EXPLANATORY STATEMENT

ISSUED BY THE AUTHORITY OF

THE MINISTER FOR HEALTH

HEALTH INSURANCE ACT 1973

DECLARATION OF QUALITY ASSURANCE ACTIVITY

UNDER SECTION 124X

QAA No. 2/2015

Part VC of the *Health Insurance Act 1973* (the Act) creates a scheme (known as the Commonwealth Qualified Privilege Scheme) to encourage efficient quality assurance activities. Those activities help to ensure the quality of health services that are funded by the Government, including through Medicare benefits, the Pharmaceutical Benefits Scheme and/or Health Program Grants. The scheme encourages participation in such activities by protecting certain information from disclosure, and also by providing some protection from civil liability to certain persons engaged in those activities in good faith, in respect of those activities.

In order for Part VC of the Act to apply to an activity, the Minister must make a Declaration pursuant to section 124X of the Act that the activity described in the declaration is a quality assurance activity to which Part VC applies. Regulations 23C to 23G of the *Health Insurance Regulations* 1975 (the Regulations) set out the public interest criteria that must be met by quality assurance activities in order to be declared under section 124X of the Act.

This Declaration under subsection 124X(1) applies to Part VC of the Act to the following activity:

1. Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program (the Activity).

An overview of the Activity for which the Declaration pursuant to section 124X of the Act is made is contained in the Attachment.

Before the Minister can make a Declaration, certain requirements must be met:

• Firstly, the Minister must be satisfied that the persons engaged in the Activity are authorised to do so as described in paragraph 124X(3)(a) of the Act.

The Activity meets the requirements of paragraph 124X(3)(a) as the persons engaged in the Activity are authorised to do so by the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (an association of health professionals – cardiac surgeons) through the Australasian Cardiac Surgery Research Institution (ACSRI) (a research body) and is supported by two State governments (Victoria and New South Wales) and individual institutions.

• Secondly, paragraph 124X(3)(b) of the Act provides that the Minister must be satisfied that it is in the public interest to have Part VC of the Act apply to the Activity. In doing so, the Minister must have regard to criteria prescribed by the Regulations.

The Activity meets the criteria as follows:

- As required by regulation 23C, the Activity includes the disclosure of non-identifying information that concerns the quality of service assessed, evaluated or studied. Outcomes from this Activity will include by ACSRI annual reporting to the Department of Health, participating hospitals and units and ongoing quarterly reports to relevant ACSRI committee/s and participating hospitals.
- Regulation 23D does not apply as the Activity will be engaged in more than one State or Territory.
- Regulation 23E does not apply as the Activity has previously been engaged in Australia. The Activity was previously declared to be a quality assurance activity to which Part VC applies in 2008 (QAA 2/2008).
- Regulation 23F applies as the Activity has previously been carried out in Australia. This is a re-declaration of QAA 2/2008. The Minister's re-declaration will continue to encourage full participation in the Activity by persons who provide health services and by providing participants with a greater degree of confidence and security that their participation is primarily for the benefit of maintaining and enhancing the quality of adult cardiac surgical care in Australia.
- Regulation 23G does not apply as the Activity does not include the assessment or evaluation by a person of the services, skill or performance of a health practitioner for the purpose of determining the health care practitioner's clinical practising rights.

Consultation

Consultations regarding the application for declaration of this Activity were undertaken in 2014 (September and December) and 2015 (January to March). This included obtaining advice on the potential value of declaring this Activity as a quality assurance activity for the purposes of the Act, the methodology used to conduct the Activity, and whether the application met the criteria required for declaration to be made, particularly the criteria relating to whether it is in the public interest to declare the Activity.

Those consulted included members of the Qualified Privilege Advisory Group, which includes an external clinician; a legal expert; a quality manager working in the field of health care quality assurance; and a consumer representative.

The Declaration of this Activity will not result in any direct or substantial indirect effect on business.

The Declaration has effect from the day after registration on the Federal Register of Legislative Instruments. This Declaration ceases to be in force at the end of 5 years after it is signed.

The Declaration is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

1. AUSTRALIAN AND NEW ZEALAND SOCIETY OF CARDIAC AND THORACIC SURGEONS' CARDIAC SURGERY MONITORING PROGRAM

Purpose

This activity has established a standardised database and definitions for clinical information on adult cardiac surgical patients. The data, which is transmitted to a central database repository, is collected and analysed, and the outcomes are evaluated statistically to determine the adequacy of performance of hospital units and individual surgeons. The data set and definitions are reviewed bi-ennially in order to allow integration with other evolving databases. This activity expands the Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program and aims to eventually include all public and private hospital units.

Objective/s

The primary objective of this activity is to maintain and enhance the quality of adult cardiac surgical care in Australia by acquiring relevant, defined data in a standardised format, analysing and monitoring aggregated data and enacting an effective peer review process that includes defined escalation protocols.

This activity also involves:

- providing comparative information on the quality of cardiac surgery on an individual, unit, State and National level;
- establishing Australian-specific algorithms to enable comparisons of surgical performance;
- conducting and facilitating research on the outcomes of cardiac surgery based on de-identified information; and
- recording details of and ultimately tracking the function of, prostheses used in cardiac surgery.

Statement of Compatibility with Human Rights

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

DECLARATION OF QUALITY ASSURANCE ACTIVITY UNDER SECTION 124X OF THE HEALTH INSURANCE ACT 1973 – QAA 2/2015

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

This Legislative Instrument declares the quality assurance activity titled *Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program* as a quality assurance activity under section 124X of the *Health Insurance Act 1973* (the Act).

This Activity is being conducted by the Australasian Cardiac Surgery of Research Institution (ACSRI) and involves the establishment of a standardised database and definitions for clinical information on adult cardiac surgical patients. The data, which is transmitted to a central database repository, is collected and analysed, and the outcomes are evaluated statistically to determine the adequacy of performance of hospital units and individual surgeons. This Activity expands the Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program and aims to eventually include all public and private hospital units.

The primary objective of this Activity is to maintain and enhance the quality of adult cardiac surgical care in Australia.

A declaration under section 124X of the Act encourages participation in the declared quality assurance activity by protecting certain information from disclosure and providing some protection from civil liability to people participating in the activity as part of a committee for the purposes of assessing or evaluating the services of another person. However, the Qualified Privilege Scheme (QPS) created by Part VC of the Act does not remove the right of individuals to seek legal redress to resolve disputes with their doctor nor allow medical practitioners to avoid scrutiny by medical registration boards and/or health complaints processes.

Human rights implications

This Legislative Instrument engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The QPS is aimed at encouraging participation in quality assurance activities that help ensure the highest possible health care standards are maintained. The quality assurance activity described in this Legislative Instrument will help maintain and enhance the quality of adult cardiac surgical care in Australia.

Conclusion

This Legislative Instrument is compatible with human rights as it promotes human rights.

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Department of Health