## **EXPLANATORY STATEMENT**

#### Health Insurance Act 1973

Health Insurance (Professional Services Review – Sampling Methodology)

Determination 2017

#### Authority

The Professional Services Review Scheme (the **Scheme**) is established under Part VAA of the *Health Insurance Act 1973* (the **Act**). Section 79A specifies the object of that Part as being "to protect the integrity of the Commonwealth Medicare benefits, dental benefits and pharmaceutical benefits programs and, in doing so:

- (a) protect patients and the community in general from the risks associated with inappropriate practice; and
- (b) protect the Commonwealth from having to meet the cost of services provided as a result of inappropriate practice."

The Scheme involves the review of a practitioner's provision of services to determine whether the practitioner has inappropriately rendered or initiated services which: (a) attract a Medicare benefit; (b) attract a dental benefit; or (c) involve prescribing or dispensing of a pharmaceutical benefit. A review under the scheme is conducted by a Professional Services Review Committee consisting of peers of the practitioner (**Committee**). There are a range of directions that may be made under the Act in relation to persons who have inappropriately rendered or initiated services of that kind.

Services to be investigated are referred to a Committee by the Director of Professional Services Review. In investigating the provision of services included in a particular class of referred services under the Scheme, a Committee may have regard only to a sample of the services included in the class (subsection 106K(1) of the Act).

Subsection 106K(3) of the Act provides that the Minister may make written determinations specifying the content and form of sampling methodologies that may be used by a Committee when investigating the provision of services in a particular class.

#### Purpose

The Health Insurance (Professional Services Review – Sampling Methodology) Determination 2017 (the **Determination**) is made under subsection 106K(3) of the Act. The Determination sets out a sampling methodology that a Committee may use to make a finding of inappropriate practice in relation to the provision of particular identifiable services and to be able to extrapolate the results to a larger number of similar services within the referral period.

The Determination repeals the *Health Insurance (Professional Services Review – Sampling Methodology) Determination 2006* (the **Previous Determination**). The Previous Determination was due to have been automatically repealed, in accordance with section 50 of the *Legislation Act 2003*, on 1 April 2017.

No material changes have been made to the specific sampling methodology in the Determination. The sampling methodology consists of:

- (a) a single sample of no less than 25 provided services randomly drawn from the class of referred services being investigated; and
- (b) the determination, according to a prescribed formula, of the proportion of services in the sample that constitutes inappropriate practice.

Minor changes have been made to update drafting, however, these do not alter the operation of the Determination.

The sampling methodology is designed to achieve a specific level of statistical accuracy (i.e. 95% of the time the estimate produced will be within 10% of the actual true result). The sampling methodology provides for matters to be examined more expeditiously and consequently involves fewer Professional Services Review Committee sitting days.

## Consultation

The sampling methodology in the Previous Determination was the result of an extensive consultation process in 2006 with the Australian Medical Association (AMA) and the Statistical Society of Australia Inc., prior to the Previous Determination being made. The methodology was developed in consultation with, and was endorsed by, Professor Des Nicholls, an Accredited Statistician.

In 2016, the Department of Health examined the suitability of the Previous Determination. The Department also consulted with the AMA and the Professional Services Review (PSR) agency. Both the AMA and the PSR agency agreed that the Determination is fit-for-purpose and achieving its objectives efficiently and effectively and should be remade without change. The Determination continues to be a crucial element of the PSR Scheme.

In 2017, the Office of Best Practice Regulation (OBPR) was consulted regarding the proposal to remake the Current Determination in its current form. OBPR advised that the remake of the determination will have a minor regulatory impact and a Regulation Impact Statement is not required.

Details of the Determination are set out in the Attachment.

The Act specifies no conditions which need to be met before the power to make the Determination may be exercised.

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

The Determination commences on the day after registration on the Federal Register of Legislation.

## <u>Details of the Health Insurance (Professional Services Review – Sampling Methodology) Determination 2017</u>

#### PART 1 PRELIMINARY

#### **Section 1 - Name of Determination**

Section 1 provides that the Determination may be cited as the *Health Insurance* (*Professional Services Review - Sampling Methodology*) Determination 2017.

#### Section 2 - Commencement

Section 2 provides that the Determination is to commence on the day after it is registered.

#### **Section 3 – Authority**

Section 3 provides that the Determination is made under section 106K of the *Health Insurance Act 1973*.

#### Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to this Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms

#### **Section 5 - Definitions**

Section 5 defines the following terms as used in the Determination:

- (a) 'Act' means the *Health Insurance Act 1973*.
- (b) 'final report' means a final report prepared under section 106L of the Act or a draft report prepared under section 106KD of the Act that is, because of the operation of section 106KE, also a final report.

The notes to section 4 also clarify that certain terms used in the Determination are defined in subsections 3(1) and 81(1) of the Act.

#### PART 2 SAMPLING METHODOLOGY

## **Section 6 - Purpose**

Section 6 specifies that Part 2 sets out the content and form of a sampling methodology that may be used by a Committee in investigating the provision of services included in a particular class of services referred to the Committee, where regard is to be had only to a sample of services included in the class.

## Section 7 – Application of sampling methodology

Section 7 provides that the sampling methodology specified in Part 2 of the Determination is applicable to services provided, within the meaning given by subsection 81(2) of the Act, that are:

- (a) individual items; or
- (b) multiple items for the same patient on 1 occasion; in a particular class of referred services.

Under subsection 81(2) of the Act, a person provides a service if that person, a practitioner employed by the person, or a practitioner employed by a body corporate of which the practitioner is an officer, renders or initiates the service.

A 'class of services' is defined in subsection 81(1) of the Act to mean services of the same kind, or similar kinds.

## **Section 8 - Sample**

Subsection 8(1) provides that the Committee must have regard to a sample of no fewer than 25 provided services randomly drawn from a class of referred services being investigated.

Subsection 8(2) provides that the Committee may:

- (a) omit a service from the sample; and
- (b) include another provided service, randomly drawn from the same class, in its place.

Subsection 8(3) provides that if the Committee omits a service and includes another provided service in its place under subsection 8(2), the Committee must state its reasons for doing so in the draft report and final report it prepares in respect of the person under review to whom the sample relates.

## Section 9 – Determining percentage of inappropriate practice in sample

Subsection 9(1) provides that a committee relying on subsection 106K(1) of the Act (that is, having regard to a sample of a class of services) must work out, in accordance with subsection 9(2) of the Determination, the proportion of services in the sample in relation to the provision of which the person under review engaged in inappropriate practice.

Subsection 9(2) provides that for subsection 9(1), the proportion is to be expressed as a percentage, and sets out the relevant formula to calculate this percentage, where:

$$100 \times \left(d - \sqrt{\frac{4d \times (1-d) \times (N-s)}{N \times (s-1)}}\right)$$

d is the number of services in the sample that the Committee has determined are services in relation to the provision of which the person under review has engaged in inappropriate practice, divided by s.

s is the number of services in the sample.

N is the number of services in the class.

Subsection 9(3) provides that the percentage must be expressed as a whole number (if necessary, for that purpose, rounded down to the nearest whole number).

#### Section 10 – Disregarding sample results less than 10%

Section 10 provides that, for the purpose of subsection 106K(1) of the Act, the methodology specified in the Determination may be used by a Committee only if the percentage worked out under section 9 is equal to, or greater than, 10% of the sample of the particular class of referred services under investigation.

The notes to section 10 clarify that:

- it is considered that no conclusion can be drawn from a result less than 10% because the result may not be statistically valid; and
- information about a service may be considered under section 106H of the Act even if, because of section 10 of the Determination, a sample including that service cannot be considered under section 106K of the Act.

#### PART 3 TRANSITIONAL

#### **Section 11 - Definitions**

Section 11 defines the following terms as used in Part 3:

- (a) 'commencement time' means the commencement of this Determination.
- (b) 'previous determination' means the *Health Insurance (Professional Services Review Sampling Methodology) Determination 2006.*

# Section 12 – Continued operation of the previous determination to certain investigations

Section 12 provides that the *Health Insurance (Professional Services Review – Sampling Methodology) Determination 2006* continues to apply to the investigation of services under section 93 of the Act that began prior to the commencement time, where a final report has not been made in relation to the investigation.

#### **SCHEDULE 1 - REPEALS**

## Health Insurance (Professional Services Review – Sampling Methodology) Determination 2006

Item 1 provides that the *Health Insurance (Professional Services Review – Sampling Methodology) Determination 2006* is repealed.

## **Statement of Compatibility with Human Rights**

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

## Health Insurance (Professional Services Review – Sampling Methodology) Determination 2017

This 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**

The Determination is made under subsection 106K(3) of the *Health Insurance Act 1973* ('the Act'). The Determination repeals the *Health Insurance (Professional Services Review – Sampling Methodology) Determination 2006* and remakes it without substantive change. The Determination commences on the day after it is registered.

The Professional Services Review Scheme ('PSR Scheme') involves the review of a practitioner's provision of services to determine whether the practitioner has inappropriately rendered or initiated services which: (a) attract a Medicare benefit; (b) attract a dental benefit; or (c) involve prescribing or dispensing of a pharmaceutical benefit. A review under the scheme is conducted by a Professional Services Review Committee consisting of peers of the practitioner ('PSR Committee').

The Determination sets out the content and form of a sampling methodology that PSR Committees may use to make a finding of inappropriate practice in relation to the provision of particular services and to be able to extrapolate the results to a larger number of similar services during the referral period. The sampling methodology is not mandatory and a PSR Committee may use a different sampling methodology if, and only if, the PSR Committee has been advised by a statistician accredited by the Statistical Society of Australia Inc. that the sampling methodology is statistically valid, in accordance with subsection 106K(4) of the Act.

## **Human rights implications**

The Determination 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.

#### **Analysis**

The aim of the PSR Scheme is to protect the integrity of the Medicare benefits, dental benefits and pharmaceutical benefits programs by protecting patients and the community from the risks associated with 'inappropriate practice' and also protecting the Commonwealth Government from having to meet the cost of services provided as a result of inappropriate practice. The PSR Scheme supports the right to health and social security by preventing patients from receiving or being referred for services that they do not clinically need (that is, services that would be unacceptable to the general body of practitioners in the relevant profession) and by ensuring that the Commonwealth's limited resources are directed to the most effective health services.

Medical practitioners commonly provide thousands of services a year which attract Medicare benefits. In cases involving a high number of services, it is impracticable for a PSR Committee to examine all of the services provided by the person under review to determine every instance of inappropriate practice in the referral period. The use of a sampling methodology to ascertain the level of inappropriate practice in relation to the provision of all referred services is a viable alternative; allowing matters to be dealt with more expeditiously and involving fewer PSR Committee sitting days.

The Determination does not alter the existing processes involved in a review by a PSR Committee which have been in place since 2006. For example, it does not affect:

- the right of a person under review to challenge appointments to a PSR Committee reviewing the person (s 96 of the Act);
- the right of a person under review in relation to hearings of the PSR Committee, including the rights to attend hearings, be accompanied by a lawyer, call witnesses and question persons giving evidence before the hearing (s 103(1) of the Act);
- the requirement to afford a person under review the opportunity to see a written draft report if any preliminary findings of inappropriate practice have been made (s 106KD of the Act); and
- any right of a person under review to seek judicial review of decisions.

The Australian Medical Association was consulted and agrees with current arrangements continuing.

## Conclusion

The Legislative Instrument is compatible with human rights because it maintains existing arrangements and the protection of human rights.

Greg Hunt
Minister for Health