AUDIT FINDINGS

Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)

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Three structural findings against Australian regulatory frameworks

1. Auditing Organisation

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2. Document Under Audit

Title	Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy
Version	Version 2 (2025) (“AusPATH SOC 2025”)
Publication Date	30 April 2026
Publishing Body	Australian Professional Association for Trans Health (AusPATH)
Scope	Adults aged 18 years and over; the document defers care of those under 18 to the Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents (p.9)
Audit Date	11 June 2026

3. Audit Methodology

This audit applies documentary analysis only. Each finding is verifiable from the document itself by reading the page reference cited. No contested empirical or clinical claims about gender-affirming care are required for any finding to be sustained.

The Australian regulatory frameworks against which the document is tested include:

- National Health and Medical Research Council Standards for Clinical Practice Guidelines
- Australian Commission on Safety and Quality in Health Care (ACSQHC) informed consent framework, comprising the clinician fact sheet "Informed consent in health care" (September 2020) and the practical guidance documents "Informed consent: practical guidance for clinicians," "for patients," and "for substitute decision-makers" (May 2026)
- Rogers v Whitaker (1992) 175 CLR 479 – material risk disclosure standard
- AHPRA Good Medical Practice: A Code of Conduct for Doctors in Australia 2020
- Australian Consumer Law s.18 (misleading or deceptive conduct in trade or commerce)

These frameworks apply to clinical practice in Australia regardless of whether the document under audit cites them. The audit asks whether the document under audit satisfies, engages with, or specifies processes adequate to satisfy the requirements of those frameworks. Where it does not, the finding rests on the document's own text and the framework's settled requirements, both check-able independently.

Three findings are presented. Each is independently sufficient. Each finding stands on its own.

Finding 1 — Internal inconsistency between the cited ACSQHC definition and the operational model

Statement

AusPATH SOC 2025 cites the Australian Commission on Safety and Quality in Health Care (ACSQHC) definition of informed consent on p.12 and, on the same page, describes an operational "informed consent model" that does not specify processes aligned with the matters the ACSQHC definition requires. The cited definition and the operational model both appear on p.12 and can be read in sequence. The two passages cannot both be true descriptions of the same practice; the document is internally inconsistent on its central concept.

Evidence

Under the heading "Informed consent model of care" at p.12, AusPATH SOC 2025 first quotes the ACSQHC definition verbatim:

> *"A person's decision, given voluntarily, to agree to a health care treatment, procedure or other intervention that is made following the provision of accurate and relevant information about the healthcare intervention and alternative options available; and with adequate knowledge and understanding of the benefits and material risks of the proposed intervention relevant to the person who would be having the treatment, procedure or other intervention."* (p.12, quoting ACSQHC)

The ACSQHC clinician fact sheet "Informed consent in health care" (September 2020) sets out, under the heading "For there to be valid informed consent, the person consenting must:", four matters: have the legal capacity to consent; give their consent voluntarily; give their consent to the specific treatment, procedure or other intervention being discussed; and have enough information about their condition, treatment options, the benefits and risks relevant to them, and alternative options to make an informed decision. The ACSQHC has subsequently issued (May 2026) practical guidance for clinicians that specifies the requisite information includes:

> *"the expected outcomes, benefits, risks and alternative options, relevant to that person, including: doing nothing; watching and waiting; and/or lifestyle interventions."* (ACSQHC, May 2026 — Informed consent: practical guidance for clinicians)

AusPATH SOC 2025 then describes its operational model on the same p.12:

> *"Under this model, the threshold for initiation of GAHT is simply informed consent. Mental health professionals still play an important role but are engaged when requested by the individual or when significant coexisting mental health concerns require management before initiating hormonal care. This model separates supportive mental health care from the assessment of gender incongruence."* (p.12)
>
> *"As GPs, our role is to facilitate and respect these choices."* (p.12)

The operational model does not specify processes for two matters that the cited ACSQHC definition contains and that the May 2026 ACSQHC guidance enumerates. First, alternatives. The document does not present alternatives to gender-affirming hormone therapy. The terms "exploratory therapy," "watchful waiting," and "no treatment" as a clinical option do not appear in the document. Mental health support is positioned as adjunct to GAHT, not as an alternative pathway. Mental health conditions are explicitly excluded as contraindications:

> *"Mental health conditions, including eating disorders and neurodiversity, are not contraindications for initiating GAHT under the informed consent model."* (p.20)

Second, verification of adequate knowledge and understanding. The document specifies no process by which the clinician verifies that the patient has "adequate knowledge and understanding of the benefits and material risks" beyond tick-box acknowledgements in the Appendix B consent forms.

Both passages appear on p.12 of the document. The document quotes the ACSQHC definition at the top of the section and then describes a model that does not specify processes aligned with the matters that definition contains.

Regulatory significance

The ACSQHC informed consent framework is the standard incorporated into the National Safety and Quality Health Service Standards and recognised in the Australian Charter of Healthcare Rights. AusPATH SOC 2025 cannot simultaneously cite the ACSQHC definition as authoritative and describe an operational model that does not specify processes aligned with the matters that definition contains. The internal inconsistency is documentary and uncontested: both passages appear on p.12 and can be read in sequence. Either the cited definition is being used as a rhetorical citation while the operational model departs from it, or the operational model is incomplete relative to its own cited standard. In either case, services that follow the AusPATH operational model cannot, as a matter of structure rather than implementation, deliver informed consent as the ACSQHC defines it.

The strength of this finding is that it does not require the audit to take a view on whether gender-affirming hormone therapy is or is not clinically appropriate. It rests entirely on the document's own text against the document's own cited standard.

Finding 2 — Structural impossibility of satisfying the ACSQHC capacity principles under the AusPATH model

Statement

The ACSQHC clinician fact sheet "Informed consent in health care" (September 2020) specifies, under the heading "Principles for assessing legal capacity," six matters a person must be able to do for legal capacity to make a particular decision. The fifth matter requires the person to "weigh up the consequences of those choices, including the choice to refuse treatment." Weighing the choice to refuse treatment presupposes that an alternative to the proposed treatment is available and has been presented. AusPATH SOC 2025 presents no alternative to gender-affirming hormone therapy across the body of the document. The fifth matter is therefore structurally unmeetable under the AusPATH operational model — not occasionally unmet through implementation failure, but unmeetable in principle because the antecedent condition (presented alternatives to weigh) does not exist.

Evidence

The ACSQHC clinician fact sheet (September 2020) states that a person has legal capacity to make a particular decision when they are able to do all of the following: understand the facts involved; understand the treatment choices; understand how the consequences of treatment affect them; retain the information and recall the details; weigh up the consequences of those choices, including the choice to refuse treatment; and communicate their decision and understanding of its implications. The fact sheet specifies all six matters are required ("able to do all of the following"), not a subset. Material risks are defined in footnote 1 of the fact sheet by reference to Rogers v Whitaker (1992) 175 CLR 479.

The ACSQHC has subsequently issued (May 2026) practical guidance for clinicians that specifies the requisite information for informed consent includes:

> *"the expected outcomes, benefits, risks and alternative options, relevant to that person, including: doing nothing; watching and waiting; and/or lifestyle interventions."* (ACSQHC, May 2026 — Informed consent: practical guidance for clinicians)

AusPATH SOC 2025 does not present alternatives to gender-affirming hormone therapy. Mental health support is positioned as adjunct to GAHT, not as an alternative pathway. The document explicitly frames the clinician role as facilitative:

> *"Under this model, the threshold for initiation of GAHT is simply informed consent. Mental health professionals still play an important role but are engaged when requested by the individual or when significant coexisting mental health concerns require management before initiating hormonal care. This model separates supportive mental health care from the assessment of gender incongruence."* (p.12)
>
> *"As GPs, our role is to facilitate and respect these choices."* (p.12)

Mental health conditions are explicitly excluded as contraindications:

> *"Mental health conditions, including eating disorders and neurodiversity, are not contraindications for initiating GAHT under the informed consent model."* (p.20)

The terms "exploratory therapy," "watchful waiting," and "no treatment" as a clinical option do not appear in the document. A patient cannot weigh the choice to refuse treatment in favour of an alternative when no

alternative has been offered for weighing. A clinician cannot verify that a patient has weighed alternatives when the clinician has not presented any. The capacity assessment required by ACSQHC therefore cannot be completed in respect of the fifth matter within the AusPATH model. The May 2026 ACSQHC practical guidance for clinicians enumerates the specific alternatives ("doing nothing," "watching and waiting," and lifestyle interventions) the document does not present.

Regulatory significance

Where one of the ACSQHC capacity principles cannot be structurally satisfied under a protocol, valid consent under that protocol is structurally compromised. This is not an argument about whether individual clinicians do or do not properly assess capacity in practice. It is an argument that the protocol they are instructed to follow does not contain the inputs (presented alternatives) required for one of the six capacity matters to be completed. The implication is that any prescription of GAHT undertaken in accordance with the AusPATH SOC 2025 informed consent model is exposed to the argument that the fifth matter of the ACSQHC capacity principles could not have been satisfied on the available information, because no alternative was presented for the patient to weigh.

This exposure exists independent of the clinician's intention or care, and is sharpened by the May 2026 ACSQHC practical guidance, which now explicitly enumerates "doing nothing" and "watching and waiting" as alternatives that informed consent discussions must include. Both the 2020 and May 2026 ACSQHC documents remain live and complementary; the 2020 fact sheet provides the legal grounding (Rogers v Whitaker, capacity principles); the May 2026 guidance provides the operational enumeration of alternatives that must be discussed.

Finding 3 — Failure to disclose material risks within the meaning of Rogers v Whitaker in Appendix B consent forms

Statement

The Australian legal standard for disclosure of material risks is set by Rogers v Whitaker (1992) 175 CLR 479, which the ACSQHC fact sheet incorporates by reference in footnote 1. A risk is material if a reasonable person in the patient's position would likely attach significance to it. The two consent forms in Appendix B of AusPATH SOC 2025 — the oestradiol-based GAHT consent form (commencing p.72) and the testosterone-based GAHT consent form (commencing p.74) — do not disclose the findings of the major contemporary independent systematic reviews characterising the evidence base for gender-affirming hormone therapy as low or very low certainty for many outcomes. The forms also omit categories of risk that a reasonable person in the patient's position would likely attach significance to.

Evidence

The two consent forms in Appendix B list named physical effects in four tick-box categories: permanent changes; reversible changes; side effects; and potential risks. The testosterone form, for example, lists potential risks including polycythaemia, increased risk of stroke, new or worsened obstructive sleep apnoea, and similar items. Both forms include the general formulation:

> *"Research is ongoing to fully understand the extent and likelihood of these risks. My provider will continue to monitor my health and address any issues that develop."* (Appendix B consent forms)

No reference is made anywhere in either consent form to the following matters that, on the Rogers v Whitaker test, a reasonable person in the position of a patient considering gender-affirming hormone therapy would likely attach significance to:

- The findings of the Cass Review (final report, April 2024) commissioned by NHS England, which characterised the evidence underpinning gender-affirming hormone therapy in adolescents and young adults as of low quality and called for major reform of the model of care.
- The University of York systematic reviews (2024) commissioned to support the Cass Review, which graded the certainty of evidence for outcomes of cross-sex hormones as low or very low for the majority of outcomes assessed.
- The United States Department of Health and Human Services Review ("Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices," May 2025), which characterised the evidence base as poor and called into question the affirmative model of care.
- GRADE certainty-of-evidence ratings published in the systematic reviews, which are the standard methodology by which evidence quality is communicated to patients in informed consent.
- Detransition rates as reported in the contemporary literature.
- Persistence of mental health comorbidities post-treatment.
- Lifelong medical dependency (the requirement for ongoing hormone therapy, monitoring, and management of complications across the patient's lifespan).

These categories are not contested empirical claims; they are documented in the named systematic reviews and government-commissioned evidence assessments. Their absence from the AusPATH SOC 2025 consent forms is verifiable on inspection of Appendix B.

A reasonable person in the position of a patient considering gender-affirming hormone therapy — particularly given the irreversibility of some changes acknowledged on the consent forms themselves (e.g., enlargement of erectile genital tissue, deepened voice, increased facial and body hair under testosterone) — would likely attach significance to the existence of government-commissioned systematic reviews characterising the underlying evidence as low or very low certainty. This is not a contested clinical claim; it is the Rogers v Whitaker test applied to documented facts about what AusPATH does and does not include in its consent process.

Regulatory significance

The Rogers v Whitaker standard is settled Australian law incorporated into the ACSQHC informed consent framework. Clinicians using the AusPATH SOC 2025 consent forms in their published form are providing patients with risk information that omits material findings from the current systematic reviews. This omission is reproducible and verifiable — the systematic reviews are named and published, and the consent forms are reproduced in full in Appendix B. The exposure is to civil liability for breach of duty of care under Rogers v Whitaker, regulatory action by AHPRA under the Code of Conduct (which requires the provision of accurate information about treatment options), and consumer protection action under the Australian Consumer Law (ss 18 and 29) for misleading conduct by omission where services represent the consent process as comprehensive.

The strength of this finding, like the other two, is that the absence is documentary and verifiable on inspection. The systematic reviews are named and published; the consent forms are reproduced in

Appendix B; the omission can be confirmed by a reader in minutes. No view on contested clinical questions is required for the finding to be sustained.

How the three findings relate

Each finding is independently sufficient. If only Finding 1 were correct, the document would be internally inconsistent on its central concept and could not be relied upon as a clinical standard. If only Finding 2 were correct, valid consent under the protocol would be structurally compromised in respect of one of the ACSQHC capacity principles regardless of how the document is read. If only Finding 3 were correct, every service using the appended consent forms would be exposed to Rogers v Whitaker liability for omission of material risks.

Compounded, they describe a document that (a) misrepresents its own concept by citing a standard whose operational matters it does not specify processes for, (b) prescribes a model in which one of the ACSQHC capacity principles cannot be operationally satisfied because no alternative is presented for the patient to weigh, and (c) supplies consent forms that omit material risks within the meaning of Rogers v Whitaker. These are three distinct points of regulatory failure on the same documentary record.

If a single finding were to lead a regulatory submission, Finding 3 is the strongest in regulatory terms because it converts directly into Rogers v Whitaker exposure that AHPRA, the Medical Board, and the ACCC can each act on under their own jurisdictions without needing to take a view on contested clinical questions. Finding 1 is the strongest for parliamentary or NHMRC engagement because it sits squarely on the document's own face. Finding 2 is the strongest in technical regulatory terms because it identifies a structural impossibility rather than an implementation failure, which is harder for the document's authors to remediate without restructuring the model itself.