



**Australian Government**  
**Department of Health and Aged Care**

# **Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review**

Public consultation  
September 2024



## Introduction

Artificial Intelligence (AI) can help solve urgent and emerging challenges in our health care system and support the health care workforce dedicate more time to delivering care. However, along with the potential opportunities of AI in health care, there is community concern about the safety and risks of AI. There are concerns that current legislative and regulatory frameworks do not adequately mitigate potential for harm.

There are high-risk use cases for AI in health care. With the rapid rollout and fast pace of innovation of AI, new settings may be required to ensure the safe adoption of AI. The right regulatory settings for AI-powered systems are critical.

In 2023 and 2024, the Australian Government has followed a whole of economy approach on AI, including the Department of Industry, Science and Resources (DISR) consultation on AI in 2023 and publishing a response paper in 2024, as well as a range of AI initiatives across other parts of the economy. The 2024-25 Budget included funding for priority reviews of consumer, privacy and health care laws. As part of this, the Department of Health and Aged Care (the department) is now consulting to clarify and strengthen legislation and regulation for AI in Australia’s health care settings.









With the **Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review** (the Review), the department will consider the [range of legislation](#) that we administer. In doing so, we are considering three critical questions related to the safe and responsible use of AI in Australia’s health and care.

What about AI are we trying to regulate?

Who is affected by AI and related regulation?

How could we regulate to prevent AI harms and to enable benefits of AI?

We are taking a balanced approach to the Review. In the public consultation, we ask that submissions consider the benefits and risks of AI and potential regulatory changes across Australia’s health care system. For example:

							
Clinical care	Billing	Insurance	Digital systems	Consent and Privacy	Health data	Training, literacy, and competency	Liability and responsibility

## Background

The rapid development of commercial AI solutions reveals opportunities for AI to solve urgent and emerging challenges in the Australian health care system. The Productivity Commission’s report [Leveraging Digital Technology in Healthcare](#),<sup>1</sup> suggested automating low-complexity tasks could potentially free up to 30% of clinicians’ time to focus on patient care.

Our work builds on the consultation on AI held by DISR in 2023, and [submissions to the Senate Select Committee on Adopting AI](#) in 2024.

DISR’s [Proposals paper for introducing mandatory guardrails for AI in high-risk settings](#)<sup>2</sup> identified main risk areas that are different for AI: autonomy, general cognitive capabilities, adaptability, speed and scale, opacity and high realism. The government also acknowledged widespread public concern over rapid technological advancements in AI.

<sup>1</sup> Productivity Commission 2024, *Leveraging digital technology in healthcare*, Research paper, Canberra

<sup>2</sup> Department of Industry, Science and Resources (2024). *Proposals paper for introducing mandatory guardrails for AI in high-risk settings*.

Complementary to this public consultation, is the Australian Government proposals paper for introducing mandatory guardrails for AI in high-risk settings. Further information on the proposals paper is available at <https://consult.industry.gov.au/ai-mandatory-guardrails>. Feedback received on this proposals paper will inform the Government's regulatory response to help mitigate the potential risks of AI and increase public trust and confidence in its development and use. We are working closely together with DISR, and while the mandatory guardrails proposals paper takes a whole of economy approach to AI, this consultation covers specific health care aspects of AI.

This means that you don't need to provide your feedback twice, since the scope is different between the two pieces and there is regular exchange of information between DISR and the department about these.

## What do we want to do?

We want to help people in Australia, including consumers and health care professionals, realise better outcomes through AI. To do this, we need to support the safe use of AI and prevent harms occurring from AI in health care settings.

This consultation paper is designed to inform you about the current and potential uses of AI in health care and consult with you on benefits, risks and possible regulatory solutions. Your response is valuable for shaping reforms that will enable the safe use of AI. You will help develop an approach that reflects the diverse views and experiences of Australians, informing all stages of AI development, clinical use and patient care.

## What is the scope of the consultation paper?

This consultation covers the use of AI within healthcare settings in Australia. It also includes consideration of the benefits and risks of AI.

The department is seeking community perspectives on:

- The benefits to be gained by using AI in health care
- The risks of AI to be managed in health care
- Clarity on whether changes are required to ensure safe use – these could be regulatory changes or other kinds of changes such as education or guidelines
- Other effects of AI on people, workflow, health care information, the health care system
- Other perspectives that may not have been highlighted or emerged in the public domain.

*Scenario: A telehealth appointment with a patient where a doctor is using software and wearable technology to make a diagnosis*

### Our consultation

- Patient consent and confidentiality
- Data quality, suitability, storage
- Implications for Medicare
- Medico-legal liability
- Impacts of AI on the doctor using the products and on the patient
- Use of human or automated decision making
- Equity of health access and outcomes
- Sustainability and environmental impacts



### TGA consultation

- What types of software using AI should be regulated
- Clinical and technical evidence needed to demonstrate the safety and performance of the product
- How the regulated AI works

This consultation paper does not cover the use of AI in the department. It also does not cover the regulation of therapeutic goods like software as a medical device (SaMDs). The Therapeutic Goods Administration (TGA) is conducting a [consultation on therapeutic goods and AI](#). While the TGA consultation specifically relates to products that come under the therapeutic goods framework, this overall consultation by the department covers practice and related issues across the whole portfolio of health and aged care.

## What do we mean by AI?

AI refers to software, websites or apps that use mathematics to predict the most likely answer, unlike more traditional software that has rules programmed into it.

In this review, we are using the definitions used by the Department of Industry Science and Resources (DISR) in their [mandatory guardrails](#) paper<sup>2</sup> as:

*“AI system: a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.”*

**Machine learning** are the patterns derived from training data using machine learning algorithms, which can be applied to new data for prediction or decision-making purposes.

**Generative AI models** create novel content such as text, images, audio and code in response to prompts.

## What does AI look like in health care in Australia?

AI is already being used in a range of ways in Australian health and care settings. While some examples have been outlined below, there are numerous other ways that AI may be used in health and care settings.

- Cancer screening: analyse images to detect cervical, breast and prostate cancer.
- Aged care homes: AI robots for companions and for monitoring.
- Scribes: generative AI is used to listen in on patient visits to their general practitioner (GP) to automatically generate notes, care plans and orders for tests.
- Clinical decision support: combine information about diseases and treatment pathways and suggest diagnoses and tests from entering patient symptoms.
- Chatbots: assist in finding information on health care websites.
- AI in surgical tools: help detect polyps in screening for colon cancer, or to assist in surgery.
- Skin checks: analyse photographs to check skin health, detect melanoma or other skin cancers.
- AI in medical records: analyse risks to patients, to predict bed usage or surges on the healthcare system.

New AI products are constantly being developed and used within healthcare settings. While these new products and uses have benefits, they also introduce new risks.

## Tell us about AI in health care

This public consultation provides an opportunity for all stakeholders to share their views and contribute to the review of legislation and regulation for Safe and Responsible Artificial Intelligence in Health Care.

### What benefits will AI have for healthcare consumers and providers?

The Productivity Commission *Leveraging digital technology in healthcare research report*<sup>3</sup> found that the health care sector has the most potential to benefit from AI adoption.

The clinical opportunities now and into the future for AI to benefit the Australian healthcare system are broad, spanning diagnosis to monitoring to drug discovery and research.

For consumers, AI might assist in navigating an increasingly complex healthcare system, allow for real time language translation into a preferred language and use of health care outside of traditional business hours. Populations with the greatest potential to benefit from AI, include people in regional communities, shift workers and those who speak languages other than English who may have difficulty using services<sup>4</sup>.

For healthcare providers, AI may support the provision of quality health care by reducing the human factors that can impact patient safety, such as fatigue, burn-out and cognitive biases<sup>5</sup>.

1. **How can AI benefit health and care in Australia and how can we measure and deliver these benefits?**
2. **Can AI improve access to care, and what regulations could be amended or added to enable this?**

### Are there specific risks to using AI in health care?

Health care is often considered a high-risk use case for AI due to its direct impact on patient safety<sup>6</sup>. However, should all AI-driven services or support in health care be considered high-risk?

In the Government's *interim response to the Safe and responsible AI in Australia consultation*<sup>8</sup> it is defined high risk defines AI in health care as high risk, as the harm caused by AI in this setting can be difficult or impossible to reverse. The [Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings](#)<sup>7</sup> released by DISR on 5 September 2024, seeks further consultation on a principles-based approach to defining high-risk AI and a definition to capture general-purpose AI models.

In healthcare settings, AI must be used safely with the right regulatory approach. Meanwhile, AI should be able to continue to grow and deliver efficiency and productivity gains in low-risk settings.

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<sup>3</sup> Productivity Commission 2024, *Leveraging digital technology in healthcare*, Research paper, Canberra

<sup>4</sup>Arora, A., Alderman, J.E., Palmer, J. et al. The value of standards for health datasets in artificial intelligence-based applications. *Nat Med* 29, 2929–2938 (2023). <https://doi.org/10.1038/s41591-023-02608-w>

<sup>5</sup> Brown C, Nazeer R, Gibbs A, Le Page P, Mitchell AR. Breaking Bias: The Role of Artificial Intelligence in Improving Clinical Decision-Making. *Cureus*. 2023 Mar 20;15(3):e36415. doi: 10.7759/cureus.36415. PMID: 37090406; PMCID: PMC10115193

<sup>6</sup> Department of Industry, Science and Resources . (2024). Safe and responsible AI in Australia consultation - Australian Government's interim response. i

<sup>7</sup> Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings, September 2024, Australian Government Department of Industry, Science and Resources.

The use of AI-enabled robots for medical surgery<sup>8</sup> and AI systems prioritising emergency health care services<sup>8</sup> will also fall under high-risk categorisation. Some examples of low-risk could be helping people to find their way around a hospital campus, and chatbots to help find content on websites.

### 3. What risk does AI pose to patients/consumers or healthcare professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?

In Australia, people have varying degrees of access to AI and to health care due to various factors that affect health. These include social, environmental, structural, economic, cultural, biomedical, commercial, and digital influences in our lives, work, and aging<sup>9</sup>.

[Australia's 8 Artificial Intelligence \(AI\) Ethics Principles](#) are a voluntary framework that can help build frameworks that ensure designed to ensure AI is safe, secure and reliable for all Australians.

**Human, societal and environmental wellbeing:** AI systems should benefit individuals, society and the environment.

**Human-centred values:** AI systems should respect human rights, diversity, and the autonomy of individuals.

**Fairness:** AI systems should be inclusive and accessible, and should not involve or result in unfair discrimination against individuals, communities or groups.

It is crucial to consider the potential for AI to perpetuate societal injustices and have a disproportionate impact on vulnerable and underrepresented groups, such as those based on age, disability, race, sex, gender identity, and sexual orientation<sup>10</sup>.

### 4. What factors are important for rural, regional or remote Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI in health care? What considerations should be made to ensure all Australians have access to the benefits of AI?

Research has shown that experienced health care providers trust their knowledge and expertise more than an AI system<sup>11</sup>. Additionally, there is automation bias, which is the tendency for humans to rely too much on decision support systems and delegate their responsibilities to them rather than remaining vigilant<sup>12</sup>. Healthcare providers who are short on time may be more susceptible to these biases and follow automated guidance without verifying it, which could pose risks to patient outcomes if the AI system makes a mistake. This potential risk could be reduced by promoting AI literacy among healthcare providers.

### 5. Should health care professionals have a choice about whether they use AI as part of their work?

<sup>8</sup> Artificial Intelligence Act (Regulation (EU) 2024/1689), Official Journal version of 13 June 2024'. Interinstitutional File: 2021/0106(COD)

<sup>9</sup> Department of Health and Aged Care 2021, National Preventive Health Strategy 2021–2030 Strategy paper, Canberra

<sup>10</sup> Australian Government (2022). Australia's AI Ethics Principles. [online] Industry.gov.au.

<sup>11</sup> Lambert, S.I., Madi, M., Sopka, S. et al. An integrative review on the acceptance of artificial intelligence among healthcare professionals in hospitals. *npj Digit. Med.* 6, 111 (2023). <https://doi.org/10.1038/s41746-023-00852-5>

<sup>12</sup> Goddard, K., Roudsari, A., & Wyatt, J. C. (2012). Automation bias: a systematic review of frequency, effect mediators, and mitigators. *J Am Med Inform Assoc*, 19(1), 121-127. doi:10.1136/amiajnl-2011-000089



## What are the possible regulatory changes?

The rapid development and increasing presence of AI in health and aged care settings pose novel challenges that call for thoughtful regulation. Regulation can be targeted at different entities in health and aged care to achieve different results. For example, AI regulation could be targeted at:

- Clinicians and how they use AI to perform their jobs
- Organisations that deploy AI to increase the performance of their health or aged care services
- Software vendors who create AI models and tools
- Organisations who collect, use or sell health data which is used in the development of AI tools. This may be Government, hospitals, universities or private companies.
- Liability when there is misuse or adverse events when using AI
- AI suggesting treatment pathways formulated to maximise billing or claiming.

These entities already need to comply with existing rules, for example, our existing laws around privacy and medical negligence will continue to determine how data can be used and the standard of care which must be provided.

In some cases, it may already be clear how existing rules and standards will apply to AI. In other cases, it may be helpful to clarify how these rules will apply to AI, or to create new rules to accommodate novel aspects of AI use.

A combination of different regulatory tools will likely be needed to adequately support the safe use of AI in health and aged care settings. Some options for regulatory approaches are:

- Update existing laws: current laws may be amended to fill gaps and create new rules for specific AI issues or provide clarification on how these laws apply to the use of AI in health and care.
- Introduce new laws: new legislation may be required to set general standards for AI development and oversight. These laws could be for all industries, just for health and aged care, or specific types of AI (like generative AI).
- Create a regulatory body: an independent body could be established to monitor and enforce AI rules or performance in health and aged care settings.
- Non-regulatory changes:
  - Create a new certification scheme for AI-based which can be used in health and aged care settings. This could be a quick way for clinicians and patients to identify whether a product has met certain standards. Home energy ratings operate in a similar manner.
  - Develop policies/procedures/standards: non-legislative policies, procedures and standards may be enough to ensure AI tools are safe, effective and secure. It is easier to change and adapt these types of rules rather than legislation, enabling more flexibility as AI continues to develop.
  - Publish guidelines for the use of AI in certain health or aged care settings.
  - Develop guidance resources for the technology industry that develops AI products.
  - Provide education and training: training programs for health and care professionals can support the effective use of AI tools.
  - Boost public AI information: initiatives to increase understanding of AI among the public can help patients and healthcare consumers engage with AI safely and effectively.

6. **What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?**
7. **How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?**
8. **Should there be an Australian body specifically dedicated to overseeing AI in health care?**

The Department of Health and Aged Care portfolio [administers many laws](#) on behalf of our ministers including the *Health Insurance Act 1973*, *National Health Act 1953*, and the *Medical Indemnity Act 2002*.

9. **Are there any specific changes to existing health care laws that would address AI-related harms or help AI to be used safely?**
10. **Which international approaches should we consider, if any, that are specific to health care?**

## Is AI always right?

AI is often presented as an assistant or a way to support the work of health care professionals. However, it is also capable of making decisions or automating workflows that are currently performed by humans. AI outputs can fast track answers or patterns that humans may find difficult to see but also introduce new risk.

AI is trained on, or learns from, very large amounts of data. The way AI arrives at answers is difficult to explain or break down, in part due to the size of data used, and also due to reluctance to reveal proprietary information by the producers of AI.

AI operates in a way that may produce varying answers to a question. Occasionally, AI may provide incorrect or made-up responses, called "hallucinations." This occurs because AI uses mathematical techniques based on probability, meaning it guesses the most probable answer.

As a result, errors are difficult to find and to understand why they have occurred.

Generative AI, like ChatGPT or Claude, tends to quickly produce fluent and polished responses to questions that look very plausible. This is one of the main advantages, but it also makes it difficult to identify errors in the response.

Some studies have shown that AI products in health care can be biased, leading to errors in diagnosis<sup>13</sup>. Efforts are being made internationally [to improve the diversity and quality of data](#) that is used to develop AI, with the goal of increased accuracy and less bias.

### Human in the Loop

Means where a person is always involved to review, control or make a decision. This may need to be an expert or clinician for health use.

11. **Should humans be able to overrule a finding or decision made by AI?**

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<sup>13</sup> Ahmed MI, Spooner B, Isherwood J, Lane M, Orrock E, Dennison A. A Systematic Review of the Barriers to the Implementation of Artificial Intelligence in Healthcare. *Cureus*. 2023 Oct 4;15(10):e46454. doi: 10.7759/cureus.46454. PMID: 37927664; PMCID: PMC10623210.



**12. Should there always be a person or “human in the loop” to make decisions or deliver a healthcare service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?**

**13. Should errors made by AI be reported? If yes, how should they be reported?**

## How should healthcare data and transparency be managed for AI use?

It is not always visible when AI is being used for ambient listening, within a website or app, or to do analysis in the background. Ambient listening means that sounds are being recorded in the background, for example, throughout a consultation with a patient.

Reports and results can be generated by AI, without any disclosure that AI is the source or part of the process. It may not be apparent to clinicians or consumers when AI is being used. It may also not be clear that consumer data is being captured by the AI product and used for another purpose, such as developing new AI products for commercial use.

**14. Should there be transparency about when AI is involved in health or care, and should consent be requested from the consumer or healthcare professional?**

Many AI tools have been developed for general use (such as ChatGPT) yet are being used in a health care setting. This means they have been developed without the usual controls and validation that would be applied to a medical or health care products.

Some AI tools available for healthcare practitioners are designed specifically for health care and have been developed for a therapeutic purpose. Some professions are increasingly using new AI such as medical scribing tools to support workload management<sup>14</sup> and efficiency in practice to develop or edit documents.

**15. Generative AI may be developed for general use, yet used in health care. Should generative AI have any special treatment, regulatory or otherwise?**

At present, the majority of AI is produced or operated by overseas organisations and delivered through the cloud, although there are Australian developers of AI. This means that:

- The AI product is based on data from other countries or demographics and may not be representative of our diverse Australian population. In turn, this means it may be biased or less accurate when used in an Australian context.
- Your data may be sent or stored overseas as part of how the AI does its work and may also be used for companies to develop new products for commercial use.
- It may not be clear who has access to the data or what it is used for.
- Additionally, you may not be able to see if AI is part of a website or software as it is not always visible.

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<sup>14</sup> Ghatnekar S, Faletsky A, Nambudiri VE. Digital scribe utility and barriers to implementation in clinical practice: a scoping review. *Health Technol (Berl)*. 2021;11(4):803-9.

Management of patient privacy and consent when collecting, sharing, storing, and using sensitive health care data is a critical consideration. AI technologies that use sensitive healthcare data to train and refine models, require explicit consent from a consumer in line with the *Privacy Act 1988*.

**16. What protections are needed for patient data used or generated by AI that are different for health care?**

**17. Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?**

**18. Should your healthcare information be kept in Australia?**

**If yes, would your view change if this reduced ability to access advances in AI made overseas?**

**19. Are there any specific safety considerations that have not been raised elsewhere?**

## Your submission matters

It is essential to have effective regulation, promote best practices, and educate about the responsible use of AI to secure its benefits for the Australian community. Understanding and developing frameworks and mitigations for health-specific risks will support the use of AI in a safe and responsible way.

Your submissions will help create an evidence base for reform with options that balance relevant social and economic interests. This crucial next step will help to minimise harm while enabling benefits from AI in the Australian healthcare system.

## How to respond

You are welcome to answer as many or as few of the consultation questions as you wish, and to raise any additional matters relating to this subject.

The department welcomes all feedback, including additional measures or proposals to address the content outlined in this paper.

Please submit your responses through [the consultation hub](#) for Safe and Responsible Artificial Intelligence in Health Care or via email to [DigitalFutures@health.gov.au](mailto:DigitalFutures@health.gov.au) by 14 October 2024.

If you wish to submit a response in a non-written format, such as a voice recording, please email us at [digitalfutures@health.gov.au](mailto:digitalfutures@health.gov.au)

## Consultation questions

We invite stakeholders to provide input by responding to the following questions:

1. How can AI benefit health care in Australia and how can we measure and deliver these benefits?
2. Can AI improve access to care, and what regulations could be amended or added to enable this
3. What risk does AI pose to patients/consumers or health care professionals? Are the risks high or low? What criteria could be used to characterise risk? Should consumers be informed when AI is used in these low-risk ways?
4. What factors are important for rural and regional Australia when assessing the benefits, risks, and safety of AI? Are there other communities that face specific risks when implementing AI-driven health care? What considerations should be made to ensure all Australians have access to the benefits of AI?
5. Should health care professionals have a choice about whether they use AI as part of their work?
6. What unique considerations are specific to AI in health care, and why? Should the government address them through regulatory change?
7. How does the use of AI differ in healthcare settings compared to general or other sectors such as finance, education, etc.?
8. Should there be an Australian body specifically dedicated to overseeing AI in health care? If so, how would this body differ from a broader organisation like the National AI Centre?
9. Are there any specific changes to existing healthcare laws that would address AI-related harms or help AI to be used safely?
10. Which international approaches should we consider, if any, that are specific to health care?
11. Should humans be able to overrule a finding or decision made by AI?
12. Should there always be a person or “human in the loop” to make decisions or deliver a health care service? Are there any circumstances in which it would be acceptable to have fully automated health or care decisions made by an AI product?
13. Should errors made by AI be reported? If yes, how should they be reported?
14. Should there be transparency about when AI is involved in health care, and should consent be requested from the consumer or health care professional?
15. Generative AI may be developed for general use, yet used in health care. Should generative AI developed have any special treatment, regulatory or otherwise?
16. What protections are needed for patient data used or generated by AI that are different for health care?
17. Is it acceptable for developers of AI products to use patient data to develop their products or to sell patient data collected from use of AI?
18. Should your healthcare information be kept in Australia? If yes, would your view change if this reduced ability to access advances in AI made overseas?
19. Are there any specific safety considerations that have not been raised elsewhere?