

Variation in Sex Characteristics (Restricted Medical Treatment) Regulation 2023

Subordinate law SL2023–35

made under the

Variation in Sex Characteristics (Restricted Medical Treatment) Act 2023

EXPLANATORY STATEMENT

This explanatory statement relates to the *Variation in Sex Characteristics (Restricted Medical Treatment) Regulation 2023* (the **regulation**) as made by the Executive. It has been prepared to assist the reader of the regulation. It does not form part of the regulation and has not been endorsed by the Legislative Assembly.

This statement must be read in conjunction with the regulation. It is not, and is not meant to be, a comprehensive description of the regulation. What is said about a provision is not taken as an authoritative guide to the meaning of a provision, this being a task for the courts.

BACKGROUND

Under section 46 of the *Variation in Sex Characteristics (Restricted Medical Treatment) Act 2023* (the **Act**) the Executive is permitted to make regulations on a range of matters covered by the Act. When making a regulation for section 7 (the definition of variation in sex characteristics), the Executive must first consult with a number of office-holders. This was undertaken prior to the making of clause 3 of this regulation.

Several elements of this regulation relate to conditions of membership of the Restricted Medical Treatment Assessment Board (the **Board**) and how the Board will work.

OVERVIEW OF THE REGULATION

The purpose of the regulation is to provide additional details on aspects of the operation of the Act in five areas:

1. What variations in sex characteristics do not require prior approval for what would be restricted medical treatments;
2. What treatment, while not permanent in its effect, nevertheless requires prior approval under the Act before proceeding;
3. How assessment committees work;
4. Additional eligibility requirements that apply in some of the categories of membership of the Board; and
5. What information about reportable treatments must be provided to the Board.

What variations in sex characteristics do not require prior approval for what would be restricted medical treatments?

The government considered a range of information and evidence in determining if there were some variations in sex characteristics that did not need the protections of the approval process in the Act. This information included assessing the frequency with which issues were raised around the outcome of care for people with different variations; the classification of variations in sex characteristics in the medical literature; the views of stakeholder organisations; and the potential for ambiguity or confusion when determining whether a particular bodily condition was a variation in sex characteristic or not.

Based on the information available, it was determined that the scheme should initially not require prior approval of restricted medical treatment in five instances:

- (a) bladder exstrophy;
- (b) epispadias;
- (c) hypospadias, other than proximal hypospadias with cryptorchidism;
- (d) polycystic ovary syndrome (PCOS);
- (e) undescended testis.

For all five of these conditions, the primary reason for their exclusion is that they are not generally considered by the medical literature to be variations in sex characteristics. However, because they could be considered to represent atypical sexual or reproductive parts of the person's anatomy, they could engage the definition of a variation, through section 7(2)(b)(ii) of the Act, and therefore be captured and require a treatment plan when a prescribed person sought treatment.

In addition, for hypospadias other than proximal hypospadias with cryptorchidism, PCOS and undescended testis, the literature was less clear about whether there were elevated levels of risk of human rights violations arising from treatment for these conditions, compared to other variations in sex characteristics that are being regulated.

There is an additional consideration in making the regulation to support managing the establishment of the scheme. Hypospadias other than proximal hypospadias with cryptorchidism, PCOS and undescended testis all occur at significantly higher frequencies than those conditions broadly recognised as variations in sex

characteristics. If they were included, they would both place the legislative scheme under significant pressure through relatively high numbers of treatment plan applications, and divert resources from consideration of all the other, often more complex, cases of variations in sex characteristics.

What treatment, while not permanent in its effect, nevertheless requires prior approval under the Act before proceeding?

The Act defines restricted medical treatment as surgical or medical procedure or treatment (including the prescription or administration of a drug) that permanently changes the person's sex characteristics, or which makes changes to the person's sex characteristics that are only reversible with a further medical procedure or treatment (section 8(1)(a)). It then provides that a regulation can be made to also extend the definition to a surgical or medical procedure or treatment (including the prescription or administration of a drug) that temporarily changes the person's sex characteristics (section 8(1)(b)).

The purpose of this regulation is to bring under the Act's protection mechanism a non-permanent treatment that has been identified as having an elevated risk of violating children's human rights. This treatment is vaginal dilation, a procedure for creating or enlarging a vaginal opening, using a dilator – typically a plastic or silicone cylinder with a rounded or tapered end. The treatment is used in a range of circumstances, of which treatment of certain variations in sex characteristics is only one. In this instance, particularly for children, it can present some risks, that consideration of a treatment plan by the Board will help ameliorate.

How assessment committees work

The Act provides that regulations can be made about the operation of the Board. The regulation requires that minutes of meetings be kept. While this would be generally regarded as good practice, the regulation, by making it a requirement, guarantees that there are permanent records of the making of Board decisions.

Additional eligibility requirements that apply in some of the categories of membership of the Board

The Act describes five membership categories for the Board: human rights; medicine; ethics; variation in sex characteristics; and provision of psychosocial support. The Act provides that a regulation may prescribe other criteria for the appointment of a person as a member (section 31(6)).

In discussion with experts and stakeholders, the government identified several ways in which membership criteria would usefully be prescribed in more detail.

In the medicine category, without further regulation, it would be possible for a person to be validly appointed who, while qualified in medicine, had no experience or expertise in the kinds of care typically provided to people with variations in sex characteristics. It would strengthen the Board's capacity to make sound decisions if there were additional criteria that explicitly linked Board membership to the specialist

expertise involved in undertaking medical treatment, particularly permanent medical treatments, on people with variations. The regulation therefore requires that a person being appointed in the medicine category must have qualifications or expertise in at least 1 of the following areas:

- (a) adolescent and young adult medicine;
- (b) clinical genetics;
- (c) general paediatrics;
- (d) neonatology;
- (e) paediatric endocrinology;
- (f) paediatric or adolescent gynaecology;
- (g) paediatric urology.

In the variation in sex characteristics category, without further regulation, it would be possible for the requirement to be interpreted as meaning any kind of experience related to variations in sex characteristics. However, the policy intention is that the Board will be informed by lived experience of variations, brought in through this category of membership. The regulation therefore requires that a person to be appointed in this category must have lived experience of a variation in sex characteristics. It gives examples that make clear that this can be either through having a variation, or being a parent or carer for someone with a variation in sex characteristics.

In the provision of psychosocial support category, the regulation sets out a range of types of professional or peer support care that will be regarded as the provision of psychosocial support. These are based on the professions and types of care services that are recognised in the published literature and by stakeholders as important to this aspect of care of people with variations. The types of care included are:

- (a) psychological support; or
- (b) social work services; or
- (c) counselling, including genetic counselling, services; or
- (d) support or care for the psychosocial needs of people with a variation in sex characteristics.

What information about reportable treatments must be provided to the Board?

Section 43 of the Act establishes some reporting requirements in relation to reportable medical treatments.

The information that the Act requires is: if the treatment was undertaken under a treatment plan—details of the plan; the prescribed person's age; and the prescribed person's variation in sex characteristics. The Act provides that a regulation may prescribe the provision of any other information regarding reportable treatments.

The reporting requirements in the Act have several purposes:

- To assist the Board to understand what treatments are being performed on prescribed persons who have variations in sex characteristics;
- To enable the Government, through the advice of the Board, to monitor the effects of the VSC legislation and regulations, particularly the scope of the variations that are included, and therefore to allow it to consider whether the legislation is meeting its intended objectives;
- To support stakeholders, including the medical professions, to obtain through the Board's Annual Report (section 44) a systematic picture of permanent treatments occurring across the ACT population of prescribed persons.

All stakeholders have expressed support both for having better data about VSCs, and for an evidence-based approach to monitoring the effects of the legislation. To achieve this, effective reporting requirements are essential.

For the reporting to be meaningful, the Board needs to obtain information not only about the variation in sex characteristics of a patient, but also what treatment has taken place. The regulation requires that, when notifying the Board under section 43(1) that a reportable medical treatment has taken place, the treating doctor reports what the treatment was that they provided and when it started.

The regulation specifies the reporting of when a reportable treatment starts. This is so that, for treatments that involve ongoing actions (such as the regular administration of a hormone), a separate report does not need to be provided every time an instance of that course of treatment is administered.

CONSULTATION ON THE PROPOSED APPROACH

Consultation with a range of peak bodies and experts took place. Organisations including Australia and New Zealand Society for Paediatric Endocrinology and Diabetes, Society of Paediatric Urology of New Zealand and Australia, Australia and New Zealand Association of paediatric Surgeons, Intersex Human Rights Australia, Equality Australia, Relationships Australia and A Gender Agenda, were invited to provide input on a draft of the regulation. This invitation was also made to health professionals in Canberra Health Services. A workshop was held on 17 August 2023, at which medical specialists, human rights experts and other stakeholders discussed the draft regulation. The final regulation reflects some of the proposals arising from that discussion.

CONSISTENCY WITH HUMAN RIGHTS

The regulation has been analysed for consistency with the *Human Rights Act 2004*.

Right engaged

The regulation engages the following right under the *Human Rights Act 2004*:

- Section 12 (a): Everyone has the right not to have his or her privacy, family, home or correspondence interfered with unlawfully or arbitrarily.

Right limited – the right to privacy

1. Nature of the right and the limitation (ss 28(2)(a) and (c))

Section 12 (1) of the *Human Rights Act 2004* provides that everyone has the right not to have his or her privacy, family, home or correspondence interfered with unlawfully or arbitrarily.

The right to privacy of prescribed persons who have a variation in sex characteristics will be limited by this regulation in two ways additional to how that right is limited by the Act, and which is explained in detail in the Explanatory Statement to the Act (pages 30-36).

First, clause 4 of this regulation prescribes vaginal dilation under section 8(1)(b) of the Act as a treatment that is required to be managed as a restricted medical treatment. This extends the range of medical treatment of a person with a variation in sex characteristics for which treatment decisions will no longer be a private matter between their decision-makers and their treating medical practitioner.

Second, clause 9 of this regulation requires additional information about certain medical treatments to be reported to the Board. These are the details of each reportable treatment undertaken, and the date the reportable treatment started.

2. Legitimate purpose (s 28(2)(b))

Vaginal dilation is being prescribed because during consultations on the legislation, people with variations in sex characteristics reported experiencing the same types of risk and harm arising from this treatment as from those treatments that permanently change a person's sex characteristics, or which make changes to the person's sex characteristics that are only reversible with a further medical procedure or treatment. The regulation therefore subjects it to the same oversight as other restricted medical treatments.

As explained in the Explanatory Statement to the Act (p.30), the purpose of this protection is to ensure:

treatment decisions for people with variations in sex characteristics uphold the rights of the prescribed person receiving the treatment. In particular, their rights not to be subjected to medical treatment without their free consent; to enjoy their human rights without discrimination; and the rights of a child to special protection, particularly to ensure they are being consulted and heard in the decision-making process.

As set out in the Explanatory Statement to the Act, both health professionals and community advocates have sought better information about what treatments are being undertaken on people with variations in sex characteristics. Reporting requirements are also necessary so that the Board can understand how the Act is operating and what treatments are occurring without approval, under the Act's various exemptions (including through some variations in sex characteristics being exempted from approval requirements by this regulation).

However, without clause 9 of the regulation, for some prescribed persons who have a variation in sex characteristics, the Board would not be made aware of what treatment they were receiving or when it occurred. Without this information, the Board would lack an understanding of what medical interventions are occurring among people with variations in sex characteristics. This would in turn limit the ability of the Board to offer effective advice when meeting its responsibilities under section 30(b) of the Act.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

For vaginal dilation, the rational connection is that by prescribing this treatment, it allows the introduction of safeguards and oversight of the rights that otherwise would not be present.

For the reporting requirement, the rational connection is the same as for the Act in respect of report requirements. Without the requirements, the board would lack the legal capacity to obtain information about what treatments were being undertaken, or to develop reports or advice based on that information. As the Explanatory Statement to the Act explains (p.33):

It would therefore be unable to determine the effects of its decisions, and the board and government would be unable to assess whether the Bill is effective in meeting its goals for regulating certain treatments for prescribed people with variations in sex characteristics.

4. *Proportionality (s 28(2)(e))*

The reasons for subjecting vaginal dilation to the regulatory regime of the Act rather than to some alternative, less restrictive, regime are the same as those set out in the Explanatory Statement to the Act (p.34). These are that a professional disciplinary rule would not achieve the objective because the Australian professional disciplinary system is peer-based and not consistent with a reform (such as this Act) that is designed to change practice, rather than to maintain quality of existing practice. A non-legislative alternative would likewise not work, as explained in the Explanatory Statement to the Act (p.34):

because it would cover public health settings, but not private practice. As a result, this option would also not achieve effective non-discriminatory protection, because the way rights were upheld would depend on whether the

health service was public or private. Published studies also indicate problems with compliance with non-legislated approaches to changing health care practice.

The circumstances under which vaginal dilation will be regulated are narrow on the same basis as for all treatments that the Act regulates. These are that approval is only required when:

- The medical procedure is not urgent (see the Act sections 25, 26 and Dictionary);
- The treatment affects the person's sex characteristics (the Act section 8);
- The treatment will permanently change the person's sex characteristics (the Act section 8); and
- The person does not have capacity to consent to the medical procedure for themselves (the Act sections 9, 14(a)).

CLAUSE NOTES

Clause 1 Name of regulation

Clause 1 names the regulation as the *Variation in Sex Characteristics (Restricted Medical Treatment) Regulation 2023*.

Clause 2 Commencement

Clause 2 provides for the commencement of most of the regulation on the 23 December 2023, which is the commencement date of the *Variation in Sex Characteristics (Restricted Medical Treatment) Act 2023*, other than other than section 10 and part 4 of that Act.

Section 9 of the regulation, which sets out additional reporting requirements for reportable treatments, commences on 23 December 2024, which is when section 10 and part 4 of the *Variation in Sex Characteristics (Restricted Medical Treatment) Act 2023* commence.

Clause 3 Excluded conditions—Act, s 7 (1), def variation in sex characteristics, par (c)

Clause 3 provides that five conditions that may be considered to be variations in sex characteristics are to be excluded from being considered to be a variation in sex characteristics under the Act. The conditions are:

- (a) bladder exstrophy;
- (b) epispadias;
- (c) hypospadias, other than proximal hypospadias with cryptorchidism;
- (d) polycystic ovary syndrome (PCOS);
- (e) undescended testis.

Clause 4 Temporary restricted medical treatment—Act, s 8 (1), def restricted medical treatment, par (b)

Clause 4 provides that vaginal dilation is a restricted medical treatment.

Clause 5 Operation of assessment committee—additional requirements—Act, s 18 (4)

Clause 5 provides that an assessment committee must keep minutes of its meetings.

Clause 6 Membership of assessment board—criteria for medicine category—Act, s 31 (6)

Clause 6 provides a list of areas in which at least one of which a person must have qualifications or expertise, in order to be able to be appointed to the Board as a member in the medicine category. Those areas are:

- (a) adolescent and young adult medicine;
- (b) clinical genetics;
- (c) general paediatrics;
- (d) neonatology;
- (e) paediatric endocrinology;
- (f) paediatric or adolescent gynaecology;
- (g) paediatric urology.

Clause 7 Membership of assessment board—criteria for variation in sex characteristics category—Act, s 31 (6)

Clause 7 provides that to be appointed to the Board as a member in the variation in sex characteristics category, a person must have lived experience of a variation in sex characteristics. It provides two examples of what constitutes lived experience.

Clause 8 Membership of assessment board—criteria for provision of psychosocial support category—Act, s 31 (6)

Clause 8 sets out the types of qualifications or experience that a person must have in order to be appointed to the Board in the psychosocial support category. Those types are:

- (a) psychological support; or
- (b) social work services; or
- (c) counselling, including genetic counselling, services; or
- (d) support or care for the psychosocial needs of people with a variation in sex characteristics.

Clause 9 Reporting treatment in relation to sex characteristics—Act, s 43 (1) (b) (iv)

Clause 9 sets out information that must be reported regarding treatment in relation to sex characteristics. This information is the details of each reportable treatment undertaken; and the date the reportable treatment started.

Clause 10 Reportable treatment—Act, s 43 (2), def reportable treatment, par (c)

Clause 10 inserts a list of conditions that are for reporting purposes to be considered as variations in sex characteristics in the event that a surgical or medical procedure or treatment in relation to the condition is administered that would be restricted medical treatment if the condition were not an excluded condition. This list of conditions is the same as those that are excluded from the legislation's approval requirements by virtue of clause 3 of the regulation.

The purpose of these two clauses together is to exempt certain variations in sex characteristics from the legislation's approval requirements, but not from the legislation's reporting requirements.