EXPLANATORY STATEMENT

*Health Insurance Act 1973*

*Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021*

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the general medical services table (the GMST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the GMST.

The GMST is set out in the regulations made under subsection 4(1) of the Act. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020*.

**Purpose**

The Australian Government is committed to offering every person in Australia access to safe and effective COVID-19 vaccines at no cost.

The first part of the Government’s COVID-19 vaccination program (known as phase 1A) has commenced with the Pfizer vaccine being delivered to hospital ‘hubs’ and residential aged care and disability care facilities. These sites will commence vaccination of groups including quarantine and border workers, frontline healthcare workers, and aged care and disability care residents and staff that are the most vulnerable.

The second part of the Government’s vaccination program (known as phase 1B) will commence in March 2021. Under this phase, the Government will work with General Practitioner-led Respiratory Clinics, Aboriginal Community Controlled Health Services and accredited general practices to vaccinate certain cohorts of persons aged 18 years of age and older.

On 24 January 2021, the Australian Government announced it was seeking expressions of interest from accredited general practices to take part in phase 1B of the vaccination program.

Successful applicants will be supplied the AstraZeneca COVID-19 vaccine to commence vaccinating priority population groups, including persons 70 years of age or older, other health care workers, Aboriginal and Torres Strait Islanders 55 years or older, persons with an underlying medical condition, and critical and high risk workers. General practice will also be involved in latter phases of the vaccination program which aims to vaccinate all Medicare-eligible persons aged 18 years of age and older.

The purpose of the *Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021* (the Determination) is to list 16 new Medicare Benefits Schedule (MBS) items to support general practices to administer the COVID-19 vaccine.

General practices supplied with the vaccine will be able to provide a service to assess if a person who is at least 18 years of age is suitable to receive the COVID-19 vaccine if:

* the service is provided at a location where the vaccine is immediately available for administration to the patient; and
* the service is provided to the patient at no cost (known as ‘bulk-billing’).

The service can be performed by general practitioners (GPs) and other medical practitioners (OMPs), or by a person on behalf of the medical practitioners (such as a registered nurse or other health professional registered under the Health Practitioner Regulation National Law) if it is provided in accordance with acceptable clinical practice and under supervision of the medical practitioner. Medical practitioners do not have to personally attend the service but they must be on-site, must supervise the service in accordance with clinical standards, and accept full responsibility for the service.  
  
The majority of patients are expected to receive the service twice; on the occasion they receive the first and second dose of the COVID-19 vaccine. Medical practitioners can claim an assessment service where the vaccine is not administered if:

* the patient is assessed as unsuitable for the vaccine; or
* the patient is assessed as suitable for the vaccine, but the patient chooses not to receive the vaccine at the time of the attendance.

**Consultation**

Consultation was undertaken with the Australian Medical Association, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine, Rural Doctors Association of Australia and the Australian Primary Health Care Nurses Association on the role of primary care within the COVID-19 vaccine program and the requirements of the MBS assessment service.

Details of the Determination are set out in the Attachment.

The Determination commences the day after this instrument is registered.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Authority: Subsection 3C(1) of the

*Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021*

Section 1 – Name

Section 1 provides the name of the Determination is the *Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Determination commences the day after this instrument is registered.

Section 3 – Authority

Section 3 provides that the Determination is made under subsection 3C(1) of the *Health Insurance Act 1973* (the Act).

Section 4 – Definitions

Subsection 4(1) defines terms used in the Determination.

Subsection 4(2) provides that, unless a contrary intention appears, a reference to provisions of specified laws is a reference to those provisions as in force from time to time. The specified laws are the:

1. the Act;
2. regulations made under the Act;
3. *National Health Act 1953*;
4. regulations made under the *National Health Act 1953.*

Section 5 – Treatment of relevant services

Subsection 5(1) of the Determination provides that a service in the Schedule, provided in accordance with the Determination and as a clinically relevant service, is to be treated for the provisions specified in subsection (2) as if it were both a professional service and a medical service prescribed as an item in the general medical services table. The specified provisions in subsection (2), subject to the contrary intention in subsection (3), are each provision of the Act, the *National Health Act 1953*, and regulations made under those Acts that relate to medical services and professional services.

Subsection 5(3) of the Determination excludes subsection 19(4) of the Act from having application to the items in the Schedule. Subsection 19(4) of the Act provides that a Medicare benefit is not payable for a professional service if it is rendered in the course of carrying out a ‘mass immunization’. The services in the Determination have been excluded from being treated as professional services for this provision to provide general practice certainty that a Medicare benefit can be paid for an attendance to assess a patient’s suitability for the administration of a COVID-19 vaccine.

Section 6 – Application of general provisions of the general medical services table

Section 6 of the Determination provides that an item in the Schedule will be treated as if it were specified in clause 1.2.8 of the general medical services table (GMST). Clause 1.2.8 of the GMST provides that the items specified do not apply to a service described in the item if the service is provided at the same time as, or in connection with, certain ‘non‑Medicare services’.   
  
Section 7 – Services may be rendered on behalf of a medical practitioner

Section 7 of the Determination provides that an item in the Schedule can be rendered by:

* a medical practitioner; or
* a ‘relevant health professional’ on behalf of a medical practitioner.

A relevant health professional is defined in section 4 of the Determination and means a person who is registered in a health profession regulated under the Health Practitioner Regulation National Law (other than the medical profession). This would include a person registered by the Nursing and Midwifery Board of Australia.

Services rendered on behalf of a medical practitioner must be provided in accordance with subsection 3(17) of the Act. That is, the service must be rendered in accordance with accepted clinical practice and under the supervision of the medical practitioner who remains responsible for the service. It is not expected that a supervising medical practitioner will personally attend all assessments provided by a relevant health professional on their behalf. However it is expected that the supervising medical practitioner will remain physically present at the location and available to attend assessments if required.

Section 8 – Restrictions on items

Subsection 8(1) of the Determination provides that an item in the Schedule only applies if a COVID-19 vaccine is immediately available for administration to the patient at the location the assessment is performed. This includes assessments performed at a practice location and assessments performed in other locations.

This is intended to allow a patient who has been assessed as suitable and consents to receive a COVID-19 vaccine to be vaccinated immediately following the Medicare Benefits Schedule service.

Subsection 8(2) of the Determination provides that an item in the Schedule cannot be associated with a service to which items 10988, 10990, 10991 or 10992 of the GMST apply. The bulk-billing incentive items (10990, 10991 and 10992) are excluded as the fee for the assessment items includes an amount to renumerate medical practitioners for bulk-billing. The Aboriginal and Torres Strait Islander health practitioner vaccination item (10988) has been excluded as it is not intended this item should be claimed in association with the COVID-19 vaccine assessment items.

Subsection 8(3) of the Determination provides that an item in the Schedule cannot be claimed if the service is rendered as part of an episode of ‘hospital treatment’ or ‘hospital-substitute treatment’, as defined by section 3 of the Act.

Schedule – Relevant services

The Schedule lists 16 items for the purpose of assessing patient suitability to receive a COVID-19 vaccine. The services are available to a person ‘eligible for a COVID-19 vaccine’ if the service is ‘bulk-billed’ and any clinically relevant patient history and limited examination and management have been undertaken.

***eligible for a COVID-19 vaccine***

Eligible for a COVID-19 vaccine, as defined in section 4, means a person who is at least 18 years of age. This aligns with the Therapeutic Goods Administration (TGA) provisional approval of the AstraZeneca COVID-19 vaccine, which will be supplied to practices as a part of phase 1B of the Government’s vaccination program.

The other TGA approved COVID-19 vaccine, the Pfizer COMIRNATY vaccine, will not be supplied to general practices as a part of phase 1B. The Pfizer vaccine is being used in phase 1A and will be administered at certain hospitals and other sites due to its unique cold storage requirements. The Pfizer vaccine, and services associated with the administration of the vaccine, are being funded by Commonwealth and State and Territory Governments under other arrangements.

It is intended that the use of the terminology ‘a COVID-19 vaccine’ will enable the Australian Government program flexibility in determining the types of COVID-19 vaccine to be administered through general practices. This is contingent on any new vaccine receiving provisional approval from the TGA, the approval being for the persons aged 18 years and older, and the Commonwealth supplying that vaccine to general practice.

***Bulk-billed***

A medical service is bulk-billed, as defined in section 4 of the Determination, if a person eligible for a Medicare benefit enters into an agreement under section 20A of the Act to assign their benefit to the medical practitioner who, or on whose behalf, the service is rendered and the medical practitioner accepts that assignment as full payment for the service. This means that patients will receive the assessment service at no cost.

* First dose in standard hours

Subgroup 1 lists four new items for the purpose of a COVID-19 vaccine assessment service (93624, 93625, 93626 and 93627). These items are expected to be used for services provided in standard hours, with separate items for use in the after-hours period. Items 93624 and 93625 are for services performed by, or on behalf of, general practitioners. Item 93624 is for services performed in metropolitan areas (Modified Monash 1) and 93625 is for services performed in regional and remote areas (Modified Monash 2 to 7).

Items 93626 and 93627 are for the provision of services by, or on behalf of, a medical practitioner who is not a general practitioner. Item 93626 is for services rendered in metropolitan areas (Modified Monash 1) and 93627 is for services rendered in regional and remote areas (Modified Monash 2 to 7).

The fee for these attendances are relatively higher than the equivalent attendance for the second (or subsequent) dose in subgroup 3. The higher fee recognises that medical practitioners, or a person on their behalf, are likely to need to spend additional time assessing a patient’s suitability for the first dose of a COVID-19 vaccine and answering questions the patient may have.

* First dose in after hours

Subgroup 2 lists four new items for the purpose of the COVID-19 vaccine assessment service in after-hours (93634, 93635, 93636 and 93637). These items must be performed in the after-hours period, as defined in subsection 4(1). Items 93634 and 93635 are for services performed by, or on behalf of, a general practitioner. Item 93634 is for services performed in metropolitan areas (Modified Monash 1) and 93635 is for services performed in regional and remote areas (Modified Monash 2 to 7).

Items 93636 and 93637 are for the provision of services by, or on behalf of, a medical practitioner who is not a general practitioner. Item 93636 is for services rendered in metropolitan areas (Modified Monash 1) and item 93637 is for services rendered in regional and remote areas (Modified Monash 2 to 7).

The fee for these attendances are relatively higher than the equivalent attendance for the second (or subsequent) dose in subgroup 4. The higher fee recognises that medical practitioners, or a person on their behalf, are likely to need to spend additional time assessing a patient’s suitability for the first dose of a COVID-19 vaccine and answering questions the patient may have.

* Second (and subsequent) dose in standard hours

Subgroup 3 lists four new items for the purpose of the COVID-19 vaccine assessment service (93644, 93645, 93646 and 93647). These items are expected to be used for services not provided in an after-hours period, with separate items for use in the after-hours period. Items 93644 and 93645 are for services performed by, or on behalf of, a general practitioner. Item 93644 is for services performed in metropolitan areas (Modified Monash 1) and 93645 is for services performed in regional and remote areas (Modified Monash 2 to 7).

Items 93646 and 93647 are for the provision of services by, or on behalf of, a medical practitioner who is not a general practitioner. Item 93646 is for services performed in metropolitan areas (Modified Monash 1) and 93647 is for services performed in regional and remote areas (Modified Monash 2 to 7).

* Second (and subsequent) dose in after hours

Subgroup 4 lists four new items for the purpose of the COVID-19 vaccine assessment service in after-hours (93653, 93654, 93655 and 93656). These items must be performed in the after-hours period, as defined in subsection 4(1). Items 93653 and 93654 are for services performed by, or on behalf of, a general practitioner. Item 93653 is for services performed in metropolitan areas (Modified Monash 1) and 93654 is for services performed in regional and remote areas (Modified Monash 2 to 7).

Items 93655 and 93656 are for the provision of services by, or on behalf of, a medical practitioner who is not a general practitioner. Item 93655 is for services performed in metropolitan areas (Modified Monash 1) and item 93656 is for services performed in regional and remote areas (Modified Monash 2 to 7).

**Statement of Compatibility with Human Rights**

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

*Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021*

This 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 Determination**

The Australian Government is committed to offering every person in Australia access to safe and effective COVID-19 vaccines at no cost.

The first part of the Government’s COVID-19 vaccination program (known as phase 1A) has commenced with the Pfizer vaccine being delivered to hospital ‘hubs’ and residential aged care and disability care facilities. These sites will commence vaccination of groups including quarantine and border workers, frontline healthcare workers, and aged care and disability care residents and staff that are the most vulnerable.

The second part of the Government’s vaccination program (known as phase 1B) will commence in March 2021. Under this phase, the Government will work with General Practitioner-led Respiratory Clinics, Aboriginal Community Controlled Health Services and accredited general practices to vaccinate certain cohorts of persons aged 18 years of age and older.

On 24 January 2021, the Australian Government announced it was seeking expressions of interest from accredited general practices to take part in phase 1B of the vaccination program.

Successful applicants will be supplied the AstraZeneca COVID-19 vaccine to commence vaccinating priority population groups, including persons 70 years of age or older, other health care workers, Aboriginal and Torres Strait Islanders 55 years or older, persons with an underlying medical condition, and critical and high risk workers. General practice will also be involved in latter phases of the vaccination program which aims to vaccinate all Medicare-eligible persons aged 18 years of age and older.

The purpose of the *Health Insurance (Section 3C General Medical Services – General Practice Attendance for Assessing Patient Suitability for a COVID-19 Vaccine) Determination 2021* (the Determination) is to list 16 new Medicare Benefits Schedule (MBS) items to support general practices to administer the COVID-19 vaccine.

General practices supplied with the vaccine will be able to provide a service to assess if a person who is at least 18 years of age is suitable to receive the COVID-19 vaccine if:

* the service is provided at a location where the vaccine is immediately available for administration to the patient; and
* the service is provided to the patient at no cost (known as ‘bulk-billing’).

The service can be performed by general practitioners (GPs) and other medical practitioners (OMPs), or by a person on behalf of the medical practitioners (such as a registered nurse or other health professional registered under the Health Practitioner Regulation National Law) if it is provided in accordance with acceptable clinical practice and under supervision. Medical practitioners do not have to personally attend the service but they must be on-site, must supervise the service in accordance with clinical standards, and accept full responsibility for the service.  
  
The majority of patients are expected to receive the service twice; on the occasion they receive the first and second dose of the COVID-19 vaccine. Medical practitioners can claim an assessment service where the vaccine is not administered if:

* the patient is assessed as unsuitable for the vaccine; or
* the patient is assessed as suitable for the vaccine, but the patient chooses not to receive the vaccine at the time of the attendance.

**Human rights implications**

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

*The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *‘highest attainable standard of health’* takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

*The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The right of equality and non-discrimination*

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR). Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

This instrument advances the right to health and the right to social security by providing persons aged 18 years of age and older an assessment attendance for the COVID-19 vaccine at no out-of-pocket cost. The attendance will facilitate this cohort of person receiving access to the COVID-19 vaccine.

The Determination engages the right of equality and non-discrimination because only people 18 years or over are ‘eligible for a COVID-19 vaccine’ and can be provided an assessment service under the 16 new MBS items. This limitation is reasonable, necessary and proportionate. As part of the Australian Government’s vaccination program, general practices will be supplied with the AstraZeneca vaccine. The AstraZeneca vaccine’s provisional approval by the Therapeutic Goods Administration (TGA) is for use in persons 18 years and over. The Pfizer vaccine is not being supplied to general practices because of its unique cold storage requirements.

**Conclusion**

This instrument is compatible with human rights as it advances the right to health and the right to social security. The instrument advances these rights by providing patients 18 years or age and older a pathway for access to the COVID-19 vaccine through a general practice.

**Paul McBride**

**First Assistant Secretary**

**Medical Benefits Division**

**Health Resourcing Group**

**Department of Health**