

EXPLANATORY STATEMENT

National Occupational Respiratory Disease Registry Act 2023

National Occupational Respiratory Disease Registry Rules 2024

Purpose and operation

The purpose of the *National Occupational Respiratory Disease Registry Rules 2024* (Rules) is to designate silicosis as a prescribed occupational respiratory disease for the purposes of the National Occupational Respiratory Disease Registry (National Registry).

The Rules also operate to:

- prescribe certain kinds of medical practitioner for the purposes of the definition of ***prescribed medical practitioner*** in section 8 of the *National Occupational Respiratory Disease Registry Act 2023* (Act);
- nominate the period within which a prescribed medical practitioner who diagnoses an individual with a prescribed occupational respiratory disease must notify the Commonwealth Chief Medical Officer (CMO) of the minimum notification information about the individual under subsection 14(1) of the Act; and
- prescribe the Commonwealth authorities to which minimum notification included in the National Registry may be disclosed for the purposes of paragraph 22(1)(a) of the Act.

The Rules allow new occupational respiratory diseases to be prescribed quickly, facilitating early intervention and an effective response to emerging occupational respiratory disease threats.

The Rules designate medical practitioners who are registered as specialists in the specialities of occupational and environmental medicine or respiratory and sleep medicine to be prescribed medical practitioners for the purposes of the definition in section 8 of the Act.

Section 7 of the Rules sets a timeframe of 30 days in which minimum notification information must be provided to the CMO, in circumstances in which a prescribed medical practitioner diagnoses an individual with a prescribed occupational respiratory disease and mandatory reporting requirements of subsection 14(1) apply. This 30-day period commences the day after the day on which the diagnosis is made.

The scope of minimum notification information is specified in the *National Occupational Respiratory Disease Registry Determination 2024* (F2024L00288). The reporting of minimum notification information to the CMO within the 30 day timeframe specified by the Rules will involve the notification of personal information relating to individuals diagnosed with an occupational respiratory disease.

Personal information is a necessary component of minimum notification information, in that it ensures the National Registry can distinguish between notifications made for persons diagnosed with an occupational respiratory disease. Personal information is also required to enable State and Territory work health and safety agencies to contact patients, and to seek

additional information, if necessary, to ensure they can appropriately assess risks of occupational exposure.

For new or emerging diseases, the number of diagnoses may initially be low and the potential for duplicate reporting would significantly undermine the utility of the data to inform policy decision making in addressing the risks of occupational respiratory disease. High quality data will enable the National Registry to accurately record the incidence of occupational respiratory diseases in Australia and assist in preventing further workers being exposed to respiratory disease-causing agents.

Part 3 of the Act provides a framework for the lawful handling of information held in the National Registry, including the specific circumstances in which collecting, recording, using or disclosing such information can be authorised. The Act provides for a sanction of imprisonment for 2 years, 120 penalty units, or both, for the unauthorised handling of protected information.

Section 8 of the Rules prescribes the Australian Bureau of Statistics and the Australian Institute of Health and Welfare as Commonwealth authorities to which minimum notification information may be disclosed in accordance with subsection 22(1) of the Act. The ability for minimum notification information captured by the National Registry to be shared with these Commonwealth authorities improves the understanding of occupational respiratory diseases in Australia and assists in preventing future worker exposure to respiratory disease-causing agents. Minimum notification information is disclosed to Commonwealth authorities for purposes connected with the performance of functions, or the exercise of powers, of the Commonwealth authority.

These Commonwealth authorities have extensive experience handling sensitive health data and in using data to produce accurate, meaningful information for the Australian public. Each organisation has existing policies for the handling of personal information which align with obligations set out in the *Privacy Act 1988* and the Australian Privacy Principles.

The ability for Commonwealth authorities, such as the Australian Bureau of Statistics and the Australian Institute of Health and Welfare, to link data held in the National Registry with other data sources held or accessed by those authorities will significantly improve Australia's ability to understand occupational respiratory disease and design interventions to best protect Australian workers.

Minimum notification information will also be made available to State and Territory health, and work health and safety agencies. Access to minimum notification information is necessary to allow relevant State and Territory authorities to effectively investigate the occurrence of occupational respiratory disease within workplaces or, if necessary, seek additional information directly from individuals residing in, or diagnosed with occupational respiratory diseases, in the relevant jurisdiction. This will allow the relevant State and Territory authorities to assess the risks of occupational exposure to disease-causing agents and consider appropriate action to reduce further exposure in the workplace.

Relevant State and Territory authorities will also receive broader statistics, pursuant to subsection 26(2) of the Act, which will assist those authorities to understand the nature and extent of occupational respiratory disease in Australia.

Researchers can also request access to information from the National Registry, with applications assessed on a case-by-case basis in accordance with the Act and the Department's data access and release framework.

The Registry Operator will assess applications on behalf of the Department to determine whether the research is of a kind to which the guidelines made under sections 95 or 95A of the *Privacy Act 1988* apply. Identifiable personal information will only be disclosed for research purposes where those purposes cannot be achieved using de-identified information, and where the researcher has relevant Ethics Committee approval. Researchers will not have access to information that identifies a patient's prescribed medical practitioner or any workplace identifying information.

In addition to these legislative arrangements, there is a framework of policy safeguards in place to provide further privacy protections, including:

- Use of a dedicated electronic database, established to collect and store information disclosed in the course of making notifications in accordance with the Act. The electronic database must be operated in accordance with the *Privacy Act 1988* and the Australian Privacy Principles.
- Prescribed medical practitioners will be provided access to the physician portal and will only be able to access personal information in relation to patients they have diagnosed with, or are treating for, an occupational respiratory disease.
 - The Registry Operator is required to verify the physician's identity prior to providing the physician with access to relevant data held in the National Registry.
 - A physician can create an invitation in the portal for an individual to become their agent, whose identity will also undergo verification. An invitation is only valid for 24 hours and the arrangement can be terminated by the physician at any time.
- Access by State and Territory authorities is limited to 10 nominated officers from health and work, health and safety agencies in each State and Territory being able to access the agency officer portal at any point in time.
 - Agency officer access to minimum notification information held in the National Registry will be limited to information relating to individuals who have been diagnosed in, or were exposed to, disease-causing agents in their relevant jurisdiction, as well as individuals residing in the relevant jurisdiction.
 - Expectations for appropriate and lawful use of information held in the National Registry by relevant State and Territory authorities will be set out in an exchange of letters between the Department and the relevant State and Territory authorities.
- Commonwealth authorities and researchers will, where requests for data held in the National Registry are approved, be provided extracts of data by the Department or Registry Operator on request, and will not have direct access to the National Registry.

The operation of the National Registry will also be supported by appropriate procedures for registry operation and data governance. Staff involved in the operation of the National Registry will receive annual training on how to appropriately deal with personal information,

including the handling of data breaches in accordance with the Department's data breach response plan.

Background

The National Registry was a recommendation of the National Dust Disease Taskforce, in response to an increase in silicosis cases in people working with engineered stone benchtops. The National Dust Disease Taskforce recommended that only diagnoses of silicosis be made mandatory to notify, with the capacity to prescribe other occupational respiratory diseases over time.

The Act, together with the *National Occupational Respiratory Disease Registry (Consequential Amendments) Act 2023*, the Determination and the Rules, creates a legislative framework for the establishment and ongoing management of the National Registry.

Authority

Section 33 of the Act provides that the Minister may, by legislative instrument, make Rules prescribing matters required or permitted by the Act to be prescribed by the Rules, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Information that may be prescribed by the Rules includes:

- the kinds of medical practitioner that will fall within the definition of a ***prescribed medical practitioner*** in section 8 of the Act;
- the occupational respiratory diseases that fall within the definition of a ***prescribed occupational respiratory disease*** in section 8 of the Act;
- the period within which a prescribed medical practitioner who diagnoses an individual with a prescribed occupational respiratory disease must notify the CMO of the minimum notification information, in circumstances set out in subsection 14(1) of the Act;
- the Commonwealth authorities to which minimum notification information included the National Registry that is protected information may be disclosed, per paragraph 22(1)(a) of the Act;
- the kinds of information in statistical reports at a national level;
- the kinds of information which the CMO can publish in reports; and
- the relevant State and Territory authorities to which disclosures can be made.

Commencement

This instrument commences the later of:

- (a) the day after registration on the Federal Register of Legislation; and
- (b) the day the *National Occupational Respiratory Disease Registry Act 2023* commences.

However, the instrument will not commence at all if the *National Occupational Respiratory Disease Registry Act 2023* does not commence.

Consultation

The Rules, as well as the primary legislation and the Determination forming the framework for the National Registry, were developed in consultation with a Registry Steering Committee and Registry Build Advisory Group representing peak medical bodies, State and Territory health and work health and safety agencies, Commonwealth work health and safety agencies, the National Dust Disease Taskforce, unions, industry and the research community. Feedback was assessed on its impacts and incorporated where appropriate, in accordance with subsection 33(2) of the Act.

The decision to designate silicosis as the only prescribed occupational respiratory disease requiring mandatory notification was made as a result of this consultation process. It balances the burden of reporting by physicians with the benefits of understanding the incidence of occupational respiratory disease to assist in targeting and monitoring the effectiveness of interventions and prevention strategies.

General

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

Details of this instrument are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the National Occupational Respiratory Disease Registry Rules 2024

Part 1—Preliminary

Division 1 – Preliminary

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Occupational Respiratory Disease Registry Rules 2024*.

Section 2 – Commencement

Section 2 provides that the instrument commences the later of:

- (a) the day after registration on the Federal Register of Legislation; and
- (b) the day the *National Occupational Respiratory Disease Registry Act 2023* commences.

However, the instrument will not commence at all if the *National Occupational Respiratory Disease Registry Act 2023* does not commence.

Section 3 – Authority

Section 3 provides that the instrument is made under *National Occupational Respiratory Disease Registry Act 2023*.

Division 2 – Definitions

Section 4 – Definitions

Section 4 provides that in this instrument, the definition of:

- *Act* is the *National Occupational Respiratory Disease Registry Act 2023*;
- *Health Practitioner Regulation National Law* has the same meaning as *National Law* has in the *Health Insurance Act 1973*.

Section 5 – Prescribed medical practitioners

Section 5 provides that ***prescribed medical practitioners*** for the purposes of section 8 of the Act are medical practitioners registered under the Health Practitioner Regulation National Law as a specialist in the specialty of occupational and environmental medicine or respiratory and sleep medicine.

Section 6 – Prescribed occupational respiratory diseases

Section 6 provides that silicosis is a *prescribed occupational respiratory disease* for the purposes of the definition of section 8 of the Act.

Part 2—National Occupational Respiratory Disease Registry

Section 7 – Period for notifying information—diagnosing prescribed medical practitioner

Section 7 provides the timeframe within which minimum notification information must be provided to the CMO, in circumstances in which a prescribed medical practitioner diagnoses an individual with a prescribed occupational respiratory disease and the mandatory reporting requirements of subsection 14(1) apply. Section 7 prescribes a timeframe of 30 days after the day the practitioner makes the diagnosis.

Part 3—Dealing with information in the National Registry

Section 8 – Commonwealth authorities to which minimum notification information included in the National Registry may be disclosed

Section 8 provides that the Australian Bureau of Statistics and the Australian Institute of Health and Welfare are Commonwealth authorities for the purposes of paragraph 22(1)(a) of the Act. This will facilitate the sharing of minimum notification information about an individual that is included in the National Registry with these Commonwealth authorities.

Statement of Compatibility with Human Rights

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

National Occupational Respiratory Disease Registry Rules 2024

Issued by the authority of the Minister for Health and Aged Care under the *National Occupational Respiratory Disease Registry Act 2023* (Act).

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 Disallowable Legislative Instrument

The *National Occupational Respiratory Disease Registry Rules 2024* (Rules) operate to:

- prescribe certain kinds of occupational respiratory diseases for the purposes of the definition of ***prescribed occupational respiratory disease*** in section 8 of the Act;
- prescribe certain kinds of medical practitioner for the purposes of the definition of ***prescribed medical practitioner*** in section 8 of the Act;
- nominate the period within which a prescribed medical practitioner who diagnoses an individual with a prescribed occupational respiratory disease must notify the Commonwealth Chief Medical Officer of the minimum notification information about the individual under subsection 14(1) of the Act; and
- prescribe the Commonwealth authorities to which minimum notification included in the National Registry may be disclosed for the purposes of section 22 of the Act.

The Rules designate silicosis to be a prescribed occupational respiratory disease for the purposes of section 8 of the Act.

The Rules designate medical practitioners who are registered as specialists in occupational and environmental medicine or respiratory and sleep medicine to be prescribed medical practitioners for the purposes of section 8 of the Act. Under section 7 of the Rules, a prescribed medical practitioner who diagnoses an individual with a prescribed occupational respiratory disease is required to notify the Chief Medical Officer of the minimum notification information within 30 days after making the diagnosis.

The Rules also prescribe the Australian Bureau of Statistics and Australian Institute of Health and Welfare as authorities to which minimum notification information may be disclosed. The ability for data captured by the National Registry to be shared readily with these Commonwealth authorities will enhance understanding of occupational respiratory diseases in Australia and assist in preventing future worker exposure to respiratory disease-causing agents.

Human rights implications

This Disallowable Legislative Instrument engages the following rights:

- Right to health – contained in Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and Article 2 on the progressive realisation of this right.
- Right to a safe workplace – contained in Articles 4 and 8 and subparagraph (c) of Article 11 of the International Labour Organization Convention No. 155 concerning Occupational Safety and Health and the Working Environment done at Geneva on 22 June 1981; and the Protocol of 2002 to the Occupational Safety and Health Convention 1981, made in Geneva on 20 June 2002.
- Protection of privacy and reputation – contained in Article 17 of the International Covenant on Civil and Political Rights (ICCPR).

Right to health

The Rules engage Articles 2 and 12 of the ICESCR by assisting the progressive realisation of the right of everyone by all appropriate means to the enjoyment of the highest attainable standard of physical and mental health. 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 Rules assist the advancement of this human right by specifying the prescribed occupational respiratory diseases, diagnoses of which either must or may (depending on the circumstances) be notified to the National Registry. The Rules also set timeframes for the timely notification of diagnoses of prescribed occupational respiratory diseases in relevant circumstances. Further, the Rules specify the Commonwealth authorities with which minimum notification information held in the National Registry can be shared. This will support the identification of industries, occupations job tasks and workplaces where there is a risk of exposure to respiratory disease-causing agents to enable the application of timely and targeted prevention activities to reduce worker exposure and disease.

Right to a safe workplace

The Rules engage Articles 4 and 8 and paragraph (c) of Article 11 of the International Labour Organization Convention No. 155 concerning Occupational Safety and Health and the Working Environment; and the Protocol of 2002 to the Occupational Safety and Health Convention 1981.

The Rules assist the advancement of this human right by supporting the notification of information on diagnoses of occupational respiratory disease, which are to be included in the National Registry with the aim of reducing further worker exposure and disease.

Protection of privacy and reputation

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual’s privacy, family, home and correspondence. For interference with privacy not to be arbitrary,

it must be reasonable in the particular circumstances. Reasonableness, in this context, incorporates notions of proportionality to the end sought and necessity in the circumstances.

The Rules engage Article 17 of the ICCPR by designating a disease as a prescribed occupational respiratory disease and limiting the number of prescribed occupational respiratory diseases to one (silicosis). Notification of any other occupational respiratory diseases requires patient consent. The Rules also set out the Commonwealth authorities to which minimum notification information about an individual may be disclosed, and limit the number of Commonwealth authorities to which such information may be disclosed.

Conclusion

This Disallowable Legislative Instrument is compatible with human rights because it advances the protection of human rights as outlined above and, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

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