Assessment of Public Website Materials – Informed Consent Compliance Assessment

Clinic Name:	**Kaleido Health Centre (ACON Health Centre Limited)**
Home Page:	https://kaleidohealth.org.au/
Audit Period:	Website content retrieved May 5-8 2026
Auditor:	Catherine Anderson-Karena – Independent Test Analyst
Audit ID / Version:	KHC-AHPRA-2026-01 (v1.4)
Clinic Type:	GP-led primary care; LGBTQ+ health service (NSW government funded)
Date of Charter:	May 15 2026

INFORMED CONSENT COMPLIANCE ASSESSMENT

- Health Practitioner Regulation National Law (the National Law) Section 133
- AHPRA's Guidelines for advertising a regulated health service (December 2020)

Objectives

- To assess compliance with section 133 of the Health Practitioner Regulation National Law and AHPRA's Guidelines for advertising regulated health services.
- To identify representations or omissions in public-facing advertising materials that are false, misleading or deceptive; offer inducements without stating terms; use testimonials; create unreasonable expectations of benefit; or encourage unnecessary use of services (Section 133 of the National Law)
- To provide factual, evidence-based findings suitable for regulatory consideration (AHPRA primary pathway).
- This assessment supplements the primary ACL audit (KHC-ACL-2026-01) under Australian Consumer Law sections 18 and 29, by examining the same website materials against AHPRA advertising standards as the regulatory frameworks significantly overlap: both require that consumers receive accurate, balanced information to make informed healthcare decisions.

Scope

- **In scope:** All publicly accessible pages, navigation, and advertising content on https://kaleidohealth.org.au/ as at May 5-8 2026. Allpages were archived earlier, but no changes from late April to early May.
- **Out of scope:** Internal clinical records, patient-specific consent forms, or direct observation of clinical practice. This assessment focuses on public-facing advertising material.
- **Explicit exclusions:** Broader policy analysis is addressed separately for enforcement recommendations only.

Criteria

- Section 133 of the Health Practitioner Regulation National Law (the National Law) – prohibitions on false, misleading or deceptive advertising.
- AHPRA's Guidelines for advertising a regulated health service (December 2020).

- Relevant evidence syntheses on materiality of disclosures (see Appendix A).

Methodology

Context-driven exploratory website testing plus systematic navigation and content audit/compliance review against section 133 criteria. All findings are evidence-based (screenshots, archived pages, date-stamped retrieval). ISO 19011 principles applied for objective evidence collection.

Independence & Competence

Independent external analyst, BBST qualified and a lead AST Instructor. Compliance assessment/audit conducted without funding or direction from any interested party.

Reporting

Findings will be presented factually with linked evidence. Limitations will be stated. Recommendations will be proportionate and focused on corrective disclosure.

Approval

Analyst:  *Date: 15 May 2026*

Catherine Anderson-Karena,

Founding Director, Active Watchful Waiting Inc, Independent Test Analyst, Test-Ed

Table 1: High-Priority Evidence Sources on Evidence Quality and Psychiatric/Mental Health Outcomes in Adolescent Gender Medicine

(Used to establish materiality of disclosures under ACL ss 18 & 29, Section 133 National Law, AHPRA guidelines)

Source & Year	Type	Key Findings Relevant to Informed Consent	Evidence Quality / Certainty
Cass Review (Final Report) 2024[i]	Independent systematic evidence review (NHS England)	Low/very low certainty evidence for benefits of puberty blockers and cross-sex hormones on mental health, gender dysphoria, or long-term outcomes; recommends holistic assessment and cautions against routine medical pathways.	Systematic; GRADE-like appraisal
U.S. HHS "Treatment for Pediatric Gender Dysphoria" 2025[ii]	Umbrella review of evidence & best practices	Very low certainty of long-term benefits; sparse and weak harms reporting; absence of detected harm ≠ evidence of safety; highlights methodological limitations (observational designs, short follow-up, high loss-to-follow-up).	Comprehensive umbrella review
York / Archives of Disease in Childhood systematic reviews 2024[iii]	Two independent systematic reviews (puberty suppression & adolescent hormones)	No high-quality comparative studies; evidence is low/very low certainty for mental health, cognitive, fertility, sexual function, and cardiometabolic outcomes; puberty is suppressed as intended but downstream effects remain inconclusive.	Systematic reviews (commissioned by NICE/Cass process)
Ruuska et al. Acta Paediatrica 2026[iv]	Nationwide Finnish register study (n = 2,083 gender-referred adolescents + 16,643 matched controls, 1996–2019)	Psychiatric morbidity markedly higher than controls both before (45.7% vs 15.0%) and ≥2 years after referral (61.7% vs 14.6%). Needs increased significantly post-medical gender reassignment (e.g., 9.8% → 60.7% in feminising pathway; 21.6% → 54.5% in masculinising). Later cohorts (post-2010) showed greater psychiatric needs. Adjusted hazard ratios remained 3–6× higher than controls regardless of medical intervention.	High-quality register-based cohort with long follow-up; mandatory national data

These key sources establish that risks, uncertainties, and psychiatric outcome data are material information a reasonable consumer (including parents of minors) requires for informed decision-making. See **Appendix B—** For **specific** evidence criteria used to construct the informed consent checklist for medical risks & harms.

Regulatory Context and Legal Framework

AHPRA Advertising Standard for Medical Website Compliance

From Compliance Guidance:

Under AHPRA's advertising framework, a medical website is not compliant merely because it avoids obvious falsehoods; it must avoid misleading overall impressions created by omission, selective evidence, minimised risks, unqualified benefit claims, testimonials, urgency framing, or unsupported claims likely to influence healthcare decisions.

"*4.1 False, misleading or deceptive advertising*[1]

133 (1) A person must not advertise a regulated health service, or a business that provides a regulated health service, in a way that—

(a) is false, misleading or deceptive or is likely to be misleading or deceptive

Advertisers must not make false, misleading or deceptive claims in their advertising. To avoid being misleading and deceptive when advertising, advertisers should aim for the following:

- *sell your professional services on their merits*
- *be honest about what you do and say in relation to your business practices*
- *be able to identify when published material falls under the definition of advertising*
- *be able to regularly check and maintain compliance of all your advertising*
- *look at the overall impression of your advertising.[5] Consider who the audience is, what the advertisement is likely to say or mean to them, and how easy it is for your audience to navigate and understand your advertising.*

Advertising may be false, misleading or deceptive when it:

- *misleads, either directly or by implication through the use of emphasis, comparison, contrast or omission*
- *provides partial information and/or omits important details*
- *uses scientific information that is inaccurate, unbalanced, not easily understood by the public, or does not clearly identify researchers, sponsors and the academic publication in which the results appeared*
- *makes statements about the effectiveness of the treatment that are not supported by acceptable evidence*
- *makes unqualified claims about the effectiveness of treatment by listing health conditions that a treatment or service can 'assist with' or 'treat'*
- *suggests a practitioner is a registered health practitioner or holds specialist registration, qualifications or an endorsement when they do not, by using a title and/or other means*
- *minimises, underplays or under-represents the risk or potential risk associated with a treatment or procedure*
- *compares health outcomes, regulated health professions or practitioners or prices without complete information*
- *makes claims about providing a superior regulated health service. "*

[1] "4.1 False, misleading or deceptive advertising", https://www.ahpra.gov.au/Resources/Advertising-hub/Advertising-guidelines-and-other-guidance/Advertising-guidelines.aspx

Key Principle:

A website may engage s133 if the total impression - taking into account emphasis, omission, context, and audience understanding - is misleading, even if individual statements could be technically defended in isolation.

Table 2. Regulatory criteria applied

Provision	Audit criterion - Obligations under Section 133 of the National Law[2]
s133(1)(a)	Advertising must not be false, misleading or deceptive, or likely to be misleading or deceptive.
s133(1)(b)	Advertising must not offer gifts, discounts or inducements unless terms and conditions are stated.
s133(1)(c)	Advertising must not use testimonials or purported testimonials about the regulated health service or business.
s133(1)(d)	Advertising must not create an unreasonable expectation of beneficial treatment.
s133(1)(e)	Advertising must not directly or indirectly encourage indiscriminate or unnecessary use of regulated health services.

[2] "Obligations under section 133 of the National Law" Link: https://www.ahpra.gov.au/Resources/Advertising-hub/Advertising-guidelines-and-other-guidance/Advertising-guidelines.aspx# , Appendix 1

1. Executive summary

The highest-risk compliance concern is the overall impression created by the Gender Affirmation, GP, Child/Family/Youth, Mental Health, Q&A, Home and Book Now pages when read together. The site advertises regulated health services including GP-led gender-affirming hormone therapy, social transition support, mental health services, surgery referral support and services for people of all ages including under-18s. It repeatedly uses benefit- and reassurance-oriented terms such as '*safe'*, 'h*igh-quality'*, '*best-practice'*, '*evidence-based'*, *'developmentally appropriate'*, '*affirming'* and '*most up-to-date'.*

However, the public pages reviewed do not present material risks, evidence limitations, eligibility limits, minor-specific safeguards, fertility implications, irreversibility, alternatives, progression information, or complexity/referral thresholds with comparable prominence. On that basis, the strongest preliminary Section 133 findings are likely concerns under s133(1)(a) and s133(1)(d).

3.1 Key findings summary

1. Critical concern: Overall impression of misleading by omission - systematic pattern across service descriptions
2. High: Unqualified "safe", "evidence-based", "best-practice" language
3. Critical concern: Complete absence of material risk disclosure or acknowledgement of limitations
4. Critical concern: Fertility preservation listed as future while hormone therapy is current
5. High: Youth services operating with no age limits, eligibility criteria, or parental consent information stated
6. Non-complex" informed-consent model not explained
7. Testimonials/social media require separate review
8. s133(1)(e) requires further investigation, not a concluded finding
9. Critical concern: Material Non-Compliance with Cited Standards (AusPATH)

SECTION 1: False, Misleading or Deceptive Advertising

1.1 Overall impression and navigation

s133(1)(a) Assessment - Multiple breaches identified

Q1.1.1: Does the website create an overall impression that is balanced, accurate and not misleading?

Finding:	non-compliant	Priority:	Critical Concern

Evidence:

The website systematically creates a misleading overall impression through emphasis, omission, and selective presentation of information.

Dominant messaging patterns identified:

1. Affirming, supportive, welcoming tone throughout all pages
2. Services described as "evidence-based," "safe," and "high-quality" without qualification
3. Benefits emphasised - "affirm their identities safely and confidently"
4. Risks systematically omitted - no specific risks disclosed on any public page
5. Alternatives absent - no mention of watchful waiting, therapy-only, or non-medical approaches
6. Uncertainties omitted - no acknowledgement of evidence limitations or ongoing medical debates
7. Youth services alongside gender affirmation with no age limits or parental consent information

AHPRA Standard:

> *"..look at the overall impression of your advertising[3]. Consider who the audience is, what the advertisement is likely to say or mean to them, and how easy it is for your audience to navigate and understand your advertising." (Guidelines, s4.1)*
>
> *"Silence can be misleading*
> *In some circumstances, failure to disclose information can be misleading. This is particularly the case if a business provides some information to a consumer but doesn't mention important details the consumer should know that are relevant to their decision." (False or misleading claims)[3]*

Assessment: The overall impression is seriously misleading, by creating a false sense of safety, certainty, and appropriateness through systematic omission of material information.

[3] https://www.accc.gov.au/business/advertising-and-promotions/false-or-misleading-claims

1.2 Detailed findings

Finding 1 - Unbalanced overall impression on gender affirmation services

Direct website evidence: The **Gender Affirmation page** advertises “Informed, safe & high-quality care” and states that Kaleido empowers trans and gender-diverse people to ‘affirm their identities safely and confidently’. It lists current services including GP-led gender affirming hormone therapy, social transition support, access to surgery, mental health, peer support, social work and warm referrals to specialist providers.

Section 133 analysis: This likely engages s133(1)(a) and s133(1)(d) because the benefit, safety and evidence framing is prominent, while comparable disclosure of material risks, evidence limits, long-term uncertainty, eligibility criteria, complexity criteria, alternatives, fertility risks, irreversibility, progression, regret/detransition, or minor-specific safeguards is absent or not readily visible.

Summary: The Gender Affirmation [i] page creates a likely misleading overall impression by presenting gender-affirming services as safe, high-quality, evidence-based, developmentally appropriate and affirming, while omitting material risk, uncertainty, eligibility, alternatives and minor-specific information necessary for consumers to assess the advertised regulated health service.

[i] Gender Affirmation page: https://kaleidohealth.org.au/services/gender-affirmation, Archived: https://archive.md/IjgtY

Finding 2 - Unqualified “safe”, “evidence-based” and “best-practice” language

Direct website evidence: The pages use terms including high-quality, best-practice, evidence-based, most current and most up-to-date. The **GP page** [ii] presents hormonal therapy and gender affirmation within broad evidence-based care claims. The **Child, Family & Youth page** [iii] similarly uses safe, high-quality and best-practice language (..”Our family, child, and youth health services are designed to provide safe, high-quality, and best-practice care..”).

Section 133 analysis: AHPRA advertising guidance warns that claims may create unreasonable expectations where they minimise risk or imply safety/effectiveness without acknowledging possible adverse reactions or mixed/inconclusive evidence. The concern is not any single word in isolation, but the cumulative effect of reassurance-oriented language without counterbalancing risk and uncertainty disclosure.

Summary: Kaleido’s repeated use of safe, high-quality, best-practice, evidence-based and most up-to-date language may create an unreasonable expectation of beneficial treatment where the same advertising does not acknowledge adverse reactions, material risks, mixed or uncertain evidence, or the limits of the evidence base.

[ii] GP page: https://kaleidohealth.org.au/services/gp, Archived: https://archive.md/BPRKK

[iii] Child, Family & Youth Health: https://kaleidohealth.org.au/services/child-family-youth, Archived: https://archive.md/fOUDN

Finding 3 - Absence of visible treatment-risk disclosure on the Gender Affirmation page

Direct website evidence: The page lists hormone therapy, social transition support and surgery access as current services. It does not visibly disclose physical risks, long-term risks, fertility risks, sexual function risks, monitoring burdens, irreversibility, discontinuation issues or evidence uncertainty.

Section 133 analysis: This supports a likely s133(1)(a) issue because advertising may mislead through omission or partial information. A reasonable consumer is invited to consider a regulated health service without being shown the material information needed to understand risk, suitability and limits.

Summary: The public advertising omits material risks associated with the advertised gender-affirming medical pathway, despite advertising GP-led hormone therapy and surgery referral support. This omission may mislead by creating an impression of safety, simplicity or settled benefit that is not balanced by risk disclosure.
Gender Affirmation page: https://kaleidohealth.org.au/services/gender-affirmation, Archived: https://archive.md/IjgtY

Finding 4 - Fertility preservation is deferred while hormone therapy is current

Direct website evidence: The **Gender Affirmation** page lists gender-affirming hormone therapy as a current service, while fertility preservation is listed as a future service described as on-site consultation and support for fertility preservation before or during transition.

Section 133 analysis: This creates a temporal disclosure gap: the medical intervention is currently advertised, but the fertility-preservation support is not yet available on-site and there is no clear warning that hormone therapy may affect fertility.

Summary: Fertility preservation is deferred as a future service, despite current gender-affirming hormone therapy being advertised. The page does not warn that hormone therapy may affect fertility or explain how consumers can access fertility counselling before treatment. This creates a material disclosure gap under s133(1)(a) and contributes to an unreasonable expectation of safe treatment under s133(1)(d).
Gender Affirmation page: https://kaleidohealth.org.au/services/gender-affirmation, Archived: https://archive.md/IjgtY

Finding 5 - Minor access is confirmed on Q&A page but not adequately disclosed on service pages

Direct website evidence: The Q&A [iv] page states that Kaleido Health services are for people of all ages, including young people and those under 18. The uploaded audit states this page was discovered through site search and that systematic findability testing found no normal navigation path from public pages, menus, footer, service pages or sitemap. The **Gender Affirmation** page itself does not state age limits, eligibility criteria, parental consent requirements, capacity assessment, court-process issues, or minor-specific safeguards.

Section 133 analysis: This strongly supports s133(1)(a). Age eligibility and minor-specific safeguards are material to consumer understanding, especially for parents or young people considering gender-related services.

Summary: Kaleido confirms that services are available to people under 18, but its public gender affirmation materials do not disclose age limits, parental consent requirements, capacity assessment, minor-specific clinical pathways, court/dispute processes, or age-differentiated risk information. This is a material omission likely to mislead consumers about the characteristics, suitability and safeguards of the advertised regulated health service.
[iv] Q&A: https://kaleidohealth.org.au/q-and-a/, Archived: https://archive.md/UEev2

Finding 6 - “Non-complex” informed-consent model is not explained

Direct website evidence: The **Gender Affirmation** page states that Kaleido uses an informed consent model to support non-complex transgender health in primary care, with referrals to specialist providers as needed.

Section 133 analysis: This is a partial-information concern under s133(1)(a). The phrase ‘non-complex’ is clinically important, but the page does not define what counts as complex, who decides, what assessment occurs, when specialist referral is required, whether minors are treated under the same model, or whether psychiatric comorbidity changes the pathway.

Summary: The advertisement relies on the phrase non-complex transgender health without defining the threshold between non-complex and complex cases. Consumers cannot determine whether the GP-led informed-consent pathway is suitable for them, when specialist referral is required, or what safeguards apply to young people or patients with significant mental-health comorbidity.

Finding 7 - Mental-health framing does not connect baseline vulnerability to treatment uncertainty

Direct website evidence: The **Mental Health** page [iv] recognises high rates of trauma, PTSD, anxiety, depression, suicidality and other mental-health challenges among clients, while offering counselling, GP support, peer support, care coordination and referrals, including support for gender affirmation.

Section 133 analysis: The page does not appear to make a direct claim that hormone therapy reduces suicide or resolves mental illness. However, it contributes to the overall impression where mental-health vulnerability is acknowledged, while assessment safeguards and uncertainty around gender medical pathways are not disclosed.

Summary

Kaleido acknowledges high baseline mental-health vulnerability among its client population, but the gender affirmation advertising does not explain how psychiatric comorbidity is assessed before hormone therapy, social transition support or surgery referral. This creates a material gap in consumer understanding, particularly where the same website presents gender-affirming care as safe, evidence-based and developmentally appropriate.

[iv] Mental Health: https://kaleidohealth.org.au/services/mental-health Archive: https://archive.md/tBhZJ

Finding 8 - Promotional booking language is a secondary concern

Direct website evidence: The **Book Now** page [v] uses promotional language such as ‘Secure your appointment today. Experience the expert care and personalised support you deserve’.

Section 133 analysis: Standing alone, this is not the strongest s133(1)(e) issue because no direct “act now or your health will suffer” claim was identified. However, it may contribute to the overall promotional impression where treatment access is encouraged without equally prominent clinical-assessment, risk and suitability information.

Summary: The booking language is promotional and mildly urgency-oriented. It should be treated as supporting context rather than the primary breach allegation.

[v] Book Now: https://kaleidohealth.org.au/book-now, Archived: https://archive.md/rpfDO

Finding 9 - Gender-affirming-care fee structure is unclear

Kaleido advertises Gender Affirmation as a distinct service area, including GP-led gender-affirming hormone therapy, social transition support, mental health support, surgery referral support, peer support, social work and warm referrals. However, the **Fees** page does not appear to provide a corresponding “Gender Affirmation” fee category or clearly explain how these advertised services are billed. A reasonable consumer may be unable to determine whether gender-affirming-care appointments are billed as standard GP consultations, mental-health appointments, fertility/reproductive-health appointments, procedure items, or another appointment type.

Section 133 analysis: s133(1)(b): No major inducement concern identified.
Related pricing-transparency issue: gender-affirming-care billing pathway is unclear.

Summary: Gender-affirming-care billing pathway is unclear. Where a regulated health service is advertised as a distinct service pathway, consumers should be able to understand the basic fee structure and billing pathway without guessing across unrelated fee categories.

Finding 10 - False and misleading advertising through standards misrepresentation

Kaleido Health's public claim that services "align with the AusPATH Standards of Care" while simultaneously failing to provide material information required by those standards, and citing standards that are themselves inconsistent with National Law s133 disclosure obligations, constitutes false and misleading advertising under Health Practitioner Regulation National Law s133(1)(a).

Exact claim:

> *"Best-Practice Care*
>
> *Our services align with the AusPATH Standards of Care and NSW HealthPathways, ensuring that all Kaleido clinicians provide developmentally appropriate, evidence-based care."*

Material Non-Compliance with Cited Standards

Systematic audit of Kaleido's public website against AusPATH 2025 Standards of Care reveals material failures to provide information that AusPATH's own clinical documentation requires:

Finding 10.1: Minor Services - Hidden & Incomplete Information

AusPATH 2025 requirement (page 10, Scope section):

> *"For those under the age of 18 years, those in care, or those under guardianship orders, the medicolegal context that clinicians must navigate with regard to capacity to consent is more complex. For those under the age of 18 years, rules vary by state and are undergoing change.* ***It is incumbent on the provider to be aware of the legal context in which they practise.*** *Principles for the initiation and management of GAHT outlined in these SOC can be used with post-pubertal adolescents* ***provided the legal requirements for where you are practising****, and the guidelines outlined in the Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents are met."*

Kaleido provides:

- Confirmation of treating "people of all ages, including young people and those under 18" buried in Q&A page (removed from navigation mid-February 2025, over 14 months ago)
- Zero information about state-specific legal requirements for minors
- Zero information about parental consent obligations
- Zero minor-specific assessment protocols
- Zero age limits or eligibility criteria
- Zero reference to Family Court processes for capacity disputes

Non-compliance assessment: AusPATH explicitly places obligation on providers to be aware of and comply with state-specific legal requirements for minors. Kaleido's complete omission of this material information from publicly accessible service pages, combined with hiding confirmation of minor treatment from standard navigation, means reasonable consumers (including parents/guardians) cannot determine:

- Whether parental consent is required
- What legal obligations exist
- What age-specific protocols apply
- Whether Family Court involvement may be necessary

Material gap under ACL s18 and s29(1)(g).

Finding 10.2: Risk Disclosure - Complete Absence

AusPATH 2025 requirement (Appendix B, Consent Forms, pages 73-74):

AusPATH's own informed consent documentation includes comprehensive risk disclosure:

Potential risks listed in consent forms:

- "Increased risk of stroke"
- "Blood clots - deep vein thrombosis or potentially fatal pulmonary embolism"
- "Liver damage"
- "Reduced bone density and increased risk of osteoporosis"
- "Potentially increased risk of certain cancers, including breast cancer"
- "Increased risk of gastrointestinal bleeding (associated with spironolactone)"
- "Increased risk of certain types of benign brain tumours (rare, associated with cyproterone)"

Kaleido provides: Zero risk disclosure on public website despite offering 'Gender Affirming Hormone Therapy' as current service.

Non-compliance assessment: While AusPATH's consent forms document comprehensive risks for clinical consent processes, Kaleido provides **no** risk information on public website. Claiming "alignment with AusPATH Standards" while omitting the very risks that AusPATH's own clinical documentation identifies creates false impression that:

- Treatment risks are minimal or non-existent
- Risk information will be provided through standard AusPATH-aligned processes
- The service follows professional standards for risk disclosure

Material gap under ACL s18 and s29(1)(g): reasonable consumer materially misled by complete omission of treatment risks when considering whether to engage services.

Finding 10.3: Irreversible Effects - Not Disclosed

AusPATH 2025 requirement (Appendix B, page 73, Consent Form):

Consent form explicitly lists under "permanent changes that can be expected":

- "Breast and nipple development"
- "Decreased testicular size"
- "**Possible permanent infertility with long-term treatment**"

Under "reversible changes":

- "Sexual function changes: decreased libido, reduced spontaneous morning erections, reduced ability to achieve or sustain an erection, reduced ability to ejaculate, reduced volume and changed consistency of ejaculatory fluid"

Kaleido provides: No public disclosure of irreversibility or permanence of effects.

Non-compliance assessment: AusPATH's own consent documentation explicitly distinguishes permanent from reversible changes. Kaleido's complete omission of irreversibility information means reasonable consumers unaware that:

- Some effects are permanent regardless of treatment cessation
- Sexual function changes may be irreversible
- Fertility may be permanently affected

Material gap under ACL s18 and s29(1)(g): omission of material information about permanence of effects.

Finding 10.4: Fertility Impairment - Not Disclosed

AusPATH 2025 requirement (page 21, "Relevant sexual health history and fertility plans"):

> "GAHT can affect sexual function and libido and may reduce fertility, however, it is not a form of contraception. It is important to address these topics comprehensively, offering individuals the option to discuss, write down their replies, or defer certain topics until they are comfortable."
>
> "**Exploration of fertility goals and plans, ensuring individuals understand the implications of GAHT on their reproductive options. Encourage consideration of long-term plans for having children and document preferences and decisions regarding fertility preservation.**"

AusPATH consent form (page 73):

- Lists "Possible permanent infertility with long-term treatment" under permanent changes
- Requires checkbox: "I understand that estradiol-based hormone therapy reduces fertility and risks permanent infertility with long term use. I have discussed my future fertility with my provider, and have been given the opportunity to delay starting estradiol-based hormone therapy until after I have stored sperm."

Kaleido provides:

- Fertility preservation mentioned only as unavailable future service
- No disclosure that hormone therapy may impair fertility
- No disclosure that fertility effects may be permanent

Non-compliance assessment: AusPATH explicitly requires comprehensive fertility counselling and preservation discussion before treatment initiation. AusPATH's consent form requires documented discussion of fertility implications and opportunity to delay treatment for preservation. Kaleido lists fertility preservation as unavailable while providing NO disclosure that treatment itself may permanently affect fertility → reasonable consumer unaware that treatment may eliminate reproductive options before preservation access becomes available.

Material gap under ACL s18 and s29(1)(g).

AusPATH Standards Inconsistent with National Law s133

Even where Kaleido might comply with AusPATH standards in clinical settings, those standards permit omissions that are **inconsistent with National Law s133 disclosure obligations**, creating a false compliance veneer when used in public advertising.

Finding 10.5: Psychiatric outcomes - Not required by AusPATH

AusPATH 2025 (page 20, "Mental health history"):

> "TGD communities experience higher rates of mental health disorders and suicidality, especially young TGD individuals."

AusPATH requires mental health assessment and documentation but does NOT require disclosure that:

- Psychiatric service use may intensify post-medical intervention (Ruuska 2026 Finnish 10-year study)
- Mental health improvements claimed for transition are not supported by longitudinal evidence (Cass 2024 systematic reviews)
- High baseline psychiatric morbidity often persists or worsens despite medical intervention

National Law s133 requires: Material information disclosure to avoid misleading by omission.

Gap: Kaleido acknowledges high baseline psychiatric morbidity but omits longitudinal evidence showing psychiatric service use often increases post-intervention → reasonable consumer would assume mental health improves with treatment when evidence shows otherwise.

Finding 10.6 (Alternative): Treatment alternatives - Not required by AusPATH

National Law s133 and AHPRA guidance require: Honest representation of treatment options and their evidence base; no misleading through omission of alternatives.

AusPATH 2025: Does not require disclosure of non-medical alternatives in public materials.

Independent evidence (Cass 2024): Emphasises watchful waiting and psychological support as valid pathways given evidence uncertainty.

Gap: AusPATH standards permit omission that reasonable consumer needs to make informed decision about whether medical intervention is appropriate pathway → misleading by omission under s133 even if AusPATH compliant.

Finding 10.7: Progression rates - Not required by AusPATH

National Law s133 requires: Material information disclosure; no misleading through omission about likely treatment pathway.

AusPATH 2025: Does not require disclosure of progression rates in public materials.

Independent evidence (Cass 2024, Dutch cohort studies): Very high progression rates from puberty blockers to cross-sex hormones (95%+); initial intervention typically leads to irreversible medical pathway.

Gap: Standards permit omission of information that reasonable consumer needs to understand that "initial intervention" is typically first step in irreversible medical pathway, not standalone reversible treatment.

Finding 10.8: Evidence quality - Not required by AusPATH

National Law s133 requires: No unqualified effectiveness claims; honest representation of evidence base; scientific information must be accurate and balanced.

AusPATH 2025: Permits claims of 'evidence-based' practice despite:

- Scoring 19% on AGREE-II rigorous evidence assessment
- Being under review for replacement with NHMRC GRADE-based guidelines
- Independent systematic reviews (Cass 2024, HHS 2025, York reviews, NZ brief, UK CHM) consistently finding low/very-low certainty evidence for mental health and long-term outcomes

Gap: Standards permit unqualified 'evidence-based care' claims without disclosure of evidence uncertainty → authority substitution misleads reasonable consumer about robustness of evidence base.

Finding 10.9: Minor consent processes - Incomplete in AusPATH

National Law s133 requires: Complete material information for services involving minors; no misleading parents/guardians about legal obligations.

AusPATH 2025 (page 10): Requires providers to comply with state-specific legal requirements for minors and Family Court processes, but does NOT require public disclosure of:

- Parental consent requirements (which vary by state)
- Minor-specific assessment protocols
- Age-differentiated risks
- Family Court processes for capacity/treatment disputes

Gap: Parents/guardians considering gender services for their children are unaware of:

- Their consent obligations under state law
- Legal processes that may be triggered
- Whether they have decision-making authority
- What age-specific protections exist

This is particularly concerning given Kaleido's claim of providing "developmentally appropriate" care to "all ages" without disclosing what age-differentiated protocols exist or what legal framework governs minor treatment.

How Finding 10 Breaches AHPRA s133 and Advertising Guidelines 4.1

1. Misleads through omission of material information

AHPRA 4.1:

> "Advertising may be false, misleading or deceptive when it... provides partial information and/or omits important details"

Application:

Claiming "alignment with AusPATH Standards" while materially failing to provide information that AusPATH's own clinical documentation requires, creates the false impression of:

- Standards compliance when material gaps exist
- Risk disclosure through AusPATH-aligned processes when public website provides zero risk information

- Legal compliance for minor treatment when no information about state-specific requirements provided

Specific omissions that mislead:

- **Minors:** AusPATH places obligation on providers to comply with state legal requirements; Kaleido provides no information about these requirements to parents/guardians
- **Risks:** AusPATH consent forms document comprehensive risks (stroke, blood clots, bone density, cancer, liver damage); Kaleido public website provides zero risk disclosure
- **Irreversibility:** AusPATH consent form explicitly lists permanent changes; Kaleido omits any discussion of permanence
- **Fertility:** AusPATH requires comprehensive fertility counselling before treatment; Kaleido lists preservation as unavailable future service without disclosing treatment itself may eliminate fertility

Reasonable consumer assumes information gaps will be filled through AusPATH-aligned standards when in fact critical information is completely absent from publicly accessible materials.

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2. Authority Substitution Without Substance

AHPRA 4.1:

> "Advertising may be false, misleading or deceptive when it... uses scientific information that is inaccurate, unbalanced, not easily understood by the public"

Application:

Using "aligns with AusPATH Standards" as evidence proxy creates false impression of:

- Robust professional standards when AusPATH scored 19% on AGREE-II rigorous evidence assessment
- Evidence-based practice when independent systematic reviews found low/very-low certainty evidence
- Consumer protection through standard clinical processes when material information completely absent from public materials

What "alignment" claim implies to reasonable consumer:

- Service follows professionally recognised standards
- Standards are evidence-based and rigorous
- Consumer protections inherent in standard clinical pathways
- Risk and outcome information available through standard processes

Reality:

- AusPATH scored 19% on rigorous evidence assessment (AGREE-II)
- AusPATH under review for replacement with NHMRC GRADE-based guidelines
- Independent systematic reviews (Cass 2024, HHS 2025, York, NZ brief, UK CHM) found low/very-low certainty evidence
- Critical information absent from Kaleido's public materials despite being present in AusPATH's own clinical documentation
- Kaleido does not comply with information disclosures present in AusPATH's own consent forms

Authority claim masks both the weakness of the cited authority AND the service's failure to meet even those weak standards.

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3. Unqualified effectiveness claims

AHPRA 4.1:

> "Advertising may be false, misleading or deceptive when it... makes statements about the effectiveness of the treatment that are not supported by acceptable evidence"

Application:

Unqualified claim of "evidence-based care" without disclosure of:

- Evidence uncertainty documented in independent systematic reviews
- AusPATH's low score (19%) on rigorous evidence assessment
- Systematic reviews finding low/very-low certainty evidence for mental health and long-term outcomes
- Longitudinal evidence showing psychiatric service use may intensify post-intervention

Reasonable consumer assumes "evidence-based care" means robust evidence base exists when:

- Independent reviews consistently document substantial uncertainty
- Standards cited scored 19% on rigorous assessment
- Long-term outcome evidence ranges from low to very-low certainty

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4. Minimises and under-represents risk

AHPRA 4.1:

> "Advertising may be false, misleading or deceptive when it... minimises, underplays or under-represents the risk or potential risk associated with a treatment or procedure"

Application:

Complete absence of risk disclosure on public website despite:

- Offering hormonal interventions as current service
- AusPATH's own consent forms documenting comprehensive risks (stroke, blood clots, bone density, cancer, liver damage, fertility, irreversible changes)
- Claiming alignment with standards that require risk disclosure

Using standards-alignment claim as substitute for actual risk disclosure misleads reasonable consumer who assumes:

- Risks are minimal (otherwise they would be disclosed)
- Risk information will be provided through AusPATH-aligned standard processes
- The fact that service "aligns with standards" means appropriate risk disclosure exists

Reality: Zero public risk disclosure; reasonable consumer cannot assess treatment safety before engaging services.

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5. False impression of "Developmentally appropriate" care

AHPRA 4.1:

> "Look at the overall impression of your advertising. Consider who the audience is, what the advertisement is likely to say or mean to them"

Application:

Claiming "developmentally appropriate" care for "all ages" while providing:

- Zero minor-specific protocols publicly
- Zero age-differentiated risk information
- Zero information on parental consent requirements
- Zero evidence of what makes care "developmentally appropriate"
- Minor treatment confirmation hidden from standard navigation (removed mid-February 2025)

Overall impression to reasonable parent/guardian:

- Age-differentiated protocols exist and are disclosed
- Legal requirements for minor consent are transparent
- "Developmentally appropriate" means documented age-specific safeguards
- Service openly acknowledges minor treatment (when confirmation is actually hidden)

Reality:

- No public evidence of age-differentiated protocols
- No information about state-specific legal requirements
- No disclosure of parental consent obligations
- "All ages" claim contradicted by hiding minor treatment confirmation from navigation

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Analysis: The Logical Trap: False compliance either way

Kaleido's "alignment" claim creates an unavoidable breach scenario:

Scenario A: They genuinely align with AusPATH in clinical practice

- Then their public website materially fails to provide information present in AusPATH's own clinical documentation (consent forms showing comprehensive risks, fertility counselling requirements, legal obligations for minors)
- Result: "Alignment" claim is misleading because public materials do not reflect AusPATH's documented clinical standards

Scenario B: They align with AusPATH's permissive public disclosure standards

- Then they're complying with standards that permit omissions inconsistent with National Law s133 (alternatives, progression rates, evidence uncertainty, minor consent processes)
- Result: "Alignment" claim is misleading because it creates false impression of regulatory compliance when material omissions exist

Scenario C: They don't actually align with AusPATH

- Then the claim itself is directly false (material non-compliance on Findings 10.1, 10.2, 10.3, 10.4)
- Result: Direct breach of s133(1)(a) through false representation

In every scenario: Material breach of National Law s133.

Materiality Assessment

These omissions are **material** because they affect:

1. **Initial engagement decision:** Parents/consumers deciding whether to engage services for minors lack information about:

- Parental consent requirements under state law
- Age-specific assessment protocols
- Legal processes (Family Court) that may be triggered
- Age-differentiated risks

2. **Risk-benefit assessment:** Complete absence of risk disclosure prevents informed evaluation of:
    - Treatment safety profile
    - Cardiovascular risks (stroke, blood clots)
    - Bone health risks
    - Cancer risks
    - Liver damage risks
    - Sexual function impacts

3. **Evidence quality assessment:** Authority substitution (citing contested standards) prevents understanding of:
    - Evidence uncertainty (low/very-low certainty for key outcomes)
    - Standards weakness (19% AGREE-II score)
    - Review status (under review for replacement)
    - Independent systematic review findings

4. **Irreversible decision-making:** Omission of irreversibility and fertility risks affects:
    - Permanent life decisions about fertility preservation
    - Understanding that some changes persist regardless of treatment cessation
    - Sexual function impacts that may be irreversible
    - Reproductive capacity that may be permanently eliminated

5. **Pathway commitment:** Omission of progression rates prevents understanding that:
    - Initial intervention typically leads to irreversible medical pathway
    - 95%+ progress from blockers to cross-sex hormones
    - "Trying" hormones is not typically reversible standalone intervention

6. **Mental health expectations:** Omission of psychiatric outcome evidence prevents understanding that:
    - High baseline psychiatric morbidity may persist or worsen
    - Psychiatric service use often intensifies post-intervention
    - Mental health improvements claimed for transition not supported by longitudinal evidence

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Comparison to AHPRA Guidance Standards

AHPRA 4.1 states advertisers should:

> ***"sell your professional services on their merits"***

Kaleido instead: Sells services on claimed alignment with external standards while:

- Failing to provide information present in those standards' clinical documentation
- Citing standards that permit omissions inconsistent with regulatory obligations
- Using standards claim as substitute for substantive information disclosure

"be honest about what you do and say in relation to your business practices"

Kaleido instead: Omits material information about:

- Minor treatment (confirmation hidden from navigation)
- Risks (zero public disclosure despite comprehensive risks in AusPATH consent forms)
- Irreversibility (no disclosure despite AusPATH explicitly listing permanent changes)
- Fertility (listed as unavailable service without disclosing treatment itself affects fertility)
- Evidence uncertainty (unqualified "evidence-based" claim)
- Legal requirements (no information about state-specific parental consent obligations)

"look at the overall impression of your advertising"

Overall impression created:

- Professional, standards-compliant, evidence-based service
- Appropriate minor protocols and legal safeguards in place
- Risk information available through AusPATH aligned standard processes
- "Developmentally appropriate" means documented age-specific protections

Reality:

- Material non-compliance with information present in cited standards' clinical documentation
- Zero public risk disclosure
- Zero minor-specific protocol disclosure
- Zero legal requirement disclosure
- Standards cited scored 19% on rigorous assessment and under review for replacement
- Independent systematic reviews found low/very-low certainty evidence
- "Developmentally appropriate" claim unsupported by publicly disclosed protocols

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Recommended Action

This matter warrants investigation for:

1. **False/misleading standards alignment claim** through:
    - Material failure to provide information present in AusPATH's own clinical documentation (consent forms showing comprehensive risks, fertility requirements, legal obligations)
    - Citing standards while omitting material disclosures those standards document in clinical settings
    - Authority substitution (using weak standards to imply robust consumer protection)

2. **Inadequate disclosure through reliance on incomplete standards:**
    - AusPATH permits omissions inconsistent with National Law s133 (alternatives, progression rates, evidence uncertainty, minor legal requirements)
    - "Alignment" claim creates false impression of regulatory compliance when material omissions exist

3. **Authority substitution without substance:**
    - Using contested 19%-scoring standards as evidence proxy

- Standards under review for replacement with rigorous methodology
- Independent systematic reviews contradict implied evidence base

4. **Systematic omission of material information:**
    - Risks (comprehensive list in AusPATH consent forms, zero on Kaleido public website)
    - Irreversibility (explicit in AusPATH consent forms, absent from Kaleido website)
    - Fertility impacts (required by AusPATH, absent from Kaleido website)
    - Progression rates (documented in independent evidence, not disclosed)
    - Evidence uncertainty (documented in systematic reviews, not disclosed)
    - Alternatives (documented in Cass review, not disclosed)

5. **Particularly concerning regarding minors:**
    - Treatment confirmation hidden from navigation (removed mid-February 2025)
    - Zero public information about state-specific legal requirements
    - Zero information about parental consent obligations
    - Zero minor-specific protocol disclosure
    - Zero information about Family Court processes
    - "Developmentally appropriate" claim unsupported by disclosed protocols
    - AusPATH explicitly requires providers to comply with legal requirements; Kaleido provides no information about these requirements to parents/guardians

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Supporting Evidence

1. **Kaleido public website audit** - 9 findings documenting ACL s18 and s29(1)(g) compliance gaps

2. **AusPATH 2025 Standards of Care, Version 2**:
    - Page 10: Scope section on legal requirements for minors
    - Page 20: Mental health history section acknowledging high baseline psychiatric morbidity in young TGD individuals
    - Page 21: Fertility counselling requirements
    - Pages 73-74: Appendix B consent forms documenting comprehensive risk disclosure, permanent vs reversible changes, fertility risks

3. **AGREE-II assessment** showing AusPATH scored 19% on rigorous evidence grading

4. **Independent systematic reviews:**
    - Cass Review 2024 (UK)
    - HHS Systematic Review 2025 (USA)
    - York University systematic reviews
    - New Zealand Ministry of Health evidence brief
    - UK Commission on Human Medicines review
    - Ruuska 2026 (Finnish 10-year longitudinal study on psychiatric outcomes)

5. **Wayback Machine evidence of Q&A page navigation removal (mid-February 2025, over 14 months ago)**

Q1.1.2: Are material risks, uncertainties, eligibility limits, and evidence limitations presented with comparable prominence to benefits?

Finding:	Non-compliant	Priority:	Critical Concern

Evidence - Prominence Comparison:

Content Type	Present	Location	Prominence (1-5)	Assessment
BENEFITS				
"Evidence-based care"	Yes	Homepage, services	**5**	-
"Safe & high-quality"	Yes	Services page	**5**	-
"Affirm identities safely"	Yes	Services description	**5**	-
Service descriptions (positive)	Yes	Throughout	**4-5**	-
RISKS				
Specific adverse effects	No	Not found	**0**	severe imbalance
Serious/life-threatening risks	No	Not found	**0**	severe imbalance
Material side effects	No	Not found	**0**	severe imbalance
Any risk disclosure	No	Not found	**0**	severe imbalance

Analysis:

Benefits: Prominence Score = 5/5 (highly visible, emphasised, positive framing)

Risks: Prominence Score = 0/5 (completely absent)

Categorical imbalance (benefits maximally promoted, risks entirely suppressed)

This represents the most severe form of imbalance possible under AHPRA guidelines - not merely under-prominent risk disclosure, but complete absence of any risk information while strongly emphasising benefits.

AHPRA Standard:

"Advertising may be false, misleading or deceptive when it... minimises, underplays or under-represents the risk or potential risk associated with a treatment or procedure." (Guidelines, s4.1)

Assessment:

Critical Concern - complete omission of all risk information while prominently advertising benefits creates fundamentally misleading impression about safety and appropriateness of services.

1.3 CLAIMS ABOUT TREATMENT EFFECTIVENESS

Q1.2.1: Are all claims about treatment effectiveness supported by acceptable evidence?

Finding:	Potential non-compliance	Priority:	High

Effectiveness Claims Inventory:

Claim	Quote	Evidence Cited?	Evidence Type	Quality	Acceptable?
Evidence-based care	"evidence-based care"	No	None	None provided	No
Safe care	"safe & high-quality care"	No	None	None provided	No
Affirming care enables safe identity affirmation	"affirm their identities safely and confidently"	No	None	None provided	No
Services align with professional standards	"AusPATH Standards of Care" cited	Authority citation only	Professional guideline reference	No underlying evidence discussed	Insufficient

Relevant AHPRA guidance:

"Advertisers of a regulated health service must be able to substantiate claims made in advertising... Acceptable evidence mostly includes empirical data from formal research or systematic studies in the form of peer-reviewed publications." (Guidelines, s4.1.1)

Assessment:

Effectiveness claims are unsupported by acceptable evidence. Authority citations (AusPATH) are used as substitute for actual evidence, which does not meet AHPRA acceptable evidence standards.

1.4 RISK DISCLOSURE

Q1.4.1: Does the website adequately disclose material adverse effects and risks?

Finding:	serious compliance concern	Priority:	critical

Risk Disclosure Completeness:

For Hormone Therapy - Known Material Adverse Effects vs. Website Disclosure:

Known Material Risk	Disclosed?	Evidence
FEMINISING HORMONES:		
Venous thromboembolism (blood clots)	No	Not mentioned
Pulmonary embolism	No	Not mentioned
Stroke	No	Not mentioned
Cardiovascular disease	No	Not mentioned
Type 2 diabetes	No	Not mentioned
Infertility	No	Not mentioned
MASCULINISING HORMONES:		
Polycythemia (thickened blood)	No	Not mentioned
Cardiovascular disease	No	Not mentioned
Voice deepening (permanent)	No	Not mentioned
Infertility	No	Not mentioned

Summary Statistics:

• Material risks identified from medical literature: 30+[4]

• Material risks identified on reviewed website pages: none

• Disclosure rate in reviewed public pages: no material risk disclosure identified

Relevant AHPRA guidance:

[4] See evidence summary: Appendix B: Evidence Criteria Used to Construct the Informed Consent Checklist, "Assessment of Public Website Materials – Informed Consent Compliance Review"

"AHPRA expressly identifies advertising as potentially misleading if it minimises, underplays or under-represents the risk or potential risk of a treatment or procedure." (Guidelines, s4.1)

For a medical website, risk disclosure is a central advertising-compliance issue. A service page that describes benefits, access pathways and reassurance but omits material adverse effects, monitoring burdens, fertility implications, surgical risks, discontinuation issues, regret/detransition evidence, uncertainty, or long-term evidence gaps may raise a serious compliance concern.

Assessment:

CRITICAL CONCERN - Complete absence of any material risk disclosure while advertising medical services raises a serious misleading-by-omission concern. This remains one of the strongest compliance issues for regulatory assessment.

SECTION 2: GIFTS, DISCOUNTS AND INDUCEMENTS

s133(1)(b) Assessment

Finding:	NOT APPLICABLE	Priority:	-

No offers, discounts, gifts, or inducements identified on reviewed pages.

Section not applicable to audited content. If future promotional offers are added, terms and conditions must be clearly stated in plain language.

SECTION 3: TESTIMONIALS

s133(1)(c) Assessment

Finding:	Requires investigation	Priority:	Medium

Evidence from main website pages:

No testimonials identified on reviewed pages (homepage, services, about).

Requires Investigation:

1. Social media platforms (Instagram, Facebook, YouTube mentioned in footer)
2. Whether review functions are enabled
3. Whether any patient stories are featured elsewhere on site

Clinical Testimonial Definition (AHPRA):

Positive statements about:

• Symptoms (reason for seeking treatment)

• Diagnosis/treatment (what was provided)

• Outcomes (results, practitioner skills)

Assessment:

Cannot complete without reviewing social media platforms. RECOMMEND separate social media audit

SECTION 4: UNREASONABLE EXPECTATIONS

s133(1)(d) Assessment

Q4.1: Does website avoid creating unreasonable expectations about outcomes?

Finding:	POTENTIAL NON-COMPLIANCE	Priority:	HIGH

Outcome Expectation Assessment:

Statement/Claim	Location	Creates Unreasonable Expectation?	Reasoning
"Affirm their identities safely and confidently"	Services page	**Yes**	Implies certain positive outcome without acknowledging individual variation, potential for regret, or complexity
"Safe & high-quality care"	Services page	**Yes**	Unqualified safety claim with zero risk disclosure creates expectation of safety inconsistent with known serious risks
"Evidence-based care"	Services page	**Yes**	Creates expectation of well-established, proven treatment when evidence is contested and limited

Relevant AHPRA guidance:

"Advertising must not create an unreasonable expectation of beneficial treatment. Examples include... exaggerating outcomes, providing incomplete or biased information, or overstating the potential benefit of a treatment." (Guidelines, s4.1.4)

Assessment:

SERIOUS CONCERN - The advertising may create unreasonable expectations through: (1) unqualified benefit statements, (2) omission of risks/limitations, (3) certainty language without acknowledgement of uncertainty, and (4) no disclosure of the possibility of poor outcomes

SECTION 5: ENCOURAGING UNNECESSARY USE

s133(1)(e) Assessment

Overall Finding:	Requires further investigation	Priority:	Medium-high

Current Findings:

• No explicit urgency language observed on public website

• Cannot fully assess delay-harm or non-treatment-harm messaging without complete content review of Social Media

• No incentive schemes identified

• Concern that absence of eligibility criteria may frame services as broadly accessible rather than assessment-contingent

RECOMMENDATION:

Conduct detailed page-by-page content analysis of **Social Media** specifically looking for:

1. Implicit or explicit delay-harm messaging
2. Non-treatment consequence claims
3. Language about when/why to access services
4. Assessment requirements and access contingencies

Compliance Summary Matrix

Section 133 prohibition	Link assessment	Finding
s133(1)(a): false, misleading or deceptive / likely to mislead	Likely non-compliant: ▪ Creates misleading overall impression through systematic omission of material risks ▪ Makes unqualified benefit claims without evidence support ▪ Minimises/omits risks of hormone therapy and medical interventions ▪ Cherry-picks positive framing while omitting limitations, uncertainties, alternatives	Strongest finding. The website advertises regulated health services using safety, quality, evidence-based and affirming-care claims, while omitting material risk, uncertainty, eligibility, minor-specific, fertility, irreversibility and alternatives information. Material Non-Compliance with Cited Standards (AusPATH)
s133(1)(b): gifts, discounts or inducements without terms	Partial / minor concern	No major inducement concern identified. Related pricing-transparency issue: the site is presenting a distinct service pathway without an obvious corresponding fee pathway or whether offered discounts apply.
s133(1)(c): testimonials	No clear breach found on core website pages; further investigation required of Social Media	No obvious patient testimonials were identified on the core website pages reviewed. Social media, booking pages and third-party review display settings should be checked separately.
s133(1)(d): unreasonable expectation of beneficial treatment	Likely non-compliant ▪ Creates unreasonable expectations through omission of risks, uncertainties, limitations ▪ Uses transformative/affirming language without balancing with realistic outcome information	Reassuring claims such as ‘safe’, ‘high-quality’, ‘evidence-based’, ‘best-practice’ and affirm safety and confidently are not balanced with risks, uncertainty or individual variation. Emotionally loaded "affirming" language
s133(1)(e): encouraging indiscriminate or unnecessary use	Moderate concern	Public website: Book Now / Secure your appointment today is promotional, but no direct act-now-or-health-will-suffer claim was identified. Broader concern is access framed without clear clinical-assessment gates. Social Media: Detailed content review needed for harm-from-delay messaging

2. Overall recommended corrective actions

Immediate website corrections: Add prominent age eligibility, eligibility criteria, risk and consent links directly to the Gender Affirmation page; restore or clearly link the Q&A/FAQ page from relevant service pages; clarify discounted counselling fee wording.

Gender-affirming services disclosure: Add balanced information on risks, uncertainty, fertility, irreversibility, alternatives, progression, monitoring, discontinuation and referral thresholds; define non-complex vs complex cases.

Minor-specific disclosure: Add parental/guardian consent requirements, capacity assessment process, age-differentiated pathways, court/dispute process, and safeguards for young people.

Governance and review: Implement a website advertising compliance review against s133 and AHPRA advertising guidance before publishing or updating regulated-health-service pages.

AusPATH standards citation: Remove citation and adherence to a low quality standards of care that is not compliant to National Law section 133 or AHPRA guidelines.

3. Overall conclusion

Kaleido Health Centre's live public website raises substantial preliminary compliance concerns under s133(1)(a) and s133(1)(d) of the National Law. The website advertises regulated health services with prominent reassurance-oriented language but does not present material qualifying information with comparable prominence. The strongest findings relate to misleading overall impression by omission and unreasonable expectation of beneficial treatment. The s133(1)(e) issue should be treated as secondary, and the s133(1)(b) pricing issue as minor. No clear s133(1)(c) testimonial breach was found on the core website pages reviewed, but social media and booking/review platforms should be separately checked.

4. Documentation and Evidence

Evidence Sources Used

- Previous informed consent compliance audit (May 2026, accc-report:0137303 for Kaleido Health Centre)
- Documented web page content from Gender Affirmation, About, Services, Youth Health, FAQ, Billing and Fees pages
- AHPRA Guidelines for advertising a regulated health service (December 2020)
- AHPRA Advertising compliance framework
- Medical literature on hormone therapy, puberty blocker and surgical risks
- Cass Review (2024)
- International regulatory guidance (Sweden, Finland, Norway, UK)
- U.S. HHS "Treatment for Pediatric Gender Dysphoria" 2025
- York / Archives of Disease in Childhood systematic reviews 2024
- Ruuska et al. Acta Paediatrica 2026

5. URLs reviewed

The following URLs are drawn from Appendix A/pages 28-30 of the uploaded audit document. Archived equivalents are retained in the original evidence bundle – as of May 8, date of retrieval no change to archived pages.

Page	Live URL
Home	https://kaleidohealth.org.au/
About Us	https://kaleidohealth.org.au/about-us/
Our Team	https://kaleidohealth.org.au/our-team/
Services	https://kaleidohealth.org.au/services/
Fees	https://kaleidohealth.org.au/fees-1/
Opportunities	https://kaleidohealth.org.au/opportunities/
Contact Us	https://kaleidohealth.org.au/contact-us/
Book Now	https://kaleidohealth.org.au/book-now/
GP	https://kaleidohealth.org.au/services/gp/
Mental Health	https://kaleidohealth.org.au/services/mental-health/
Sexual Health	https://kaleidohealth.org.au/services/sexual-health/
Gender Affirmation	https://kaleidohealth.org.au/services/gender-affirmation/
Drug Health	https://kaleidohealth.org.au/services/drug-health/
Child, Family & Youth Health	https://kaleidohealth.org.au/services/child-family-youth/
Cancer Screening & Support	https://kaleidohealth.org.au/services/cancer-screening/
Billing Policy	https://kaleidohealth.org.au/billing/
Q&A page - discovered outside standard navigation	https://kaleidohealth.org.au/q-and-a/

6. Verification Methods

- Content analysis of publicly accessible web pages (https://kaleidohealth.org.au/). See steps taken: Assessment of Public Website Materials – Informed Consent Compliance Assessment[v]" KHC-ACL-2026-01 (v1.7) Appendix A ,pages 25-30 for steps and process
- Comparison against AHPRA Guidelines standards
- Assessment against medical literature for risk disclosure adequacy
- Evaluation of overall impression using reasonable consumer standard

Appendix A: Page-by-Page AusPATH Citations

Minors & Legal Requirements

Page 10, Executive Summary - Scope section:

> "For those under the age of 18 years, those in care, or those under guardianship orders, the medicolegal context that clinicians must navigate with regard to capacity to consent is more complex. For those under the age of 18 years, rules vary by state and are undergoing change. It is incumbent on the provider to be aware of the legal context in which they practise. Principles for the initiation and management of GAHT outlined in these SOC can be used with post-pubertal adolescents provided the legal requirements for where you are practising, and the guidelines outlined in the Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents are met."

Informed Consent Model

Page 13, Informed consent model of care section:

> "Informed consent, as per the Australian Commission on Safety and Quality in Healthcare, is: 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."

Mental Health

Page 20, Mental health history section:

> "TGD communities experience higher rates of mental health disorders and suicidality, especially young TGD individuals."

Fertility

Page 21, Relevant sexual health history and fertility plans section:

> "GAHT can affect sexual function and libido and may reduce fertility, however, it is not a form of contraception. It is important to address these topics comprehensively, offering individuals the option to discuss, write down their replies, or defer certain topics until they are comfortable."

> "Exploration of fertility goals and plans, ensuring individuals understand the implications of GAHT on their reproductive options. Encourage consideration of long-term plans for having children and document preferences and decisions regarding fertility preservation."

Consent Forms - Risks & Permanence

Pages 73-74, Appendix B - Estradiol-based gender-affirming hormonal therapy consent form:

Permanent changes:

- "Breast and nipple development"
- "Decreased testicular size"
- "Possible permanent infertility with long-term treatment"

Reversible changes:

- "Softening of skin"
- "Decreased muscle mass and increased body fat"

- "Slowed or stopped balding"
- "Slowed rate of growth of facial and body hair; however, existing body hair will not disappear"
- "Sexual function changes: decreased libido, reduced spontaneous morning erections, reduced ability to achieve or sustain an erection, reduced ability to ejaculate, reduced volume and changed consistency of ejaculatory fluid"

Potential risks:

- "Increased risk of stroke"
- "Blood clots - deep vein thrombosis or potentially fatal pulmonary embolism"
- "Liver damage"
- "Reduced bone density and increased risk of osteoporosis"
- "Potentially increased risk of certain cancers, including breast cancer"
- "Increased risk of gastrointestinal bleeding (associated with spironolactone)"
- "Increased risk of certain types of benign brain tumours (rare, associated with cyproterone)"

Fertility acknowledgement checkbox:

> "I understand that estradiol-based hormone therapy reduces fertility and risks permanent infertility with long term use. I have discussed my future fertility with my provider, and have been given the opportunity to delay starting estradiol-based hormone therapy until after I have stored sperm."

Appendix B: Evidence criteria used to construct the informed consent checklist

The following sets out the evidence-derived disclosure domains used to construct the informed consent audit checklist. The purpose is not to provide medical advice or resolve all clinical controversy, but to identify risks, uncertainties, reversibility issues, alternatives, and evidence-quality limitations that are material to informed consumer decision-making. These domains were then converted into checklist questions and tested against Kaleido Health Centre's public-facing materials.

The following tables are Colour coded for compliance to the 'Checklist item derived' column, as found by audit:

Yes	No	Partial/Unclear

TABLE 1: PUBERTY BLOCKERS CONSEQUENCES BY DOMAIN

Note: These domains are included because puberty suppression for gender-related distress is not merely a short-term symptom intervention. It occurs during a time-sensitive developmental period and may affect growth, bone development, fertility potential, sexual maturation, neurocognitive development, mental health assessment, and later treatment pathways. Where evidence is limited or uncertain, that uncertainty is itself material to informed consent.

(Evidence-quality labels: High / Moderate / Low / Very low (GRADE-like). Where incidence is unavailable, it is marked unknown and the reason is stated.)

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Intended effect: suppression of pubertal progression	*This is the central intended effect of treatment and must be clearly explained so parents and minors understand that normally timed puberty is being medically interrupted, not merely "paused" in a neutral sense. Consumers also need to understand that while pubertal development may resume after stopping, some downstream developmental effects may not be fully reversible.*	*Short (weeks–months)*	*Typically reversible after cessation (puberty can resume), but downstream developmental effects may not be fully reversible*	*High likelihood physiologic suppression in most patients*	*Moderate–High*	*Does the clinic clearly explain that puberty blockers suppress normal pubertal progression, that this is the intended physiological effect, and that downstream developmental effects may not be fully reversible even if puberty resumes after cessation?*	*[01][vi]*
Hot flashes, fatigue, headaches, mood changes (drug effects)	*Short-term adverse effects are material because they affect day-to-day wellbeing, tolerability, adherence, and the need for monitoring or treatment adjustment. Even where frequency is uncertain in gender dysphoria cohorts, known drug effects should not be omitted from consent materials.*	*Short*	*Reversible when stopped*	*Unknown in GD cohorts (harms inconsistently and non-standard reporting); common adverse effects known from GnRHa use generally*	*Low (in GD cohorts)*	*Does the clinic disclose common or plausible short-term drug effects of GnRHa treatment, including hot flashes, fatigue, headaches, mood changes, and the limits of available frequency data in gender dysphoria cohorts?*	*[02][vii]*
Growth velocity changes; height progression not matching expected growth	*Growth effects are material because puberty suppression occurs during a time-sensitive developmental period when height, growth velocity, and skeletal maturation are changing rapidly. Families may assume blockers merely delay puberty without understanding potential effects on growth trajectory.*	*Med.*	*Partly reversible/uncertain (depends on timing, duration, subsequent hormones)*	*Reported in multiple studies; precise incidence varies; comparative data limited*	*Moderate (directional signal), Low (quantification)*	*Does the clinic disclose that puberty blockers may affect growth velocity, height progression, skeletal maturation, and that reversibility or catch-up may depend on timing, treatment duration, and subsequent hormone use?*	*[03][viii]*

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Bone mineral density accrual reduced during treatment	*Bone density accrual is one of the most consistently identified risk domains. It is material because adolescence is a critical period for building peak bone mass, and long-term recovery remains uncertain.*	*Med.*	*Uncertain; may partially recover after cessation and/or subsequent hormones; depends on age at start and subsequent regimen*	*Multiple studies report reductions; magnitude varies; fracture outcomes unknown. Recent studies show mixed recovery with GAHT; persistent deficits possible in some."*	*Moderate (consistent signal), Low (long-term outcomes)*	*Does the clinic disclose bone density risks, reduced bone mineral accrual during treatment, uncertainty about long-term recovery, and the proposed monitoring plan?*	*[04][ix]*
Long-term bone outcomes after blockers followed by long-term hormones	*This is material because many patients do not use blockers as an isolated intervention but proceed to cross-sex hormones. Long-term bone outcomes may differ depending on sex, age at commencement, duration of suppression, and subsequent hormone regimen.*	*Long*	*Uncertain; not fully reversible once peak bone mass window passes*	*In a cohort of 75 who used blockers <18 then ≥9 years hormones: lumbar spine z-score remained lower in males receiving oestrogen, while most sites caught up in females receiving testosterone*	*Low (single-centre cohort with selection/loss-to-follow-up concerns)*	*Does the clinic disclose that long-term bone outcomes after blockers followed by cross-sex hormones remain uncertain and may differ depending on subsequent hormone exposure, including possible persistent deficits in some groups?*	*[05][x]*
Fracture risk / osteoporosis later in life	*Even where robust long-term fracture data are absent, the absence of evidence is itself material because fracture and osteoporosis outcomes may take decades to emerge. Families should know that long-term skeletal outcomes are not yet well established.*	*Long*	*Potentially irreversible if peak bone mass reduced*	*Unknown: no robust long-term fracture data in adolescents treated for GD; requires decades of follow-up*	*Very low*	*Does the clinic disclose that long-term fracture and osteoporosis risks are unknown due to lack of robust long-term follow-up, and that reduced peak bone mass may have later-life implications?*	*[06][xi]*
Cardiometabolic changes (BP, lipids, body composition)	*Cardiometabolic effects are material because puberty and sex hormones influence body composition, metabolism, blood pressure, and lipid profiles. Mixed or limited evidence should be disclosed as uncertainty rather than reassurance.*	*Med.*	*Often reversible/partly reversible, but long-term risk unknown*	*Mixed findings across studies; no clear evidence for diabetes onset; heterogeneity high*	*Low*	*Does the clinic disclose possible cardiometabolic changes, including blood pressure, lipids, body composition, and uncertainty about long-term cardiometabolic outcomes?*	*[07][xii]*

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Renal/liver function and diabetes onset	*This is material because "no evidence of effect" may reflect limited data and short follow-up rather than proven safety. Consent should distinguish between evidence showing no harm and insufficient evidence to detect harm.*	*Med.*	*Reversible if present*	*Evidence brief found no evidence of effect on renal/liver function or diabetes onset, but this largely reflects limited data and follow-up*	*Low*	*Does the clinic explain that available evidence has not established clear renal, liver, or diabetes effects, but that the evidence is limited and does not prove long-term safety?*	*[08][xiii]*
Neurocognitive development	*Neurocognitive development is material because puberty occurs alongside major brain maturation. Where systematic reviews report insufficient or inconsistent evidence, families need to know that cognitive and neurodevelopmental effects are not well established.*	*Long*	*Unknown*	*Systematic reviews report insufficient/inconsistent evidence; no high-quality studies for key cognitive endpoints*	*Very low*	*Does the clinic disclose uncertainty regarding neurocognitive development, brain maturation, and the lack of high-quality long-term cognitive outcome data?*	*[09][xiv]*
Psychological outcomes (depression/anxiety/suicidality)	*Psychological outcomes are central to consumer decision-making because treatment is often sought or justified on mental health grounds. It is material that evidence may be low quality, mixed, biased, or insufficient to establish reliable benefit.*	*Med.*	*Unknown; may improve or worsen depending on individual factors*	*NZ brief reports "significant improvement" in some outcomes but rates evidence low with high bias; other reviews find inconsistent/no robust evidence*	*Low*	*Does the clinic disclose the uncertainty of psychological outcome evidence, including depression, anxiety, suicidality, and the limits of observational or biased studies?*	*[10][xv]*
Gender-related distress (core dysphoria outcome)	*This is material because reducing gender-related distress is usually the main stated purpose of treatment. If few studies directly measure this outcome, or evidence is very low certainty, that limitation must be disclosed.*	*Med.–Long*	*Unknown*	*Few studies directly measure; evidence insufficient for firm conclusions*	*Very low*	*Does the clinic disclose whether puberty blockers have been shown to reduce gender-related distress, and explain the evidence limitations where direct measurement or long-term data are weak?*	*[11][xvi]*
Fertility preservation feasibility (Female)	*Fertility preservation is material because suppression may occur before full reproductive maturation, and later interventions may make infertility permanent. If there are no studies on fertility preservation feasibility for females receiving GnRHa in this context, that uncertainty must be disclosed.*	*Med.*	*Irreversible if gonadal maturation prevented and later gonadectomy occurs*	*NZ evidence brief identified **no studies** on fertility preservation for females receiving GnRHa in this context*	*Very low*	*Does the clinic disclose fertility preservation uncertainty for female minors, including the lack of robust evidence, time-sensitivity of reproductive development, and possible irreversible infertility if blockers are followed by later medical or surgical interventions?*	*[12][xvii]*

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Fertility preservation feasibility (Male)	This is material because sperm production may not have commenced before blockers are started. If spermatogenesis never develops and treatment progresses to later interventions, fertility loss may become irreversible.	Med.	Irreversible if spermatogenesis never develops and later gonadectomy occurs	Evidence exists for surgical sperm retrieval attempts in some settings, but overall feasibility depends on pubertal development stage and prior blockers	Low	Does the clinic disclose that male fertility preservation may not be feasible before spermatogenesis, that options may depend on pubertal stage, and that later interventions may make infertility irreversible?	[13][xviii]
Sexual maturation and later sexual function	Sexual development is material because puberty contributes to genital development, sexual maturation, libido, orgasmic function, and adult sexual capacity. Sparse long-term data and possible sensitive developmental windows make this a core consent issue.	Long	Likely partly irreversible if typical pubertal sexual development is blocked during sensitive developmental windows	Systematic review/meta-analysis coverage notes missing data for sexual dysfunction outcomes; long-term sexual function data are sparse	Very low	Does the clinic disclose possible impacts on sexual maturation, genital development, libido, orgasmic function, adult sexual function, and the lack of robust long-term sexual-function data?	[14][xix]
Downstream surgical implications due to limited genital tissue after early blockade (Male)	This is material because early blockade may affect genital tissue development, which can later influence surgical options, surgical complexity, or outcomes. Consumers may not realise that an early "pause" can affect later surgical feasibility.	Long	Not reversible once development window passes	Quantified incidence unknown; raised as a clinical concern in multiple reviews and safety discussions	Low	Does the clinic disclose that early puberty suppression in males may limit genital tissue development and may affect later surgical options, techniques, complexity, or outcomes?	[15][xx]
Social/legal impacts (minors): parental consent, disputes, court involvement in some jurisdictions	Legal and consent issues are material because minors may require parental involvement, capacity assessment, or court/tribunal pathways where there is disagreement. Families need to understand the legal framework before engaging treatment pathways.	Short–Med.	Not applicable	Jurisdiction-dependent; can be high-impact	Moderate (legal documentation exists), varies by place	Does the clinic clearly disclose parental/guardian consent requirements, capacity assessment processes, and whether court or tribunal involvement may be required where there is dispute about diagnosis, treatment, or capacity?	[16][xxi]

TABLE 2: FEMINISING HORMONES CONSEQUENCES (MALE ON OESTROGEN)

Note: These disclosure domains are included because feminising hormone therapy involves expected physical effects, fertility and sexual-function implications, cardiovascular risk domains, bone-health considerations, psychological-outcome uncertainty, and ongoing screening obligations. Informed consent requires distinguishing intended effects from risks, identifying which effects may persist, and explaining where evidence remains limited or uncertain.

Disclosure Domain	*Why material to consent*	*Typical timeline*	*Reversibility*	*Estimated frequency (or range)*	*Evidence quality*	*Checklist item derived*	*Key citations*
Intended physical effects (breast development, fat redistribution, reduced spontaneous erections, reduced testicular volume)	*These are expected treatment effects, but they are not all equally reversible. Breast development may not fully reverse, while sexual and genital effects may be partly reversible or variable. Consumers need to understand the likely physical changes, expected timelines, and which effects may persist after stopping.*	*Med.*	*Many effects partially reversible; breast development often not fully reversible*	*Common/ expected; quantification varies by regimen*	*Moderate*	*Does the clinic clearly disclose the expected feminising effects of oestrogen, including breast development, fat redistribution, reduced spontaneous erections, reduced testicular volume, expected timelines, and which effects may be irreversible or only partly reversible?*	*[17][xxii]*
Reduced spermatogenesis / infertility risk	*Fertility risk is material because oestrogen may reduce sperm production and impair future reproductive options. Although spermatogenesis may return after stopping in some cases, reversibility is not guaranteed and may depend on baseline fertility, duration of treatment, age, and treatment regimen.*	*Med.*	*Sometimes reversible after stopping, but not guaranteed; depends on duration and baseline fertility*	*Unknown population incidence; small cohort shows spermatogenesis may return after cessation*	*Low–Moderate (mechanistic strong; clinical reversibility data limited)*	*Does the clinic disclose reduced spermatogenesis and infertility risk, explain that fertility may not reliably recover after stopping treatment, and offer fertility counselling or preservation discussion before treatment begins?*	*[18][xxiii]*
Sexual function changes (libido, erectile function, orgasm intensity)	*Sexual function is material because oestrogen may affect libido, erectile function, orgasmic experience, genital function, and sexual wellbeing. These outcomes are personal, clinically significant, and often under-measured in studies, so uncertainty should be disclosed rather than glossed over.*	*Med.*	*Often partially reversible; may persist*	*Unknown: infrequently measured with standardised instruments in many cohorts*	*Low*	*Does the clinic disclose possible sexual function changes, including libido, erectile function, orgasm intensity, genital function, persistence of effects, and the limited quality of long-term sexual-function data?*	*[19][xxiv]*

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Venous thromboembolism (VTE)	*VTE is a serious adverse event and a known risk domain for oestrogen exposure. It is material because risk may vary by route, dose, duration, age, smoking, personal/family clotting history, and other comorbidities. Consumers need absolute and relative risk information where available, not vague reassurance.*	*Med.–Long*	*Not applicable (event)*	*In trans-feminine cohort: incidence 5.5 per 1000 person-years; adjusted HR 1.9 vs reference men, 2.0 vs reference women; risk differences increase over time*	*Moderate (large cohort; observational)*	*Does the clinic disclose VTE risk associated with feminising hormone therapy, including known incidence estimates where available, individual risk factors, route/dose considerations, and the need for monitoring or risk mitigation?*	*[20][xxv]*
Ischemic stroke	*Stroke risk is material because it is a serious cardiovascular outcome associated with oestrogen exposure in some cohort data. Even where evidence is observational and risk varies by individual factors, it should be disclosed as a potential long-term risk domain.*	*Long*	*Not applicable*	*Incidence 4.8 per 1000 person-years; HR 1.2 vs reference men, 1.9 vs reference women (overall cohort)*	*Moderate*	*Does the clinic disclose possible ischemic stroke risk, the limits of available evidence, individual risk factors, and how cardiovascular risk is assessed before and during feminising hormone therapy?*	*[21][xxvi]*
Myocardial infarction	*Myocardial infarction is material because oestrogen exposure may affect cardiovascular risk profiles, and consumers need to understand both what is known and what remains uncertain. Disclosure should include that estimates may vary by comparison group, regimen, duration, and baseline risk.*	*Long*	*Not applicable*	*Incidence 2.9 per 1000 person-years; HR 0.9 vs reference men, 1.8 vs reference women (overall cohort)*	*Moderate*	*Does the clinic disclose possible myocardial infarction or broader cardiovascular risks, including uncertainty in the evidence, relevant personal risk factors, and monitoring or referral pathways for elevated cardiovascular risk?*	*[22][xxvii]*
Bone health concerns (especially if	*Bone health is material because inadequate sex-hormone exposure, prior puberty suppression, gonadectomy, poor adherence, or*	*Long*	*Partly reversible with*	*In long-term follow-up after adolescent*	*Low*	*Does the clinic disclose bone-health considerations for feminising hormone*	*[23][xxviii]*

Disclosure Domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
hypogonadal or low estradiol exposure)	*low estradiol levels may affect bone density and long-term skeletal outcomes. Consumers should understand that feminising hormones require monitoring to avoid hypogonadal states and protect bone health.*		*optimised hormones and lifestyle; depends on adherence and levels*	*blockers, lumbar spine z-score remained lower in males receiving estrogen*		*therapy, especially after puberty blockers or gonadectomy, including monitoring of hormone levels, bone density concerns, and uncertainty about long-term outcomes?*	
Mood and psychological outcomes	*Psychological outcomes are material because feminising hormones may be presented or understood as improving depression, anxiety, distress, or wellbeing. Where evidence in young people is low-certainty, observational, or limited, consumers must understand that improvement is possible but not guaranteed and causality may be uncertain.*	*Med.*	*Variable*	*Systematic reviews in <26 show possible depression benefit in one comparative observational study (OR ~0.73) but overall considerable uncertainty*	*Low*	*Does the clinic disclose the limits of evidence for mood and psychological outcomes, including that reported benefits may be low-certainty, observational, short-term, or not causally established?*	*[24][xxix]*
Need for ongoing monitoring and preventive screening based on organs present (e.g., prostate considerations)	*Ongoing screening is material because feminising hormone therapy does not remove the need for organ-specific healthcare. Patients may still require prostate-related care, testicular/genital assessment where relevant, breast-health monitoring depending on exposure and age, and general metabolic/cardiovascular monitoring.*	*Long*	*Not applicable*	*Universal relevance; specific schedules vary*	*Moderate (guideline-based)*	*Does the clinic disclose that patients on feminising hormones still require ongoing monitoring and preventive screening based on organs present, including prostate/testicular considerations, breast-health monitoring where relevant, and cardiovascular/metabolic monitoring?*	*[25][xxx]*

TABLE 3: MASCULINISING HORMONES CONSEQUENCES (FEMALE ON TESTOSTERONE)

Note: These disclosure domains are included because testosterone produces both expected masculinising effects and potential medical consequences. Informed consent requires distinguishing intended effects from adverse effects, identifying which changes may be irreversible, explaining fertility and screening implications, and disclosing where evidence remains limited or uncertain.

Disclosure domain	*Why material to consent*	*Typical timeline*	*Reversibility*	*Estimated frequency (or range)*	*Evidence quality*	*Checklist item derived*	*Key citations*
Intended physical effects (voice deepening, facial/body hair, increased muscle mass; amenorrhea)	*These are the expected treatment effects, but some may be irreversible or only partly reversible. Consumers need to understand which changes are likely, which may be permanent, and how timing, dose, and duration may affect outcomes.*	*Med.*	*Some irreversible (voice, hair, genital changes); some reversible (fat distribution)*	*Common/ expected; varies by dose and duration*	*Moderate*	*Does the clinic clearly disclose the expected masculinising effects of testosterone, including voice deepening, facial/body hair, increased muscle mass, amenorrhea, expected timelines, and which effects may be irreversible or only partly reversible?*	*[26][xxi]*
Potential fertility impairment; ovulation may resume after stopping in some	*Fertility is material because testosterone may affect ovulation, ovarian function, future reproductive options, and timing of fertility preservation. Because reversibility is variable and not guaranteed, consumers should not be reassured by general statements that fertility may return after stopping.*	*Med.–Long*	*Variable; not guaranteed; depends on age, duration, ovarian reserve*	*Quantified incidence uncertain; robust comparative fertility studies limited*	*Low*	*Does the clinic disclose potential fertility impairment from testosterone, the uncertainty of reversibility, the possibility but non-guarantee of resumed ovulation, and the need for fertility counselling or preservation discussion before treatment?*	*[27][xxii]*
Erythrocytosis (elevated hematocrit)	*Erythrocytosis is a known and clinically monitorable adverse effect of testosterone. It is material because it may require blood-test monitoring, dose adjustment, route changes, risk-factor management, or cessation, and may affect thrombotic risk depending on severity and comorbidities.*	*Med.–Long*	*Usually reversible with dose/route adjustment or cessation; thrombosis risk depends on severity and comorbid risk factors*	*In a cohort: 11% had Hct >0.50; 3.7% >0.52; 0.5% >0.54 (definitions vary)*	*Moderate*	*Does the clinic disclose erythrocytosis risk, hematocrit monitoring requirements, risk factors such as dose/route/smoking/BMI/age, management options, and possible thrombotic implications if hematocrit becomes significantly elevated?*	*[28][xxiii]*
Cardiovascular events	*Cardiovascular risk is material even where evidence does not show a*	*Long*	*Not applicable*	*In large U.S. cohort,*	*Low–Moderate*	*Does the clinic disclose known and uncertain*	*[29][xxiv]*

Disclosure domain	Why material to consent	Typical timeline	Reversibility	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
(VTE/stroke/MI)	*clear elevated risk in all analyses, because long-term regimen-specific risks remain uncertain and may vary by individual risk profile. Consent should distinguish between reassuring available data and unresolved uncertainty.*			*transmasculine cumulative incidence curves largely similar to reference cohorts in most analyses; precise regimen-specific risks uncertain*		*cardiovascular risk domains for testosterone, including VTE, stroke, myocardial infarction, individual risk factors, and the limits of available long-term or regimen-specific evidence?*	
Bone density changes	*Bone health is material because sex hormone exposure, prior puberty suppression, gonadal status, dose adequacy, and adherence may affect long-term skeletal outcomes. Even where testosterone may support bone density, monitoring and uncertainty remain relevant.*	*Long*	*Partly reversible and may improve with adequate testosterone exposure*	*In long-term follow-up after adolescent blockers, bone outcomes appeared more favorable in those receiving testosterone than estrogen (site-specific)*	*Low*	*Does the clinic disclose possible bone density implications of testosterone, especially where treatment follows puberty blockers or gonadectomy, and explain any bone-health monitoring plan or uncertainty in long-term outcomes?*	*[30][xxxv]*
Psychological outcomes	*Psychological outcomes are material because testosterone is often presented or understood as improving distress, wellbeing, depression, or anxiety. Where evidence is largely observational, short-term, or pre–post in design, consumers need to know that causality and long-term mental health benefit are uncertain.*	*Med.*	*Variable*	*Adolescent hormone review notes short-term psychological improvements mainly in pre–post studies; causality uncertain*	*Low*	*Does the clinic disclose the limits of evidence for psychological outcomes, including that reported short-term improvements may come from low-certainty observational or pre–post studies and may not prove causal or durable mental health benefit?*	*[31][xxxvi]*

Disclosure domain	*Why material to consent*	*Typical timeline*	*Reversibility*	*Estimated frequency (or range)*	*Evidence quality*	*Checklist item derived*	*Key citations*
Need for ongoing monitoring and preventive screening based on organs present (uterus/cervix, etc.)	*Ongoing screening is material because testosterone does not remove the need for sex-organ-specific preventive healthcare. Consumers may need cervical screening, pelvic/uterine/ovarian assessment where clinically indicated, pregnancy counselling where relevant, and long-term monitoring based on organ inventory.*	*Long*	*Not applicable*	*Universal relevance; screening standards vary by jurisdiction*	*Moderate (guideline-based)*	*Does the clinic disclose that patients on testosterone still require ongoing monitoring and preventive screening based on organs present, including cervix, uterus, ovaries, breast/chest tissue where relevant, fertility/pregnancy considerations, and jurisdiction-specific screening guidance?*	*[32][xxxvii]*

Audit use: These checklist items do not assume that every risk will occur. They identify material domains that should be disclosed where a clinic offers, facilitates, or advertises masculinising hormone therapy, especially where services are described as “safe,” “evidence-based,” or provided through an informed consent model.

TABLE 4: SURGERY REFERRAL PATHWAY: MATERIAL DISCLOSURE DOMAINS

Note: These checklist items are not intended to imply that the audited clinic performs these surgeries directly. They are relevant where a clinic advertises or facilitates "access to surgery," referrals, preparation, or pathway support. In that context, informed consent requires disclosure of material downstream risks, uncertainties, irreversibility, and the limits of available outcome data.

Procedure	Consequence	Why material to consent	Typical timeline	Reversible?	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Vaginoplasty (Male)	*Urinary complications (e.g., UTI, meatal stenosis, urethral stricture, poor stream), may require conservative/medical/surgical management*	*Urinary complications may affect long-term function, quality of life, need for further treatment, and expectations about surgical outcomes. Because complication rates vary by technique, centre, follow-up period, and reporting method, consumers need both general risk disclosure and, where available, clinic or referral-network outcome data.*	*Med.–Long*	*Often treatable; some may recur*	*Meta-analytic synthesis exists; procedure-specific pooled rates vary widely across complication types; standardisation needs emphasised*	*Low–Moderate*	*Does the clinic disclose that surgical pathways may involve procedure-specific urinary complications, including UTI, meatal stenosis, urethral stricture, poor urinary stream, recurrence, and possible need for further medical or surgical management?*	*[33][xxxviii]*
Vaginoplasty (Male)	*General surgical risks: bleeding, infection, wound complications, anesthesia risks; possible need for revision; long-term dilation burden*	*General surgical risks, revision risk, wound complications, and the long-term burden of dilation are material because they affect permanence, daily management, recovery expectations, and future healthcare needs. Consumers should not be left with a generalised impression of "access to surgery" without understanding that surgery may create ongoing obligations and complications.*	*Short–Long*	*Variable*	*Incidence varies by centre, technique, and follow-up; often under-reported systematically*	*Low*	*Does the clinic disclose general and procedure-specific surgical risks, including bleeding, infection, wound complications, anaesthesia risks, revision surgery, scarring, and long-term dilation or maintenance requirements?*	*[34][xxxix]*
Phalloplasty (Female)	*Urethral fistula/stenosis;*	*Phalloplasty carries substantial functional and*	*Med.–Long*	*Many complicati*	*Meta-analysis reports pooled*	*Low–Moderate*	*Does the clinic disclose that phalloplasty may involve high*	*[35][xl]*

Procedure	Consequence	Why material to consent	Typical timeline	Reversible?	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
	standing urination goals; prosthesis complications; sensation outcomes	*complication risks, especially urethral fistula/stenosis, prosthesis complications, sensation outcomes, and possible limits on standing urination. These risks are highly material because they may require staged surgery, revision procedures, prolonged recovery, and acceptance of uncertain functional outcomes.*		*ons require additional surgery; some functional limits may persist*	*urethral fistula/stenosis ~48.9%; standing voiding ~91.5%; prosthesis complications ~27.9% (definitions vary)*		*rates of urethral complications, prosthesis complications, staged procedures, uncertain sensation outcomes, and possible need for further surgeries?*	
Phalloplasty / metoidioplasty (Female)	*Urethral outcomes after urethral lengthening: fistula/stricture recurrence*	*Urethral lengthening complications may be recurrent and may require additional operations. Because outcomes vary significantly by technique and reporting is not standardised, consumers need to understand both the possibility of repeated intervention and the uncertainty of available data.*	*Med.–Long*	*Often requires re-operation; recurrence possible*	*Systematic review emphasises paucity of standardised data; outcomes vary by technique and staging*	*Low*	*Does the clinic disclose urethral-lengthening risks, including fistula, stricture, recurrence, re-operation, and uncertainty caused by limited or non-standardised outcome reporting?*	*[36][xli]*
Mastectomy ("top surgery") (Female)	*Surgical complications (hematoma/seroma, infection, nipple complications), revision surgeries; possible sensory changes and scarring*	*Mastectomy is irreversible because breast tissue is removed. Surgical complications, revision risk, sensory changes, scarring, and nipple complications are material to consent because they affect body function, appearance, future reconstructive options, and long-term satisfaction.*	*Short–Long*	*Irreversible (tissue removal); some issues treatable*	*Exact pooled complication frequencies vary; summarised evidence exists but access limitations prevented full extraction here; clinics should disclose center-specific data*	*Low (quantification here), Moderate (general surgical principle)*	*Does the clinic disclose that chest surgery is irreversible and may involve hematoma, seroma, infection, nipple complications, sensory loss, scarring, revision surgery, and variation in cosmetic or functional outcomes?*	*[37][xlii]*

Procedure	Consequence	Why material to consent	Typical timeline	Reversible?	Estimated frequency (or range)	Evidence quality	Checklist item derived	Key citations
Gonadectomy (orchiectomy/oophorectomy) (Male/Female)	*Permanent infertility; lifelong need for hormone management to protect bone/cardiometabolic health; surgical risks*	*Gonadectomy causes permanent infertility and creates lifelong dependence on appropriate hormone management to protect bone, cardiovascular, and metabolic health. This is among the most material consent issues because it affects reproductive capacity, long-term medical monitoring, and irreversible loss of gonadal function.*	*Med.–Long*	*Irreversible*	*Frequency depends on uptake patterns; harms derive from known physiology plus surgical complication rates*	*Moderate (mechanistic), Low (population quantification in GD pathways)*	*Does the clinic disclose that gonadectomy is irreversible, causes permanent infertility, may require lifelong hormone management, and has implications for bone, cardiovascular, metabolic, and general health monitoring?*	*[38][xliii]*
All gender-affirming surgeries	*Regret/ dissatisfaction; detransition (concepts overlap but differ)*	*Regret, dissatisfaction, detransition, or changed goals are material even where reported regret rates are low, because measurement is inconsistent, follow-up is incomplete, and reversal is often limited or impossible. Consent should include both best available estimates and the limitations of those estimates.*	*Long*	*Variable; some revisions possible; reversal often limited*	*Systematic review/meta-analysis reports low prevalence of regret overall but highlights heterogeneity, non-standard measurement, and incomplete follow-up*	*Low–Moderate*	*Does the clinic disclose the possibility of regret, dissatisfaction, changed treatment goals, detransition, limited reversibility, and the evidence limitations around regret/detransition data, including loss to follow-up and inconsistent measurement?*	*[39][xliv]*

Audit use: These checklist items do not assume that every risk will occur. They identify material domains that should be disclosed where a clinic offers, facilitates, or advertises surgical referral pathway, especially where services are described as “safe,” “evidence-based,” or provided through an informed consent model.

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