI.

Robust data governance must be integrated into healthcare regulatory structures to safeguard clinicians and patients from the harms of system errors, patient privacy breaches, or systemic bias. The safe and efficient management of AI databases across industries nationally is potentially the most complex regulatory challenge, particularly as data storage and use cannot be confined absolutely to the Australian jurisdiction.

International harmonisation

International regulators have advanced further than Australia in managing emerging technologies using AI. The government must seek alignment with international standards to ensure Australian requirements do not inhibit growth and innovation in the technology sector, nor expose our digital systems to risk. This is particularly important regarding management of databases undergirding AI capabilities.

Australia's current policies favour domestic data storage for health data, which strengthens our systems against cyber-attacks. However, this arrangement carries significant infrastructure costs and can limit Australian competition with international rival software and AI innovation. Conversely, storing data overseas could compromise domestic healthcare services when the servers are down. The AMA strongly encourages the government to consult widely with medical device manufacturers and sponsors to strike a balance.

Systemic bias and clinical integrity

Erroneous or imbalanced data will produce poor and even dangerous health outcomes. AI has the potential to further marginalise specific communities, ethnicities, or cultural groups if appropriate measures are not taken to guarantee a diversity of data is used in the training of machine learning algorithms. AI regulation must anticipate and identify every instance where data may influence algorithmic or systemic bias in AI, generate erroneous reports, or produce ill-founded advice to patients. One safeguard should be to program AI tools towards targeted population groups; i.e. the AI tools used in specific countries for specific populations will need to be trained on data specific for those populations.

The AMA supports the management of AI integrity through continuous auditing and improvement regimes to ensure algorithms are based on current, equitable, and reliable data. Embedded human points of intervention within the clinical process remain a constant safeguard against AI-generated errors.

Data quality

Data quality assurance must be central in the regulatory response to AI, since this bears directly upon the performance and reliability of AI applications. Healthcare databases will experience exponential growth as AI proliferates. The efficacy of machine learning — a vital function to AI performance and integrity — depends greatly upon huge amounts of available, high-quality data in the action of mimicking data patterns. AI — itself an 'end user' in many emerging applications — will over time generate more data in both closed databases and the public domain. Technology experts are already flagging potential 'model collapse' in the future if the quality of data should decline as AI-generated information proliferates and comes to dominate databases.

Safeguards for AI use in clinical practice must consider how data quality can be maintained. Raw patient data is routinely collected while delivering healthcare. Policy must consider how increasing proportions of health data collected and shared across healthcare services will be composed by AI. This trend means clinician review of the outputs of generative AI remains imperative to protect clinical decision making and record keeping. Policy must mitigate against any reduction in the quality and diversity of AI model behaviour associated with 'regurgitative data' in healthcare applications and tools. This may require automated labelling for AI-generated content within applications to differentiate datasets used by AI and clinical decision making in the future.

Profiling

Patient profiling is necessary and occurs through accessing health services and receiving care. The AMA recognises AI will enable healthcare services to connect and integrate broader sources of patient information (system interoperability) to construct comprehensive patient profiles that support medical professionals to evaluate patient health. Increasingly comprehensive, centralised patient data is also a more valuable commodity for data brokers and cyber hackers alike. The proposed changes to the *Privacy Act* currently in review do not address profiling through data sharing. The AMA emphasises this review of AI regulation must incorporate protections against tracking, targeting and profiling by data brokers, major retailers, rental platforms and data-matching firms.

Foundation models

'Foundation models' are the most extensive datasets powering AI, and they are largely unregulated for quality. Often drawn from the internet, these large-scale machine learning models constitute the foundational, versatile building blocks in AI. General, scalable and transferrable, they facilitate the development of a range of applications across different industries.

Examples such as OpenAI's GPT-4 and Google's LaMDA have gained prominence with the rise of generative AI applications like ChatGPT and Bard. These models are owned and employed across national jurisdictions around the world.

The AMA is concerned:

- The vast training datasets are difficult to review, complicating consent, copyright, personal data protection, and liability.
- These models consolidate the power of big tech and raise competition issues. Few technology firms can meet the high computational demands, which means model ownership is concentrated in the hands of large corporate entities.

- The general-purpose nature of these models complicates the allocation of risks and liabilities between end users, foundation model owners and software developers using the foundation models.

The government must consider how Australia's regulatory framework can provide transparency regarding AI applications with software based upon foundation models and ensure liability is apportioned to big tech owners. GPAI model providers should be required to create and publish a detailed summary of the data used in the training of their foundational modelling.

Cyber security

Health data without sufficient cyber protections poses a serious risk to patients' wellbeing and healthcare services. The sensitive and imperishable nature of health information makes it a valuable commodity for software providers and a predictable target for pernicious cyber security attacks. Health data leaks are devastating to the individual and ruinous to health services and technology providers alike.

The AMA calls for implementation of stringent governance and security measures to protect sensitive patient data collected by AI systems. Clear and enforceable regulation underpinning a transparent and accessible legislative landscape is essential to engender the trust of clinicians and consumers who may allow their data to be used within AI systems. Regulation must incorporate cyber security standards for all digital health technologies, to ensure AI applications do not compromise health data.

Patients are the owners of their health data. Healthcare providers, private health insurance providers and clinical software developers/operators are the custodians of patient data, not the data owners. National legislation and regulation must ensure data custodians are only permitted to share data within approved health systems and service providers. Data sharing enables health system interoperability and must be an undergirding principle for the regulatory structure we adopt.

The AMA understands AI products must be permitted to use patient data in the function of their application or a suite of applications. This is essential for the improvement and general accuracy of the AI function. However, data custodians' use of health data within AI applications must adhere to defined usage parameters appropriate to the application and management of data security risks.

Regulations must facilitate full disclosure and patient consent for the use of health data and any AI-generated health information, advice, treatment, or diagnostic procedure to be undertaken. While the patient's information remains in databases it cannot be applied to uses other than what was disclosed to the patient or clinician when it was collected. Regulatory frameworks must also clarify data protocols in the instance when software ownership changes with the sale of a business, a merger, or shareholder-related restructuring. The sale of data must be prohibited between software developers.

As part of a national regulatory response to AI, the AMA recommends the Privacy Act Review adopt national-level digital data privacy and ownership protections, based upon the General Data Protection Regulation (GDPR) models of the EU and UK. Patients must be the assured owners of their health data, and transparency limitations must be imposed to determine how, when and by whom patient data can be accessed.

5. Accounting for AI in healthcare legislation

The AMA sees several regulatory barriers to balancing AI's potential with adequate safeguards. The barriers to successful implementation of AI in healthcare are often the same ones that slow down or disable health system interoperability:

- inconsistent implementation of technical standards, resulting in an inability to integrate information
- divergent policies related to privacy and security that govern electronic health records across jurisdictions.

Current regulation of AI is fragmented, indirect, and inconsistent. Businesses and individuals who develop and use AI are subject to laws relating to privacy, online safety, corporations, intellectual property, data regulation, copyright, and anti-discrimination, which apply to all sectors of the economy. Laws governing AI application in the healthcare sector are currently limited to specific contexts that impact some development and deployment of AI, such as in medical devices.

Legislative amendments must clarify how to integrate AI tools into best practice, establish general standards to guide the development of AI tools, and manage clinical risk. Providers should be required to provide assurances they meet with basic data governance standards and have appropriate insurance. The capacity to scale up regulatory requirements will be required as the functionality and performance of clinical support software over time and incorporates additional AI tools to streamline consultation processes, such as diagnostic supports.

Since legislative requirements across jurisdictions in Australia differ, change must be coordinated through strong engagement from jurisdictional stakeholders to identify potential issues and manage them accordingly. A health advisory body to oversee AI in healthcare could facilitate cohesion across legislative frameworks. The AMA would welcome participation in any such governance body.

6. TGA regulation of medical devices

The TGA is trusted and respected by the medical profession, and as such should expand its current AI regulatory role as much as is feasible. AMA members have expressed support for a TGA-approved list of AI tools to ensure they can be trusted. The challenge is to ensure this does not become too burdensome for the TGA or for developers.

The existing regulation of software-based medical devices under the *Therapeutic Goods Act 1989* provide a sound basis for managing innovation in medical devices. However, amendments to existing TGA regulation may be required to provide oversight of digital products entering the healthcare market. TGA classification rules require clarification to account for AI.

Because the regulatory landscape for AI stretches across multiple legal instruments — including consumer, data protection, competition, copyright, and anti-discrimination law — TGA regulation must address gaps for AI tools used in healthcare. Even if an alternative framework sets accreditation standards equal to or more stringent than TGA regulatory processes, contingencies should be built

into any conditional exemptions to ensure that if, later, the alternative accreditation or regulatory framework is weakened or removed, full TGA regulation automatically resumes.

Definitions and scope

The exclusion of certain software from regulation requires re-evaluation due to the increasing complexity of both medical devices and digital tools used in healthcare. The AMA is particularly concerned the scope of the TGA's regulated devices is too narrow to capture a significant number of AI applications already used in healthcare. The AMA argues even low-risk software can pose patient harm. The scope of regulation should be broadened to ensure AI applications used in clinical contexts are captured under the medical device framework.

The TGA's current definition for 'medical device' is insufficient to ensure the efficacy and safety of healthcare products. The increasing complexity of software used in health and wellness applications is moving these devices from a general information functionality towards incorporating diagnostic tools. Regulation must be flexible to respond to AI applications that begin as general-purpose tools and end as therapeutic goods. Manufacturers require clear direction to interpret if their products qualify as medical devices.

Exempting certain medical devices supports a more streamlined regulatory process for sponsors, which is important to support continued innovation of AI products. However, devices not deemed to be clinical decision support software can change in function over time. While some exemptions may be considered — especially where alternative frameworks like NPAAC exist — these must be carefully assessed to ensure they don't lower safety standards.

The AMA is wary of vague exemptions, especially for clinical decision support software, which could change in function over time. We support ongoing discussions between the TGA and stakeholders to consider how exemptions can be monitored to ensure patient safety.

TGA post-market action against products that fail to meet safety, quality, and performance standards must be swift in responding to reported adverse events. There would need to be resourcing considerations to ensure this does not impede existing regulatory roles.

General purpose AI (GPAI)

General purpose AI (GPAI) will be comprised of increasingly broad-ranging applications that could become threatening interlopers where regulation is concerned. Software developers are attentive to market need but will not design software using AI with clinical boundaries in mind. GPAI is adaptable to a variety of purposes, both direct and integrated with other systems. In healthcare it is difficult to demarcate absolutely the realms of general versus clinical use. GPAI cannot be restricted to administrative (and generally less risky) functions in healthcare.

The AMA asserts that a GPAI tool, when used in the clinical context, must be deemed clinical in function and therefore be subject to regulation. The AMA opposes broad exclusions for software that meet or approximate the definition of a medical device. Non-medical generative AI like ChatGPT is not within the TGA's remit for regulating software-based medical devices. If coordination between government and vendor innovation within clinical systems is insufficient, the use of general-purpose technology for clinical application will likely increase without appropriate oversight.

GPAI is generative AI with the built-in capability to generate content from a database, trained on an ongoing basis by scraping, analysing and processing publicly available data from the internet. When used by medical practitioners, GPAI may also collect and integrate sensitive health data even in routine, administrative functions. Privacy, security and quality considerations apply equally to GPAI as to purpose-built clinical AI systems.

AI scribes provide a case example for GPAI, now broadly adopted by GPs and other practitioners for their considerable time-saving capabilities. They can significantly reduce administrative burden and scribe accuracy will improve over time as additional AI tools are incorporated to streamline consultation processes.

The supportive role GPAI provides to clinical decision making, and the risks associated with inaccuracy or expanded functions requires TGA regulation. This does not need to be onerous at base levels, with providers stating they meet basic data governance standards, have appropriate insurances etc. Some monitoring to ensure compliance will be required.

The proposed AI health advisory body could support the TGA in determining the terms and parameters of an AI tool's use according to its specific function in the clinical context. The TGA's current regulatory mechanisms can differentiate GPAI tools and provide for specific exemptions and exclusions where appropriate.

7. Clinical governance

Human oversight and intervention: Perhaps the most important principle the AMA has enunciated is that final clinical decisions influenced by AI must involve human oversight. AI must never compromise medical practitioners' clinical independence and professional autonomy.

High-impact AI applications require regulated, defined human intervention points during the decision-making process. Healthcare professionals must validate and take responsibility for any decisions made with the assistance of AI tools. Final decision-making cannot be a mere formality. It must reflect meaningful human judgment, ensuring clinical context, patient values, and ethical considerations are taken into account. There is no permissible instance when a clinical decision can be made by AI without direct oversight by a medical practitioner. This principle must be bound in regulatory frameworks for clinical practice.

Mechanism of clinical responsibility

Taking a principles approach engages existing regulation of medical practitioners and embeds responsible AI practice in clinical responsibility. The ultimate decision on patient care should always be made by a human. Regulation should be clear about assigning responsibility for misdiagnosis or mistreatment associated with AI use to the individual medical practitioner. AI applications which influence critical medical decisions (e.g., diagnostic tools, treatment recommendations), receive stricter scrutiny and support the mechanism of clinical judgement tethered to Ahpra and the National Boards' oversight of clinical practice. Legislating to complement these existing mechanisms is an efficient means of supporting medical practitioners using AI to interpret their obligations to patient safety and best clinical practice.

Error reporting mechanisms must be built into processes beyond those of the TGA. This is also an important contributor to the improvement of AI application performance and accuracy over time. A

new conformity assessment should be required for action by deployers on a regular basis to ensure ongoing compliance with standards, perhaps annually.

These arrangements would be more sustainable in the context of contract arrangements between medical practices and digital tool providers. A contractual relationship would support an embedded report and review process and assist both developers and deployers in meeting their standards obligations under the regulations. Developers must be engaged in the ongoing performance assurance process to support development of better AI products and services.

Medical practices and clinicians reserve the individual right to use AI software in providing healthcare services, or not. AI must assist patients to understand when AI is being used in the provision of healthcare and uphold patients' right to make their own informed healthcare decisions.

To safeguard these principles, clinical software using AI must be clearly defined and labelled. This includes disclosure in digital products regarding which inbuilt functions use AI capabilities and those that do not. These requirements should extend to GPAI marketed to medical practitioners and clinical care contexts.

AI applications must communicate to end users where AI generated content is presented or has been used to generate advice or determine a treatment. Through standards, the government can require developers to build this transparency in digital tools. There must be no 'black box'. Full disclosure of AI processes and calculations must be enshrined within AI product regulation for healthcare. This information is essential to support clinicians in reviewing the output in support of clinical determinations and conforming with medical practice standards.

Transparency in digital tools is a prerequisite to holding healthcare professionals responsible for upholding the consumer's right to provide their consent. This should be embedded as best practice with ethical and medical responsibility taken by the medical practitioner.

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Other points

For more information regarding AMA's recommendations around AI, see the AMA Position Statement Artificial Intelligence in Healthcare.

For more detail on the AMA's advice around ADM, see the AMA Submission to Automated Decision Making and AI Regulation (2022).

For more detail on the AMA's advice regarding national regulation of AI, see the AMA Submission to the DISR proposed mandatory guardrails (2024).

See AMA Position Statement on Data Governance and Patient Privacy and AMA Position Statement System Interoperability in Healthcare.