Assisted Reproductive Treatment Regulations 2009

Regulatory Impact Statement

This Regulatory Impact Statement has been prepared in accordance with the requirements of the *Subordinate Legislation Act 1994* and the Victorian Guide to Regulation incorporating Guidelines for the Measurement of Changes in Administrative Burden.

October 2009

ASSISTED REPRODUCTIVE TREATMENT REGULATIONS 2009

REGULATORY IMPACT STATEMENT

This Regulatory Impact Statement (RIS) has been prepared to fulfil the requirements of the *Subordinate Legislation Act 1994* and to facilitate public consultation on the proposed Assisted Reproductive Treatment Regulations 2009.

In accordance with the *Victorian Guide to Regulation*, the Victorian Government seeks to ensure that proposed regulations are well-targeted, effective and appropriate, and impose the lowest possible burden on Victorian business and the community.

A prime function of the RIS process is to help members of the public comment on proposed statutory rules before they have been finalised. Such public input can provide valuable information and perspectives, and thus improve the overall quality of the regulations. The proposed Regulations are being circulated to key stakeholders and any other interested parties, and feedback is sought. A copy of the proposed Regulations is provided as an attachment to this RIS.

Public comments and submissions are now invited on the proposed Assisted Reproductive Treatment Regulations 2009. All submissions will be treated as public documents and will be made available to other parties upon request. Written comments and submissions should be forwarded by no later than **5:00pm, 17 November 2009** to:

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This Regulatory Impact Statement was prepared for the Department of Health by Regulatory Impact Solutions Pty Ltd.

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ABBREVIATIONS

ART – Assisted Reproductive Treatment

BDM Victoria– Victorian Registry of Births, Deaths and Marriages

DOH – Department of Health (Victoria)

FSA – Fertility Society of Australia

GIFT – gamete intra-fallopian transfer

ITA – Infertility Treatment Authority

IVF – in-vitro fertilisation

MCA – Multi-criteria Analysis

NCP – National Competition Policy

Premier's Guidelines – Subordinate Legislation Act 1994 Guidelines

PV – present value. Present value 'discounts' the value of money in future years to allow it to be valued in today's terms.

r. – regulation

rr. – regulations

RTAC – Reproductive Technology Accreditation Committee of the Fertility Society of Australia

SCM – Standard Cost Model

the current Act – *Infertility Treatment Act 1995*

the current Regulations – Infertility Treatment Regulations 1997

the proposed Regulations – Assisted Reproductive Treatment Regulations 2009

the new Act – *Assisted Reproductive Treatment Act 2008*. This legislation will come into operation on 1 January 2010 or before that date by proclamation.

VARTA – Victorian Assisted Reproductive Treatment Authority

VCEC – Victorian Competition and Efficiency Commission

VLRC – Victorian Law Reform Commission

VPS – Victorian Public Service

GLOSSARY OF KEY TERMS

Artificial Insemination – a procedure of transferring sperm without also transferring an oocyte into the vagina, cervical canal or uterus of a woman

Assisted Reproductive Treatment – a medical treatment or a procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes in-vitro fertilisation and gamete intra-fallopian transfer

Child – means a person who is less than 18 years of age

Commissioning parent – for a surrogacy arrangement, the person or persons who enter into the surrogacy arrangement for a woman to carry a child on behalf of the person or persons

Donor – the person who donates gametes (sperm or eggs)

Gametes – sperm or an oocyte

In-vitro Fertilisation – fertilisation of an egg in a test tube (in-vitro)

Oocyte – an ovum from a woman

Partner – the person's spouse, or a person who lives with the first person as a couple on a genuine domestic basis, irrespective of gender.

Surrogate – a woman who becomes intentionally pregnant agrees prior to conception to permanently surrender the child to another person or couple who will be the child's parent or parents

Treatment procedure – artificial insemination (other than self-insemination) or assisted reproductive treatment

SUMMARY

Context

Assisted Reproductive Treatment (ART) may be defined as procedures that are used to facilitate the birth of children when heterosexual intercourse is impossible or difficult, or carries a risk that a disease or genetic abnormality may be transferred to the child. ART is currently regulated in Victoria by the *Infertility Treatment Act 1995* (the current Act) and the Infertility Treatment Regulations 1997. In December 2008, following six years of review and consultation, new legislation – the *Assisted Reproductive Treatment Act 2008* – was passed in Parliament. This legislation expands and modernises the current Act and will replace it on 1 January 2010 if not proclaimed earlier. The Assisted Reproductive Treatment Regulations 2009 (the proposed Regulations) will give operational effect to a number of elements of the new legislation. These elements include prescribing consent forms, matters to be covered in counselling sessions, and prescribing the information to be collected from patients and other parties. While the proposed Regulations largely remake the current regulations, they have been streamlined in some areas and expanded in other areas to reflect the wider application of the new legislation.

It is important at the outset of this Regulatory Impact Statement (RIS) to highlight that it will not deal with the broader policy issues associated with ART: these have been thoroughly examined and debated when the existing legislation was reviewed and the new Act introduced. Consequently, this RIS does not examine issues concerning criminal records checks or child protection order checks. These issues are contained in the Act, not the regulations (although the regulations prescribe a consent form for child protection order checks). Instead, the proposed Regulations, and hence this RIS, deals with a relatively narrow range of matters, which give operational effect to the Act (mostly prescribing forms and information/data requirements).

Purpose of a Regulatory Impact Statement

In Victoria the *Subordinate Legislation Act 1994* requires that new or remade regulatory proposals that impose an 'appreciable economic or social burden on a sector of the public' be formally assessed in a RIS to ensure that the costs of the proposed regulations are outweighed by the benefits, and that the regulatory proposal is superior to alternative approaches. It has been determined that the burden imposed by the proposed Regulations requires assessment in a RIS.

A RIS formally assesses regulatory proposals against the requirements in the *Subordinate Legislation Act 1994* and the *Victorian Guide to Regulation*.[1] The assessment framework of this RIS examines the problem to be addressed, specifies

1 Department of Treasury and Finance, 2007, 2nd ed, *Victorian Guide to Regulation incorporating: Guidelines made under the Subordinate Legislation Act 1994 and Guidelines for the Measurement of Changes in Administrative Burden*, Melbourne

the desired objectives, identifies viable options that will achieve the objectives, and assesses the costs and benefits of the options, as well as identifying the preferred option and describing its effect. This RIS also assesses the proposed Regulations' impact on small business, undertakes a competition assessment and reports on any changes in the administrative burden to business (i.e., ART providers). Finally, it considers implementation and enforcement issues and documents the consultation undertaken.

The Assisted Reproductive Treatment Act 2008

The law plays an important role in defining and recognising families and relationships between partners, parents and children. Over time, the law has developed to reflect changes in family structures and community attitudes to different types of relationships. In 2007 the Victorian Law Reform Commission (VLRC) found that the ART law in Victoria did not include several family types, either by excluding certain categories of people from accessing ART services or in not recognising all kinds of families.[2] In response to the findings of the VLRC the Victorian Government passed the *Assisted Reproductive Treatment Act 2008*.

The overarching objective of the new legislation is to provide a framework that ensures the welfare and interests of persons, born or to be born, as a result of treatment procedures: that is, the regulatory regime should be primarily be concerned with the best interests of the child. The legislation also seeks to protect the health and wellbeing of persons undergoing treatment procedures, and to ensure that children born as the result of the use of donated gametes are able to access information about their genetic parents.

The proposed Assisted Reproductive Treatment Regulations 2009

The objectives of the proposed Regulations reflect the government's overall legislative objectives by:

- ensuring that patients and other parties are informed about the risks associated with ART (to address information gaps); and
- ensuring cost-effective collection of information (to reduce health risks, to enable a child to obtain information regarding their genetic parents, and to promote compliance with the legislation).

The proposed Regulations prescribe a number of elements of the Act and generally have a very narrow application. Broadly, the proposed regulations prescribe:

- consent forms for an ART treatment, child protection order check, and donor's consent;

[2] Victorian Law Reform Commission, *Assisted Reproductive Technology and Adoption: Final Report*, VLRC, June 2007, Melbourne, viewed at 9 September 2009, www.lawreform.vic.gov.au

- certain matters that must be covered in counselling sessions prior to a treatment, donation, surrogacy arrangement, or posthumous use of gametes or embryos;
- costs that may be reimbursed for a surrogate mother;
- information that must be kept on a register by a business (i.e., ART providers/doctors); and
- a fee of $60.60 for applying for donor information from the Central Register held by BDM Victoria.

Table 1 below describes each of the 19 proposed Regulations and shows how they derive from the *Assisted Reproductive Treatment Act 2008*.

Table 1: Description of Proposed Regulations

Reg[n]	Description	Act reference
1	Objectives of the regulations	—
2	Authorisation to make the regulations	s. 124
3	Commencement date, 1 January 2010 or earlier	—
4	Definitions – defines the 'Act'	—
5	Form of consent to treatment procedure, details contained in Schedule 1 of the regulations	s.10(1)(a)
6	Form of consent for permission to conduct a child protection order check, Schedule 2	s.11(1)(d)
7	Matter to be raised during counselling prior to a treatment procedure	s.13
8	Form of donor's consent, Schedule 3	s.17(1)(a)
9	Matter to be raised during counselling prior to donation	s.18
10	Matter to be raised during counselling prior to a surrogacy arrangement	s.43(a)
11	Costs incurred that may be reimbursed to a surrogate mother	s.44(2)
12	Matter to be raised during counselling prior to posthumous use of gametes or embryos	s.48
13	Method of disposal of embryos	s.34(2)(b)
14	Register to be kept by ART provider, details of information prescribed in Schedule 4	s.49(1)
15	Register to be kept by a doctor carrying out artificial insemination, details of information prescribed in Schedule 5	s.50(2)
16	Central register kept by the Registrar, details contained in Schedule 6 to be submitted by a doctor who has carried out artificial insemination	s.53(b)
17	Fee of 5.18 fee units (i.e., $60.60) for applying for donor information from the Central Register	s.56(3)(b)
18	Prescribes that the Voluntary Register held by BDM Victoria must be in an electronic form	s.71(4)
19	Applications for ART registration to name a contact officer	s.74(2)(c)

As mentioned above, the proposed Regulation and consequently this RIS do not examine the broader policy issues such as access by certain social groups to ART services, surrogacy arrangements, or police records and child protection order checks. These are matters are governed by Victorian Government policy and reflected in the legislation.

The proposed Regulations are the product of the extensive reviews of ART in Victoria and contained a number of changes of scope and form: nevertheless the proposed Regulations will be broadly similar with the proposal compared with the current regulations.

Given that eligibility of access of ART has been expanded, new regulations have been included in relation to counselling prior to surrogacy arrangement (Regulation 10), prescribed costs actually incurred that may be reimbursed (Regulation 11), counselling prior to posthumous use of gametes or embryos (Regulation 12). Doctors carrying out artificial insemination who are not part of an ART clinic will also be required to keep records (Regulation 15). In addition, as a result of a policy decision a new form of consent will be required in relation to child protection order checks (Regulation 6). A number of requirements currently contained in the ITA 1995 will be placed into the proposed Regulations (i.e., Regulations 9 and 15).

Overall, the wording in the regulations has been streamlined and updated, with recognition being given to reducing the regulatory burden. Attachment B compares the current Regulations with the proposed Regulations.

Costs and benefits of the proposed Regulations

Costs

Each of the proposed Regulations was examined for the likely costs they would impose on parties affected by the proposal. It is assessed that there are no costs associated with the machinery regulations (Regulations 1 to 4), while Regulation 11 deals with reimbursement of certain costs associated with surrogacy arrangements (an economic transfer) and Regulation 17 concerns a fee for applying to BDM Victoria for certain information (financial cost). The remaining regulations deal with filling out forms, record keeping or sending information to government (administrative costs) and matters to be covered during counselling (substantive compliance costs).[3]

The Victorian Government's Standard Cost Model (SCM) methodology was used to calculate the administrative costs to business and individuals associated with these regulations. Table 2 below shows that these costs over a 10-year period are approximately $3.5 million (PV), or impose an annual cost of around $356,000 (PV). Of these costs, approximately 60 per cent are imposed on business (i.e., ART providers) and 40 per cent are imposed on individuals. Given the large number of

[3] The *Victorian Guide to Regulation* identifies three categories of regulatory costs: these are compliance costs (1. administrative costs 2. substantive compliance costs), financial costs, and market costs. See section 1.4 of this RIS for explanations of these costs.

treatments per annum (assumed to be around 9,000), the administrative costs for individuals associated with each treatment are relatively low at around $80 (the average total cost of a treatment charged by a clinic is in the order of $5,000). An indicative administrative cost imposed upon ART providers is around $130 per treatment. These costs represent the 'time cost' or time forgone by having to comply with the regulations.

Table 2: Costs Imposed by the Proposed Regulations (PV), 10-Year Assessment Period

Reg[n]	Description of Regulation	Cost ($)
5	Form of consent to treatment procedures	266,951
6	Permission to conduct child protection order checks	533,901
8	Form of donor's consent	20,763
14	Register kept by registered ART provider	2,656,350
15	Register kept by doctor carrying out artificial insemination	10,384
16	Provision of information by ART provider to the Registrar	64,883
	Cost of updating forms for ART providers	9,434
Total		**$3,562,666**

*Figures rounded

Proposed Regulations 7, 9, 10 and 12 deal with matters that are required to be covered during counselling and are 'substantive compliance' costs. Stakeholders advise that these matters are covered during the ordinary course of a counselling session and as such do not add to the time or complexity of the requirement. Furthermore, stakeholders considered that the prescribed matters provided a structure or template for counselling and ensured a level of consistency across services provided by clinics. Given this, these regulations are assessed as not imposing a significant cost and a monetary cost is not attached to them. The Victorian Government also incurs costs in relation to administering the regulations. These costs are estimated to be around $59,000 over a 10-year period.

Therefore, the total quantifiable costs to business and government costs associated with the proposed Regulations are approximately $3.6 million (PV) over a 10-year period, or a cost of around $362,000 (PV) per annum. The table below shows this cost and incidence upon different groups.

Table 3: Costs imposed by the Proposed Regulations on Business, Individuals and Government (PV), 10-Year Assessment Period

Sectoral Cost	Cost ($)
Business – e.g., ART providers/doctors	2,207,704
Individuals – e.g., patients, donors, partners	1,354,962
Government – administration and compliance	59,055
Total	**$3,621,721**

*Figures rounded

Benefits

At a broad level, a regulated clinic system offers important safeguards both for persons participating in treatment (medical screening and registration of donor details, mandatory pre-treatment counselling for all parties) and the children who may be born of the treatment procedure (assessment of parental risk factors, access to records providing genetic history, access to counselling as an adult).

It is important to recognise, however, that most of these benefits are attributable to the Act rather than the proposed Regulations. For example, in a number of cases the regulations prescribe additional requirements to those contained in the legislation. That said, the benefit associated with the proposed Regulations is the operational effect given to the legislation by providing a framework of information to allow parties to make informed decisions. The proposed Regulations also establish standardised record keeping requirements to permit efficient audits and allow information to be recorded in a way that allows persons born from a treatment procedure to determine their genetic parents. The regulations provide these benefits in a manner which lowers 'search costs' and enhances compliance.

The proposed Regulations also seek to minimise costs for individuals and industry participants by prescribing information requirements that may be readily adaptable into forms for use by ART providers. If this information was not prescribed then ART providers would need to rely on the Act to estimate the specific types and level of detail required. It would be difficult for ART providers to determine the legislative requirements and may lead to not including enough information on one hand (thereby compromising compliance) or including too much information on the other hand (thereby adding to costs). Thus prescribing the information in a statutory rule reduces the 'search costs' for ART providers as well as lowering the risks of non-compliance. In short, prescribing information requirements provides regulatory certainty. Standardised information also lowers government collection and audit costs.

A further benefit is that statutory rules are an appropriate instrument for prescribing the type of matters covered by the proposed Regulations. They may be changed in a relatively straightforward and timely manner (compared to changes to legislation), are publicly available, and have an in-built review mechanism (statutory rules must be remade every 10 years).

Groups affected by the proposal include: women undergoing ART and their partners (there are approximately 9,000 women treated per annum therefore this number would be around 18,000 persons) and any existing children born as a result of ART; gamete donors (approximately 1,600); parties in surrogacy arrangements; ART providers, including clinics (15), doctors (54), and counsellors (39); and government (i.e., Department of Health, BDM Victoria, Department of Human Services and the Victorian Assisted Reproductive Treatment Authority).

Alternatives

A RIS is required to identify and assess alternatives to achieve the government's objectives. Strictly speaking, the 'do nothing' or status quo position is not an alternative. This is because the government has identified a problem (or market failure) that needs to be addressed: either by a regulatory or non-regulatory measure. The alternatives identified in this RIS are the provision of educational information (instead of counselling), performance-based standards with respect to information collection and record keeping; enhanced codes of practice or guidelines; or incorporating the regulations into the legislation.

An assessment using the Multi-criteria Analysis (MCA) methodology was undertaken (this process is described in Section 4.2.3 below) to compare the efficiency and effectiveness of these alternatives. Table 4 shows that the proposed Regulations are assessed as the most effective in achieving the government's objectives. The proposed Regulations are preferred because they: provide greater clarity concerning patient and clinic obligations; provide an effective, standardised mechanism for data collection, and allow government to audit, monitor and enforce the regime efficiently. It will be observed that the provision of information and codes of practice receive a relatively high score. This RIS finds that these instruments are important *complementary* measures and enhance the effectiveness of the proposed Regulations (it is possible that without codes and guidelines the regulations would need to be more prescriptive).

Table 4: Summary of Multi-criteria Analysis Compared to Regulations

Regulatory Proposal	MCA Assessment
Base case scenario – Status quo	**0.00**
Proposed Regulations	**32.50**
Provision of educational information	**27.75**
Performance-based standards	**16.75**
Voluntary code of practice	**28.5**
Incorporation into the Act	**29.50**

The risk of not proceeding with the proposed Regulations is that parties would not receive adequate information, the quality of the information held by government could not be guaranteed, and compliance would be more difficult and costly to undertake. Overall, this would lead to diminished effectiveness of administering the Act, and therefore would not be in the best interest of the child.

Small business impact, restrictions on competition, and changes in the administrative burden

The financial impact of the proposed Regulations predominantly falls on businesses (i.e., ART providers) that are larger than small businesses (i.e., employ more than 20 staff). The relatively straightforward nature of the proposed Regulations makes it unlikely that any small businesses would be disadvantaged in terms of lacking the expertise or resources to comply with the requirements.

Assessed against the 'competition test' in the *Victorian Guide to Regulation*, this RIS concludes that the proposed Regulations do not impose restrictions on competition. The cost impact on individuals (approximately $80) and business approximately $130) of the proposed Regulations is considered relatively minor in the context of costs in the ART market segment and should not discourage consumers from accessing ART services. While a number of restrictions on the market may be identified, these controls are imposed by the Act rather than the regulations themselves. The proposed Regulations apply equally to all businesses and consumers and impose similar requirements compared to other states (however, Victoria does require police records checks and child protection order checks).

The *Reducing the Regulatory Burden* initiative commits the Victorian Government to reducing the administrative costs of regulation. Accordingly, this RIS uses the Standard Cost Model methodology and the associated guidelines on the *Measurement of Changes in Administrative Burden* to inform its cost–benefit analysis and to measure any changes to the administrative costs. Administrative costs are those costs incurred by business to demonstrate compliance with the regulation or to allow government to administer the regulation (e.g., reporting, notification, or recording requirements). This is commonly known as red tape.

The analysis in this RIS finds that the new regulatory costs imposed by the proposed Regulations will not lead to a material change in the administrative burden on business in Victoria. This assessment is based on calculations made using the SCM methodology, which estimates the increase of administrative costs on business to be in the order of $8,000 per annum.

Conclusion

This Regulatory Impact Statement concludes that:

- **the benefits to society of the proposed Regulations exceed the costs;**
- **the net benefits of the proposed Regulations are greater than those associated with any practicable alternatives;**
- **the proposed Regulations do not impose restrictions on competition; and**
- **the proposed Regulations will not lead to a material change in the administrative burden on businesses.**

Public consultation

The prime objective of the RIS process is to help members of the public comment on proposed Regulations before they are finalised. Public input, which draws on practical experience, can provide valuable information and perspectives, and thus improve the overall quality of regulations. The proposed Regulations are being circulated to key stakeholders and feedback is sought. The Department of Health (DOH), which will be responsible for administering the *Assisted Reproductive Treatment Act 2008* when it is proclaimed, welcomes and encourages feedback on the proposed Regulations.

While comments on any aspect of the proposed Regulations are welcome, stakeholders may wish to comment on:

- the consent forms (rr. 5, 6 and 8) and whether they contain appropriate information in a suitable format;
- whether or not the matters prescribed for counselling (rr. 7, 9, 10 and 12) are appropriate;

- whether or not the information requirements contained in the Schedules (r. 14 (Schedule 4), r. 15 (Schedule 5), r. 16 (Schedule 6)) are appropriate, could be streamlined or simplified, and is the wording in the requirements clear?
- whether the types of costs actually incurred by a surrogate mother that may be reimbursed should cover a narrower or broader range of items (r. 11). Do the expense items in the proposal allow for activity that could materially benefit surrogate mother by providing some form of financial gain?;
- whether or not a less prescriptive approach has merit;
- any practical difficulties associated with the proposed Regulations; and
- any unintended consequences associated with the proposed Regulations.

All submissions will be treated as public documents and will be made available to other parties upon request.

1. WHAT IS THE ISSUE/PROBLEM TO BE ADDRESSED?

1.1 Background

Social context

Since the 1960s there have been substantial changes in the structure of Australian families. Changes include a growth in the proportion of single parent families and blended families, and increases in the number of people living in same-sex relationships. In addition, the number of people who use in-vitro fertilisation or other forms of assisted reproductive technology has steadily increased over the past decade.

Assisted reproduction

Given that 3.1 per cent of babies born in Australia are from ART procedures, this reinforces the importance of ensuring a safe and well-managed ART system.

For the purposes of this RIS 'assisted reproductive treatment' is defined as medical treatment or a procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes in-vitro fertilisation (IVF) and gamete intra-fallopian transfer (GIFT).[4] Such treatment is used to help a person to give birth to a child when conception through heterosexual intercourse is impossible or difficult, or carries a risk that a disease or genetic abnormality may be transmitted to the child.

A woman may be assisted to conceive if semen is placed in her vagina (birth canal), cervix (the opening to her uterus) or directly into her uterus. This is known as assisted insemination. Vaginal insemination does not necessarily require medical assistance. If a woman has access to semen she can perform vaginal insemination herself by injecting semen (usually fresh) into the vagina, usually using a plastic syringe (known as self-insemination). Intra-uterine insemination does require medical assistance as it involves the placement of sperm into the womb using a fine catheter.

The most common form of ART is IVF, followed by gamete intra-fallopian transfer (GIFT). IVF is the procedure by which a woman's egg and a man's sperm are mixed in a laboratory. It involves mixing the egg with sperm and allowing the process of fertilisation to take place over a number of hours in a culture dish. Provided fertilisation occurs in the laboratory and the resultant embryos look normal, the embryos are transferred into the uterus of the woman. GIFT is a medical procedure developed to treat infertility. Eggs are collected from a woman's ovaries and are then placed together with sperm (which has been collected and washed) directly into the woman's fallopian tube using a fine sterile plastic tube.

[4] Section 3 of the Act

Some couples provide their own sperm and eggs for the procedure, while about 6 per cent of births result from donated sperm or eggs (referred to as gametes). The need to use donated gametes arises when there are difficulties conceiving, when a person carries a disease or genetic abnormality and a woman without a male partner wants to have a child.

Surrogacy involves a woman who agrees to become pregnant and give birth to a baby which she then permanently surrenders to another person or couple who will be the child's parent or parents. Surrogacy arrangements may involve the use of forms of ART, for example an embryo may be formed in a laboratory and then transferred to the surrogate's uterus. In such cases the embryo may be created with the commissioning mother's or donated eggs and fertilised with the commissioning father's or donated sperm.

An ART treatment cycle begins on the day when superovulatory drugs were commenced or from the date of the last menstrual period. In 2007 calendar year 15,007 cycles commenced, with 8,666 women treated.[5] In 2006 there were 2,573 born from ART procedures (1,671 IVF, 19 GIFT, 862 Thaw Cycle, 21 Donor Insemination).[6]

Under Victoria's current legislation, an ART procedure can only be carried out at licensed premises (however artificial insemination can be performed outside a licensed clinic by a doctor). There are currently 15 places licensed to provide ART treatment. Under the new Act licenses will be replaced by registration, which will allow related entities to operate under the registration. This will result in six registrations covering the 15 premises.

In addition, doctors are required to be licensed to carry out an ART procedure, to transfer an embryo to a woman, to carry out donor insemination at a place which is not licensed. Counsellors are required to be approved to provide counselling about the types of treatment procedures to patients or to counsel a donor prior to donor treatment. During 2007/08 there were 54 doctors and 39 counsellors registered under the Act. Under the new Act doctors and counsellors will no longer be required to be 'approved'.

Regulatory developments in Victoria

Victorian legislation regulating ART was first enacted in 1984. Victoria was the first jurisdiction internationally and the first state in Australia, to enact legislation regulating assisted reproduction. This legislation was introduced following recommendations made by a committee established in 1982 by the Victorian Government, the Committee to Consider the Social Ethical and Legal Issues arising from IVF, headed by Professor Louis Waller (the Waller Committee).

The Waller Committee concluded that IVF and the use of donated sperm, eggs and embryos were acceptable practices, but that safeguards should be implemented to control their use. In particular, it recommended that IVF should only be conducted

[5] Infertility Treatment Authority, 2008, Annual Report. p. 23
[6] ibid., p.26

in authorised hospitals, and that counselling and information should be provided to people prior to treatment to ensure free and informed consent. The committee also recommended that participants in the IVF program be married and have attempted alternative means of conception for at least 12 months before joining the program, and that admission to donor treatment programs be based on need.

In addition, the committee recommended that donors should receive counselling and provide consent prior to donation, and that a registry to enable donors, recipients and donor conceived people to obtain non-identifying information about each other be introduced. Based on these recommendations the *Infertility (Medical Procedures) Act 1984* was introduced and came into effect on 1 July 1988.

Between 1990 and 1991 a detailed review of this Act was undertaken. Given the impact of technological innovation and the experience of the interpretation and operation of the Act, it was decided to pass new legislation to regulate ART. The new legislation, the *Infertility Treatment Act 1995,* came into effect on 1 January 1998.

The principal differences between the new and old Act were the abolition of the 12-month waiting period to enter the IVF program, the introduction of the right of people born as a result of donor treatment procedures to obtain identifying information about their donors, and the establishment of a new licensing authority and regulatory body, the Infertility Treatment Authority.

Following the decision in the *McBain* case[7], in October 2002 the VLRC received the terms of reference from the Victorian Government to enquire into, and report on, the desirability and feasibility of changes to the *Infertility Treatment Act 1995* to expand eligibility criteria in respect of all forms of assisted reproduction.

Following a comprehensive review and consultation process, in March 2007 the final report including 130 recommendations for changes to the law was delivered to the Attorney-General. The Attorney-General tabled the report in Parliament, and this resulted in the subsequent introduction and passing of the *Assisted Reproductive Treatment Act 2008*. The most significant change in the new legislation is the expansion of eligibility of parties that can access ART. Reflecting changes in the community, single women or women in same-sex relationships who are fertile will be able the access ART for the first time. Police records checks and child protection order checks will also be required for all parties wishing to access ART.

1.2 Rationale for Government Intervention

1.2.1 Rationale for government intervention

Public policy usually begins from the premise that activities should be unregulated unless the market does not deliver socially efficient outcomes. That is, government intervention in markets may be justified on economic efficiency grounds, or to

[7] McBain v The State of Victoria & Ors [2000] 99 FCR 116

achieve social and environmental objectives. In the case of ART, addressing 'market failure' is less relevant than the social objectives. Key rationales for government intervention may include ensuring the 'best interests' of children born as a result of ART, the managing of scientific developments, and in the past, limiting the types of persons who can access ART. With respect to the interests of the child, a case could be mounted that the state has a responsibility to protect the legitimate interests and needs of children because they are incapable of participating in the decision-making process in relation to their own conception.

While social objectives are the primary reason for government intervention in ART, such intervention also seeks to manage risks and to ensure that parties receive adequate information (e.g., establishing procedures to support patients through the process and ensure they are able to make informed decisions about treatment options).

However, this RIS acknowledges that the question of whether, and to what extent, the law should govern the use of ART is controversial. Some people think ART is simply a medical procedure that should not be regulated differently from any other treatment. According to this view, the principles of individual autonomy and reproductive freedom should prevail and decisions should be made by the treating doctor and the patient, subject to the normal requirement for a proper standard of care. Another argument against regulation is that because there is no consensus in the community about what ethical principles should apply to reproductive choices, moral and ethical decisions should be made by the individuals concerned and not imposed by the state. Further, interference by the state may hinder developments in treatment-enhancing technologies. Proponents of this view also argue that clinical issues can be addressed through professional self-regulation in the form of guidelines and codes of practice.

On the other hand, some people argue that ART is different from other forms of medical treatment because the creation of children raises complex moral and social questions. On these grounds, it is argued that ART should be regulated by the state. Supporting this there appears to be agreement in the literature produced by policy makers and academics that a degree of careful and balanced intervention by the state in ART is justified to in order to:

- protect patients and children to be born against genuine risk of harm by implementing safeguards and ensuring the quality of services;
- establish procedures to support patients through the process and ensure they are able to make informed decisions about treatment options;
- control particularly harmful or unacceptable activities such as the implantation of multiple embryos,
- instil public trust and confidence in the delivery of services using emerging technologies;
- make decision-making processes fair and transparent and the people responsible for those decisions accountable;
- clarify parental status where donated gametes have been used to conceive a child;

- provide access to information about a donor conceived person's genetic origins;
- control the expenditure of public funds;
- constitute an independent party in this process, and assist in resolving conflicts and formalising an expression of public interest; and
- provide processes for consultation and review about future changes to legislation, particularly in response to rapidly changing technology.

The use of ART raises issues which go beyond the interests of particular individuals and may affect the whole community. Different participants in ART (primarily patients, their partners, donors, and children born as a result) have different interests and needs which must be protected and balanced. The state is able to play an important role in helping to ensure this is done in a fair and transparent way.

People have a range of views about the ethical and social implications of creating children through the use of ART. This makes it particularly important that ART is open to public scrutiny and the public has the opportunity to express their views about the conditions under which it is provided. Regulation can identify the public interests which must be considered when treatment is provided and give democratic legitimacy to decisions about ethical and moral issues.

It should be highlighted that many of the points above relate to the broader case for government intervention in the sphere of ART. The proposed Regulations have a much more narrow focus and may be justified on the grounds of:

- establishing procedures to support patients through the process and ensure they are able to make informed decisions about treatment options;
- creating administrative certainty and confidence in the system;
- ensuring efficient allocation of resources (i.e., by charging fees to recover the cost of government services).

1.3 Risks of Non-intervention

The risk of not proceeding with the proposed Regulations is that parties would not receive adequate information, the quality of information held by government could not be guaranteed, and compliance would be more difficult and costly to undertake. Overall, these would diminish of the effectiveness of administering the Act, which would not be in the best interests of the child.

1.4 Type and Incidence of Costs

The *Victorian Guide to Regulation* identifies three categories of regulatory costs: these are compliance costs, financial costs, and market costs.[8]

Compliance costs can be divided into 'substantive compliance costs' and 'administrative costs'. Substantive compliance costs are those costs that directly lead to the regulated outcomes being sought. These costs are often associated with content-specific regulation and include modifying behaviour or undertaking specified training in order to meet government regulatory requirements. A requirement to seek counselling would be considered a substantive compliance cost.

Administrative costs, often referred to as red tape, are those costs incurred by business to *demonstrate* compliance with the regulation or to allow government to administer the regulation. Administrative costs can include those costs associated with familiarisation with administrative requirements, record keeping and reporting, including inspection and enforcement of regulation. The majority of costs affecting ART providers and users are administrative costs. Attachment A contains a description of the regulatory costs imposed by each regulation, while Attachment B compares the current Regulations with those proposed.

Financial costs are the result of a concrete and direct obligation to transfer a sum of money to the government or relevant authority. Such costs include administrative charges and taxes. For example, the fee for an application for information (r. 17) is a financial cost.

Market costs are those costs that arise from the impact that regulation has on market structure or consumption patterns. These costs are often associated with licensing of certain activities, prescribing qualifications or limiting access to a certain profession or industry in some other way. When barriers to entry are created, this can allow incumbents to charge higher prices and can result in reduced service levels and stifle innovation. Given the narrow focus of the regulations, it is not expected that they will impose market costs.

1.5 Issues Requiring Clarification

1.5.1 Broader problems dealt with by the Act

A key finding of the VLRC report was that Victoria's regulation of ART had failed to keep pace with the emergence of new families and developments in reproductive technology. Currently in Victoria the law does not include several family types, either by excluding certain categories of people from accessing ART services or in not recognising all kinds of families. As discussed above, the Victorian Government introduced new legislation to deal with these issues.

8 DTF, 2007, ibid., p. F-7

In addition, techniques of assisted reproduction are evolving rapidly. Many of the medical and social consequences of ART are not yet fully understood. Regulation can deal with this uncertainty by monitoring practices, controlling use of particular technologies, and implementing protections against identifiable harms and risks. The regulatory scheme must be able to respond to technological change, to address emerging problems and to respond to shifts in social attitudes. As will be shown below, the experience in Victoria has demonstrated that social changes, changes in technologies, and interpretation of the law have resulted in a modernising of the regime regulating ART.

The proposed Regulations prescribe and give operational effect to elements of the Act. The Act itself, however, deals with the broader problems the government seeks to address. These are relevant to the proposed Regulations as they seek to provide greater effectiveness of the Act, and for context and completeness these are briefly discussed below. The specific problems the regulations seek to address are discussed in Section 1.6.

1.5.2 Access to ART

Previously, the legislation in Victoria required that a woman must be 'unlikely to become pregnant' to have treatment in a clinic. She must also have been married or in a de facto relationship with a man. In 2000, the Federal Court of Australia decided in *McBain v The State of Victoria* that the latter was inconsistent with the federal anti-discrimination law and was therefore invalid. (The marital status requirement would also now be contrary to the principles of equality of treatment espoused in Victoria's *Charter of Human Rights and Responsibilities.*) Since then, clinics have been able to treat women who are not married or not in relationships with men, as long as they are clinically infertile. These women are able to be treated with donor sperm.

However, single women or women in same-sex relationships who wish to use donor sperm from a clinic because they do not have male partners but who are not clinically infertile **cannot** access treatment (the new Act will change this when it is proclaimed).

The restrictions in the current law have a substantial impact on certain groups of women wishing to have children. Single or lesbian women may need to travel interstate or overseas to access clinical services. This causes women significant expense and inconvenience. Moreover, it may mean that their children have no right to access information about their donors, if that jurisdiction continues to permit anonymous donations. Other women who are ineligible for treatment in clinics may make private arrangements to self-inseminate with sperm from donors who may or may not be known to them. This exposes women and children to unacceptable health risks, as there is no guarantee the donor will be screened for communicable or heritable genetic diseases. The protections offered by Victorian system, such as the legal right to access information about donors, counselling, and the screening of sperm for disease is not always available to these women.

Surrogacy arrangements that do not involve any payment are legal in Victoria. However, the law currently makes it very difficult for a surrogate mother to have

treatment in a reproductive clinic. She must be 'unlikely to become pregnant' to receive treatment. If the couple commissioning the surrogacy want to use their own embryo, the surrogate's husband must also be infertile.

The restrictions in Victoria have meant that people wanting to use surrogacy to have a child have travelled interstate or overseas to do so. When this happens, the child born may lack the full protection of Victorian law. It is particularly important that surrogacy arrangements are undertaken with care. Surrogacy arrangements are more complex than other forms of ART because a surrogate mother will surrender her child.

1.5.3 Rights of children – Information on identity

Prior to the introduction of legislation all donors were anonymous, and no central records were kept about donations made before 1988. In the period between 1988 and 1998, the central register recorded information about the donor but obtaining identifying information about a donor from this period depends on the donor having consented to release of the information. Donor-conceived people born before 1998 are often angry and frustrated because that they cannot find out about their donor (unless the donor has entered his or her details on the voluntary register).

It is considered sufficiently important for children to know the identity of their donors that Victorian law now recognises the right of donor-conceived people to be able to discover the identity of their donors. Currently in Victoria, people born after 1998 have a right to know the identity of their donor and may apply for this information when they turn 18.

Under the new legislation, BDM Victoria will manage the Central Registers and Voluntary Registry.

1.5.4 Risks to children

The current restrictions limit access to reproductive treatment on the basis of whether people are married or in de facto relationships, and whether they are clinically infertile. These restrictions are not based on identified risks to children. Research shows that having single, lesbian or gay parents does not pose any greater risk to children's wellbeing as compared to children with a mother and father. . Screening people who wish to access treatment and dealing with other issues, which may affect children may minimise risk to children born as a result of ART; however, this RIS acknowledges that this is a controversial area.

1.5.5 Posthumous use of eggs and embryos

There have been a few cases in Victoria where people have died and their partners have subsequently wanted to use their sperm or an existing embryo to have a child. These cases were dealt with by the courts because the legislation specifically banned procedures involving the gametes of persons known to be dead (s. 43 of the 1995 Act). The new legislation will provide regulatory certainty for the person wanting to use eggs, sperm or an existing embryo when their partner dies. Given

these special circumstances it is important that parties are adequately informed of the implications of the use of such sperm or embryo (e.g., possible impacts on a child born from this procedure). Therefore, the legislation and proposed Regulations require parties to undergo counselling.

1.5.6 Reimbursed costs incurred by surrogate mothers

A key principle of the Act is that "at no time should the use of treatment procedures be for exploiting in trade or otherwise the reproductive capabilities of men or women or children born as a result of treatment procedures". [9] Reflecting this, the Act prohibits 'commercial surrogacy' and imposes considerable penalties for doing so (a penalty of up to $28,037 or 2 years imprisonment or both). Section 44 of the Act states that a surrogate mother must not receive any material benefit or advantage as a result of a surrogacy arrangement.

However, the reimbursement of a narrow range of costs actually incurred by the surrogate mother, which directly arise from the pregnancy, will not compromise the general position that surrogate arrangements must be 'altruistic'. This was the view of the Victorian Parliament (see s. 44(2) of the Act).

Commercial surrogacy is prohibited in all Australian jurisdictions. Only two jurisdictions in Australia, however, specifically deal with re-imbursement of costs – Victoria (in the proposed Regulations) and West Australia (WA) (specified in legislation rather than regulation). WA has a broader definition of surrogacy related costs than Victoria. Specifically, the WA legislation limits reasonable expenses to costs incurred in the surrogacy arrangement to a number of categories as follows:

- reasonable medical expenses associated with the pregnancy which are not otherwise provided for through Medicare, private health insurance or any other benefit;
- health, disability and life insurance during the course of the pregnancy;
- in the absence of any entitlement to paid maternity or other leave, lost earnings up to a maximum of two months;
- any additional lost earnings or medical expenses incurred as a result of special circumstances arising during the pregnancy;
- reasonable post-natal medical expenses;
- reasonable pre- and post-natal psychological counselling expenses related to the surrogacy arrangement; and
- reasonable legal, advisory or assessment expenses associated with the surrogacy arrangement

[9] Section 5(b) of the Act

The scope in Victoria of reimbursable costs actually incurred is narrower than those permitted in WA. DOH considers that the scope in the proposed Regulations will minimise any possible misuse of the provisions in the legislation and proposed Regulations.

In Victoria the surrogacy arrangement will be supported by the ART provider and the professional opinion of the clinicians will be used to identify reasonable costs and if related to the surrogacy (e.g., gestational diabetes may require medication which would be a reimbursable cost). The issue of other medically related costs will also be subject to the professional opinion of the treating clinician. Reimbursement will occur privately between parties.. It is not proposed to prescribe an upper limit on the amounts.

The Patient Review Panel must approve and has oversight of all surrogacy arrangements and all parties are required to undergo counselling and seek legal advice. As part of the broader approval role, the Patient Review Panel may set conditions and provide oversight to ensure that reimbursable expenses under the proposed Regulations are not abused.

1.5.7 Rapid scientific developments

Developments in ART present a significant challenge for regulators: legislation can quickly become redundant, unworkable or obstructive if the matters being regulated changes. These problems generally arise when legislation is prescriptive, that is, when it is specific about what treatments can or cannot be provided and there is no scope for flexibility in the application of the law.

Although the restrictive consequences of legislation are often intentional, because governments have made decisions about where the boundaries should lie in respect of scientific advances, a lack of flexibility can have a range of undesirable effects. In particular, it may result in legal challenges to the validity of the legislation, as in the case of *McBain v State of Victoria*, or people may seek specific redress from the courts, as in the posthumous use of sperm cases of *AB v Attorney-General (Vic)* and *YZ v Infertility Treatment Authority*.

Assisted reproductive treatment facilitates the birth of children in circumstances which not long ago were unimaginable. For example a person or couple may commission a woman to act as a surrogate mother using sperm and eggs donated by third parties. Parents are able to select embryos for implantation that are unaffected by a genetic disease or condition which they would otherwise be at risk of transmitting.

Some people in the community regard these advances as positive developments for human reproduction. Some are opposed to all forms of interference or assistance in the process of conception. Others do not oppose ART, but are cautious about the implications of new treatments and technologies for individuals and for society in general. As some forms of ART become more widely used community attitudes to them change. Therefore, rapid technological change and diversity of community

opinion presents challenges for governments seeking to monitor and control the provision of ART services.

1.6 Problems the proposed Regulation seek to address

Provision of Information – Counselling

To make informed decisions about their treatment, all participants in ART need to understand all the procedures involved, including any health risks and psychosocial consequences associated with them. The parties currently required to receive counselling include the woman receiving ART, her partner (if any), the donor(s) and commissioning parents in relation to surrogacy arrangements.

Having children through ART, and in particular through donor treatment procedures and using sperm or eggs from a deceased partner, involves consideration of a range of issues. Counselling and provision of information assists people to understand the medical and psychological implications of treatment and are important avenues for exploring how to protect the best interests and meet the particular needs of any child to be born.

Some ART treatments use donated sperm, eggs or embryos to help a woman or couple to have a child. The 1995 legislation requires that all donors receive counselling and have medical checks prior to donation. If the woman, her partner (if any) and the donor have not adequately explored their respective roles in relation to the child, the potential for future conflict escalates.

Counselling is also crucial for people planning to have children with the assistance of known donors and/or surrogate mothers. A known donor is distinct from a partner. A known donor is, for example, a friend or relative who donates a gamete. Counselling is compulsory in these circumstances in order to ensure that both parties are aware of the issues related to donating genetic material and to understand post-birth issues. For example, issues such as whether the donor has ongoing contact with the child should be raised. In addition, the act of donating a gamete to a friend or relative is likely to have a major impact on the relationship between the donor and the recipient, and these issues and expectations should be canvassed and agreements reached or mediated through counselling.

Counselling in relation to surrogacy arrangements needs to cover additional matters, including, the commissioning persons' expectation, possible effects on the children of the surrogate woman carrying the pregnancy and relinquishing the child, the conduct of the pregnancy (e.g., alcohol consumption, smoking, prenatal testing, termination of the pregnancy, etc). Further, parties need to understand the consequences of any party changing their mind or withdrawing from the arrangement.

Providing a forum for all participants to explore the roles they will each play in the child's life can help to minimise or avoid conflict in the future. Specialist counselling services should be available for all people involved in the conception of a child through ART.

Under the proposed Regulations, it is important to note that counselling is only required once and it is prior to a treatment procedure (section 13 of the Act). For example, a patient would undergo counselling once prior to an initial treatment procedure. Subsequent treatments – even three or four treatments – would not require further counselling. Only in exceptional circumstances may further counselling be required. It is not consider necessary to prescribe the number of sessions over and above the mandatory requirement as situations will depend on the individual circumstances of the patient and the professional judgement of the counsellor.

Managing Information – Records

The 1984 and 1995 legislation required that prescribed information in relation to donor gametes be recorded on a central register, recognising and addressing the needs of persons born of donor procedures have access to information regarding their genetic heritage. This register was established and maintained by the Health Department under the 1984 Act and maintained by the Infertility Treatment Authority under the 1995 legislation.

Access to genetic heritage is an important aspect of a person's life and in many ways defines their identity: the experience of the *Bringing them home: The 'Stolen Children' report* specifically, and issues with adoption more generally has validated this. From 1988 in Victoria donation of gametes could no longer be made anonymously, and since 1995 donors have been required to undertake counselling prior to donation and advised that the donor conceived child has the right to obtain both identifying and non-identifying information.

Additionally, with the increasing use of genetic screening, identification of inheritable genetic disorders/diseases the donor conceived person is able to discover if they have a propensity to a particular disease. For example, a history of a particular type of cancer would allow the person born of a donor procedure to seek screening, make lifestyle adaptations, or seek early intervention.

A 2001 amendment to the 1995 legislation established the voluntary register, which records information about donors and persons born of donor procedures who voluntarily submit their information and any wishes in relation to contact. The voluntary register is the only vehicle available to persons conceived with gametes donated before 1 July 1988 to exchange information with donors, who donated on the condition of anonymity before this date.

Forms of Consent

The Act requires that consent be obtained from parties undergoing an ART procedure. For example, s. 10(1)(a) required information for consent to a treatment procedure, s. 11(1)(d) deals with the form of consent to conduct a child protection order check, and s. 17(1)(a) deals with the form of donor's consent. The public policy rationale for obtaining consent (which requires a person's signature) is to provide a process that allows a person to consider carefully the implications and consequences of participating in the ART process. Signed consent forms may also

have legal implications and provide evidence to clinics that a person agrees to participate in the ART process.

The proposed Regulations seek to lower compliance costs by prescribing the form of consent information, and seek to provide flexibility by allowing ART providers to incorporate this information into their existing package of forms.

2. OBJECTIVES OF GOVERNMENT INTERVENTION

2.1 Government Policy

As noted earlier, in 2002 the Victorian Government requested the VLRC to examine the feasibility and desirability of making changes to the *Infertility Treatment Act 1995*, with regard to the eligibility criteria for ART and adoption, the regulation of surrogacy and issues surrounding parental recognition. The VLRC's final report was tabled in Parliament in June 2007. A key finding of the VLRC report was that Victoria's regulation of ART had failed to keep pace with the emergence of different compositions for families and developments in reproductive technology.

The Victorian Government adopted the key findings of the report and in September 2008 it introduced a Bill into Parliament for the regulation of ART, artificial insemination and surrogacy arrangements. The Assisted Reproductive Treatment Bill 2008 was assented to on 11 December 2008 (but will come into operation by no later than 1 January 2010). The new legislation repeals the *Infertility Treatment Act 1995*, and makes consequential amendments to the *Status of Children Act 1974* with regard to legal parentage, as well as other relevant Victorian legislation.

More generally, the new legislation is consistent with the equal opportunity legislation and government policy concerning sexual diversity.

2.2 Regulatory Framework

The *Assisted Reproductive Treatment Act 2008* is the principal legislative instrument that will manage ART in Victoria. The Act also recognises that industry accreditation contributes to the regulatory framework. There are also national guidelines and an industry code of practice that complements the Act, along with other more general legislative requirements that apply to medical practitioners.

2.2.1 The Assisted Reproductive Treatment Act 2008

Broadly, the new legislation will:

- regulate access to treatment procedures (including consent and counselling requirements);
- set down the requirements for donors;
- regulate storage of gametes and embryos;
- regulate the posthumous use of gametes;
- provide for the recording of and access to information; and
- establish registers to capture the information.

The Act also establishes the Victorian Assisted Reproductive Treatment Authority (VARTA), which will replace the ITA, and also clarifies the status of parties involved in ART.

Section 1 of the new Act sets out the purpose of this legislation, and relevant to the proposed Regulations, provides for:

- regulating the use of assisted reproductive treatment and artificial insemination procedures (other than self-insemination);
- regulating access to information about treatment procedures carried out under the Act; and
- providing for the keeping of the Central Register and the Voluntary Register by BDM Victoria.

Section 5 of the new Act provides guiding principles in relation to administering the Act and includes:

- the welfare and interests of persons born or to be born as a result of treatment procedures are paramount;
- children/persons born as the result of the use of donated gametes have a right to information about their genetic parents;
- the health and wellbeing of persons undergoing treatment procedures must be protected at all times; and
- that a person seeking to undergo treatment must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

2.2.2 Victorian Assisted Reproductive Treatment Authority

The *Infertility Treatment Act 1995* established the regulatory body to oversee the administration of the Act in Victoria, the ITA. The ITA's functions include administering licensing and approvals systems, considering requests for extensions to storage periods, and approving the import or export of gametes or embryos.

Under the new Act, the ITA will be renamed the Victorian Assisted Reproductive Treatment Authority. VARTA will focus on the role of community consultation and community education on matters relevant to assisted reproductive treatments. This will include the continued development of resources that support parents who have children born through the use of donated gametes to tell their children of their genetic origins. However, it will not administer the donor registers currently held by the ITA. The new Act establishes that the registers be managed by BDM Victoria.

2.2.3 NHMRC Guidelines

The National Health and Medical Research Council (NHMRC), a Commonwealth statutory authority, has through its ethics committee issued national guidelines for the ethical use of reproductive technology in clinical practice and research.

Specifically, the guidelines require that participants in ART be provided with relevant information, receive counselling and give informed consent to treatment. They do not address eligibility for treatment or how the welfare of the child might be taken into account in decisions about treatment outside these requirements. The guidelines do however state that clinics 'should maintain documented practices and procedures, identifying the line of responsibility for each' and should develop specific protocols for access to, and eligibility for, treatment. The NHMRC guidelines also deal with matters such as storage arrangements for gametes and embryos, record keeping and data reporting, and the introduction of innovative procedures. It should be noted that these guidelines by themselves do not have the force of law.

2.2.4 Reproductive Technology Accreditation Committee accreditation

The NHMRC guidelines require that all clinics offering ART must obtain accreditation by a recognised authority. The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA) provides this accreditation. RTAC's responsibilities include setting and monitoring standards for ART centres, and publishing a Code of Practice.

All Victorian clinics are RTAC-accredited and must abide by RTAC requirements in addition to complying with Victorian law.

2.2.5 Medical practice regulation

Medical practitioners providing ART services are also subject to general medical regulation under the *Medical Practice Act 1994*, the *Health Services Act 1988* and the *Health Services (Conciliation and Review) Act 1987,* and are also expected to comply with the Code of Ethics of the Australian Medical Association.

2.3 Objectives

The Act sets out the purpose and guiding principles of the legislation (see Section 2.2.1 above). The overarching objective of the legislation is to ensure the best interests of the child born or to be born as a result of treatment procedures. The legislation also seeks to ensure that the health and wellbeing of persons undergoing treatment procedures are protected, and that children born as the result of the use of donated gametes have a right to information about their genetic parents.

The objectives of the proposed Regulations reflect the government's overall legislative objectives by:

- ensuring that patients are informed (address information gaps); and

- ensuring cost-effective collection of information (to reduce risks and to ensure the right of a child concerning information on their genetic parents).

In relation to the fee component of the proposed Regulations, the objective is to recover the efficient costs of providing services.

2.4 Authorising Provision

The proposed Regulations are made under section 124 of the *Assisted Reproductive Treatment Act 2008*. This section provides, among other things, that the Governor-in-Council may make regulations generally prescribing any matter or thing required or permitted by the Act to be prescribed or necessary to be prescribed to give effect to the Act including:

- forms for notices or other documents required under the Act;
- fees for the purposes of the Act;
- counselling required by the Act, including the mandatory matters and the form it must take;
- the keeping of records and registers for the purposes of the Act, including the Central Register and the Voluntary Register; and
- the disposal of embryos removed from storage.

3. OPTIONS TO ACHIEVE THE OBJECTIVES

3.1 Regulatory and Non-regulatory Options

The *Subordinate Legislation Act 1994* requires that a RIS must assess the costs and benefits of the proposed Regulations. This Act also requires that a RIS identifies practical alternatives to the proposed Regulations and assess the costs and benefits of these compared to the proposed Regulations. A RIS is not required to identify alternatives that are not practicable or feasible. This section describes the viable non-regulatory and regulatory options for achieving the objectives set out in Section 2.

The scope of consideration of feasible regulatory and non-regulatory options is limited by the existing powers of the Act and the limited focus of the proposed Regulations. Nevertheless, this RIS identifies and discusses viable options as follows:

- statutory rules and variations to these;
- voluntary codes of practice;
- provision of educational information;
- performance standards; and
- incorporation of the regulations into the Act.

In identifying options it seems reasonable to assume that in certain cases the regulations are the only viable option because they 'give effect' or 'operationalise' key elements of the Act. While these suppositions should be avoided, clause 2.04 of the Subordinate Legislation Act 1994 Guidelines (the Premier's Guidelines) states when the Act requires that a thing or matter be prescribed in regulations, then it must be provided in the Regulations:

> "where the authorising Act dictates the form of subordinate legislation required, for example, where the authorising legislation provides for fees to be prescribed by statutory rule, *there is no discretion* to set those fees by another method."[10] (emphasis added)

This is relevant in relation to proposed Regulation 11, which prescribes certain costs that may be reimbursed, and the proposed Regulation 17, which prescribes a fee for an application for information concerning section 56(3)(b) of the Act. There are no practicable alternatives for these regulations.

Along these lines, legislation often requires further detail to be prescribed in the regulations. For example, the proposed Regulations prescribe various issues to be addressed for parties undergoing counselling. In most cases the items that must be discussed are contained in the Act: the regulations prescribe additional items. Thus, even in the absence of the proposed Regulations, legislative requirements for

[10] *Subordinate Legislation Act 1994* Guidelines, Revised 2007, Section 2.04.

counselling remain. Therefore, the specific framework of the Act narrows the focus of the proposed Regulations and the range of viable alternatives.

A number of options were considered neither feasible nor practicable. These options include economic incentives and negative licensing. Economic incentives[11] may be offered to encourage good behaviour. An example in Victoria is offering a driver a discount on the cost of a licence if the driver has demonstrated a good record. However, in the case of ART activities economic incentives would be difficult to assess, would not address many of the issues dealt with by the proposal, and could be expensive. Moreover, it would be difficult to justify rewarding certain behaviour for a person or clinic for simply complying with requirements.

Negative licensing regulates industry participants who have shown serial non-compliance or who have committed serious breaches. This option would require a significant change in government policy and would only deal with the most serious offences. Moreover, a characteristic of negative licensing is that it is essentially reactive and deals with serious problems after they have occurred. In the case of ART activities serious breaches may not be detected for many years after they have occurred (e.g., poor record keeping). Consequently, there are very few examples of negative licensing regimes operating in Victoria.

3.1.1 Option 1 – Proposed Regulations

A statutory rule (also known as a regulation) is a regulatory vehicle used extensively by governments to give operational effect to primary legislation. Statutory rules can be an effective policy tool. They can be used by government to achieve a range of policy objectives including: the prevention or reduction of an activity which is harmful to business, the environment or to other people; to ensure that people engaged in some occupations possess a requisite level of knowledge and competence; and to define rights, entitlements or obligations.

The Premier's Guidelines provide guidance regarding the matters suitable for inclusion in statutory rules. These include matters relating to detailed implementation of policy, general principles and standards (rather than the policy, principle or standard itself), prescribing fees to be paid for various services, prescribing forms for use in connection with legislation, and prescribing processes for the enforcement of legal rights and obligations.

The proposed Regulations prescribe details to give effect to and to expand upon elements of the Act. They prescribe forms and detailed schedules of information to be collected, as well as specifying what information should be covered in counselling sessions. Changes in technology, practical experience or other developments may require changes to the matters specified in the regulations. Changing such matters is relatively straightforward compared to changing

[11] Economic incentives also include monetary penalties for non-compliance. Penalties are an important element of the Acts' enforcement regime.

legislation. Another advantage of statutory rules is that they require formal review at least every 10 years through the RIS process.

3.1.2 Option 1.A – Variation of the Proposed Regulations

In a number of cases, there are no practical regulatory alternatives other than to alter the scope or extent of the proposed Regulations. As noted above, clause 2.04 of the Premier's Guidelines cited above notes that in some circumstances there is no discretion other than to prescribe some matters in statutory rules.

However, there is scope to consider variations to the proposed Regulations and consider whether they are effective and cost efficient. For example, should the proposed Regulations specify in greater detail the type counselling or matters to be discussed. Similarly, the proposed Regulations could narrow or broaden the types of costs incurred that could be reimbursed for surrogate mothers. These issues are discussed in Section 4.3.2 below.

Finally, consideration could be given to narrowing the wording in proposed Regulation 11 (reimbursement of costs actually incurred by a surrogate mother) to reflect 'reasonable' travel costs associated with attending 'medical procedures' that are 'directly' related to the pregnancy or birth. This approach may limit any potential misuse of this provision compared with the current wording of the proposed Regulation. Ultimately, the wording of the proposal should strike a balance between being flexible enough to apply to a range of circumstances, while being narrow enough to prevent the regulation being used as a device to commercialise surrogacy arrangements.

DOH, through this RIS process, encourages and welcomes further comments on the proposed Regulations.

3.1.3 Option 2 – Provision of educational information

While strictly speaking, the base case would include some form of counselling even in the absence of the proposed Regulations (because the requirements for counselling are established under the Act), for the purposes of analysis in the RIS the option of providing additional information is considered. This option complements the base case counselling requirement rather than displacing it.

This option would involve specific information posted on the websites of the clinics, VARTA or DOH and could include information packs and brochures published to address the issues that would be raised in counselling sessions (i.e., counselling prior to treatment, donation, surrogacy arrangements and to posthumous use of gametes or embryos). It could include 'questions and answers' type of information aimed to provide parties with information to allow them to make informed decisions. This option would not be suitable for other elements of the proposed Regulations. A requirement could be imposed on application forms whereby parties would need to 'tick a box' to confirm that they had considered the information.

Delivering educational information in this manner is likely to be successful where the target audience can be easily identified and reached economically. This is the case with parties involved in the ART process. However, information campaigns may be less effective than other regulatory approaches as they rely on voluntary compliance rather than being supplemented by the element of coercion (such as to ability to impose penalties or sanctions).[12] The cost of education campaigns vary considerably, ranging from many millions of dollars (e.g., safe driving campaigns) to targeted mail-outs to certain professions or licensees. The ITA currently posts detailed information on its website (see 'Infertility and Assisted Reproductive Technology (ART)': http://www.ita.org.au).

3.1.4 Option 3 – Codes of practice

Self-regulation (or voluntary codes of practice or standards) refers to the benchmark actions or procedures, as determined by the particular industry or profession that are generally acceptable within the peer group and the wider society. The relevant industry is solely responsible for enforcement. Self-regulation usually implies that businesses in an industry or members of a group have accepted mutual obligations. These obligations are often described in a code or industry standards.

Self-regulation has potentially significant benefits. As major industry participants or groups often set the industry standards, there may be greater awareness of obligations, and compliance may be high. In addition, self-regulation utilises the expertise and experience of those in the industry, and may encourage innovative behaviour of industry participants. Self-regulation also lowers administrative costs for government.

However, the major disadvantage associated with voluntary codes is the absence of a mechanism to ensure compliance and enforcement. Disciplinary processes, where they exist, may not be transparent. Self-regulation is typically suitable for cases where the problem to be addressed is a low-risk event, or an event of low impact.[13] In addition, self-regulation is more effective where non-compliance can be observed and negative impacts are imposed on a person/business reputation (i.e., breaking an industry code for an ethical or privacy issue is likely to reflect badly on a business if made public).

In the context of ART, the existing NHMRC guidelines and RTAC Code of Practice are relevant (these are discussed below).

3.1.5 Option 4 – Performance-based standards

Regulation may take the form of prescriptive rules, which focus on the inputs, processes and procedures of a particular activity. One of the main advantages of prescriptive regulation is that it provides certainty and clarity. By setting out requirements in detail, it provides standardised solutions and facilitates straight-

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Victorian Guide to Regulation, pp. B6 – B7

[13] Department of Treasury and Finance, 2007, ibid., B−1 p. 129

forward enforcement. They can also provide clarity concerning a government requirement and may lower 'search costs'[14] or prevent ART providers from over-engineering the solution.

However, because of their inflexibility, prescriptive regulations may be unsuitable in certain situations, e.g., where circumstances are subject to change. Performance-based standards specify desired outcomes or objectives, but not the means by which these outcomes have to be met. The main advantages that performance-based standards have over prescriptive regulation are the greater flexibility afforded to regulated parties in achieving the desired outcomes, and their ability to be used in situations where circumstances may change over time.

Nevertheless, they do have some disadvantages. For example, the greater flexibility and freedom offered by performance-based regulations is often cited as a problem for those being regulated as it can lead to uncertainty as to whether the actions they undertake are sufficient to satisfy the standards set by the regulations.[15] Related to this, performance-based standards may generate uncertainty because circumstances giving rise to prosecutions may be determined subjectively. This in turn may increase government enforcement costs because the interpretation of such standards may be challenged or determined in the court/tribunal system.

Developments in assisted reproductive technology present a significant challenge for lawmakers: legislation can quickly become redundant, unworkable or obstructive if the subject matter being regulated changes. These problems generally arise when legislation is prescriptive, that is, when it is specific about what treatments can or cannot be provided and there is no scope for flexibility in the application of the law. In the case of the proposed Regulations, the information requirements listed in Schedules 4, 5, and 6 could be developed by clinics (perhaps based on the NHMRC Guidelines) and information could be kept 'in accordance with industry standards'.

3.1.6 Option 5 – Extending the coverage of existing legislation

It would be technically possible to incorporate the proposed Regulations into the Act. This would achieve similar policy objectives, however the regulatory vehicle would be different (i.e., the proposals contained in legislation rather than statutory rules). This has the disadvantage of disabling the government's ability to move quickly to change, for example, an information requirement in a Schedule.

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[14] 'Search costs' are divided into external and internal costs. External costs include the monetary costs of acquiring the information, and the opportunity cost of the time taken up in searching. Internal costs include the mental effort given over to undertaking the search, sorting the incoming information, and integrating it with what the consumer or business already knows. Internal costs are determined by the parties' ability to undertake the search, which depends on factors including prior knowledge, education and training.

[15] It is feasible that codes of practice could be used to set down criteria that may reduce the subjective element of performance-based standards by establishing benchmarks by which performance can be measured.

3.2 Regulatory Arrangements in other Jurisdictions[16]

The Commonwealth does not have the constitutional power to legislate over ART. This means that there are different approaches to regulation across states and territories. As in Victoria, New South Wales[17], South Australia[18] and Western Australia[19] have directly regulated the provision of ART services. These states have legislation that sets out criteria for access to treatment and requires doctors providing infertility treatment to be licensed by a specific statutory agency. The legislation also provides for codes of practice that detail clinical practice standards. The legislation in South Australia and Western Australia also establishes a state regulatory body which licenses clinics that provide ART services.

New South Wales

The New South Wales Parliament passed the *Assisted Reproductive Technology Act* in November 2007 allowing gamete donors to specify the recipients of their sperm or egg with regard to marital status, sexual orientation, ethnic origin or religious belief.

Under the Assisted Reproductive Technology Act clinics must apply for registration to the Director-General of the Department of Health. The Director-General is responsible for maintaining a central donor register.

The objectives of the Act, as set out in Part 1, section 3, are: 'to prevent the commercialisation of human reproduction'; and to protect the interests of persons born as a result of treatment, gamete donors, and women undergoing treatment. The Act provides that non-compulsory counselling services be made available to those seeking treatment.

Under the Act, gametes of a deceased person or a person in a persistent vegetative state can be used, provided that their consent was obtained prior to their losing the ability to consent. Gametes may be obtained from a child if a medical practitioner certifies that there is a reasonable risk the child will become infertile before they reach adulthood.

Western Australia

The *Human Reproductive Technology Act 1991* established the Reproductive Technology Council (RTC), which issues licenses to practitioners and oversees ART in WA. The legislation allows couples or individuals to access IVF treatment if they are infertile or risk passing on a genetic disease. Embryos may be stored for up to ten years.

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[16] This section is an edited extract from the Parliamentary Library Research Service, Department of Parliamentary Services, *Current Issues Brief: Assisted Reproductive Treatment Bill 2008*, by Claire Higgins, No. 5, October 2008.

[17] *Assisted Reproductive Technology Act 2007* (NSW)

[18] *Reproductive Technology Act 1988* (SA)

[19] *Human Reproductive Technology Act 1991* (WA)

South Australia

The *Reproductive Technology (Clinical Practices) Act 1988* established the South Australian Council on Reproductive Technology (SACRT), which oversees the practice of ART in conjunction with the South Australian Department of Health. SACRT places ultimate priority on the welfare of children born through ART practices. Sperm donors can choose to remain anonymous, although non-identifying details must be maintained in the interests of the resultant child. Before receiving IVF treatment patients are required to sign a Statutory Declaration concerning their criminal history (with particular regard to children) and that of their partner. They must also declare that they have never had a child removed from their guardianship.

The actual practice of ART is strictly regulated: no more than three embryos may be implanted in a woman at any one time. Embryos may only be stored for a maximum of ten years, and Pre-Implantation Genetic Diagnosis is not permitted for the purposes of gender selection. There are however, no age limits on IVF recipients. Following the birth of triplets to a 52 year old South Australian woman in 1998, SACRT established a Working Party to develop guidelines on the treatment of older women. ART is not to be offered to women who have come to the natural end of their fertility (i.e. menopause).

The Reproductive Technology (Clinical Practices) Act restricted access to ART on the basis of marital status, and in 1996 the Supreme Court of South Australia ruled that this contravened the Sex Discrimination Act. Interpretations of the Reproductive Technology (Clinical Practices) Act are now required to take the Commonwealth legislation into account. Women who are single or in a same sex relationship are able to access ART in South Australia, but – as in Victoria – only if they are infertile.[118] SACRT suggested in a related discussion paper that fertile lesbian women could organise their own artificial insemination in the privacy of their own home.

Northern Territory

Reproductive treatment services in the Northern Territory are provided by South Australian practitioners, and the Northern Territory Department of Health requires clinics to follow South Australian law in most respects. The Territory's *Anti-Discrimination Act 1992* does not apply to artificial insemination, therefore single women and same sex couples cannot access treatment.

Other Jurisdictions

Queensland, Tasmania and the Australian Capital Territory have not passed specific ART statutes. These jurisdictions adhere to national ethical standards for treatment, best practice guidelines and standards developed by national bodies, such as the NHMRC guidelines and the RTAC code of practice.

International Arrangements

International regulatory regimes range from prohibitive or restrictive legislation, to facilitative legislation to no legislation at all. Italy and Germany, for example, have

adopted a very restrictive and cautious approach to ART. Controls on the use of ART and access to treatment exist in Canada, the United Kingdom and New Zealand, where legislation contains broad principles to which practitioners must adhere when making decisions about treatment. In the United Kingdom, a code of practice operates in conjunction with a statutory licensing system to regulate the conduct of treatment. There is some control over fertility treatment in most Scandinavian countries, ranging from liberal legislation in Sweden to strict legislative control in Norway. In the United States, approximately thirty states have enacted legislation in the area.

4. COSTS AND BENEFITS OF THE OPTIONS

4.1 Base Case

The 'base case' describes the regulatory position that would exist in the absence of the proposed Regulations. The base case of doing nothing is not, strictly speaking, an alternative given that the government has identified a problem that needs to be addressed. It is necessary to establish this position in order to make a considered assessment of the incremental costs and benefits of the viable options.

The base case therefore would be represented by:

- the *Assisted Reproductive Treatment Act 2008* but the matters intended to be prescribed would have no effect. That is:
  - consent would still be required but forms for treatment (r. 5, Schedule 1) and child protection order checks (r. 6, Schedule 2) would be not be prescribed;
  - certain matters regarding counselling would not be prescribed (r. 10) and some counselling may not be required to be undertaken at all (e.g., rr. 7, 8 and 13);
  - information would not be prescribed in relation to the register kept by an ART provider (r. 14, Schedule 4), a register kept by a doctor (r. 15, Schedule 5) and information to be provided to BDM Victoria (r. 16, Schedule 6); and
  - a fee would not be prescribed for information to the Central Register (r. 17).
- the NHMRC Guidelines;
- the RTAC's Code of Practice;
- normally efficient business practice, e.g., record keeping, counselling

Arising from the points above, if the proposed Regulations were not made there would be two broad adverse outcomes: first, compliance with the Act could be more costly for persons seeking treatment (greater search costs and less clarity regarding obligations) and this would possibly result in greater enforcement costs to government; second, the government's broad objective of protecting the interests of the child may be diminished.

4.2 Methodology

4.2.1 Assessment of costs

The inherent characteristic of regulation is to modify behaviour in order to achieve certain outcomes. This can impose costs on individuals or businesses known as 'compliance costs'. In simple terms, compliance costs are the costs of complying with regulations. In the context of the Standard Cost Model (SCM), these can be

divided into 'administrative costs' and 'substantive compliance costs'.[20] It is important to note that only 'administrative costs' are measured by the SCM.

As outlined in Section 1.4, administrative costs are those costs incurred by businesses to demonstrate compliance with the regulation or to allow government to administer the regulation. These costs can include costs associated with administrative requirements such as record keeping, reporting or submitting applications. Proposed Regulations 5, 6, 8, 14, 15, 16 and 19 impose reporting/record keeping requirements to government and are therefore administrative costs. In accordance with the requirements under Measurement of Changes in Administrative Burden in the *Victorian Guide to Regulation*, administrative costs in the RIS are calculated using the Standard Cost Model methodology.[21]

Substantive compliance costs are those costs that lead directly to the regulated outcomes being sought. Proposed Regulations 7, 9, 10 and 12 which deal with counselling are therefore substantive compliance costs.

As noted earlier, under clause 2.04 of the Premier's Guidelines where the authorising Act dictates the form of regulation, viable options are limited.[22] This is relevant in relation to the assessment of proposed Regulations 11 and 17, which prescribe the costs and fees. It is clear that the Act does not contemplate alternatives to these regulations.

4.2.2 Discounted cash flow

Every effort was made to identify and quantify the costs and benefits imposed by the proposed Regulations. As far as possible, likely costs were identified and a Present Value of the costs was calculated. A discount rate of 3.5 per cent was used over a 10-year period (i.e., the life of regulations in Victoria).[23] This allows future costs and benefits to be examined in terms of today's dollar value. Assumptions underlying these calculations are contained in Attachment D.

4.2.3 Multi-criteria analysis

In many cases the benefits specific to the proposed Regulations proved difficult to quantify in monetary terms. Multi-criteria Analysis (MCA) is presented in this RIS as an alternative assessment tool to complement the quantitative analysis. The MCA approach is described in part 5–18 of the *Victorian Guide to Regulation.* This approach is useful where it is not possible to quantify and assign monetary values to the impacts of a proposed measure (e.g., measures that have social impacts). Furthermore, it represents a convenient way of comparing a range of alternative approaches.

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[20] Department of Treasury and Finance (2007), ibid., p. F−7
[21] Standard Cost Model Formula – Administrative Cost = (tariff x time) x (population x frequency)
[22] Subordinate Legislation Act 1994 Guidelines, Revised 2007, Section 2.04
[23] Department of Treasury and Finance, 2007, ibid., p. C-9

This technique requires judgements about how proposals will contribute to a series of criteria that are chosen to reflect the benefits and costs associated with the proposals. A qualitative score is assigned, depending on the impact of the proposal on each of the criterion weightings, and an overall score can be derived by multiplying the score assigned to each measure by its weighting and summing the result. If a number of options are being compared, then the option with the highest score would represent the preferred approach.

Four criteria were chosen and weightings selected. The first two criteria reflect the objectives and purpose of the Act, which are to have the best interests of the child in mind with respect to the adequate provision of information to parties undergoing treatment (criterion 1) and to ensure that adequate information is obtained and records are kept (criterion 2). Criterion 1 relates to helping parties accessing ART to better understand the consequences of decisions by correcting information asymmetries/information gaps. Criterion 2 relates to information provided to children resulting from gamete donations. As noted earlier, access to genetic heritage is an important aspect of a person's life and in many ways defines their identity, and the experience of adoption has validated this. Also related to this criterion is the element of 'good record keeping', which may minimise the chance of mistakes that could have health or psychological impacts in parties receiving treatment. The third criterion reflects the government's commitment to minimise the regulatory burden on business and assesses the cost-effectiveness of the proposal. The fourth criterion assesses the cost to government of implementation of the regulatory vehicle. The criteria are described in Table 5 below.

Table 5: Multi-criteria Analysis Criteria

Criterion	Description of criterion	Weighting
Best interests of child: information provided to parties	Given that this criterion reflects the primary objective of the proposal, it is assigned a relatively high weighting of 35. This criterion encompasses likely compliance/effectiveness of the regulatory options.	35
Best interests of child: adequate information recorded and kept	Given that this criterion reflects the primary objective of the proposal, it is assigned a relatively high weighting of 35. This criterion encompasses likely compliance/effectiveness of the regulatory options.	35
Cost minimisation	This criterion relates to ensuring that the costs imposed on clinics and patients are kept to a minimum. Given the importance the Victorian Government is placing on reducing the regulatory burden, this criterion is assigned a weighting of 20.	20
Cost to government	This criterion relates to ensuring that the costs imposed on government (i.e., the Victorian community) are kept to a minimum. This criterion assesses the extent to which the option would require changes to other legislative instruments and/or institutional arrangements. A weighting of 10 is assigned to this criterion.	10

For the purposes of an MCA assessment, an assigned score of zero (0) represents the base case, while a score of plus one hundred (+100) means that the alternative fully achieves the objectives. A score of minus one hundred (–100) means that the proposal does not achieve any of the objectives. In terms of assessment using the MCA, under the base case each criterion is awarded a score of zero reflecting the default position (i.e., the regulatory position in the absence of the proposed Regulations). Accordingly, the base case scenario overall receives a net score of zero (see Section 6).

4.2.4 Decision Criteria

The decision criteria implied by the *Subordinate Legislation Act 1994* is that the benefits of a proposal should outweigh the costs, and that the preferred alternative is that which results in the largest net benefit.

Given the difficulty in measuring the intangible and tangible costs and benefits associated with the alternatives, this RIS uses a number of methodologies to inform its assessment of viable options. The present value discounted cash-flow technique is used to measure the likely administrative costs; however the benefits of the proposals proved difficult to quantify. The MCA assessment tool is therefore used in an attempt to assess the costs and benefits of the viable options. As noted above, the option with the highest score represents the preferred approach.

4.3 Costs and Benefits of Options

4.3.1 Option 1 – Proposed Regulations

Costs to Business and Individuals

Each of the proposed Regulations was examined for the likely costs they would impose on parties impacted by the proposal (see Attachment C). It is assessed that there are no costs associated with the machinery regulations (rr. 1 to 4), while the Regulation 11 deals with reimbursement of certain costs associated with surrogacy arrangements (an economic transfer) and Regulation 17 concerns fees for applying to BDM Victoria for certain information (a financial cost). The remaining regulations deal with filling out forms, record keeping or sending information to government (administrative costs) and matters to be covered during counselling (substantive compliance costs).

The Standard Cost Model methodology was used to calculate the administrative costs associated with these regulations. Table 6 below shows that these costs over a 10-year period are approximately $3.5 million (PV), or impose a cost of around $356,000 per annum (PV) (see Attachment E for detailed calculations). Of these costs, approximately 60 per cent are imposed on business (i.e., ART providers) and 40 per cent are imposed on individuals.[24] Given the large number of treatments per

[24] This assumes that 50 per cent of the costs associated with regulations 14 and 15 are attributable to individuals. This is because individuals enter much of the data (e.g., in patient information forms) that is held in the registers.

annum (around 9,000 in 2010), the administrative costs for individuals associated with each treatment are relatively low at around $80 (the average total cost of a treatment charged by a clinic is in the order of $5,000). An indicative cost imposed upon ART providers is around $130 per treatment. These costs represent the 'time cost' or time forgone by having to comply with the regulations.

Table 6: Costs Imposed by the Proposed Regulations (PV), 10-Year Assessment Period

Reg[n]	Description of Regulation	Cost ($)
5	Form of consent to treatment procedures	266,951
6	Permission to conduct child protection order checks	533,901
8	Form of donor's consent	20,763
14	Register kept by registered ART provider	2,656,350
15	Register kept by doctor carrying out artificial insemination	10,384
16	Provision of information by ART provider to the Registrar	64,883
	Cost of updating forms for ART providers	9,434
Total		**$3,562,666**

Proposed Regulations 7, 9, 10 and 12 deal with matters that are required to be covered during counselling and are 'substantive compliance' costs. Stakeholders advise that these matters are covered during the ordinary course of a counselling session and as such do not add to the time or complexity of the requirement. Furthermore, stakeholders considered that the prescribed matters provided a useful structure for counselling and ensured a level consistency across clinics (also see Assumption 4, Attachment D). Given this, these regulations are assessed as not imposing a significant cost and a monetary cost was not attached to them. (A corollary of this is that the benefits specifically attributable to the proposed Regulations are also incremental, largely reflecting the base case, e.g., the NHMRC Guidelines, RTAC Code of Practice, normal business practice, etc.)

Government Costs

The Victorian Government incurs costs in relation to the administration and enforcement of the regulations. Administration includes the tasks preformed by BDM Victoria[25] in relation to processing and recording the information sent to them under proposed Regulation 16 and costs associated with performing audits on records kept under the proposal (such audits cover a wider scope than these matters, however).

25 The only births to be notified to BDM are those arising from the donor treatment program and births arising from artificial insemination performed by a doctor outside of a clinic.

Table 7 below shows the costs of administering and ensuring compliance with the proposed Regulations is estimated to be around $59,000 over a 10-year period (see Attachment F for detailed cost calculations).

Table 7: Government Costs (PV), 10-Year Assessment Period

Government Cost	Cost ($)
BDM entry of Schedule 6 data	**$59,055**

* Numbers rounded.

Total Quantifiable Costs of the Proposed Regulations

Therefore, the total quantifiable costs to business and government costs associated with the proposed Regulations are approximately $3.6 million (PV) over a 10-year period, or a cost of around $362,000 (PV) per annum. Table 8 below shows the sectors comprising this cost.

Table 8: Costs imposed by the Proposed Regulations on Business, Individuals and Government (PV), 10-Year Assessment Period

Sectoral Cost	Cost ($)
Business – e.g., ART providers/doctors	2,207,704
Individuals – e.g., patients, partners, parties	1,354,962
Government – Administration and compliance	59,055
Total	**$3,621,721**

Benefits of the proposed Regulations

At a broad level, a regulated clinic system offers important safeguards both for persons participating in treatment (medical screening and registration of donor details, mandatory pre-treatment counselling for all parties) and the children who may be born as a result of treatment (assessment of parental risk factors, access to records providing genetic history, access to counselling as an adult).

At the outset, however, it is important to stress that most of these benefits are attributable to the Act rather than the proposed Regulations. For example, in a number of cases the regulations add additional requirements to those contained in the legislation. That said, the benefits associated with the proposed Regulations are that they give operational effect to the legislative framework. They ensure that parties are provided with specific information to allow them to make informed decisions; they establish standardised record keeping requirements; and they do so in a manner which lowers 'search costs' and enhances compliance.

The proposed Regulations also seek to minimise costs for individuals and industry participants by prescribing information requirements that may be readily adaptable into forms for use by ART providers. If this information was not prescribed then ART providers would need to rely on the Act to estimate the specific types and level of detail required. This may or may not satisfy DOH and may lead to 'over engineering' the requirement adding to costs or not including enough information thereby compromising compliance. Thus prescribing the information in a statutory

rule reduces the search costs for ART providers as well as lowering the risks of non-compliance by providing clinics with regulatory certainty. Standardised information also lowers government audit costs.

A further benefit is that statutory rules are an appropriate regulatory instrument for prescribing the matters covered by the proposed Regulations. They may be changed in a relatively straightforward and timely manner (compared to changes to legislation), are publicly available, and have an in-built review mechanism (statutory rules must remade every 10 years).

Multi-criteria Analysis

To assist in assessing the benefits of the proposed Regulations and to provide a comparison with other options, an MCA assessment was undertaken. The proposed Regulations seek to achieve the government's objectives ensuring that information is provided and recorded, thus contributing to the efficient operation of the Act.

With respect to the provision of information criterion, a score of 50 is assigned. This moderate score reflects the base case and that counselling is required under the Act and NHMRC Guidelines, and would be undertaken in any case by ART providers. The benefits relate to providing a minimum consistency of counselling across clinics. Similarly, the information kept by ART providers in a register is assigned a score of 50. A normally efficient business would keep such information and the NHMRC Guidelines also require similar information to be kept, hence a full score of 100 is not assigned.

The proposed Regulations impose greater costs on ART providers than the base case (e.g., child protection order checks are not required under the NHMRC Guidelines) and a score of -50 is assigned to cost minimisation criterion. Statutory rules provide a feasible, efficient and cost-effective regulatory vehicle to deliver the government's objectives; hence a relatively high score of 75 is assigned to the feasibility of implementation criterion. Overall, the MCA assessment results in a net score of +32.50.

Table 9: Multi-criteria Analysis Assessment of proposed Regulations

Criteria	Weighting	Assigned Score	Weighted Score
Information provided to parties	35	50	17.50
Information recorded	35	50	17.50
Cost minimisation	20	-50	-10.00
Cost to government	10	75	7.50
Total	**100%**		**+32.50**

4.3.2 Option 1.A – Variation of the Proposed Regulations

In a number of cases, there are no practicable regulatory alternatives other than to alter the scope or extent of the proposed Regulations. With respect to alternatives to the proposed Regulations, clause 2.04 of the Premier's Guidelines cited above notes that in some circumstances there is no discretion other than to prescribe some

matters in statutory rules. However, there is scope to consider the regulatory obligations in the proposed Regulations and to consider whether they are practical, effective, and cost efficient.

For example, with respect to counselling, to ensure flexibility it is not considered appropriate for the proposed Regulations to impose restrictions on the professional judgement of the ART counsellors. The length of sessions, type of sessions (e.g., group, telephone, video) are decisions best made by the counsellor and should not be prescribed. The proposed Regulations seek to prescribe a minimum benchmark of matters to be discussed, and depending on the party receiving counselling, the ART counsellor will decide if additional counselling is needed on other matters.

Another variation to the proposal could be to consider the types of costs actually incurred by a surrogate mother that may be reimbursed. These could be narrowed to just, for example, travel costs related to the pregnancy and birth. Alternatively, the types of costs could be expanded to include certain pre- and post-birth costs (e.g., dietician costs, exercise classes, alternative medicines). It should be noted, however, that compensation for 'loss of income' would not be permitted under the Act because the legislation specifies that costs must actually have been incurred (not an opportunity cost).

When considering whether the type of costs that may be reimbursed should be narrowed or expanded, two policy objectives come into play. The first objective is to allow 'reasonable' costs to be reimbursed so that potential surrogate mothers are not discouraged because of their economic circumstances (i.e., an equity/market access objective). The second objective reflects the overarching policy that surrogacy arrangements must be altruistic: expanding the type of costs may allow abuse or 'creative' arrangement, which results in particular surrogacy arrangement becoming quasi-commercial. The proposed Regulations have been considered by DOH and set to balance these policy objectives, however input is encouraged from stakeholders as to the scope of reimbursable costs.

Further variations the proposed Regulations are considered below in Sections 4.3.3 and 4.3.4.

Overall, as part of the consultation process DOH welcomes stakeholder comments on:

- the consent forms (rr. 5, 6 and 8) and whether they contain appropriate information in a suitable format;
- whether or not the matters prescribed for counselling (rr. 7, 9, 10 and 12) are appropriate;
- whether or not the information requirements contained in the Schedules (r. 14 (Schedule 4), r. 15 (Schedule 5), r. 16 (Schedule 6)) are appropriate, could be streamlined or simplified, and is the wording in the requirements clear?
- whether the types of costs actually incurred by a surrogate mother that may be reimbursed should cover a narrower or broader range of items (r. 11);

- whether or not a less prescriptive approach has merit;
- any practical difficulties associated with the proposed Regulations; and
- any unintended consequences associated with the proposed Regulations.

4.3.3 Option 2 – Provision of educational material

To make informed decisions about their treatment, participants in ART need to understand all the procedures involved, including any health risks and psychosocial consequences.

Given that the provision of information to patients, partners and donors has been identified as an issue to be addressed, consideration could be given to providing educational material to parties instead of counselling (i.e., rr. 7, 9, 10 and 12). Currently detailed information is located on the ITA and clinic websites. Such information could be highlighted, brochures printed, and 'information packs' further developed thereby allowing the individual to inform themselves. Development of a new website and assembling the information could cost in the order of $30,000 to $40,000, with annual maintenance costs of around $6,000 to $8,000.

While this option would potentially lower 'search costs', there are potentially large risks associated with the patient and other parties not being fully informed (e.g., the decision to bring a child into the world and the attendant responsibilities).

Parties already receive a large amount of information when they commence treatment. This can often be an emotional or stressful time. In these situations, printed or web-based information may not always be absorbed. In addition, such information is generally of a generic nature (counselling can provide tailored information for specific circumstances). These decisions affect the formation of families and the lives of parents and children (particularly when a third party is involved).

For these reasons, the NHMRC Guidelines recommend counselling as an integral part of the treatment process. The Guidelines recommend that counselling services should:

- provide an opportunity to discuss and explore issues;
- explore the personal and social implications for the persons born and for the participants;
- provide personal and emotional support for participants, including help in dealing with unfavourable results;
- provide advice about additional services and support networks; and
- reflect an integrated, multidisciplinary approach, including medical, nursing, scientific and counselling staff.

These matters would be difficult to explore and convey by additional information alone. In addition, even in the absence of a regulatory requirement, clinics would continue to undertake counselling in any case.

To assist in comparing this option with the alternatives, an MCA assessment was undertaken. A relatively low score of 15 was awarded to the provision of information to parties because a large amount of information is currently provided and the benefit of additional information in this form is likely to be of marginal benefit. While the provision of educational information is valuable as providing 'base level' information, it lacks the ability to address specific circumstances.

This option does not consider information recorded therefore this is assigned the same score as the proposed Regulations (i.e, a score of 50).

This option is cost effective and would not result in direct costs to those receiving information (although this cost would be indirectly incurred by the Victorian community).

Given that this criterion approximates the base case, a score of zero is assigned. The government currently provides information and this option would be relatively cost-efficient to implement; hence a score of 50 is assigned to this criterion. Overall, this option receives a net score of +27.75.

Table 10: Multi-criteria Analysis Assessment of Educational Material

Criteria	Weighting	Assigned Score	Weighted Score
Information provided to parties	35	15	5.25
Information recorded	35	50	17.50
Cost minimisation	20	0	0.00
Cost to government	10	50	5.00
Total	**100%**		**+27.75**

4.3.4 Option 3 – Performance-based standards – data collected

Performance-based standards specify desired outcomes or objectives, but not the means by which these outcomes/objectives have to be met. In the case of the proposal, a requirement, for example, could be established that requires an ART provider to "keep information in a form to enable the department to carry out the functions of the Act". This guidance could be provided by the RTAC Code (e.g., compliance with the data reporting in the Australian and New Zealand Reproduction database requirements) and NHMRC Guidelines.

The main advantages that performance-based standards have over prescriptive regulations are the greater flexibility afforded to regulated parties in achieving the desired outcomes, and their ability to be used in situations where circumstances may change over time.

Nevertheless, they do have some disadvantages. For example, the greater flexibility and freedom offered by performance-based regulations is often cited as a problem for those being regulated as it can lead to uncertainty as to whether the actions they undertake are sufficient to satisfy the standards set by the regulations.[26]

[26] loc cit., p. 3-9

Importantly, it is likely that the form of data collected would vary across ART providers, making enforcement and administration more costly and difficult for government. ART providers would also need to devote resources to developing protocols of what information would be collected.

An MCA assessment of this option was undertaken. The first criterion relates to counselling and hence the same score is assigned as for the proposed regulations (i.e., a score of 50 is assigned). It is assessed that the quality of information recorded could be an improvement over the base case, however the quality and form is likely to vary across the sector and therefore a score of 25 is assigned against this criterion. Costs under this option would be similar to that of the base case, although ART providers would be required to expend resources in developing data inputs. Consequently, a minor negative score of -10 is assigned to this criterion. While this option would be feasible, it is likely that the government would incur additional administrative and audit costs in dealing with non-standardised data; hence of score of -75 is awarded. These together result in a net score of +16.75.

Table 11: Multi-criteria Analysis Assessment of Performance Standards

Criteria	Weighting	Assigned Score	Weighted Score
Information provided to parties	35	50	17.50
Information recorded	35	25	8.75
Cost minimisation	20	-10	-2.00
Cost to government	10	-75	-7.50
Total	**100%**		**+16.75**

4.3.5 Option 4 –Code of practice

The Victorian Government could establish a code of practice or rely upon the existing RTAC Code in relation to the general operation of ART providers. A co-regulatory model could also be developed. For example, the government in partnership with ART providers or the RTAC could develop or enhance codes covering counselling and data collection. For example, the existing RTAC Code of Practice sets down 'critical criteria' that must be measured and satisfied in order to maintain RTAC accreditation. These criteria include data monitoring (criterion 10) and data reporting (criterion 11). In addition, this code has 'good practice' criteria, which includes consent processes (criterion 3). The NHMRC Guidelines could also be incorporated into an enhanced code. These guidelines provide guidance on information provision (sections 9.1 and 9.2), counselling (section 9.3), obtaining consent (sections 9.4-10), and set down details for effective record keeping and monitoring (sections 10.1-4) and reporting of data (10.5).

The main benefit of industry codes is that they can utilise industry expertise and are usually associated with industry 'buy-in', which may encourage compliance. Codes are particularly suited to relatively homogenous groups that can be readily

identified and reached: this is the case for ART providers. In addition, codes can be tailored to the needs of particular industries and are generally more flexible than regulations. Generally, codes of practice are best suited to situations in which the risks associated with non-compliance are low. The main disadvantage of this alternative – as with an education campaign – is the possibility of non-compliance and difficulties associated with enforcement, as well as whether or not the actions of members are observable.

Industry codes are generally cost effective methods of regulation. Given the existing arrangements, such codes could each cost in the order of $50,000 to develop further, implement and communicate, with an annual ongoing cost of $5,000 to $10,000 for handling queries, disciplinary matters and updates.

Very thorough and well-established codes/guidelines form part of the base case. Options could range from voluntary codes to co-regulatory models or quasi-regulatory codes (e.g., requiring adherence to them as a condition of operation). While codes form an important part of the current regime, this RIS finds that the proposed Regulations more fully meet government objectives.

For example, the government may lose discretion to gather information concerning areas it considers necessary to regulate or monitor. These problems would be less pronounced under a compulsory code, however compliance and enforcement could remain significant issues. Industry or user codes may be relatively effective in addressing simple information gaps; however this alternative is not considered a superior option to the proposed Regulations because some of the information/issues are complex. Further, the level of detail set out in the codes tends to be of a more general nature, whereas the proposed Regulation in many cases prescribe very specific details. Codes of course could also specify this level of detail but if made compulsory would differ in name only compared to the proposed Regulation while retaining the disadvantage of not containing enforceable sanctions (note sanctions are located in the Act).

An MCA assessment was undertaken to consider this option. Codes of practice could be relatively effective in achieving the government's objectives (especially if made quasi-mandatory); however, given that enforcement is less likely to be as effective as the proposed Regulations and because they form part of the base case the information criteria is assigned a score of 30. Costs would vary depending if the industry or government developed codes, but given the existence of codes and guidelines a score of zero is assigned reflecting the base case. This option imposes few costs on government; hence a relatively high score of 75 is assigned. Together, this option results in a score of +28.5. In the case of ART, codes and guidelines should not be merely regarded as a 'belts and braces' measure: this RIS finds that the existing code and guidelines serve as important *complementary* measures.

Table 12: Multi-criteria Analysis Assessment of Codes of Conduct

Criteria	Weighting	Assigned Score	Weighted Score
Information provided to parties	35	30	10.5
Information recorded	35	30	10.5
Cost minimisation	20	0	0.0
Cost to government	10	75	7.5
Total	**100%**		**+28.5**

4.3.6 Option 5 – Extending the coverage of existing legislation

It would be technically possible to extend the coverage of the Act by incorporating the proposal into the legislation. This option is identified in the *Victorian Guide to Regulation* as an alternative that should be considered. It is well-established, however, that the benefit of statutory rules as a regulatory instrument is their administrative efficiency and flexibility. For example, if the government decided to change a data requirement in one of the schedules, this could be done by amending the regulations, which is a relatively straightforward and timely process. However if these requirements were incorporated in the Act, then any change would require a parliamentary amendment. For minor administrative matters, this is a time-consuming and a relatively complex procedure. Parliamentary amendments also consume more government resources than changes to statutory rules. Further, the lack of flexibility and timeliness may impose unreasonable constraints and costs on ART providers or patients.

The Premier's Guidelines provide guidance as to the types of matters appropriate for inclusion in regulations rather than in Acts or in instruments which are not of a legislative character. The guidelines note that significant matters should not be included in subordinate legislation, although that subordinate legislation may deal with the same issue in terms of enforcement or related matters of administration or implementation. The guidelines also note that subordinate legislation is more appropriate when: prescribing forms for use in connection with legislation; prescribing processes for the enforcement of legal rights and obligations; and dealing with matters relating to detailed implementation of policy, general principles and standards (rather than the policy, principle or standard itself).

An MCA was undertaken to assess this alternative. This alternative scores relatively highly because the substance of the measure is essentially the same as the proposed Regulations. The criteria relating to information receives the same score as the proposed Regulations, however the cost minimisation and feasibility criteria are assigned slightly lower scores. This is because legislative amendments are relatively costly and time consuming, and clause 1.09 of the Premier's Guidelines suggest that the matters contained in the proposed Regulations are unsuitable for incorporation into primary legislation. Costs (delay costs) may be incurred if technology or processes change, for example, and the legislation cannot be amended within a reasonable timeframe. While this alternative would no doubt be possible, the administrative mechanism of responding to government's or businesses' needs in a cost-efficient and timely manner makes the proposed

Regulations superior to this alternative. There is also a risk that the Act would become unnecessarily complex and unwieldy. This results in a net score of +29.5 as shown in Table 13 below.

Table 13: Multi-criteria Analysis Assessment of incorporation into legislation

Criteria	Weighting	Assigned Score	Weighted Score
Information provided to parties	35	50	17.50
Information recorded	35	50	17.50
Cost minimisation	20	-35	-7.00
Cost to government	10	15	1.50
Total	**100%**		**+29.50**

4.4 Groups Affected

Groups affected by the proposal include:

- women undergoing ART and their partners (there are currently approximately 9,000 treatments per annum) and any existing children;
- gamete donors;
- parties in surrogacy arrangements;
- ART providers, including clinics (15), doctors (54), and counsellors (39); and
- government and public entities (i.e., DOH, DHS, BDM Victoria, and VARTA).

4.A FEES

In September 2007 the Victorian Government released its *Cost Recovery Guidelines* to clarify its policy principles underpinning cost-recovery arrangements. The Guidelines establish a whole-of-government framework thereby ensuring that cost-recovery arrangements in Victoria are transparent, efficient, effective and consistent with legislative requirements and government policy. These Guidelines are framed by the principle that properly designed cost-recovery arrangements can deliver both equity and efficiency benefits to the community. However, poorly designed arrangements may create inappropriate incentives, and could potentially undermine the achievement of other government objectives.

Cost-recovery may be defined as the recuperation of the costs of government-provided or government-funded products, services or activities that, at least in part, provide private benefits to individuals, entities or groups, or reflect the costs their actions impose. The Guidelines apply to cost-recovery arrangements of government departments and general government agencies and include the recovery of the costs incurred by government in administering regulation (e.g. processing licences and applications, issuing of permits, etc).

The underlying principle of the *Cost Recovery Guidelines* is that agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, and where the beneficiaries are an identifiable group and capture the private benefits of the product or service. These characteristics are relevant for persons wishing to apply for information from a government register.

Proposed Regulation 17 — Fee for Application for Information

The Act permits disclosure of information on the Central Register to certain persons, e.g., a person born as a result of a donor treatment procedure. Section 56 of the Act deals with applications for information on the Central Register, and subsection (3)(b) requires that an application be accompanied by the prescribed fee. BDM Victoria examined the tasks and steps required to determine this fee. BDM Victoria considers that the resources used to carry out these processes were similar to those require to process a request for the 'Addition of registrable information'.[27] Consequently, proposed Regulation 17 prescribes the fee at 5.18 fee units, which is equivalent to $60.60, for applications by persons associated with a donor-conception event for information about another person also associated with that donor conception event.

Currently there are around 20 requests per annum for such information. Conservatively assuming that BDM Victoria receives 30 requests per annum, this

[27] In 2008 the Births, Deaths and Marriages Registration Regulations 2008 RIS examined these fees and found them appropriate.

would result in annual fee revenue of approximately $1,820, or about $15,100 (PV) over a 10-year period.

A detailed description of the tasks undertaken and costing of the proposed fee is contained in Attachment G.

4B. IMPACT ON SMALL BUSINESS

The *Victorian Guide to Regulation* provides a definitive guide to developing regulation in Victoria within the context of the government's vision of well-targeted, effective and appropriate regulation. In particular, it is important to examine the impact on small business because the compliance burden often falls disproportionately on that sector of the economy. [28, 29]

The impact of the proposed Regulations falls predominantly on individuals. While they do impose reporting and record keeping obligations on business, almost all businesses operating in this sector are medium sized businesses.

Given the nature and relative sophistication of the sector (i.e., medical clinics are familiar with reporting, recording keeping and other administration as part of their general responsibilities), it is not expected that the one or two providers that may be classified as small business would find it difficult to understand or comply with the requirements.

Finally, given that similar regulations have been in place for over 10 years, it is not expected that the proposed Regulations will raise any implementation issues or cause unintended consequences.

[28] Victorian Government, 2007, *Small Business Regulatory Impact Assessment Manual*, Melbourne, April 2007

[29] The ABS defines a small business as a business employing less than 20 people. ABS Cat. 1321.0

5. ASSESSMENT OF COMPETITION IMPACTS

The guiding principle in assessing competition impacts is that the regulations should not restrict competition unless it can be demonstrated that the benefits of the restriction to the community as a whole outweighs the costs, and that the objectives of the Regulations can only be achieved by restricting competition. The NCP 'competition test' was used to assess the proposed Regulations against any possible restrictions on competition. The test asks whether the proposed Regulations:

- allow only one participant to supply a product or service;
- require producers to sell to a single participant;
- limit the number of producers of goods and services to less than four;
- limit the output of an industry or individual producers;
- discourage entry by new persons into an occupation or prompt exit by existing providers;
- impose restrictions on firms entering or exiting a market;
- introduce controls that reduce the number of participants in a market;
- affect the ability of businesses to innovate, adopt new technology, or respond to the changing demands of consumers;
- impose higher costs on a particular class or type of products or services;
- lock consumers into particular service providers, or make it more difficult for them to move between service providers; and/or
- impose restrictions that reduce range or price or service quality options that are available in the marketplace.

Assessed against this test, the proposed Regulations do not impose restrictions on competition as they simply prescribe forms, information obligations and a fee. The cost impact on individuals (around $80) and business (around $130) of the proposed Regulations is considered relatively minor in the context of overall costs in the ART market segment.

While it could be argued that the ability of businesses to innovate may be affected or output may be affected (e.g., the prohibition on commercial surrogacy), these restrictions are imposed by the Act rather than the regulations themselves.

The proposed Regulations apply equally to all businesses and consumers and do not impose dissimilar requirements compared to other jurisdictions. Therefore, the proposed Regulations are considered to meet the NCP 'competition test' as set out in the *Victorian Guide to Regulation*.

6. THE PREFERRED OPTION

Key points

- The proposed Regulations are assessed as the preferred option compared to the viable options identified in this RIS because they are the most effective way to achieve the Victorian Government's policy objectives.
- The main reasons why the proposed Regulations are preferred are that they:
  - provide a framework that permits data to be collected, monitored and submitted to government in a cost-effective, standardised form;
  - lower 'search costs' for ART providers and administration costs for government;
  - provide an effective enforcement and compliance mechanism; and
  - deal with a number of matters that cannot be dealt by other means (e.g., prescribe fees, costs to be reimbursed).
- The proposed Regulations support, and are consistent with, Victorian Government policy and the Act. The proposed Regulations are relatively narrow in focus and prescribe specific elements of the Act, and compliance with the regulations is not difficult or costly. The direct costs associated with the proposed Regulations are approximately $3.5 million over a 10 year period, or about $356,000 (PV) annually, and approximately 40 per cent are imposed on business (i.e., ART providers) and 60 per cent are imposed on individuals.
- The administrative costs for individuals associated with each treatment are relatively low at around $80 (the average total cost of a treatment charged by a clinic is in the order of $5,000). An indicative administrative cost imposed upon ART providers is around $130 per treatment.
- Small business, to the extent that any are affected, are not considered to be disadvantaged by the proposed Regulations.
- The proposed Regulations are considered to meet the 'competition test' as set out in the *Victorian Guide to Regulation*.

The *Subordinate Legislation Act 1994* requires, *inter alia*, a RIS to assess the costs and benefits of proposed Regulations. The costs of the proposed Regulations were relatively straightforward to identify and cost. Their cost over a 10-year period is approximately $3.5 million (PV), or around $356,000 (PV) annually. Of these costs, approximately 40 per cent are imposed on business (i.e., ART providers) and 60 per cent are imposed on individuals. Given the large number of treatments per

annum (assumed to be around 9,000), the administrative costs for individuals associated with each treatment are relatively low at around $80 (the average total cost of a treatment charged by a clinic is in the order of $5,000). An indicative administrative cost imposed upon ART providers is around $130 per treatment.

At a broad level, benefits of the regulated clinic system is that it offers important safeguards both for persons participating in treatment (medical screening and registration of donor details, mandatory pre-treatment counselling for all parties) and the children who may be born of the treatment procedure (assessment of parental risk factors, access to records providing genetic history, access to counselling as an adult).

It is important to recognise, however, that most of these benefits are attributable to the Act rather than the proposed Regulations. Specifically, the proposed Regulations establish standardised record keeping requirements to permit efficient audits and allow information to be recorded in a way that allows persons born from a treatment procedure to determine their genetic parents. The regulations provide these benefits in a manner which lowers 'search costs' and enhances compliance.

The proposed Regulations also seek to minimise costs for individuals and industry participants by prescribing information requirements that may be readily adaptable into forms for use by ART providers. If this information was not prescribed then ART providers would need to rely on the Act to estimate the specific types and level of detail required. It would be difficult for ART providers to determine the legislative requirements and may lead to not including enough information on one hand (thereby compromising compliance) or including too much information on the other hand (thereby adding to costs). Thus prescribing the information in a statutory rule reduces the search costs for ART providers as well as lowering the risks of non-compliance. In short, prescribing information requirements provides regulatory certainty. Standardised information also lowers government collection and audit costs.

The benefits of the proposed Regulations, however, proved difficult to quantify in monetary terms, and this is further complicated by an attempt to allocate benefits between the legislation and regulations. That said, as a very broad indication of the magnitude of likely benefits, Attachment H contains two international case studies of the emotional and financial costs associated with mistakes in relation to ART process. While such mistakes are fortunately rare, this highlights the importance of a well-management ART system, which minimises the chance of these events ever occurring (i.e., mistakes may occur because of human error, but should not occur due to regulatory failure). In one such case, the court system monetarised the concept 'pain and suffering' for an incident associated with ART at $1 million. While occurring in a US jurisdiction, the magnitude of the payment illustrates the value the community (as reflected through the courts) places on a well-managements ART system.

Given the analysis in the proceeding sections, this RIS concludes that the proposed Regulations is the most effective way to achieve the Victorian Government's policy objectives, and are therefore considered the preferred option identified in this RIS. This finding is concluded against the decision criteria described in Section 4.2.4;

that is, while the quantifiable costs are largest compared to the other options, the likely benefits (which are difficult to quantify) of the regulations are assessed as exceeding the costs. The main reasons why the proposed Regulations are preferred are that they:

- provide a framework that permits data to be collected, monitored and submitted to government in a cost-effective, standardised form;
- lower 'search costs' for ART providers and administration costs for government;
- provide an effective enforcement and compliance mechanism; and
- deal with a number of matters that cannot be dealt by other means (e.g., prescribe fees, costs to be reimbursed).

Assessment of the options using the MCA framework also suggests that the proposed Regulations are superior to the alternatives, as shown in Table 14 below.

Table 14: Summary of Multi-criteria Analysis Compared to Regulations

Criteria*	Weight	Option 1**	Option 2	Option 3	Option 4	Option5
1	**35**	50	15	50	30	50
2	**35**	50	50	25	30	50
3	**20**	-50	0	-10	0	-35
4	**10**	75	50	-75	75	15
Total		**32.50**	**27.75**	**16.75**	**28.50**	**29.50**

* Criterion 1: Information provided to parties; Criterion 2: Information recorded; Criterion 3: Cost minimisation Criterion 4: Cost to government
** Proposed Regulations

The proposed Regulations do not impose a disproportionate burden on small business (almost all businesses affected by the proposal employ more than 20 staff). The proposed Regulations are also considered to satisfy the 'competition test' as set out in the *Victorian Guide to Regulation*.

The proposed Regulations impose costs on patients and other parties and ART providers. Administrative costs for individuals associated with each treatment are relatively low at around $80 (the average total cost of a treatment charged by a clinic is in the order of $5,000). An indicative administrative cost imposed upon ART providers is around $130 per treatment. The costs imposed by the proposed Regulations should not discourage individuals from assessing ART, nor should they impose barriers for the provision of ART services. Indeed, the new Act (but not the proposed Regulations of themselves) will remove barriers to access to ART.

The proposed Regulations have a narrow focus and prescribe specific information requirements that give operational effect to elements of the Act. Given the focus of the proposed Regulations the risk of not proceeding with them is that parties would not receive adequate information, the quality of the information held on the registers could not be guaranteed, and compliance would be more difficult and costly to undertake. Overall, the best interests of the child would not be served.

This Regulatory Impact Statement concludes that:

- the benefits to society of the proposed Regulations exceed the costs;
- the net benefits of the proposed Regulations are greater than those associated with any practicable alternatives;
- the proposed Regulations do not impose restrictions on competition; and
- the proposed Regulations will not lead to a material change in the administrative burden on businesses.

6A. CHANGE IN ADMINISTRATIVE BURDEN

The *Reducing the Regulatory Burden* initiative commits the Victorian Government to reducing the administrative costs of regulation. Accordingly, this RIS uses the SCM methodology and *Measurement of Changes in Administrative Burden* to measure any changes to the administrative costs. For the purposes of the measurement of change in the administrative burden, the existing burden forms the base case against which the change is measured.

Administrative costs are those costs incurred by business to demonstrate compliance with the regulation or to allow government to administer the regulation. The SCM is used solely to measure the administrative costs of regulation to business and are expressed as an annual current cost, consistent with the SCM Guidelines. It is not used to measure substantive compliance costs. Similarly, costs to government of administering and enforcing the proposed Regulations are not subject to the SCM assessment. It should also be noted that a number of new requirements (e.g., consent forms) relate to individuals and not business.

As stated earlier, the proposed Regulations largely remake the current Regulations; however, they do establish one new reporting requirement. A summary of the administrative burden is contained in Table 15 below, which shows that the proposed Regulations impose a net increase of administrative costs on business of around $8,000.

Table 15: Assisted Reproductive Treatment Regulations 2009 net impact on the administrative burden (annual current costs)

Information obligation	Existing administrative burden	Proposed change to the burden (net impact)
Information obligation 1 – (Regulation 14) Register kept by registered ART provider	Requirement currently in Schedule 1 of the current regulations.	Nil (possibly reduced burden due to simplification of schedule)
Information obligation 2– (Regulation 15) Register kept by doctor carrying out artificial insemination	Requirement currently contained in s. 63 of the Act. Obligation moved to regulations	Nil (moved to regulations)
Information obligation 3 – (Regulation 16) Information be provided to BDM Victoria by ART providers and doctors	Nil (but costs are currently incurred by ITA associated with maintaining registers)	$7,910
Information obligation 4 – (Regulation 19) Information and documents to be provided for ART registration	Currently located in the Act (negligible - less than $100)	Moved to the regulations (negligible - less than $100)
Net Impact		**$7,910**

In accordance with the Guidelines issued by the Treasurer, *Measurement of Changes in Administrative Burden*, it is therefore determined that the regulatory changes in the proposed Regulations will not lead to a material change in the administrative burden on business organisations in Victoria (see Attachment I for Statement of No Material Impact).

Reducing the Regulatory Burden

Against the new administrative burdens imposed by the proposed Regulations, when the new legislation was drafted, unnecessary burdens and duplications were removed. For example, currently all ART clinics must be registered as a private hospital or day procedure centre under the *Victorian Health Services Act 1988*, be accredited by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia (RTAC) and the Australian Council on Healthcare Standards, comply with NHMRC ethical guidelines, and have laboratory facilities which must be accredited by the National Association of Testing Authorities. Under the new legislation ART clinics will no longer need to apply separately to VARTA for a licence to operate: if an ART clinic has a RTAC licence it may apply to VARTA to become a registered ART provider. In addition, the current Act requires doctors, clinical scientists and counsellors to be separately approved by the ITA. This will no longer be required.

7. IMPLEMENTATION AND ENFORCEMENT ISSUES

Monitoring and Enforcement

The ITA advises that compliance with the current legislation and regulations has been high, and a strategy of education and information provision has been used to minimise the risks of non-compliance. While a number of investigations have been conducted over the past 10 years, issues identified have been resolved without the need for sanctions. In addition, the ITA currently uses Conditions for Licence and guideline documents (located on the website) to provide clarity and guidance to assist compliance for ART providers. The ITA consider that these arrangements have worked well to date.

The donor registers currently managed by the ITA will be transferred to BDM Victoria, which will have responsibility for them. Under the new arrangements, VARTA will not be auditing clinic records and comparing with the Central Donor Registers. The ITA previously checked clinic data where there were questions about data provided from clinics for the Central Registers and general audits were also conducted for quality assurance processes. BDM Victoria will be responsible for maintaining the Central Register and Voluntary Register and processing applications for information from these registers in line with legislative provisions.

Registered ART providers will be required under the Act to be accredited by the RTAC of the Fertility Society of Australia. Such accreditation is required for clinics in order for their patients to receive benefits under the Commonwealth pharmaceutical benefits scheme.

Consultation has been undertaken with ART providers to ensure the smooth introduction of the new Act and proposed Regulations. DOH and DHS will assist providers in relation to clarifying new legislative requirements.

8. EVALUATION STRATEGY

The *Subordinate Legislation Act 1994* revokes statutory rules following 10 years of operation. This allows the government to examine whether there is still a problem that requires government intervention, and to take account of any changes or developments since the regulation was implemented. When regulations are remade, the government assesses whether the objectives of the regulation are being met, whether practical experience suggests ways in which they can be improved, or whether a different regulatory approach is warranted. Final development of the regulations is informed by public input through the RIS process.

It is not anticipated that the proposed Regulations will require a formal review once they are in place. This is because they largely remake the current Regulations which have been in operation for 10 years. The data requirements and forms associated with the new proposals are relatively straightforward and are unlikely to require a formal review in addition to the RIS process.

That said, DOH will be monitoring the implementation of the new legislation and regulations closely, and should any issues arise with respect to the proposed Regulations these will be rectified.

It is also relevant to note that the RTAC conducts surveillance audits of ART providers at least every 12 months, including compliance, data monitoring, and data reporting.

9. CONSULTATION

The process leading to the introduction of the Act, and hence the proposed Regulations, involved extensive research and consultation over a seven year period.. As noted earlier, following the decision in the *McBain* case, in October 2002 the Victorian Law Reform Commission received the terms of reference from the Victorian Government to enquire into and report on the desirability and feasibility of changes to the *Infertility Treatment Act 1995* to expand eligibility criteria in respect of all forms of assisted reproduction.

In January 2004, a consultation paper was published which explained the current law and identified issues in the inquiry. The VLRC received 255 submissions in response to the consultation paper. In August of that year, three occasional papers written by experts working in the field were published. In the following month a public forum on the inquiry was held, attended by approximately 150 people in September. During 2004 the VLRC also attended 14 meetings and forums with experts, community groups, service providers and statutory authorities to discuss specific aspects of issues identified in the inquiry and general progress on the reference.

In 2005 the VLRC published three position papers covering the key areas of the project: *Position Paper One: Access, Position Paper Two: Parentage* and *Position Paper Three: Surrogacy.* Fourteen meetings and forums were held on the three areas covered in the position papers. Over 750 submissions were received in response to the interim recommendations contained in these papers. Further consultations were undertaken with members of the community, experts, practitioners, and users of assisted reproductive technology.

During 2006, further consultations were held to discuss the commission's interim recommendations, including another series of roundtable discussions and meetings.

The VLRC's staff continued to undertake research and in March 2007 the final report including 130 recommendations for changes to the law was delivered to the Attorney-General. The Attorney-General tabled the report in Parliament and this resulted in the subsequent introduction and passing of the *Assisted Reproductive Treatment Act 2008*.

Since the Act was passed, DOH has contacted all licensed ART providers to discuss implementation of the proposed Regulations. In August 2009 a forum was held with licensed ART providers to seek comments on an exposure draft of the regulations. Four clinics and the Victorian Branch of the Australian and New Zealand Infertility Counsellor's Association also provided written comments following this forum and are summarised as follows:

- that the regulations specify that counselling be undertaken on a one-to-one basis, rather than in groups;
- that the counselling matters were too general and should be more prescriptive;

- that 'loss of income' be included as a prescribed cost;
- clarification as to whether counselling is required for artificial insemination cycles (as it is for donor insemination); and
- comments relating to police records checks and child protection order checks.

Clinics also provided very detailed comments on the wording of regulations and schedules. These comments will be considered as part of the RIS process. Some of the comments raised to date deal with policy matters (e.g., re-imbursement of costs) or matters covered by the Act (e.g., police record checks). It was also clarified that clinics did not need to provide new forms for patients but could include the information required by the consent forms in their current forms.

In August 2009 a meeting was also held with the ITA and comments sought on the exposure draft. Comments centred on technical aspects of the wording and clarifying the differences between the current and proposed Regulations.

Consultation informed the hours and costings used in this RIS. As a result, a new cost of updating forms was included in the costs.

This RIS will be publicly available on the DOH website at (www.health.vic.gov.au/art) and will be advertised in the Herald Sun on 15 October 2009 and the Victorian Government Gazette on 20 October 2009. Copies of this RIS have been forwarded to key stakeholders inviting comments.

This RIS represents another step in the consultation process and DOH welcomes comments or suggestions with respect to the nature, extent, and likely impacts of the proposed Regulations, and any variations that may improve the overall quality of the proposed Regulations.

The *Subordinate Legislation Act 1994* requires that the public be given at least 28 days to provide comments or submissions regarding the proposed Regulations. Given that persons currently excluded from ART will be able to access such treatment when the regulations come into effect, DOH supports action to ensure that they come into effect as soon as possible. Consequently the consultation period for this RIS will be 28 days, with written comments required by no later than **5.00pm, 17 November 2009**.

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10. ATTACHMENTS

Attachment A

DESCRIPTION OF PROPOSED STATUTORY RULE

Machinery Regulations – Regulations 1 to 4

Regulations 1 to 4 are machinery regulations and set out the objectives, authorising provision, commencement, and definitions.

Specifically, proposed **Regulation 1** notes that the objective of the Regulations is to prescribe various matters necessary to give effect to the Act.

Proposed **Regulation 2** provides that the regulations are authorised to be made under section 124 of the Act.

Proposed **Regulation 3** provides that the proposed Regulations will come into operation on 1 January 2010 unless proclaimed earlier .

Proposed **Regulation 4** provides a definition for the proposed Regulations. It defines the 'Act' as meaning the *Assisted Reproductive Treatment Act 2008*.

Forms, Requirements, Registers and Fees – Regulations 5 to 19

Division 2 of the Act sets out the general requirements for treatment procedures. Section 10(1)(a) provides that a woman may undergo a treatment procedure only if the woman and her partner, if any, have consented, in the prescribed form, to the carrying out of a procedure of that kind. Proposed **Regulation 5** prescribes this information, which is contained in Schedule 1. This is basically a consent form requiring the following fields to be completed: the name, address details, type of procedure and signatures from the woman, partner of the woman (if any), and counsellor.

As part of the consent requirements under section 10(1) of the Act, section 11(1)(d) requires that permission be provided from the woman and her partner, if any, for a child protection order check to be conducted in relation to the woman and her partner, if any. Proposed **Regulation 6** prescribes the form of child protection order check, which is contained in Schedule 2.

Section 13 of the Act requires that before a woman consents to undergo a treatment procedure, the woman and her partner, if any, must have received counselling (including counselling in relation to the prescribed matters) from a counsellor who provides services on behalf of a registered ART provider. Proposed **Regulation 7** prescribes certain matters including: the options or choices available to the particular woman and her partner, if any; the possible outcomes of a treatment procedure; advising children about their donor origins and rights to information; and issues relating to genetic siblings who share a common genetic parent but are raised in different families.

Section 17 of the Act deals with matters concerns a oocyte, sperm or embryo donor's consent. Subsection (1)(a) provides that this consent must be in the prescribed form. Proposed **Regulation 8** prescribes this form, which is set out in Schedule 3.

Section 18 of the Act requires that before a person gives consent to donate gametes or an embryo under section 16, the person must have received counselling (including counselling in relation to the prescribed matters) from a counsellor who provides services for a registered ART provider. Proposed **Regulation 9** prescribes two matters that must be discussed as part of this counselling, i.e., the requirements of the Act in relation to disclosing the identity of the donor to the Registrar and disclosing information to donor-conceived children if they seek that information; and any issue or concern raised by the donor in relation to the donation, for example, the possible impact of donation on the donor's partner.

Section 43(a) of the Act requires that before a surrogacy arrangement is entered into the commissioning parent, the surrogate mother and the surrogate mother's partner, if any, must undergo counselling, by a counsellor providing services on behalf of a registered ART provider, about the social and psychological implications of entering into the arrangement, including counselling about the prescribed matters. Proposed **Regulation 10** prescribes these matters and covers such areas as the implications of surrogacy for the relationship between the commissioning parent and the surrogate mother; the implications of surrogacy for any existing children of the surrogate mother or the commissioning parent; and the attitudes of all parties towards the conduct of the pregnancy.

Section 44 of the Act prohibits a surrogate mother from receiving any material benefit or advantage as a result of a surrogacy arrangement. There are significant penalties for a breach of this section. However, the Act does not prevent a surrogate mother being reimbursed for the costs actually incurred by her as a direct consequence of entering into the surrogacy arrangement. Proposed **Regulation 11** prescribes these costs as any reasonable medical expenses associated with the pregnancy or birth that are not recoverable under Medicare, health insurance or other scheme; any legal advice obtained about the legal consequences of entering into the arrangement; and travel costs related to the pregnancy and birth.

Section 48 of the Act requires a woman who will undergo a treatment for the posthumous use of gametes or an embryo to undergo counselling by a counsellor providing services on behalf of a registered ART provider, in relation to the prescribed matters. Proposed **Regulation 12** prescribes these matters as: the grieving process; and the possible impact on the child to be born as a result of the treatment procedure.

For the purposes of section 34(2)(b) of the Act, proposed **Regulation 13** requires that an embryo must be disposed of by allowing the embryo to stand in its container, at room temperature, in a secure area for a period of not less than 24 hours.

Section 49 of the Act requires registers to kept by registered ART providers and doctors in relation to ART procedures. This section lists fourteen categories of

information, which is prescribed by proposed **Regulation 14** and contained in Schedule 4.

Section 50 of the Act requires a doctor carrying out artificial insemination to keep a register that includes the prescribed information in relation to each artificial insemination carried out by the doctor; if donor sperm is used for the artificial insemination, the donor; the woman who is inseminated and her partner, if any; a person born as a result of the artificial insemination, including particulars of the birth, if known to the doctor; each consent given in relation to the artificial insemination or withdrawal or lapsing of the consent. Proposed **Regulation 15** prescribes details under each of the areas, which is contained in Schedule 5.

Section 53 of the Act requires the Registrar of Births, Deaths and Marriages to keep a Central Register containing certain prescribed information. Proposed **Regulation 16** prescribes this information in Schedule 6. This relates to the suburb of the hospital or place where birth occurred; the donor identification code; any genetic abnormality of the donor; the donor's build; the donor's height; the donor's blood group; the donor's place of birth; and the ethnic background of the donor's parents and grandparents. Proposed Regulation 16 also requires that the registered ART provider or doctor who has carried out artificial insemination to provide the information set out in Schedule 6 to the Registrar.

The Act permits disclosure of information on the Central Register to certain persons, e.g., a person born as a result of a donor treatment procedure. Section 56 of the Act deals with applications for information on Central Register, and subsection (3)(b) requires that an application be accompanied by the prescribed fee. Proposed **Regulation 17** prescribes that fee at 5.18 fee units, which is equivalent to $60.60. This proposed fee is based on the current fee for the 'Addition of registrable information', which requires the same resources to alter/extract information from the Registry.

The Registrar of Births, Death and Marriages must keep a Voluntary Register that contains information about donor treatment procedures. This will allow persons to obtain details about their relevant donors. Proposed **Regulation 18** prescribes that this register must be kept in an electronic form that is readily convertible into legible print in the English language.

Section 74 of the Act allows a person who holds accreditation granted by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia to apply for registration as a registered ART provider. This application must be in writing, be accompanied by evidence that the person holds RTAC accreditation, and proposed **Regulation 19** will require the name of the designated officer appointed by the ART provider. This regulation essentially requires the name of a contact person as part of the application process.

Attachment B

COMPARISON OF PROPOSED REGULATIONS WITH CURRENT REGULATIONS

Proposed Regulation	Current Regulation	Description	Change
1	1	Objective	Machinery – no change
2	2	Authorising provision	Machinery – no change
3	3	Commencement	Machinery – no change
4	4	Definition	Machinery – no change
5	5	Form of consent to treatment procedure.	There is no consent form in current regulations as the requirements were specified in s. 9 of Act
6	n.a.	Permission to conduct child protection order check	**New**
7	6	Counselling prior to treatment procedure	Simplified but substantially similar
8	8	Form of donor's consent – the current requirement requests information and does not have a consent focus.	Simple consent form has replaced the detailed list of questions, which are currently in the regulations.
9	7	Counselling prior to donation	Simplified but substantially similar
10	n.a.	Counselling prior to surrogacy arrangement	**New**
11	n.a.	Prescribed costs actually incurred that may be reimbursed	**New**
12	n.a.	Counselling prior to posthumous use of gametes or embryos	**New**
13	12	Disposal of embryos	No change
14	13	Register kept by registered ART provider	Substantially similar but has been updated to reflect previous experience and to take into account privacy and other considerations. A number of information obligations have been removed.
15	14	Register kept by doctor carrying out artificial insemination	**New**

COMPARISON OF PROPOSED REGULATIONS WITH CURRENT REGULATIONS (continued)

Proposed Regulation	Current Regulation	Description	Change
16	n.a.	Central Register kept by the Registrar	**New**
17	19	Fee for applications for information	The fee was previously prescribed as 'nil'; new fee based on full cost recovery.
18	n.a.	Requirements for entries in the Voluntary Register	**New** – government requirement. The voluntary register was not in the Act when the 1997 regulations were made.
19	n.a	Information and documents to be provided for ART registration	**New** (replaces Part 8 of the 1995 Act)
	Current Regulations	**Description**	**Revocation**
	9	Counselling requirements to research	Revoked – not carried over into the new Act. Research components now has stand alone legislation
	10	Manner of lodging consent to research using gametes	Revoked
	11	Use of gametes produced by children	Revoked (now contained in new s. 26 of the new Act)
	15	Particulars for information to be given to the Authority	Revoked
	16	Information to be given to the Authority by licensed centres and approved doctors	Revoked and significantly streamlined (see proposed Regulation 16)
	17	Information to be given to the Authority by other persons	Revoked
	18	Central Register kept by the Authority	Revoked – under the new Act the central Register will be kept by BDM Victoria
	20	Donor treatment procedures information Register	Revoked
	21	Notification of approvals and licences	Revoked
	22	Certification of document copies	Revoked
	23	Transitional concerning 1988 regulations	Revoked

Attachment C

TYPE AND INCIDENCE OF COSTS

Reg[n]	Description	Type of Cost	Impact/magnitude	Affected Party
5	Form of consent to treatment procedure	Administrative	Cost minor/population large	Woman, partner (if any), counsellor
6	Permission to conduct child protection order check	Administrative	Cost minor/population large	Woman and partner (if any)
7	Counselling prior to treatment procedure	Substantive Compliance	Negligible (see Assumption 4, Attachment D)/population large	Woman and partner, (if any)
8	Form of donor's consent	Administrative	Cost minor/population medium	Gamete donor
9	Counselling prior to donation	Substantive Compliance	Negligible (see Assumption 4, Attachment D)/population	Gamete donor, partner (if any)
10	Counselling prior to surrogacy arrangement	Substantive Compliance	Negligible (see Assumption 4, Attachment D)/population small	Commission parties and surrogate
11	Prescribed costs actually incurred that may be reimbursed	n.a	An economic transfer between surrogate mother and commissioning parties/population small	Surrogate mother
12	Counselling prior to posthumous use of gametes or embryos	Substantive Compliance	Negligible (see Assumption 4, Attachment D)/population small	Surviving patient/partner
13	Disposal of embryos	Substantive Compliance	Prescribes a procedure with very low costs associated with compliance.	ART providers

TYPE AND INCIDENCE OF COSTS (continued)

Reg[n]	Description	Type of Cost	Impact/magnitude	Affected Party
14	Register kept by registered ART provider	Administrative	Cost medium/population large	ART provider
15	Register kept by doctor carrying out artificial insemination	Administrative	Cost medium/population small	Doctor
16	Central Register kept by the Registrar	Administrative	Cost large/population large	ART provider or doctor
17	Fee for applications for information	Financial	Fees set at full cost recovery, hence no cost to government. Cost individual $60.60 per application.	Applicant seeking donor information
18	Requirements for entries in the Voluntary Register	Government cost	Cost large/population small	BDM Victoria
19	Information and documents to be provided for ART registration	Administrative	Negligible/minor	ART Provider

Note: Regulations 1 to 4 are machinery regulations and as such do not impose costs.

Attachment D

ASSUMPTIONS

Cost Assumptions

1. The discount rate used in this RIS is **3.5** per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)

2. As a proxy for valuing an hour of a person's time, the following formula is given:

   $HR_x = AE_x/AW_x \times AH_x$, where

   AE_x = average weekly earnings multiplied by 52;

   AW_x = number of weeks worked per annum (44 weeks);

   AHx = average weekly hours for full time workers (41 hours).

   See *Victorian Guide to Regulation* (Section C.2.1 Valuing staff time, p. C-5). Labour on-costs and overhead costs are excluded from the calculation for patients, partners and donors. This provides an hourly value of a person's time of **$34.50** (i.e. $1,197.50 divided by (44 x 41)). ABS Cat 6302.0 – Average Weekly Earnings, Australia, May 2009, Canberra, Full-time adult ordinary time earnings (private and public sectors) is $1,197.50 per week.

   Stakeholders have advised that clinical scientific staff complete the details information requirements in proposed Schedules 4, 5 and 6. The MyCareer salary survey of scientific staff for the March quarter 2009 provided an average salary of $76,625.84. This figure is broadly consistent with the Hays survey of salaries in the pharmaceutical sector. This provides a typical salary of a clinical research associate at $60,000 while the salary of a senior clinical research associate is $80,000 (range $70,000 - $90,000). Therefore, based on an annual salary of $76,625 and using the methodology of valuing staff time in the *Victorian Guide to Regulation* , this would provide an hourly rate of **$62.89** per hour (including employment on-costs). That is: ($76,625/(44 weeks x 41 hours)) x (1.15 (labour on-costs) x 1.5 (corporate overheads)) = $62.89.

   Schedules 4 and 5 require both the patient and ART provider to provide information. Given that the ART provider provides the majority of this information (about 80 per cent) and the patients provides the remained (20 per cent), a simple weighted average (($62.89 x 80 per cent) +($34.50 x 20 per cent)) provides a tariff for Schedules 4 and 5 of **$57.22**.

   For the purposes of deriving a tariff for the value of doctors' time in relation to proposed Regulation 15, the Medicare schedule for a visit to a general practitioner was used and assumed that a doctor sees four patients per hour. This provides an hourly tariff of **$134.20** (Source: Medicare Benefits Schedule

Book, General Practitioner, Item 23, Level 'B', Professional attendance at consulting rooms of less than 20 minutes duration: Fee: $33.55, p. 125).

3. A proportion (50 per cent) of the costs are assumed to be attributable to the proposed Regulations for costs to ART providers. This assumption relates to the situation that would arise under the 'base case'. That is, the NHMRC Guidelines and RTAC Code of Practice would apply in the absence of the proposed Regulations. Some jurisdictions, notably Queensland, Tasmania and the ACT, largely rely on these instruments. The NHMRC Guidelines and RTAC Code of Practice deal with many of the administrative matters covered by the proposed Regulations, e.g., record keeping, counselling, informed consent. Furthermore, it could be reasonably argued that a 'normally efficient business' would keep detailed patient records (not least because of other federal and state requirements relating the medical practitioners) even in the absence of the proposed Regulations and the Guidelines and Code.

   The question arises as to why the proportion of 50 per cent is assigned to the costs imposed by the proposed Regulations. It could be submitted that a much lower proportion could be assigned to the proposal, say 25 per cent or even 10 per cent. Such estimates, however, would imply a spurious accuracy in allocating proportions. Instead, this RIS submits that 50 per cent represents a reasonable and conservative estimate of the cost attributable.

4. Proposed Regulations 7, 9, 10, and 12 deal with matters prescribed that must be covered in the mandatory counselling – a requirement imposed by the Act rather than the regulations. Typically such counselling sessions take about one hour. Some more complex situations may require two or three sessions (beyond the requirements of the Act). Consultation with ART providers indicated that such counselling would be conducted in any case even in the absence of the proposed Regulations and that the matters raised in the session often exceeded the matters set down in the Act and regulations. Importantly, stakeholders also advised that the matters prescribed in the proposed Regulations would not lengthen the time of a counselling session. Stakeholders supported the matters included in the proposed Regulations as providing a structure or template for counselling and to ensure a minimum consistency across clinics.

   Given this advice, the possible substantive compliance cost associated with the prescribed matters has not been calculated as an incremental cost imposed by the proposed Regulations.

5. A growth rate of **5 per cent** per annum in assisted reproductive treatments has been assumed over the 10 year costing period. Data on treatment (cycles commenced) obtained were: 2003 – 11,256, 2004 – 12,321, 2005 – 13,168, 2006 –13,431, 2007 – 15,007 (see ITA 2008 Annual Report, p. 23). These figures provide an annual growth rate of around 5.75 per cent. This historically high rate needs to be tempered against possible changes to Medicare arrangements, clinic capacity and availability of donated gametes.

Attachment E

SUMMARY OF COST CALCULATIONS OF PROPOSED REGULATIONS

Summary of Costs of Proposed Assisted Reproductive Treatment Regulations 2009, 10-Year Assessment Period	
Costs imposed on individuals and business	
Description	**Cost ($)**
Regulation 5 – Form of consent to treatment procedures	266,951
Regulation 6 – Permission to conduct child protection order checks	533,901
Regulation 8 – Form of donor's consent	20,763
Regulation 14 – Register kept by registered ART provider	2,656,350
Regulation 15 – Register kept by doctor carrying out artificial insemination	10,384
Regulation 16 – Provision of information by ART provider to the Registrar	64,883
Cost of updating forms	9,434
Sub-total	***3,562,666***
Cost to Government	
Government administration and enforcement costs	59,055
Total	**3,621,721**

1. Costs have been discounted (3.5 per cent per annum), except for the cost of updating forms which will occur in year 1 only.

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 5 - Form of consent to treatment procedure					
Completion of Schedule 1 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	34.50	0.08	9,000	1	25,875
2	34.50	0.08	9,450	1	27,169
3	34.50	0.08	9,923	1	28,527
4	34.50	0.08	10,419	1	29,954
5	34.50	0.08	10,940	1	31,451
6	34.50	0.08	11,487	1	33,024
7	34.50	0.08	12,061	1	34,675
8	34.50	0.08	12,664	1	36,409
9	34.50	0.08	13,297	1	38,229
10	34.50	0.08	13,962	1	40,141

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)** [5]
1	$25,875				$25,000
2	$27,169				$25,362
3	$28,527				$25,730
4	$29,954				$26,103
5	$31,451				$26,481
6	$33,024				$26,865
7	$34,675				$27,254
8	$36,409				$27,649
9	$38,229				$28,050
10	$40,141				$28,456
				Total	**$266,951**

Notes:

1. The cost of an applicant's time used to calculate 'administrative costs' is $34.50 per hour, which is based on the methodology contained in the Methodology and Value for Staff Time in BIA/RIS Analysis in the Victorian Guide to Regulation. Note that corporate overheads and labour on-costs have been excluded from this rate. See Assumption 2, Attachment D.
2. Schedule 1 is a very basic form, requiring names, addresses and signatures. A desktop exercise and discussions with DOH suggest that an application form would take around 5 minutes to complete.
3. There were 8,666 women treated (Source: ITA Annual Report 2008, p. 26). Based on these figures a growth rate of 5 per cent per annum has been assumed over the 10 year costing period (see Assumption 5, Attachment D).
4. Applications are per treatment.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 6 - Permission to conduct child protection order check					
Completion of Schedule 2 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	34.50	0.17	9,000	1	51,750
2	34.50	0.17	9,450	1	54,338
3	34.50	0.17	9,923	1	57,054
4	34.50	0.17	10,419	1	59,907
5	34.50	0.17	10,940	1	62,902
6	34.50	0.17	11,487	1	66,048
7	34.50	0.17	12,061	1	69,350
8	34.50	0.17	12,664	1	72,817
9	34.50	0.17	13,297	1	76,458
10	34.50	0.17	13,962	1	80,281

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)**[5]
1	$51,750				$50,000
2	$54,338				$50,725
3	$57,054				$51,460
4	$59,907				$52,206
5	$62,902				$52,962
6	$66,048				$53,730
7	$69,350				$54,508
8	$72,817				$55,298
9	$76,458				$56,100
10	$80,281				$56,913
				Total	**$533,901**

Notes:
1. The cost of an applicant's time used to calculate 'administrative costs' is $34.50 per hour, which is based on the methodology contained in the Methodology and Value for Staff Time in BIA/RIS Analysis in the Victorian Guide to Regulation. Note that corporate overheads and labour on-costs have been excluded from this rate. See Assumption 2, Attachment D.
2. Schedule 2 is a very basic form, requiring names, addresses and signatures. A desktop exercise and discussions with DOH suggest that an application form would take around 10 minutes to complete.
3. There were 8,666 women treated (Source: ITA Annual Report 2008, p. 26). Based on these figures a growth rate of 5 per cent per annum has been assumed over the 10 year costing period (see Assumption 5, Attachment D).
4. Applications are per treatment.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 8 - Form of donor's consent					
Completion of Schedule 3 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	34.50	0.08	700	1	2,013
2	34.50	0.08	735	1	2,113
3	34.50	0.08	772	1	2,219
4	34.50	0.08	810	1	2,330
5	34.50	0.08	851	1	2,446
6	34.50	0.08	893	1	2,569
7	34.50	0.08	938	1	2,697
8	34.50	0.08	985	1	2,832
9	34.50	0.08	1,034	1	2,973
10	34.50	0.08	1,086	1	3,122

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)**[5]
1	$2,013				$1,944
2	$2,113				$1,973
3	$2,219				$2,001
4	$2,330				$2,030
5	$2,446				$2,060
6	$2,569				$2,089
7	$2,697				$2,120
8	$2,832				$2,150
9	$2,973				$2,182
10	$3,122				$2,213
				Total	**$20,763**

Notes:

1. The cost of an applicant's time used to calculate 'administrative costs' is $34.50 per hour, which is based on the methodology contained in the Methodology and Value for Staff Time in BIA/RIS Analysis in the Victorian Guide to Regulation. Note that corporate overheads and labour on-costs have been excluded from this rate. See Assumption 2, Attachment D.
2. Schedule 3 is a very basic form, requiring names, addresses and signatures. A desktop exercise and discussions with DOH suggest that an application form would take around 5 minutes to complete.
3. ITA advise that there are currently 669 donations per annum. Given the expansion of treatment access, 5 per cent growth per annum has been assumed.
4. Applications are per donation.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 14 - Register kept by registered ART provider					
Completion of Schedule 4 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	57.22	1.00	9,000	1	514,949
2	57.22	1.00	9,450	1	540,697
3	57.22	1.00	9,923	1	567,732
4	57.22	1.00	10,419	1	596,118
5	57.22	1.00	10,940	1	625,924
6	57.22	1.00	11,487	1	657,220
7	57.22	1.00	12,061	1	690,081
8	57.22	1.00	12,664	1	724,586
9	57.22	1.00	13,297	1	760,815
10	57.22	1.00	13,962	1	798,856

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)** [5]
1	$514,949				$497,536
2	$540,697				$504,746
3	$567,732				$512,062
4	$596,118				$519,483
5	$625,924				$527,011
6	$657,220				$534,649
7	$690,081				$542,398
8	$724,586				$550,259
9	$760,815				$558,233
10	$798,856				$566,324
				Sub-total	$5,312,701
				50 per cent attribution to the Regulations [7]	**$2,656,350**

Notes:

1. The cost of time used to calculate 'administrative costs' for Regulation 14 is $57.22 per hour. It is assumed that the patient/donor provides 20 per cent of this information, hence a rate of $34.50 per hour is used for this proportion (see Assumption 2, Attachment D). The remaining 80 per cent of this data is entered by scientific staff at the ART clinical. A gross-up factor of 1.75 (see C-5 of the Victorian Guide to Regulation) is applied to the rate of $35.94 to arrive at an hourly rate of $62.90. This provides a weighted average hourly rate of $57.22.
2. Schedule 4 contains detailed information on ART, including information on donors, gametes or embryos, a woman's details, each treatment procedure, etc. Not all parts in schedule 4 are filled out; this depends on types of treatment and other circumstances. This data is provided by patients, while other parts of the form are 'Office use only" and are entered by clerical staff at the clinic. A hard copy is filed and the data is also stored electronically.
3. There were 8,666 women treated (Source: ITA Annual Report 2008, p. 26). Based on these figures a growth rate of 5 per cent per annum has been assumed over the 10 year costing period (see Assumption 5, Attachment D).
4. Information requirement per treatment.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.
7. A proportion of 50 per cent is attributable to the regulations because of existing guidelines, codes and business practices (see Assumption 3, Attachment D).

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 15 - Register kept by doctor carrying out artificial insemination					
Completion of Schedule 5 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	134.20	0.50	10	3	2,013
2	134.20	0.50	11	3	2,114
3	134.20	0.50	11	3	2,219
4	134.20	0.50	12	3	2,330
5	134.20	0.50	12	3	2,447
6	134.20	0.50	13	3	2,569
7	134.20	0.50	13	3	2,698
8	134.20	0.50	14	3	2,832
9	134.20	0.50	15	3	2,974
10	134.20	0.50	16	3	3,123

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)**[5]
1	$2,013				$1,945
2	$2,114				$1,973
3	$2,219				$2,002
4	$2,330				$2,031
5	$2,447				$2,060
6	$2,569				$2,090
7	$2,698				$2,120
8	$2,832				$2,151
9	$2,974				$2,182
10	$3,123				$2,214
				Sub-total	$20,768
				50 per cent attribution to the Regulations[7]	**$10,384**

Notes:

1. The cost of doctors' time used to calculate 'administrative costs' for Regulation 15 is $134.20 per hour (see Assumption 2, Attachment D)
2. Schedule 5 contains detailed information on ART, including information on donors, a woman's details, etc in relation to artificial insemination carried out by a doctor. This schedule requires fewer details than Schedule 4.
3. Stakeholder consultation suggests around two doctors currently undertake these procedures. The estimate of 10 is a conservative estimate in the absence of any data.
4. Applications per artificial insemination. This figure is an assumption given that no data is currently collected.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.
7. A proportion of 50 per cent is attributable to the regulations because of existing guidelines, codes and business practices (see Assumption 3, Attachment D).

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Regulation 16 - Provision of information by ART provider or doctor to Central Register kept by the Registrar					
Completion of Schedule 6 Form	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year					
1	62.89	0.17	600	1	6,289
2	62.89	0.17	630	1	6,603
3	62.89	0.17	662	1	6,934
4	62.89	0.17	695	1	7,280
5	62.89	0.17	729	1	7,644
6	62.89	0.17	766	1	8,027
7	62.89	0.17	804	1	8,428
8	62.89	0.17	844	1	8,849
9	62.89	0.17	886	1	9,292
10	62.89	0.17	931	1	9,756

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Cost ($)**[5]
1	$6,289				$6,076
2	$6,603				$6,164
3	$6,934				$6,254
4	$7,280				$6,344
5	$7,644				$6,436
6	$8,027				$6,530
7	$8,428				$6,624
8	$8,849				$6,720
9	$9,292				$6,818
10	$9,756				$6,916
				Total	**$64,883**

Notes:

1. The cost of an applicant's time used to calculate 'administrative costs' is $62.89 per hour, which is based on the methodology contained in the Methodology and Value for Staff Time in BIA/RIS Analysis in the Victorian Guide to Regulation. See Assumption 2, Attachment D.
2. There are 8 basic items (e.g., place of birth, donor ID code, donor's height, build, blood group, etc) of information required to be sent to BDM. This information will be submitted electronically and is estimated to take 10 minutes to complete.
3. Clinics and doctors are required to report treatments, pregnancies and births. The figure of 600 is based on current birth statistics. It is assumed that this number will increase by 5 per cent per annum. See Assumption 5, Attachment D.
4. Information is sent for each birth.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Update of Forms					
Schedules 1 to 5	*Tariff($)* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
Year 1	62.89	30.00	5	1	9,434
				Total	**$9,434**

Notes:

1. The cost of staff time used to calculate 'administrative costs' is $62.89 per hour, which is based on the methodology contained in the Methodology and Value for Staff Time in BIA/RIS Analysis in the Victorian Guide to Regulation. See Assumption 2, Attachment D.
2. Advised by stakeholders.
3. There five clinics operating in Victoria (some of these operate across of number of locations).
4. This event will occur once.
5. This cost will be incurred in Year 1 only and therefore has not been discounted.
6. Figures may not add due to rounding.

Attachment F

GOVERNMENT ADMINISTRATIVE AND ENFORCEMENT COSTS

Costs of Proposed Assisted Reproductive Treatment Regulations 2009					
Price		**Quantity**			**Administrative Cost**
Government Administrative and Enforcement Costs					
Administration	*Tariff* [1]	*Time (hours)* [2]	*Population* [3]	*Frequency* [4]	
BDM entry of Schedule 6 data	56.46	0.17	755	1	7,101
				Total	**$7,101**

Discounted (10-Years)					
Year	**Administrative Cost ($)**				**Discounted Government Costs ($)** [5]
1	$7,101				$6,861
2	$7,101				$6,629
3	$7,101				$6,405
4	$7,101				$6,188
5	$7,101				$5,979
6	$7,101				$5,777
7	$7,101				$5,581
8	$7,101				$5,392
9	$7,101				$5,210
10	$7,101				$5,034
				Total	**$59,055**

Notes:

1. The tariff for administration costs for BDM represents the casual hourly rate (from 1 July 2009) applicable to a VPS Grade 3 officer ($32.26 per hour) officer. This average was grossed up by a factor of 1.75 to allow for salary on-costs and overheads (see Victorian Guide to Regulation, Section C.2.1, p. C-4). This provides a tariff of $56.46.
2. Time taken to process Schedule 6 data (8 fields of electronic data) is estimated to take 10 minutes.
3. Estimated number of annual Schedule 6 data inputs (annual derived from 10 year average - see population in Regulation 16).
4. Once-off or annual events.
5. The discount rate used in this RIS is 3.5 per cent. In doing so, the RIS adopts the rate published in the *Victorian Guide to Regulation* (Section C.3, p. C-9)
6. Figures may not add due to rounding.

Attachment G

APPLICATION FOR INFORMATION ON THE CENTRAL REGISTER (COST PER APPLICATION)

Fixed costs

VPS2 - Call Centre Officer

Answer enquiries (twice as many enquiries as applications. Average call time 3 minutes)

Refer more complex enquiries to ART Officer

VPS3 - ART Officer

- Receive application
- Image application & attach to electronic record
- File application form
- Process fee
- Check application compliance and take appropriate corrective action (email, telephone call or letter to applicant)
- Check Central Register to confirm applicant is eligible to make application and to confirm existence of record.
- Check births register and confirm if record is marked as donor conceived
- Confirm correct address details for person about whom identifying information is sought.
- Send registered letter to person about whom identifying information is sought to seek his or her consent to release information and mark in correspondence tab
- Send confirmation of receipt of application to applicant – may include a no record result, ineligible applicant or advice application pending consent to release identifying information
- Send letter to applicant if consent is not given to release identifying information
- Prepare letter of referral for prescribed counselling
- Receive confirmation of counselling provision and record on Central Register
- Print statement of information from Central Register and forward to applicant
- Record details of information released and name of person to whom information released on Central Register

Variable costs

(Simple variable cost)

- If application is in relation to a legacy record (one provided to BDM by ITA) confirm record details with relevant ITA provider
- If no Central Register entry for person exists and the relevant ART provider is known, telephone to check clinic records. If clinic has record:
    - confirm accuracy of Central Register record details
    - confirm relevant contact details of persons about whom information is sought
- Send second registered letter as follow up to initial request for consent to

release information if there is no response to first registered letter and mark in correspondence tab

- Where identifying information about donor is requested and the legislation does not require consent for release, Registrar must still make reasonable efforts to give notice of the intended disclosure to the donor.

(Complex variable cost)

- The location of treatment may not be known and contact may be required with all clinics offering a donor treatment program.
- It may also be possible that the Public Record Office of Victoria holds the record and that ART Officer will need to search files manually.

Fixed cost per application

			Compliant		**Non-compliant**	
BDM Officer	**Staff Cost***	**$per min**	**Time taken**	**Cost**	**Time taken**	**Cost**
VPS2	$88,850.00	0.87	6	5.22	6	5.22
VPS3	$113,200.00	1.11	50	55.50	55	61.05
Fixed Cost/ transaction			**60.72**		**66.27**	
Weighted Average cost**			**62.66**			

*Staff cost is based on the mid-point of the salary range of each position classification, rather than actual salaries. An additional 96% of salary is added to provide for on-costs (WorkCover, superannuation, payroll) and corporate overheads (records management, customer support, supervision, system maintenance costs, forms, policy development and review, etc) based on the Registry's calculations.

**This fee is a weighted average of the compliant (65%) and non-compliant (35%) applications, based on the application compliance experience for other complex applications, such as Change of Name.

The fixed cost estimates assume all Central Applications are for identifying information, which include requirements to obtain consent, notification of intended disclosure and referral for prescribed counselling.

Variable cost per application

			Simple		**Complex**	
BDM Officer	**Staff Cost***	**$per min**	**Time taken**	**Cost**	**Time taken**	**Cost**
VPS3	$113,200.00	1.11	40	44.40	360	399.60
Variable Cost/ transaction			**$44.40**		**$399.60**	

The variable costs will accrue depending on the accuracy and completeness of the information held on the Central Register and will be in addition to the fixed costs. Where legacy information is held (that is the data has been transferred from the ITA to the Registry) a variable cost will be incurred to check the content of the record with the relevant clinic prior to release.

There are approximately 5,500 records pertaining to donors and donor-conceived persons on the Central Register. Approximately 1000 of the donor-conceived persons are now adults and will be eligible to apply to the Central Register in their own right. If each donor, adult donor-conceived person and their parent(s) made an application to the Central Register, there would be at least 3,300 applications to legacy data. These applications would incur a variable cost (simple or complex) depending on the circumstances of the application (though the relative numbers are difficult to quantify).

Given the history of secrecy surrounding donor conception, it is not possible to estimate the percentage of people whose records are on the Central Register who will apply for information from legacy records. (In 2007, there were 21 applications to the Central Register[30].) It is the Registry's intention to undertake a project in the first year of operation of the Central Register to audit the legacy records and create updated records where appropriate. This will reduce the variable fee component by reducing the need to validate the record at the point of each application.

The fixed fee estimate of $62.66 approximates the current Registry fee for services to add registrable information, alter a register or change a person's name ($60.60). The Registry therefore considers that the appropriate cost recovery fee for an application to the Central Register should be $60.60 in alignment with the fee for these other similar services. This alignment will be simpler for customers to understand and Registry staff to administer.

Given the low frequency of requests for this information (currently the ITA receives about 20 requests per annum), and the likelihood that more complex requests will be a small proportion of overall requests, in the interests of administrative simplicity BDM Victoria will charge $60.60 (i.e., the fixed cost per application) for all applications.

[30] Infertility Treatment Authority Annual Report 2008, p21.

Attachment H

CASE STUDIES – EMOTIONAL AND FINANCIAL COST

IVF Mix-Up Woman 'Hands Over Baby Boy'

A US woman, who was impregnated with the wrong embryo in an IVF mix-up, has reportedly given birth. Carolyn Savage, 40, is believed to have had a Caesarean section with her husband Sean, 39, by her side. She gave birth to a health baby boy and the couple, from Sylvania, Ohio, were able to spend a few minutes with the child. They then gave the newborn to his biological parents, Shannon and Paul Morell, who live in the neighbouring state of Michigan.

After the successful IVF and birth of their youngest child last year, the Savages returned to their fertility clinic in February to try for one more. That was when the mix-up happened and both couples were informed of the mistake soon after. Mrs Savage told NBC24: "No family should have to go through this. And I guess it's our hope that by telling our story that maybe somewhere down the line when someone decides to disregard a safety and protective protocol they'll think twice."

The couple's lawyers said they were working to make sure the fertility clinic "will accept full responsibility for the consequences of their misconduct." The Morells found out about the IVF mistake the day after the Savages. Mrs Morell feared the pregnant woman, whose identity she did not know at the time, would choose to have an abortion. "I didn't think she'd want to carry the baby to term," she said. "I felt helpless." A few days later, the Morells learned that the Savages were willing to continue with the pregnancy and would hand over the baby.

Edited extract, September 25, 2009 http://news.sky.com/skynews

Mother wins $1m for IVF mix-up but may lose son by Chris Ayres

A woman who gave birth to a test-tube baby at the age of 48 has been awarded $1 million (£550,000) in damages after an infertility doctor accidentally gave her an embryo intended for a married couple.

The doctor, fearing that his patient would abort the mixed-up embryo, decided against telling her about the error, even though he knew about it within minutes of the procedure.

… The case has highlighted the lack of any legal or ethical codes to protect those who undergo in-vitro fertilisation.

Edited extract, August 5, 2004 http://www.timesonline.co.uk (edited extract)

(maybe the recent Canberra case would be more relevant given that it is in the Australian Context)

Attachment I

STATEMENT OF NO MATERIAL IMPACT

Administrative Burden Statement

In accordance with the *Victorian Guide to Regulation − Measurement of Changes in Administrative Burden* issued by the Treasurer in April 2007, it has been determined that the regulatory costs imposed by the Assisted Reproductive Treatment Regulations 2009 (the proposed Regulations) will not lead to a material change in the administrative burden on business or not-for-profit organisations in Victoria.

This assessment is based on calculations made using the Victorian Standard Cost Model methodology, which estimates the increase of administrative costs arising from the proposed Regulations on business to be in the order of $8,000 per annum, as shown in the table below. These costs are associated with a new requirement to provide details to the Registrar of Births, Deaths and Marriages of a child born as a result of artificial insemination.

Net impact on the Administrative Burden (Annual nominal costs)

Information obligation	Existing administrative burden	Proposed change to the burden (net impact)
Information obligation 1 – (Regulation 14) Register kept by registered ART provider	Requirement currently in Schedule 1 of the current regulations.	Nil (possibly reduced burden due to simplification of schedule)
Information obligation 2– (Regulation 15) Register kept by doctor carrying out artificial insemination	Requirement currently contained in s. 63 of the Act. Obligation moved to regulations	Nil (moved to regulations)
Information obligation 3 – (Regulation 16) Information be provided to BDM Victoria by ART providers and doctors	Nil (but costs are currently incurred by ITA associated with maintaining registers)	$7,910
Information obligation 4 – (Regulation 19) Information and documents to be provided for ART registration	Currently located in the Act (negligible - less than $100)	Moved to the regulations (negligible - less than $100)
Net Impact		**$7,910**

The additional administrative cost is considerably less than the figure of $250,000 per annum advised by the Department of Treasury and Finance as being the indicative threshold for materiality.