

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

*Financial Framework (Supplementary Powers) Amendment
(Health and Aged Care Measures No. 1) Regulations 2023*

The *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) confers on the Commonwealth, in certain circumstances, powers to make arrangements under which money can be spent; or to make grants of financial assistance; and to form, or otherwise be involved in, companies. The arrangements, grants, programs and companies (or classes of arrangements or grants in relation to which the powers are conferred) are specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the Principal Regulations). The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The Principal Regulations are exempt from sunseting under section 12 of the *Legislation (Exemptions and Other Matters) Regulation 2015* (item 28A). If the Principal Regulations were subject to the sunseting regime under the *Legislation Act 2003*, this would generate uncertainty about the continuing operation of existing contracts and funding agreements between the Commonwealth and third parties (particularly those extending beyond 10 years), as well as the Commonwealth's legislative authority to continue making, varying or administering arrangements, grants and programs.

Additionally, the Principal Regulations authorise a number of activities that form part of intergovernmental schemes. It would not be appropriate for the Commonwealth to unilaterally sunset an instrument that provides authority for Commonwealth funding for activities that are underpinned by an intergovernmental arrangement. To ensure that the Principal Regulations continue to reflect government priorities and remain up to date, the Principal Regulations are subject to periodic review to identify and repeal items that are redundant or no longer required.

Section 32B of the FF(SP) Act authorises the Commonwealth to make, vary and administer arrangements and grants specified in the Principal Regulations. Section 32B also authorises the Commonwealth to make, vary and administer arrangements for the purposes of programs specified in the Principal Regulations. Section 32D of the FF(SP) Act confers powers of delegation on Ministers and the accountable authorities of non-corporate Commonwealth entities, including subsection 32B(1) of the Act. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

Section 65 of the FF(SP) Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 1) Regulations 2023* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the Assisted Reproductive Technology (ART) Storage Funding Program to be administered by the Department of Health and Aged Care.

The ART Storage Funding Program delivers on the Government's election commitment published in the *Plan for a Better Future* to support the future fertility of patients with cancer and at risk of passing on genetic diseases and conditions.

The Government will provide funding of \$600 pro-rata payment per year for up to ten years for cryostorage of eggs, sperm, and embryos ('eligible materials') to registered ART organisations to store materials for two patient populations who wish to preserve their future fertility: patients diagnosed with cancer and people at risk of passing on genetic diseases or conditions, who have undergone Medicare-funded genetic testing.

ART storage organisations accredited by the Reproductive Technology Accreditation Committee and registered with Services Australia to participate in the ART Storage Funding Program will receive payments for providing eligible cryostorage services to eligible patients.

Details of the Regulations are set out at [Attachment A](#). A Statement of Compatibility with Human Rights is at [Attachment B](#).

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after registration on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has been undertaken with the Department of Health and Aged Care.

A regulation impact statement is not required as the Regulations only apply to non-corporate Commonwealth entities and do not adversely affect the private sector.

Details of the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 1) Regulations 2023*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 1) Regulations 2023*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Regulations are made under the *Financial Framework (Supplementary Powers) Act 1997*.

Section 4 – Schedules

This section provides that the *Financial Framework (Supplementary Powers) Regulations 1997* are amended as set out in the Schedule to the Regulations.

Schedule 1 – Amendments

Financial Framework (Supplementary Powers) Regulations 1997

Item 1 – In the appropriate position in Part 4 of Schedule 1AB (table)

This item adds a new table item to Part 4 of Schedule 1AB to establish legislative authority for government spending on an activity administered by the Department of Health and Aged Care (the department).

New **table item 608** establishes legislative authority for government spending on the Assisted Reproductive Technology (ART) Storage Funding Program to support costs for cryostorage of eggs, sperm, and embryos (eligible materials) that is not currently subsidised through the Medicare Benefits Schedule (MBS).

The ART Storage Funding Program delivers on the Government's election commitment published in the *Plan for a Better Future* to support the future fertility of patients with cancer or who are at risk of passing on genetic diseases and conditions.

The ART Storage Funding Program will commence from 1 July 2023 and will provide funding of \$600 pro-rata payment per year for up to ten years to registered ART organisations to store eligible materials for the following two patient populations who wish to preserve their future fertility:

- patients diagnosed with cancer; and

- people at risk of passing on genetic diseases or conditions, who have undergone Medicare-funded preimplantation genetic testing.

As costs associated with the ongoing cryostorage of eligible materials are not currently subsidised through the MBS, the ART Storage Funding Program will support vulnerable patients during a difficult period following their cancer or genetic testing diagnosis.

The payment system for the ART Storage Funding Program will be hosted by Services Australia and payments will be made directly to eligible ART organisations who are licensed by the Reproductive Technology Accreditation Committee (RTAC) and who registered with Services Australia to participate in the ART Storage Funding Program. ART organisations will receive payments for providing eligible cryostorage services to eligible patients who:

- utilise storage from 1 July 2023; and
- provide evidence of cancer treatment affecting their fertility, such as a referral, or for preimplantation genetic testing, evidence that the MBS items have been claimed (or tests covered by items have been received by the patient).

Services Australia will provide block funding payment against detailed service claim information provided by eligible ART organisations for a 6-monthly claim period in arrears. ART organisations are required to keep records of evidence of patient eligibility and provide this to the department or its representatives as requested in program assurance activities.

Up to two storage services per patient, one storage service for each type of eligible materials, will be eligible for a subsidy. In the event of a participating patient's death, subsidies for their stored materials can continue for up to two years if there are legal arrangements in place for transfer of materials to a surviving reproductive partner. Following transfer, the surviving partner becomes eligible for the subsidy and payments can continue.

Services Australia will administer the payments on behalf of the department as a demand-driven grant, in accordance with the *Commonwealth Grants Rules and Guidelines 2017* and the *Public Governance, Performance and Accountability Act 2013*. Payments will be made on a reimbursement basis, to all eligible providers who register for the program and submit claims for eligible services as set out in the grant opportunity guidelines. Grant opportunity guidelines for the Special Supplement will be developed and made available on the GrantConnect website (www.grants.gov.au). Decisions on payment of claims will be made by Services Australia in alignment with the policy outlined in the program guidelines, and, where contested, in alignment with policy advice from the department.

Services Australia will leverage existing IT system and personnel capabilities to establish and manage a payment system inclusive of eligible provider registration, service claiming and provider payment. Eligible ART organisations will submit a claim to Services Australia detailing their eligible storage services provided for two 6-monthly payment periods each year: 1 July-31 December and 1 January-30 June. Each service for which the ART organisation is seeking payment will be identified as a line of information that Services Australia will check meets agreed requirements.

Services Australia will be responsible for conducting pre-payment checks on submitted claim information to determine that submitted claims are valid, administering payments, communicating with ART organisations around claims found to be incorrect and providing guidance to ART organisations on payment questions. Both Services Australia and the department will develop and deliver communications assets including webinars for ART

organisation administration staff and fact sheets/web content for consumer-based organisations to use to promote the ART Storage Funding Program to their members. The department is responsible for designing and publishing program guidelines and supporting materials which will be communicated to ART organisations, consumer groups and internal stakeholders including Services Australia. The department will also provide robust ongoing policy advice and support to ART organisations and Services Australia. Program information designed to inform ART organisations and the public will be published by Services Australia on the Services Australia website and the department's website.

The department will additionally design, establish, and administer a program assurance strategy which will regularly audit ART organisations' submitted claims against supporting documentation to minimise risk of inappropriate claiming. Final decisions on the Commonwealth expenditure are the responsibility of the Minister for Health and Aged Care with decisions on payment eligibility being made by Services Australia in accordance with the approved program guidelines.

Independent merits review is not considered suitable for decisions made in connection with the ART Storage Funding Program payments as such decisions are automatic or mandatory in nature. The decision to make a payment will be very limited and procedural based on the ART organisations eligibility. Post-payment program assurance will review claims to ensure they were made and paid appropriately. The Administrative Review Council has recognised that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraph 3.8 of the guide, *What decisions should be subject to merit review?*).

The department identified key internal and external stakeholders early in the policy design stage of the ART Storage Funding Program and have consulted on policy parameters and program detail on an ongoing basis. Consultation with the In Vitro Fertilisation (IVF) sector supported the initial election commitment subsidy level of \$600 per eligible storage service, per year.

Consultation with other government agencies and internal department divisions was undertaken during the design phase of this program, including with Services Australia, Benefits Integrity and Digital Health Division, Grants Branch, Legal and Assurance Division and Budget Branch. Consultation with these stakeholders will be ongoing for the full program cycle to ensure all financial, legislative and assurance aspects of the program have been fully considered. This will include detailed consultation with Services Australia on the design of the payment system for the ART Storage Funding Program, and detailed communications design.

Key sector and clinical stakeholders were identified as representatives from the IVF Medical Directors Group, the Clinical Oncology Society of Australia and the Royal Australia and New Zealand College of Obstetricians and Gynaecologists. Consultation meetings were held with these representatives in July, September and November 2022. These stakeholder meetings assisted in:

- clarifying eligibility requirements;
- understanding technical tasks involved with provision of a storage service; and
- providing clinic data to assist with estimating volumes of eligible patients.

Consumer stakeholders from approximately twenty organisations were invited to attend a consultation meeting in December 2022, and given the opportunity to provide written

feedback on the proposed policy which was used to inform the policy design of the program recommended to government for decision. Consumer groups will additionally be consulted on information needs including effectiveness of communication products and channels to ensure written materials are consumer friendly.

Funding of \$14.8 million for the ART Storage Funding Program was included in the 2022-23 March Budget under the measure ‘Women’s Health Package’ for a period of four years commencing in 2022-23. The Government adjusted the funding to \$12.4 million in the October 2022-23 Budget under the measure ‘Support for New and Expecting Parents’ for a period of four years commencing in 2023-24. Details are set out in *Budget October 2022-23, Budget Measures, Budget Paper No. 2* at page 143.

Final funding of \$600 pro-rata payment per year ongoing for this item will be included in the 2023-24 Budget and the Portfolio Budget Statements for the Health and Aged Care Portfolio. Funding will come from Program 2.1: Medical Benefits, which is part of Outcome 2.

Noting that it is not a comprehensive statement of relevant constitutional considerations, the objective of the item references the social welfare power (section 51(xxiiiA)) of the Constitution.

Social welfare power

The social welfare power in section 51(xxiiiA) of the Constitution empowers the Parliament to make laws with respect to the provision of certain social welfare services including ‘medical services’.

Funding will be provided to organisations for the storage of material for later use in ART procedures or treatment, for persons with cancer or at risk of passing on genetic diseases or conditions. The storage services will be carried out by trained medical or allied health professionals to address the person’s identified medical need, and form part of the bundle of services required by the person.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 1) Regulations 2023

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

Section 32B of the *Financial Framework (Supplementary Powers) Act 1997* (the FF(SP) Act) authorises the Commonwealth to make, vary and administer arrangements and grants specified in the *Financial Framework (Supplementary Powers) Regulations 1997* (the FF(SP) Regulations) and to make, vary and administer arrangements and grants for the purposes of programs specified in the Regulations. Schedule 1AA and Schedule 1AB to the FF(SP) Regulations specify the arrangements, grants and programs. The powers in the FF(SP) Act to make, vary or administer arrangements or grants may be exercised on behalf of the Commonwealth by Ministers and the accountable authorities of non-corporate Commonwealth entities, as defined under section 12 of the *Public Governance, Performance and Accountability Act 2013*.

The *Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 1) Regulations 2023* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the Assisted Reproductive Technology (ART) Storage Funding Program to be administered by the Department of Health and Aged Care.

The ART Storage Funding Program delivers on an election commitment to provide funding to support costs of storage for eggs, sperm or embryos (eligible materials). As costs associated with the ongoing cryostorage of eligible materials are not currently subsidised through the Medicare Benefits Schedule, the ART Storage Funding Program will reduce eligible patients' out-of-pocket expenses for ART storage services.

The ART Storage Funding Program will commence from 1 July 2023 and will provide funding of \$600 pro-rata payment per year for up to ten years to ART storage organisations accredited by the Reproductive Technology Accreditation Committee for the costs of storing for future use eligible materials for:

- patients diagnosed with cancer; and
- people at risk of passing on genetic diseases or conditions, who have undergone Medicare-funded preimplantation genetic testing.

Human rights implications

This disallowable legislative instrument engages the following human right:

- the right to the creation of conditions which would assure to all medical service and medical attention in the event of sickness – Article 12 of the *International Covenant on Economic Social and Cultural Rights* (ICESCR), read with Article 2.

Right to the creation of conditions which would assure to all medical service and medical attention in the event of sickness

Article 2 of the ICESCR requires that each State Party to the Covenant undertakes to take steps to the maximum of its available resources, especially economic and technical, to realise the rights recognised in the Covenant.

Article 12 of the ICESCR recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and provides that States Parties will take appropriate steps to achieve the realisation of the right to health, including through providing health services in the event of sickness.

The ART Storage Funding Program positively impacts these rights, as it provides additional support in the form of subsidised fertility storage services for specific population groups who face additional costs associated with their fertility treatment.

The ART Storage Funding Program will remove barriers to fertility preservation for these population groups who are under additional strain due to cancer diagnosis and treatments or due to their discovering they are at high risk of passing on genetic diseases or conditions, by creating a payment to cover the cost of storage of their reproductive materials.

Conclusion

This disallowable legislative instrument is compatible with human rights because it promotes the protection of human rights.

**Senator the Hon Katy Gallagher
Minister for Finance**