

Legislation (My Health Records Instruments) Sunset-altering Declaration 2022

EXPLANATORY STATEMENT

Issued by the Attorney-General in compliance with section 15G of the *Legislation Act 2003*.

INTRODUCTION

The *Legislation (My Health Records Instruments) Sunset-altering Declaration 2022* (the Declaration) is made under subsection 51A(1) of the *Legislation Act 2003* (Cth) (the Legislation Act). It is a legislative instrument for the purposes of the Legislation Act and must be registered on the Federal Register of Legislation. The Declaration is subject to the disallowance provisions of the Legislation Act.

OUTLINE

Sunsetting is the automatic repeal of legislative instruments after a fixed period. The Australian Government's sunsetting framework is established under Part 4 of Chapter 3 of the Legislation Act. The purpose of the sunsetting framework is to ensure that legislative instruments are kept up to date and only remain in force for so long as they are needed.

Subsection 50(1) of the Legislation Act provides that a legislative instrument is automatically repealed on the 1 April or 1 October immediately on or following the tenth anniversary of its registration.

Under subsection 51A(1) of the Legislation Act, the Attorney-General may issue a declaration aligning the sunsetting days of two or more instruments, if satisfied on application by the rule-maker of the relevant instruments that:

- (a) all the instruments to be reviewed:
 - i) would (in the absence of a declaration made under section 51A of the Legislation Act) be repealed by section 50 or 51 of the Legislation Act; and
 - ii) are or will be the subject of a single review; and
- (b) the making of the declaration will facilitate the undertaking of the review or the implementation of its findings.

The day specified in the sunset-altering declaration must be 1 April or 1 October of a year that is up to five years later than the earliest sunsetting day of the instruments. The instruments will then be repealed on the day specified in the declaration instead of the previously scheduled sunsetting day of each instrument. This allows instruments to continue to be in force for a further but limited period of time when they would otherwise sunset, or to sunset earlier than the originally scheduled sunsetting day.

The objective of issuing a sunset-altering declaration is to facilitate either: the undertaking of a single review of the fitness-for-purpose of two or more thematically related legislative instruments; or the implementation of such a review's findings. This reduces administrative burden as well as the possibility of legislative inconsistencies arising from reviewing and replacing related legislation at different times.

The Declaration aligns the sunset dates of the following instruments to 1 April 2026 (together, the ‘My Health Records Instruments’):

- (a) the *My Health Records Regulation 2012* (Cth) (the Regulation); and
- (b) the *My Health Records Rule 2016* (Cth) (the Rule).

PROCESS BEFORE DECLARATION WAS MADE

Regulatory impact analysis

Sunset-altering declarations are machinery of government instruments, and are therefore not subject to the regulatory impact assessment requirements set out by the Office of Best Practice Regulation (OBPR). The OBPR reference for this standing exemption is ID 19486.

Consultation before making

Before the Declaration was issued, the Attorney-General considered the general obligation to consult imposed by section 17 of the Legislation Act.

The Department of Health consulted within the Department and externally in relation to the proposed alignment of the My Health Records Instruments. External consultations included the Australian Digital Health Agency and states and territories via correspondence to their respective Chief Information Officers. The Information Law Unit of the Attorney General’s Department and the Office of the Information Commissioner were also informed.

Sunset-altering declarations are machinery in nature, and enable legislative instruments that would otherwise sunset at different times to be aligned in order to facilitate thematic review of the instruments. This will minimise the administrative burden on stakeholders associated with the sunset review of each instrument. Any replacement instruments will be subject to further consultation and parliamentary oversight, including oversight on whether adequate consultation occurred with persons likely to be affected by the replacement instruments. As such, the Declaration is consistent with the policy intent of the sunset regime.

Statutory preconditions relevant to the Declaration

In order to align the sunset day of two or more instruments, the Attorney-General must be satisfied on written application from the relevant rule-maker that the statutory conditions in paragraphs 51A(1)(a) and (b) of the Legislation Act are met. The statutory conditions are that:

- (a) all the instruments to be reviewed:
 - i) would (in the absence of a declaration made under section 51A of the Legislation Act) be repealed by section 50 or 51 of the Legislation Act; and
 - ii) are or will be the subject of a single review; and
- (b) the making of the declaration will facilitate the undertaking of the review or the implementation of its findings.

In terms of process, the Legislation Act requires:

- (a) the responsible rule-maker to apply to the Attorney-General,

- (b) the Attorney-General to be satisfied of the statutory conditions, and
- (c) the Attorney-General to make a declaration, which is a legislative instrument and subject to disallowance.

The rule-maker for the My Health Records Instruments, the Minister for Health and Aged Care, the Hon Greg Hunt MP, provided a written application to the Attorney-General seeking a sunset-altering declaration for the My Health Records Instruments. On the basis of the information contained in the statement of reasons below, the Attorney-General is satisfied that the alignment of the My Health Records Instruments will facilitate the undertaking of a single thematic review. As such, the criteria in paragraphs 51A(1)(a) and (b) of the Legislation Act are met.

Statement of Reasons for issuing of the Declaration

For the purposes of subsection 51A(4) of the Legislation Act, this section sets out the statement of reasons for the issue of the Declaration.

The Regulation is due to sunset on 1 October 2022 and the Rule is due to sunset on 1 April 2026. The alignment of the sunset dates of these two pieces of subordinate legislation will allow them to be reviewed concurrently in a single thematic review. Both instruments deal with similar subject matter and there are interdependencies across the My Health Records (MHR) legislative suite.

The *My Health Records Act* (the MHR Act) provides for the making of rules and regulations and prescribes that the Minister must first consult with a subcommittee of the Ministerial Council. The stakeholder consultation requirements for the Regulation and the Rule are the same. The consolidation of Regulation and Rule review process is likely to result in better outcomes, allowing for stakeholders to be provided with a holistic understanding of the review's impact and scope. Further, the alignment will consolidate the resources required to engage stakeholders and conduct the review.

In February 2021, the My Health Record Independent Statutory Review was tabled. A number of the recommendations contained in the Statutory Review relate to legislative changes. In particular, to changes in the *My Health Records Act 2012*. These recommendations should be considered further before the commencement of the thematic review. In the event amendments are made to the My Health Record Act, then it is likely that there will be resultant changes to the subordinate legislative instruments. Consequently, the aligned sunset date of 1 April 2026 will allow for further consideration of the Statutory Review recommendations before commencement of the thematic review of the legislative instruments.

In addition to the Regulation, the following legislative instruments are made under the My Health Records Act:

- Sunset date 1 April 2026: My Health Records Rule 2016: (F2016C00607),
- Sunset date 1 April 2026: My Health Records (Assisted Registration) Rule 2015 (F2015L02055),
- Sunset date 1 April 2026: My Health Records (Opt-Out Trials) Rule 2016 (F2016L00094),
- Sunset date 1 April 2026: My Health Records (Information Commissioner Enforcement Powers) Guidelines 2016 (F2016L00360), and

- Sunset date 1 April 2028: The My Health Records (National Application) Rules 2017 (F2019C00092).

It is the Department of Health's intention to include most, if not all, of these legislative instruments in the thematic review. Alignment of the My Health Record and the My Health Regulation sunset dates to 1 April 2026 will allow for a single thematic review of a number of legislative instruments made under the My Health Records Act. Consequently, there is substantial work to be undertaken in the coordination of this review, and a sunset date of 1 April 2026 will ensure adequate time for comprehensive consultation to be undertaken.

The thematic review of the My Health Records Instruments will:

- provide an opportunity to review the overall impact of the My Health Records Instruments on the MHR system, and amend them in a cohesive manner to further the purposes and principles of the MHR system
- ensure that, to the extent future amendments to the MHR Act impact the My Health Records Instruments, consequential amendments are implemented consistently and chronologically in both of these pieces of subordinate legislation
- streamline consultation with relevant stakeholders
- streamline the development of any RIS and Statement of Compatibility with Human Rights, given the overlapping nature of the content of the My Health Records Instruments
- ensure that any amendments to the My Health Records Instruments are complementary and effectively support the delivery of the My Health Record System, and
- provide several efficiencies in resource allocation, including in stakeholder engagement, policy development and the drafting process.

More information

Further details on the provisions of the Declaration are provided in [Attachment A](#).

The My Health Records Instruments which are the subject of the Declaration, and which will now both sunset on 1 April 2026, are available on the Federal Register of Legislation.

Further information may be requested from the Attorney-General's Department about the operation of the Declaration, and from the Department of Health about the My Health Records Instruments to which the Declaration applies.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

The *Legislation (My Health Records Instruments) Sunset-altering Declaration 2022* (the Declaration) is compatible with human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011* (the Human Rights Act).

Overview of the Declaration

The Declaration is made under subsection 51A(1) of the *Legislation Act 2003* (the Legislation Act). Under that subsection, the Attorney-General can align the sunseting days of two or more legislative instruments if satisfied that:

- (a) all the instruments to be reviewed:
 - i) would (in the absence of a declaration made under section 51A of the Legislation Act) be repealed by section 50 or 51 of the Legislation Act; and
 - ii) are or will be the subject of a single review; and
- (b) the making of the declaration will facilitate the undertaking of the review or the implementation of its findings.

The day specified in the sunset-altering declaration must be 1 April or 1 October of a year that is up to five years later than the earliest sunseting day of the instruments. The instruments specified in the declaration will then be repealed on the day specified in the declaration instead of the previously scheduled sunseting day. The instruments specified in the Declaration are:

- (a) the *My Health Records Regulation 2012* (the Regulation); and
- (b) the *My Health Records Rule 2016* (the Rule).

The Declaration aligns the sunseting dates of the above instruments (the My Health Records Instruments) to 1 April 2026. The objective of issuing the Declaration is to facilitate the undertaking of a single thematic review into the fitness-for-purpose of the My Health Records Instruments. This will reduce administrative burden as well as the possibility of legislative inconsistencies arising from reviewing and replacing the related legislation at different times.

Human Rights Implications

Article 17 of the International Covenant on Civil and Political Rights (ICCPR) prohibits the unlawful or arbitrary interference with a person's privacy and unlawful attacks on a person's reputation. This right is also reflected in Article 22 of the Convention on the Rights of Persons with Disabilities (CRPD) and Article 16 of the Convention on the Rights of the Child (CRC).

The right to privacy includes respect for informational privacy including the right to respect the storing, use and sharing of private information and right to control the dissemination of private information. The Regulation engages the right to privacy by:

- (a) prescribing identifying information for individual healthcare providers, healthcare provider organisations and healthcare recipients that can be collected, used and disclosed to various participants;
- (b) prescribing the collection, use or disclosure of identifying information or healthcare identifiers for the purposes of assisted registration;
- (c) prescribing information in relation to a healthcare recipient needed for registration;

- (d) prescribing Department of Veterans' Affairs information that may be included in a My Health Record; and
- (e) authorising the Attorney-General's Department to collect, use and disclose identifying information for the purposes of identity verification.

The Rule engages the right to privacy by:

- (a) prescribing processes for setting access controls on an individual's My Health Record;
- (b) establishing minimum standards for providers participating in the My Health Record system in terms of training, exercising due care and skill and reporting errors, in order to minimise privacy risks; and
- (c) establishing security requirements, to minimise privacy risks.

For the My Health Record system to operate effectively and to ensure the correct healthcare recipient is registered and matched with the correct health information, identifying information must be prescribed, and collection, use and disclosure by various participants in the My Health Record system must be authorised. Without this information being shared between these parties, the individuals' identities could not be accurately verified and the My Health Records system would not be able to operate effectively or securely, and the expected health improvements would not be realised. While the Regulation adds some elements of personal information about healthcare recipients for the purpose of authorising collection, use and disclosure, any effect on the right to privacy is a proportionate, necessary and reasonable way of achieving the policy objective of improved health outcomes for all Australians.

Safeguards in place under the Rule, such as access controls and standards, procedures and obligations for My Health Record system participants are privacy positive.

A sunset-altering declaration may extend the operation of an instrument but does not change or affect the rights engaged under the original instrument, which have previously been subject to a Statement of Compatibility.

The Declaration itself is machinery in nature. It does not alter the arrangements in place under the My Health Records Instruments, but extends the operation of the Regulation to 1 April 2026. The rights engaged under the My Health Records Instruments are not changed or substantially affected by the issuing of the Declaration.

Before issuing the Declaration, the Attorney-General was satisfied that all instruments specified in the Declaration would be subject to a single thematic review. A thematic review is an effective mechanism for determining whether the instruments are fit for purpose, identifying opportunities to update, streamline and clarify the operation of the instruments and, where appropriate, reducing unnecessary regulation. The human rights impact of the My Health Records Instruments will be considered during the proposed review, and addressed in the Statement of Compatibility of each replacement instrument.

Conclusion

The Regulation and Rule are compatible with human rights because any limitation of the right to privacy is proportionate, necessary and reasonable to achieving improved healthcare for all Australians. The Declaration is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights Act, as the rights

engaged under the My Health Records Instruments are not changed or substantially affected by the issuing of the Declaration.

ATTACHMENT A

NOTES ON THE DECLARATION

Section 1 Name

This section provides that the Declaration is named the *Legislation (My Health Records Instruments) Sunset-altering Declaration 2022*. The Declaration may be cited by this name.

Section 2 Commencement

This section provides for the Declaration to commence on the day after it is registered.

Section 3 Authority

This section provides that the Declaration is made under paragraph 51A(1) of the *Legislation Act 2003*.

Section 4 Aligning of sunseting

This section provides that the following instruments are repealed by section 51A of the *Legislation Act 2003* on 1 April 2026:

- the *My Health Records Regulation 2012*; and
- the *My Health Records Rule 2016*.

Section 5 Repeal of the instrument

This section provides that the Certificate is repealed at the start of 2 April 2026.