

REPLACEMENT EXPLANATORY STATEMENT

This Explanatory Statement replaces the Explanatory Statement registered on 14 October 2021 for the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021* [F2021L01430] to reflect the reduced claim threshold of \$1,000 and include information on the privacy protections under the COVID-19 Vaccine Claims Scheme.

Issued by the Authority of the Minister for Finance

Financial Framework (Supplementary Powers) Act 1997

*Financial Framework (Supplementary Powers) Amendment
(Health Measures No. 6) Regulations 2021*

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*.

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.

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. Schedule 1AA and Schedule 1AB to the Principal Regulations specify the arrangements, grants and programs.

The *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021* (the Regulations) amend Schedule 1AB to the Principal Regulations to establish legislative authority for government spending on the COVID-19 Vaccine Claims Scheme (the Scheme), which will provide compensation for individuals who suffer moderate to significant injury as a result of being vaccinated against the coronavirus known as COVID-19. The Department of Health has policy responsibility for the Scheme, which will be administered by Services Australia.

The Scheme is part of the Government's response to the COVID-19 human biosecurity emergency as declared under the *Biosecurity Act 2015*. The objective of the Scheme is to provide streamlined access to compensation for claimants who suffer moderate to significant injuries or death, as a result of receiving a COVID-19 vaccine approved by the Therapeutic Goods Administration (TGA) and administered through a Commonwealth approved program. Claims will be assessed according to Scheme criteria and, for more significant or complex claims (including for death associated with the COVID-19 vaccines), by an independent

expert panel which will provide recommendations about whether compensation should be paid and, if so, the amount. The Scheme will be available to all persons vaccinated in Australia (or Australians vaccinated overseas under the Australian Government Overseas Network rollout).

The Scheme will support greater community confidence in the COVID-19 vaccines by providing a simple, administrative option to seek compensation, without complex and costly litigation. It will also encourage participation by health professionals in the vaccine rollout and support businesses to implement a workplace vaccination program.

The Department of Health will maintain a list of clinical conditions for which a causal link to vaccination with a COVID-19 vaccine has been established. It will also include conditions that may be related to vaccination for which causality has not been established, but that may be caused by the vaccine. In all cases, claimants will be required to provide evidence from a treating doctor that the clinical condition is likely to be caused by the vaccination.

The Scheme will be fully funded by the Commonwealth on a no-fault basis, with compensation for claimants who can substantiate a loss of over \$1,000 caused by the vaccine or its administration. In the event that Services Australia or the assessment panel determines that there is evidence of potential negligence by a health practitioner associated with the administration of the vaccine, they may recommend that the decision maker refer information to the Australian Health Practitioner Regulation Agency for review of their conduct. These steps are in keeping with the Commonwealth's intention that healthcare practitioners are incentivised to practice safely, with skill and diligence and promote confidence in the population being vaccinated.

The Scheme will be limited to the period of the COVID-19 human biosecurity emergency (backdated to February 2021) as declared under the *Biosecurity Act 2015*, plus a further 24 months from the end of the declared COVID-19 human biosecurity emergency to enable all claims to be submitted and processed.

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 the instrument is registered on the Federal Register of Legislation.

Consultation

In accordance with section 17 of the *Legislation Act 2003*, consultation has taken place with the Department of Health and Services Australia.

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 Measures No. 6) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 6) Regulations 2021*.

Section 2 – Commencement

This section provides that the Regulations commence on the day after the instrument is registered 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 (the department).

New **table item 506** establishes legislative authority for government spending on the COVID-19 Vaccine Claims Scheme (the Scheme), which will provide compensation for individuals who suffer moderate to significant injury as a result of being vaccinated against the coronavirus known as COVID-19.

On 28 August 2021, the Minister for Health and Aged Care, the Hon Greg Hunt MP, announced that the Government had finalised the details of the no-fault scheme following extensive consultation with the peak medical, healthcare, business and insurance sectors to ensure a comprehensive national scheme. The media release is available at www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/no-fault-covid-19-indemnity-scheme.

The Scheme is part of the Government's response to the COVID-19 human biosecurity emergency as declared under the *Biosecurity Act 2015*. The objective of the Scheme is to provide streamlined access to compensation for claimants who suffer moderate to significant injuries, as a result of receiving a COVID-19 vaccine approved by the Therapeutic Goods Administration (TGA) and delivered through a Commonwealth approved program. The

Scheme will be available to all persons vaccinated in Australia (or Australians vaccinated overseas under the Australian Government Overseas Network rollout).

The Scheme will provide a safety net for those individuals who can substantiate harm from a TGA approved COVID-19 vaccine. Originally, the Scheme was only intended to cover moderate to significant injuries or death, with a minimum claim threshold of \$5,000. The original explanatory statement referred to this amount. On 24 November 2021, the Government agreed to reduce the threshold for adverse harm resulting from a COVID-19 vaccine approved by the Therapeutic Goods Administration from \$5,000 to \$1,000. The objective was to provide greater levels of comfort to those yet to become vaccinated, and the practitioners supporting patients seeking vaccination.

It was considered that the need to provide an additional safety net for the anticipated number of Australians impacted by certain adverse events associated with the vaccines outweighed the potential small increase in claims costs, administration costs and the additional reporting from health practitioners.

The Scheme will not cover common, less significant, side effects such as fatigue or injection site pain, and these would be more appropriately managed through existing health programs. Claimants will be required to provide, for assessment, evidence from a treating doctor that the clinical condition is likely to be caused by the vaccination and, in the majority of cases, evidence of hospitalisation as a result of the vaccination. The department will maintain a list of clinical conditions for which a causal link to vaccination with a COVID-19 vaccine has been established. It will also include conditions that may be related to vaccination for which causality has not been established, but that may be caused by the vaccine.

The Scheme does not apply to any vaccine for other diseases which is a designated vaccine under section 9B of the *National Health Act 1953* (that is, part of the National Immunisation Program).

The Scheme has been established in response to the unique nature of the COVID-19 pandemic and to support public confidence in seeking vaccination for the benefit of themselves, their families and Australia's staged return out of COVID-19. The Scheme will support greater community confidence in the COVID-19 vaccines by providing a simple, administrative option to seek compensation, without complex and costly litigation. It will also encourage participation by health practitioners in the vaccine rollout and support businesses to implement a workplace vaccination program.

The Scheme will be administered by Services Australia in accordance with the Scheme Policy available on the department's website.

Claims greater than \$20,000 may be referred to a member of a panel of independent experts with legal backgrounds for consideration, with the panel member to make recommendations about the level of compensation that should be paid based on a review of the individual claim and the likely causation of the injury. The panel member will be able to draw on information from the TGA in the consideration of compensation for harm. The compensation is intended to be similar to what would have been provided through a common law court process. Where appropriate, Services Australia also may refer claims between \$1,000 and \$20,000 to the panel, if it is considered additional scrutiny is required.

Eligibility criteria for the Scheme and the process for making claims is available on the Services Australia website. The Scheme commenced accepting claims on 13 December 2021. Decisions about Commonwealth expenditure in connection with the compensation payments will be made by a Services Australia delegate of the Secretary of the department. Compensation payments will be made directly to eligible individuals by Services Australia.

The Scheme will be fully funded by the Commonwealth on a no-fault basis, with compensation for claimants who can substantiate a loss over \$1,000 or more caused by the vaccine or its administration. In the event that Services Australia or the assessment panel determines that there is evidence of potential negligence by a health practitioner associated with the administration of the vaccine, they may recommend that the decision maker refer information to the Australian Health Practitioner Regulation Agency for review of their conduct. These steps are in keeping with the Commonwealth's intention that healthcare practitioners are incentivised to practice safely, with skill and diligence and promote confidence in the population being vaccinated.

The Scheme provides privacy protections to claimants who provide personal information, including medical information, to enable verification and assessment of their claim by Services Australia. Personal information may only be collected, used and disclosed under the Scheme with the consent of the claimant.

If professional misconduct is suspected of health practitioners associated with the administration of COVID-19 vaccines, personal information relating to those practitioners may be disclosed to the Australian Health Practitioner Regulation Authority with the consent of the claimant. Such disclosure is also permitted under Australian Privacy Principles (APP) 3.4(b), 6.2(c), 8.2(d) and 9.2(d).

As APP entities, Services Australia and the department are bound by the provisions of the *Privacy Act 1988*. Consistent with their obligations under the *Privacy Act 1988*, Services Australia and the department jointly commissioned a privacy impact assessment to be undertaken in relation to the Scheme prior to its commencement. The purpose of the assessment was to ensure that privacy risks were appropriately identified, and addressed, throughout the development of the Scheme; and the Scheme's implementation would not give rise to unwanted policy outcomes unduly affecting an individual's right to privacy.

The Scheme will be limited to the period of the COVID-19 human biosecurity emergency (backdated to February 2021) as declared under the *Biosecurity Act 2015*, plus a further 24 months from the end of the declared COVID-19 human biosecurity emergency to enable all claims to be submitted and processed.

Payments made under the Scheme may be considered as 'other' financial arrangements as set out in the *Resource Management Guide (RMG) 411: Grants, Procurements and other financial arrangements*. More specifically, they may be considered discretionary compensation where the Australian Government is under no legal obligation to make a payment (paragraph 29 of the RMG 411 refers). Funding decisions will be made in accordance with requirements of the Commonwealth resource management framework, including the *Public Governance, Performance and Accountability Act 2013*.

For a person whose claim is not approved for compensation, or who is dissatisfied with the level of compensation offered, there will be an internal review mechanism available. For claims assessed by Services Australia, the internal review will be undertaken by a higher-level delegate in Services Australia.

Noting the review process available as detailed above, funding decisions made in connection with the Scheme are not considered suitable for independent merits review, as these are financial decisions with a significant public interest element. The Scheme responds to a need to take rapid action in order to uphold public confidence in the health system and vaccination program in the context of the global pandemic. The availability of compensation for individuals who suffer injuries because of a COVID-19 vaccine or its administration, is expected to promote confidence in the health system among both the general public and health professionals and promote vaccine uptake. The Administrative Review Council has acknowledged that it is justifiable to exclude merits review in relation to decisions of this nature (see paragraph 4.34 of the guide, *What decisions should be subject to merit review?*).

Additionally, decisions on the availability of compensation would typically involve the evaluation of complex competing facts and policies. They would rely on in-depth departmental advice and recommendations from relevant medical and legal experts and bodies. They also necessarily involve a high level of political accountability including as evidenced through the publication of expenditure on the Scheme in the department's annual report (see paragraphs 4.35 and 4.37 of the guide, *What decisions should be subject to merit review?*).

While it is acknowledged that reliance on this justification for the exclusion of merits review is rare (see paragraph 4.36 of the guide), the context of a global pandemic is an extremely rare situation.

The department has consulted with peak medical bodies, insurers, health consumer organisations and the states and territories in the development of the Scheme. Services Australia has also been consulted on the implementation and delivery of the Scheme.

Compensation under the Scheme will be administered as demand driven payments. Forecast expenditure for 2021-22 will not be separately reported in the Mid-Year Economic and Fiscal Outlook Report due to the high degree of uncertainty associated with expenditure under the Scheme. Funding for the item will come from Program 1.7: Primary Care Practice Incentives and Medical Indemnity, which is part of Outcome 1: Health Policy, Access and Support.

Actual expenditure under the Scheme will be reported in the department's annual report.

Noting that it is not a comprehensive statement of relevant constitutional considerations, the objective of the item references the following powers of the Constitution:

- the express incidental power and the executive power (sections 51(xxxix) and 61), including the nationhood aspect, and
- the social welfare power (section 51(xxiiiA)).

Executive power and express incidental power, including the nationhood aspect

The express incidental power in section 51(xxxix) of the Constitution empowers the Parliament to make laws with respect to matters incidental to the execution of any power vested in the Parliament, the executive or the courts by the Constitution. Section 61 of the Constitution supports activities that are peculiarly adapted to the government of a nation and cannot be carried out for the benefit of the nation otherwise than by the Commonwealth.

The Scheme operates in the context of the COVID-19 vaccine rollout and the need to encourage the community to be vaccinated in the context of the pandemic and the immediate and widespread health, economic and social consequences associated with COVID-19.

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, or incidental to the provision of, pharmaceutical benefits, sickness benefits and medical services.

The COVID-19 vaccine is funded by the Commonwealth and the Scheme would meet the costs of any adverse reactions to that vaccine.

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 Measures No. 6) Regulations 2021

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 Measures No. 6) Regulations 2021* (the Regulations) amend Schedule 1AB to the FF(SP) Regulations to establish legislative authority for government spending on the COVID-19 Vaccine Claims Scheme (the Scheme), which will provide compensation for individuals who suffer loss or injury as a result of being vaccinated against the coronavirus known as COVID-19. The Department of Health (the department) has policy responsibility for the Scheme, which will be administered by Services Australia.

The Scheme is part of the Government's response to the COVID-19 human biosecurity emergency as declared under the *Biosecurity Act 2015*. The objective of the Scheme is to provide streamlined access to compensation for claimants who suffer moderate to significant injuries or death, as a result of receiving a COVID-19 vaccine approved by the Therapeutic Goods Administration (TGA) and administered through a Commonwealth approved program. Claims will be assessed according to Scheme criteria and, for more significant or complex claims, by an independent member of an expert panel, who will provide recommendations about whether compensation should be paid and, if so, the amount. The Scheme will be available to all persons vaccinated in Australia (or Australians vaccinated overseas under the Australian Government Overseas Network rollout).

The Scheme will support greater community confidence in the COVID-19 vaccines by providing a simple, administrative option to seek compensation, without complex and costly litigation. It will also encourage participation by health professionals in the vaccine rollout and support businesses to implement a workplace vaccination program.

Human rights implications

This disallowable legislative instrument engages the following rights:

- the right to health – Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), read with Article 2; and
- the right to protection against arbitrary and unlawful interferences with privacy – Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR).

Right to health

Article 2(1) of the ICESCR requires each State Party to ‘take steps... to the maximum of its available resources, with a view to achieving progressively the full realization’ of the rights recognised in the ICESCR ‘by all appropriate means, including particularly the adoption of legislative measures’.

Article 12(2)(c) requires the States Parties to the ICESCR to take steps to realise the right to health including those necessary for ‘[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases.’

This measure will provide a level of assurance to the Australian public that compensation will be available for the small number of persons who have suffered a moderate to significant injury resulting from the administration or side effects of a COVID-19 vaccine.

This will promote the right to health as it is expected that the effect of this measure will contribute to a greater number of people in Australia deciding to receive a vaccination against COVID-19, which will support the right of individuals to the enjoyment of the highest standard of health and further contribute to overall community health through the prevention, treatment and control of the COVID-19 pandemic.

Right to protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person’s privacy, family, home and correspondence. It also prohibits unlawful attacks on a person’s reputation. Limitations on the right to privacy must be according to law and not arbitrary. Limitations must be reasonable and necessary in the particular circumstances, as well as proportionate to the objectives that the limitations seek to achieve.

The Scheme provides privacy protections to claimants who provide personal information, including medical information, to enable verification and assessment of their claim by Services Australia. Personal information may only be collected, used and disclosed under the Scheme with the consent of the claimant.

If professional misconduct is suspected of health practitioners associated with the administration of COVID-19 vaccines, personal information relating to those practitioners may be disclosed to the Australian Health Practitioner Regulation Authority with the consent of the claimant. Such disclosure is also permitted under Australian Privacy Principles (APPs) 3.4(b), 6.2(c), 8.2(d) and 9.2(d).

Services Australia and the department are both bound by the provisions of the *Privacy Act 1988*. Consistent with their obligations under the *Privacy Act 1988*, Services Australia and the Department of Health jointly commissioned a privacy impact assessment to be undertaken in relation to the Scheme prior to its commencement. The purpose of the assessment was to ensure that privacy risks were appropriately identified, and addressed, throughout the development of the Scheme; and the Scheme's implementation would not give rise to unwanted policy outcomes unduly affecting an individual's right to privacy.

Both Services Australia and the department have introduced measures to ensure personal information is collected, used and disclosed in accordance with the relevant APPs. Services Australia incorporates a privacy notice into the claims application form (or online portal). The information submitted with claims by individuals is collected, used and disclosed pursuant to the notice and Services Australia's general privacy policy.

Conclusion

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

**Senator the Hon Simon Birmingham
Minister for Finance**