EXPLANATORY STATEMENT

Public Governance, Performance and Accountability Act 2013

Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016

Authority

Section 87 of the *Public Governance, Performance and Accountability Act 2013* (the Act) provides for rules to establish a new body corporate.

Purpose

The purpose of the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016* (the Rule) is to establish the Australian Digital Health Agency (the Agency). The Agency will be a corporate Commonwealth entity which will be legally separate from the Commonwealth.

The Rule provides for the Agency's purpose, functions, powers, the establishment of its skills-based Board and technical advisory committees, staffing arrangements, reporting obligations, and the development of the Agency's work programme.

The Rule also includes transitional provisions dealing with the transition from the National E-Health Transition Authority (NEHTA) to the Agency so that NEHTA's assets and liabilities become those of the Agency and things done by or in the name of NEHTA become things done by or in the name of the Agency.

Background

On 3 November 2013, the Australian Government commissioned an external review of the Personally Controlled Electronic Health Record (PCEHR) system.

The PCEHR review identified several issues related to the governance of digital health broadly and the PCEHR system in particular, namely:

- governance processes around the PCEHR system did not adequately represent the industry, were overly bureaucratic in nature and did not effectively balance the needs of government and private sector organisations;
- engagement and consultation with some key stakeholders, including clinical stakeholders, has not been effective to date;
- there are currently two significant governance arrangements in place for digital health and there are perceived benefits in reducing this to one; and

- there has been a lack of transparency in the decision-making process for the PCEHR system within the NEHTA structure, whose role is to lead the uptake of digital health systems of national significance.

The review of the PCEHR system found that governance for digital health nationally is in need of significant change as it does not have the confidence of the industry. Multiple factors have contributed to this, including a significant broadening of the remit of NEHTA since its inception.

Further, digital health governance is not representative of the potential users and expected beneficiaries of the digital health system. Although the PCEHR system directly affects healthcare providers (private and public), the medical software industry and individuals, the current governance predominantly comprises public sector organisations. A prime example of this problem is the NEHTA board which is made up of the heads of the Commonwealth, State and Territory health departments.

The establishment of new governance arrangements will involve the transition of relevant functions from NEHTA to the Agency, and the PCEHR system operation currently managed by the Department of Health.

Consistent with the review of the PCEHR and the Australian Government's response to the findings of the review, the Agency will be governed by a skills-based board, supported by technical advisory committees, and will report to Commonwealth, State and Territory Health Ministers through the Council of Australian Governments' (COAG) Health Council (CHC). The Commonwealth Department of Health will retain responsibility for federal digital health policy.

Once established, the Agency will become the single accountable organisation for digital health in Australia. It will be the national body responsible for the evolution of the digital health capability, through the leadership, coordination and delivery of a collaborative and innovative approach to utilising technology to support and enhance a clinically safe and connected national health system to improve health service delivery and health outcomes for the Australian community.

Details of the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016*

For the convenience of readers, this explanatory statement will refer to the Australian Digital Health Agency and the *Public Governance, Performance and Accountability Act 2013* as the 'Agency' and the 'Act' respectively.

The term 'digital health' means any application of information and communication technologies in order to improve healthcare and health outcomes.

PART 1—PRELIMINARY

Item 1 Name

This item provides that the instrument will be named the *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016*.

Item 2 Commencement

This item specifies that the whole of the instrument will commence on the day after the instrument is registered.

Item 3 Authority

This item specifies that the instrument is made under the Act. This Rule is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Item 4 Purpose

This item specifies that the instrument prescribes matters relating to the establishment of the Agency for sections 82 and 87 of the Act.

Item 5 Definitions

This item sets out definitions used in the instrument.

Item 6 Responsible Minister

This item provides that the Health Minister is responsible for the Agency in relation to paragraph 87(n) of the Act.

Item 7 Vacancy in the office of Board member or member of a standing advisory committee

This item sets out that for the purpose of a reference to 'vacancy', there are taken to be 11 offices of the Agency's Board members (including the Board Chair); and there are taken to be 11 offices of the Agency's standing advisory committee members (including the Chair of the committee).

PART 2—THE AUSTRALIAN DIGITAL HEALTH AGENCY

Item 8 Establishment of the Australian Digital Health Agency

This item establishes the Agency. Sub-item (2) provides that the Agency is a body corporate, which must have a seal, and may sue or be sued. Sub-item (3) deals with the safe-keeping and use of the Agency's seal.

Item 9 Functions of the Agency

Sub-item (1) sets out the functions of the Agency.

The National Digital Health Strategy, which the Agency will coordinate and contribute to developing (sub-item 9(1)(a)), will outline the key national priorities for investment and development of digital health in Australia. The Agency will also be responsible for implementing aspects of the National Digital Health Strategy as directed by the Ministerial Council (sub-item 9(1)(b)).

The Agency's function of developing, implementing, managing, operating and continuously innovating and improving standards, systems and services in relation to digital health, consistent with the national digital health work programme (sub-item 9(1)(c)), will be critical to the implementation and delivery of a nationally consistent and interoperable digital health capability. Carrying out this function will require the Agency to develop, implement and manage the specifications and standards used in the digital health systems, solutions and services (such as the *My Health Record*), which constitute the national digital health work programme to facilitate the sharing of patient health information across healthcare settings. In addition to leveraging existing standards and specifications to facilitate information sharing in digital health systems, the Agency will be required to continuously improve and innovate new specifications and standards in order to generate improvements to digital health systems and capability.

The Agency will also develop and implement measures to ensure compliance by relevant industry stakeholders with agreed specifications and standards (sub-item 9(1)(f)). This may include an accreditation process for software vendors, who design, develop and maintain the operation of digital health systems and solutions, to ensure appropriate integration of the national digital health systems, solutions and services within the national digital health work programme.

In carrying out its functions under sub-items 9(1)(a) and (c), the Agency will be required to act collaboratively, where appropriate, with Commonwealth, State and Territory Governments and a range of other key stakeholders (sub-item 9(2)). These will include, for example, peak and professional organisations representing medical professionals and healthcare provider groups, peak healthcare recipient representative and support organisations, public and private sector health organisations, and the health software industry.

In developing, implementing and operating comprehensive and effective clinical governance to ensure clinical safety in the delivery of the national digital health work programme (sub-item 9(1)(d)), the Agency will be required to use a whole-of-system approach. This may involve the Agency developing and implementing across the

development lifecycle of the following components of the national digital health work programme:

- clinical risk management and assessment processes of those digital health systems which form part of the national digital health work programme in order to improve the safety and quality of patient care;

- clinical incident management systems which identify, report and set out a framework for the management and prevention of clinical incidents with the aim of improving the safety and quality of health care; and

- post implementation review of clinical governance activities and clinical safety audits.

The functions conferred on the Agency by other laws of the Commonwealth under paragraph 9(1)(h) will include the role of the system operator of the *My Health Record*. The Agency will be prescribed in regulations made under paragraph 14(1)(b) of the *My Health Records Act 2012* as the system operator for the purposes of that Act. The Agency may also undertake functions associated with the Healthcare Identifiers Services, which are set out under the *Healthcare Identifiers Act 2010*.

Sub-items (3) to (6) relate to the performance of the Agency's functions. In carrying out its functions, the Agency is to have regard to relevant intergovernmental agreements, but may also have regard to other matters (sub-items (3) and (4)). Where the Agency provides a service in line with the national digital health work programme, such as the operation of the Individual Healthcare Identifier Service, the National Authentication System for Health, or the development of the specifications for new functions to be added to the national digital health system, it may do so itself, in cooperation with another person, or by arranging for another person to do so on its behalf (sub-item (5)). The Agency may charge fees for things done in performing its functions (sub-item (6)), which may include, for example, where a single jurisdiction has sought the Agency's support for a digital health implementation which is in line with, but not part of, the national digital health work programme.

Item 10 Powers of the Agency

This item empowers the Agency to do all things necessary or convenient to perform its functions conferred under item 9.

Sub-item 10(2) outlines a non-exhaustive list of specific powers that may be exercised by the Agency.

The Agency's powers will allow it to facilitate and participate in public-private partnerships with private sector companies and organisations. However, in exercising its powers to facilitate and participate in public-private partnerships, the Agency would be subject to any directions issued to the Agency by the Minister under item 11.

Item 11 Health Minister may give directions to the Agency

This item enables the Health Minister to give written directions to the Agency in relation to the performance of its functions or the exercise of its powers, which the Agency must comply with (sub-item (4)). Such directions must not relate to a particular individual and must be consistent with the Act and any instrument made under the Act (sub-item (2)).

Reflecting that the Agency is a national body, the Health Minister cannot give a direction to the Agency unless each State/Territory Health Minister has agreed to the giving of the direction (sub-item (3)).

Sub-item (5) provides that this item does not affect the application of section 22 of the Act, which deals with the application of government policy to corporate Commonwealth entities, in relation to the Agency.

Item 12 The Agency does not have privileges and immunities of the Crown

This item provides that the Agency does not have the privileges and immunities of the Crown in right of the Commonwealth, because it is a body corporate which is legally independent from the Commonwealth.

PART 3—THE BOARD

Item 13 Establishment of the Board

This item establishes the Board of the Agency. The Board is the accountable authority of the Agency for the purposes of subsection 12(2) of the Act.

Item 14 Functions of the Board

This item specifies the functions of the Board, which are to decide the objectives, strategies and policies to be followed by the Agency; and to ensure the proper and efficient performance of the Agency's functions conferred under item 9.

Item 15 Minister may give the Board a statement setting out strategic guidance for the Agency

This item provides that the Minister may give the Board a written statement setting out strategic guidance for the Agency, which the Agency must have regard to in the performance of its functions or the exercise of its powers (sub-item (4)). Such a statement must be of a general nature, must not relate to a particular individual, and must be consistent with the Act, the Rule, or any other instrument made under the Act (sub-item (2)).

Reflecting that the Agency is a national body, the Health Minister cannot give a statement unless each State/Territory Health Minister has agreed to the Minister giving the statement (sub-item (3)).

The purpose of this provision is to allow the Commonwealth, States and Territories to communicate their expectations of the Board and the broad strategic direction they expect it to take as it performs its functions.

Item 16 Powers of the Board

This item empowers the Board to do all things necessary or convenient to be done for, or in connection with, the performance of its functions prescribed under item 14. Sub-item (2) provides that anything done in the name of, or on behalf of, the Agency by the Board or with the Board's authority is taken to have been done by the Agency.

Item 17 Delegation by the Board

This item empowers the Board to delegate any or all of its powers or functions in writing to a Board member or the Chief Executive Officer (CEO). The delegate is required to comply with any directions of the Board in exercising any of the powers or performing any functions under the delegation (sub-item (2)).

PART 4—THE BOARD MEMBERS

Item 18 Membership of the Board

This item provides for the Board to consist of a Chair and not fewer than six, but not more than ten, other members. The membership of the Board reflects the intention to establish an independent skills-based Board with a membership extending beyond representatives of government and including key digital health stakeholders.

Item 19 Appointment of Board members

This item provides for the Health Minister to appoint the Board Chair and Board members by written instrument. The Board Chair may be appointed on a full-time or part-time basis (sub-item (1)), while Board members other than the Chair are to be appointed on a part-time basis (sub-item (2)).

Sub-item (3) provides a list of the skills, experience and knowledge that a Board member must have at least one of, such as medical practice, healthcare delivery, delivery of private health services and consumer health advocacy. The Board members combined must also have experience and expertise in Board affairs; corporate governance; risk management; financial literacy; and business leadership and experience at a high level in industry. Sub-item (5) requires that the Health Minister must ensure that the Board members collectively possess an appropriate balance of skills, experience or knowledge listed in sub-item (3) and sub-item 5(b).

After consulting with the Board, the Health Minister may determine other fields in addition to those listed in sub-items (a) to (l), which reflects the level of flexibility needed to ensure that future fields of skills, experience or knowledge can be included on the Board if needed (sub-item 19(3)(m)). A determination made by the Health Minister under sub-item 19(3)(m) must be published on the Commonwealth Department of Health's website as soon as practicable after it is made (sub-item (4)).

Sub-item (6) provides that a Board member is appointed for a period specified in the instrument of appointment, which must not exceed three years.

Sub-item (7) provides that the Board member mentioned in sub-item 20(2) with skills, experience or knowledge in developing, implementing and managing national digital health policies, strategies and services (sub-item 19(3)(g)) ceases to hold office as a

Board member if he or she ceases to be an officer in the Senior Executive Service (SES) of the Commonwealth Department of Health.

Sub-item (8) provides that the performance of the functions or the exercise of the powers of the Board is not affected if the number of members falls below 7 members (which is the minimum number allowed under item 18) for a period of not more than six months.

Item 20 Prerequisites and procedures for appointment of Board members

This item sets out the requirements for the appointment of Board members including the Board Chair.

Sub-item (2) provides that one of the Board members must have the skills, experience or knowledge in developing, implementing and managing national digital health policies, strategies and services (sub-item 19(3)(g)), and must be an SES officer of the Commonwealth Department of Health nominated in writing by the Secretary of the Department. This requirement reflects the significance of the position and that only an SES officer at the Commonwealth level would possess the skills, experience or knowledge necessary to carry out the relevant responsibilities.

Sub-item (3) provides that one of the Board members must have the skills, experience, or knowledge in managing and delivering digital health systems in State and Territory health facilities (sub-item 19(3)(k)), and must be nominated in writing by the Australian Health Ministers' Advisory Council.

Sub-item (4) provides that one of the Board members must have the skills, experience or knowledge in leadership and management in the delivery of traditional and digital health services that are managed, operated or provide by a State or Territory government ((sub-item 19(3)(l)), and must be nominated in writing by the Australian Health Ministers' Advisory Council.

Sub-item (5) provides that before appointing a Board member the Health Minister must seek the support of all State/Territory Health Ministers and be satisfied that the appointment is supported by a majority of State/Territory Ministers. Under sub-item (6), if the Health Minister does not receive majority support from State/Territory Health Ministers, within 30 days of seeking their support, and the Health Minister is satisfied that it is not possible to make the proposed appointment, or it is not known whether the appointment can be made, in accordance with sub-item (5) then the Health Minister may make the appointment.

Sub-item (7) provides that the Health Minister must notify in writing all the State/Territory Health Ministers of the appointment as soon as practicable after making an appointment under sub-item (6).

Item 21 Acting Board Chair

This item provides for the Health Minister to appoint, by written instrument, a Board member to act as the Board Chair. This can be done during a vacancy in the office of the Board Chair due to the Board Chair being absent from duty or is unable to perform the duties of the office.

Sub-item (2) provides that the Minister must notify each State/Territory Health Minister as soon as practicable after appointing a Board member to act as the Board Chair after making the appointment.

The note to this item assists the reader by providing a reference to the acting appointment provisions in the *Acts Interpretation Act 1901*.

Item 22 Acting Board members

This item provides for the Health Minister to appoint, by written instrument, a person to act as a Board member apart from the Board Chair. This can be done during a vacancy in the office of a Board member; or during any period when a Board member is acting as the Board Chair, is absent from duty, or is unable to perform the duties of the office of Board member.

Sub-item (2) provides that the Minister must notify each State/Territory Health Minister as soon as practicable after appointing a Board member to act as the Board member after making the appointment.

A person must not be appointed to act as a Board member other than the Board Chair for more than six months (sub-item (3)), and is not eligible for appointment to act as a Board member unless the person is eligible for appointment as a Board member under sub-item 19(3) (sub-item (4)).

The note to this item assists the reader by providing a reference to the acting appointment provisions in the *Acts Interpretation Act 1901*.

Item 23 Remuneration of Board members

This item provides that the remuneration of Board members is to be determined by the Remuneration Tribunal, or by remuneration that is determined by the Health Minister by written instrument if there is no determination by the Remuneration Tribunal (sub-item (1)). Sub-item (2) provides that members are to be paid allowances that are determined by the Health Minister by written instrument, and sub-item (3) makes clear that this item is subject to the *Remuneration Tribunal Act 1973*.

Sub-item (4) provides that a Board member is not entitled to be paid remuneration if they are employed on a full-time basis in the service or employment of either a State; a State public statutory corporation; a tertiary education institution; a company limited by guarantee or a company in which all the stock or shares are beneficially owned by a State or by a public statutory corporation. A similar rule set out in subsection 7(11) of the *Remuneration Tribunal Act 1973* applies to a Board or committee member who has a similar relationship with the Commonwealth or a Territory.

The prescribing of remuneration and allowances, to the extent that it is not covered by the *Remuneration Tribunal Act*, is done by way of a legislative instrument (sub-item (5)).

Item 24 Leave for Board members

Sub-item (1) provides that a person who is appointed as the Board Chair on a full-time basis is entitled to the recreation leave entitlements that are determined by

the Remuneration Tribunal; and that the Health Minister may grant a full-time Board Chair leave of absence, other than recreation leave, on the terms and conditions as to remuneration or otherwise as the Health Minister determines.

A person appointed as the Board Chair on a part-time basis may be granted leave of absence by the Health Minister on terms and conditions determined by the Minister (sub-item (2)).

The Board Chair may grant leave of absence to another Board member and determine the terms and conditions of the leave (sub-item (3)). Sub-item (4) provides that if the Board member's leave of absence exceeds three months, the Board Chair must notify the Health Minister and all the State/Territory Health Ministers.

Item 25 Restrictions on outside employment

This item provides for restrictions on the Board Chair and other Board members employment outside of the Agency.

Sub-item (1) provides that a full-time Board Chair must not engage in paid employment outside of the duties of the Board Chair without the Health Minister's approval. A part-time Board Chair (sub-item (2)) and Board members (sub-item (3)) must not engage in any paid employment that the Health Minister considers to conflict (or could conflict) with the proper performance of their duties.

Item 26 Resignation of Board members

This item provides for the resignation of Board members through written resignation to the Health Minister (sub-item (1)). Any such resignation is effective from either the day the Minister receives the written notice or a later date if specified in the resignation (sub-item (2)).

Item 27 Termination of appointments of Board members

This item provides for the Health Minister, after deciding that the majority of State/Territory Health Ministers (sub-item (3)) support termination, to terminate the appointment of a Board member due to the specified circumstances outlined in sub-item (1) of the Rule. Sub-item (1) specifies the circumstances in which the Minister **may** terminate an appointment and sub-item (2) specifies the circumstances in which the Minister **must** terminate an appointment, including bankruptcy and unexplained absenteeism. Under sub-item (4) the Health Minister may terminate the appointment, under sub-item (1), if the Health Minister sought the support of the State/Territory Health Ministers but after 30 days, the Health Minister is satisfied that it is not possible to terminate the proposed appointment in accordance with sub-item (3), or it is not known whether the appointment can be terminated in accordance with that sub-item.

Sub-item (5) provides that the Health Minister must notify in writing all the State/Territory Health Ministers of the termination as soon as practicable after terminating the appointment.

Item 28 Other terms and conditions of Board members

This item provides for the Health Minister to determine other terms and conditions of appointment in relation to matters not covered by the instrument.

PART 5—PROCEDURES OF THE BOARD

Item 29 Convening of meetings

This item sets out the requirements for the Board Chair to convene meetings of the Board. A minimum of four Board meetings must be convened by the Board Chair each year (sub-item (2)). The Board Chair must convene Board meetings that are necessary for the efficient conduct of its affairs (sub-item (1)), and must convene a Board meeting if requested to do so by the Health Minister (sub-item (3)), or on receipt of a written request signed by a majority of the Board members (sub-item (4)).

Item 30 Quorum

This item provides that a quorum is established at a Board meeting if a majority of Board members, for the time being holding office, are present. This ensures that the Board can continue to function where some members are not able to attend meetings.

If a Board member is required not to be present while a matter is being considered (refer section 15 of the *Public Governance, Performance and Accountability Rule 2014*), or not to vote on a matter that is being considered which results in a quorum no longer being present, then the Board members remaining at the meeting constitute the quorum (sub-item (2)) for that matter.

Item 31 Presiding at meetings

This item provides that the Chair of the Board is to preside at all Board meetings at which he or she is present (sub-item (1)). Where the Chair is not present, a Board member elected by the Board members present is to preside (sub-item (2)).

Item 32 Voting at meetings

This item provides for Board decisions to be made on a majority basis (sub-item (1)), with the Board member presiding at the meeting having a deliberative vote, and the casting vote in the event that votes are equal (sub-item (2)).

Item 33 Minutes

This item specifies that the Board is to keep records of its meetings.

Item 34 Conduct of meetings

This item provides that the Board may regulate conduct of its meetings as it thinks fit.

The note to this item assists the reader by providing a reference to provisions of the *Public Governance, Performance and Accountability Rule 2014* (which deal with the consequence of a Board member having a material personal interest, and may affect

whether a Board member can be present at a meeting and vote in relation to a matter) and, in relation to participating in meetings, the *Acts Interpretation Act 1901*.

Item 35 Decisions without meetings

This item provides for decisions of the Board to be made without a formal meeting in the specified circumstances (sub-item (1)). A decision without a meeting cannot be made unless the Board has determined a method by which such a decision is to be made (sub-item (2)). A Board member is not entitled to vote in a decision without a meeting if that Board member would not have been entitled to vote on that proposal in a meeting of the Board (sub-item (3)). The Board must keep a record of all decisions made in accordance with this item (sub-item (4)).

PART 6—ADVISORY COMMITTEES

Division 1 – Establishing advisory committees

Subdivision A – Standing advisory committees

Part 6 establishes four technical advisory committees, and the power for the Board to create other advisory committees to support the Agency Board.

The establishment of the four standing advisory committees will embed jurisdictional representation and a mechanism for facilitating greater industry engagement within the Agency's governance framework.

Item 36 Standing advisory committees

This item provides for the Clinical and Technical Advisory Committee, the Jurisdictional Advisory Committee, the Consumer Advisory Committee, and the Privacy and Security Advisory Committee to be established (sub-item (1)). A member of a committee (other than a Board member) is to be appointed in writing by the Board (sub-item (2)) on a part-time basis and for a period not exceeding three years (sub-item (4)). The Board must consult with the Health Minister and all the State/Territory Health Ministers before appointing a committee member (sub-item (3)).

Sub-item (5) provides that a committee must comply with directions given by the Board (in relation to assistance that the committee is to provide to the Board).

Item 37 Acting standing advisory committee members

This item provides for the Board Chair to appoint, in writing, a person to act as a committee member of a standing advisory committee when there is a vacancy in the office of a committee member, or during a period when a committee member is absent from duty or unable to perform their duties (sub-item (1)). A person must not be appointed as an acting member of a standing advisory committee for more than a six month period (sub-item (2)) and is not eligible for appointment unless the person is also eligible for appointment as a member of the committee (sub-item (3)).

Item 38 Remuneration and allowances of standing advisory committee members

This item provides that the remuneration of standing advisory committee members (other than the Jurisdictional Advisory Committee) is to be determined by the Remuneration Tribunal (sub-item (1)). If no determination by the Tribunal is in operation, the member is to be paid remuneration which is determined by the Health Minister by legislative instrument under sub-item (5).

Sub-item (2) provides that the allowances of standing advisory committee members (other than the Jurisdictional Advisory Committee) are to be determined by the Health Minister by legislative instrument under sub-item (5).

Sub-item (3) makes clear that this provision is subject to the *Remuneration Tribunal Act 1973*.

Sub-item (4) provides that a standing advisory committee member is not entitled to be paid remuneration if he or she holds an office or appointment, or is employed on a full-time basis in the service of employment of a State; a State public statutory corporation; a tertiary education institution; a company limited by guarantee; or a company where all the stock or shares are beneficially owned by a State or by a public statutory corporation. A similar rule set out in subsection 7(11) of the *Remuneration Tribunal Act 1973* applies to a Board or committee member who has a similar relationship with the Commonwealth or a Territory.

Sub-item (6) states that an office of a Jurisdictional Advisory Committee member is not a public office under Part II of the *Remuneration Tribunal Act 1973*.

Item 39 Leave for members of standing advisory committees

This item provides for the Board Chair to grant members of a standing advisory committee leave of absence and to determine the terms and conditions of the leave (sub-item (1)). The Board Chair is required to notify the Health Minister and all State/Territory Health Ministers if he or she grants leave of absence greater than three months (sub-item (2)).

Item 40 Outside employment

This item provides that a standing advisory committee member must not engage in any paid employment that, in the Board's opinion, conflicts, or may conflict, with the proper performance of the standing advisory committee member's duties.

Item 41 Resignation of standing advisory committee members

This item provides for the resignation of standing advisory committee members through written resignation to the Board Chair (sub-item (1)). Any such resignation is effective from either the day the Board Chair receives the written notice or a later date if specified in the resignation (sub-item (2)).

Item 42 Termination of appointments of standing advisory committee members

This item provides for the Board, following consultation with the Health Minister and all State/Territory Health Ministers (sub-item (2)), other than the Jurisdictional Advisory Committee (sub-item 3), to terminate the appointment of a standing advisory committee member. Sub-item (1) specifies the circumstances in which the Board Chair **may** terminate an appointment.

Sub-item (3) provides for circumstances where the Board Chair **must not** terminate the appointment of a member of the Jurisdictional Advisory Committee.

Subdivision B – Other advisory committees

Item 43 Board may establish advisory committee

This item provides that the Board may establish such advisory committees as the Board considers appropriate to advise the Board on the performance of the Agency's functions (sub-item (1)). The committee's terms of reference; terms and conditions of appointment of the committee members; and the procedures to the followed by the committee may be determined by the Board (sub-item (2)). Consistent with the evolving nature of the national digital health agenda, this provision provides the Agency with the flexibility to establish other advisory committees to provide advice to the Board on the Agency's functions, should the need arise.

Sub-item (3) specifies that the committee can be constituted wholly by Board members, wholly by persons who are not Board members, or a combination of both.

An advisory committee established under this item must comply with any directions issued by the Board in relation to any assistance that the committee is to provide to the Board (sub-item (4)).

Division 2 – Clinical and Technical Advisory Committee

Item 44 Membership of Clinical and Technical Advisory Committee

This item provides that the Clinical and Technical Advisory Committee consists of a Board member and up to ten other members (sub-item (1)).

Sub-item (2) provides that, in the first instance, the Board member of the Clinical and Technical Advisory Committee, who is to be the Chair of this Committee (sub-item (4)), is the Board member with the skills, experience or knowledge in medical practice (sub-item 19(3)(a)). It is expected that this Board member will have significant clinical skills as a practising clinician, which will assist this committee in the provision of current clinical advice.

Sub-item (3) outlines the eligibility requirements for the appointment of other Clinical and Technical Advisory Committee members. The list of eligibility requirements provides for the necessary range of skills, experience, knowledge and qualifications in a broad range of clinical, healthcare provider and technical fields to allow the Clinical and Technical Advisory Committee to collectively provide advice to the Board which is reflective of the digital health sector and key digital health stakeholder groups.

Sub-item (5) provides that the Clinical and Advisory Committee may determine its own procedures subject to this item and any written directions of the Board.

Item 45 Functions of Clinical and Technical Advisory Committee

This item outlines the functions of the Clinical and Technical Advisory Committee.

The functions of the Clinical and Technical Advisory Committee are:

- providing advice on the efficient and effective delivery of clinical care through the use of digital health, which may include a range of digital health systems and solutions;
- providing advice to the Board about the architectural integration of digital health systems (including the integration of digital health systems and solutions to ensure their interoperability);
- making recommendations to the Board in relation to priorities for investment in, and development and implementation of, national digital health systems;
- providing advice to the Board on changes (which may include improvements) to the design of digital health systems to improve the useability and usefulness of digital health systems for clinicians and health consumers; and
- providing advice to the Board on proposed improvements to digital health systems to improve their usability for clinicians and users of the systems, including health consumers.

Division 3 – Jurisdictional Advisory Committee

Item 46 Membership of Jurisdictional Advisory Committee

This item provides that the Jurisdictional Advisory Committee consists of a member to represent the Department and a separate member to represent each State and Territory (sub-item (1). The Department representative must be nominated in writing by the Secretary of the Department (sub-item (2)), while the representative from each State and Territory must be nominated in writing by the head of the Health Department of the relevant State or Territory (sub-item (3)).

The Jurisdictional Advisory Committee is to be chaired on a rotating basis by the members representing each State and Territory (sub-item (4)). It may determine its own procedures (which may include procedures around which State and Territory member is to be selected as the rotating Chair) subject to this item and any written directions of the Board (sub-item (5)).

Item 47 Function of Jurisdictional Advisory Committee

This item outlines the function of the Jurisdictional Advisory Committee, which is to provide advice to the Board in order to facilitate national consistency in relation to digital health. This advice may relate to the implementation of measures and strategies to ensure the development of integrated and interoperable national and

jurisdiction-specific digital health systems and solutions. Such advice is also expected to include any matters of interest to the Commonwealth, States and Territories in relation to digital health systems and solutions and their respective priorities for development and implementation.

Division 4 – Consumer Advisory Committee

Item 48 Membership of Consumer Advisory Committee

This item provides that the Consumer Advisory Committee consists of a Board member and up to ten other members (sub-item (1)).

Sub-item (2) provides that the Board member of the Consumer Advisory Committee, who is to be the Chair of this Committee (sub-item (4)), is the Board member with the skills, experience or knowledge in consumer health advocacy (sub-item 19(3)(e)) in the first instance.

Sub-item (3) outlines the eligibility requirements for the appointment of other Consumer Advisory Committee members. The list of eligibility requirements provides for the skills, experience, knowledge and qualifications in a range of consumer health related and clinical fields that are necessary to ensure that the Committee may provide expert advice to the Board on interests and matters of significance to health consumers.

To ensure that the Consumer Advisory Committee is able to provide expert advice in relation to digital health consumer interests and issues, sub-item (5) requires the Board to ensure that at least half of the members of the Committee are comprised of members with consumer health related skills, experience or knowledge.

Sub-item (6) provides that the Consumer Advisory Committee may determine its own procedures subject to this item and any written directions of the Board.

Item 49 Functions of Consumer Advisory Committee

This item outlines the functions of the Consumer Advisory Committee.

The functions of the Consumer Advisory Committee are:

- providing advice to the Board about how to ensure that key messages about digital health are communicated effectively to relevant stakeholders and consumer health groups;

- providing advice and recommendations to the Board about how the interests of minority and special interest groups, such as indigenous health consumers, the disabled, or people with genetic disorders, to ensure that their particular interests and needs are taken into account in the design and implementation of digital health systems; and

- providing advice to the Board about how to establish and maintain effective collaboration between health consumers and health care providers in relation to digital health systems

Sub-item (2) stipulates that the Consumer Advisory Committee must consult with consumer health advocacy experts and expert clinicians to ensure that digital health systems:

- facilitate the use of digital health by consumers;
- enhance efficiency and effectiveness of clinical care; and
- meet the requirements of consumers and clinicians for usability and usefulness.

Division 5 – Privacy and Security Advisory Committee

Item 50 Membership of Privacy and Security Advisory Committee

This item provides that the Privacy and Security Advisory Committee consists of a Board member and up to ten other members (sub-item (1)).

Sub-item (2) provides that the Board member of the Privacy and Security Advisory Committee, who is to be the Chair of this Committee (sub-item (4)), is the Board member with the skills, experience or knowledge in managing developing, implementing and managing national digital health policies, strategies and services. The Chair must also be an SES officer in the Department who is to be nominated by the Secretary of the Department (sub-item 20(2)).

Sub-item (3) outlines the eligibility requirements for the appointment of other Privacy and Security Advisory Committee members. The list of eligibility requirements provides for the skills, experience, knowledge and qualifications in a range of legal, privacy, clinical, and software fields that are necessary to ensure that the Committee may provide expert advice to the Board on privacy and security matters in relation to digital health systems and solutions. Ensuring the privacy and security of digital health systems and solutions is critical to the implementation and delivery of the national digital health agenda.

Sub-item (5) provides that the Privacy and Security Advisory Committee may determine its own procedures subject to this item and any written directions of the Board.

Item 51 Functions of Privacy and Security Advisory Committee

This item outlines the functions of the Privacy and Security Advisory Committee.

The functions of the Privacy and Security Advisory Committee include:

- examining and providing advice and solutions to the Board on legal issues in relation to digital health systems, including copyright, data privacy, confidentiality, data security and legal liability issues;
- making recommendations to the Board about the long-term legal framework of digital health systems;

- monitoring privacy and security issues in relation to digital health systems and providing advice to the Board on the resolution of any problems arising from such issues;

- providing advice and recommendations to the Board in relation to standards (including compliance with standards) relating to privacy and security in relation to digital health systems; and

- providing advice to the Board about privacy and security issues encountered by users of digital health systems.

PART 7—THE CHIEF EXECUTIVE OFFICER

Item 52 Chief Executive Officer

This item specifies that there is to be a Chief Executive Officer (CEO) of the Agency.

Item 53 Role of the CEO

This item sets out the role of the CEO, being the day-to-day administration of the Agency (sub-item (1)), and empowering the CEO to do all things necessary or convenient in performing the role (sub-item (2)). Anything done in the name of, or on behalf of, the Agency by the CEO, or with the CEO's authority, is taken to have been done by the Agency (sub-item (3)).

Item 54 CEO to act in accordance with policies and directions of the Board

This item provides that the CEO is to act in accordance with any policies determined by the Board (sub-item (1)). The CEO must comply with any written directions given to the CEO by the Board in relation to the performance of the CEO's functions (sub-items (2) and (3)). However, the CEO is not required to comply with a direction from the Board to the extent that it relates to the CEO's performance of functions or exercise of powers under the *Public Service Act 1999* (sub-item (4)).

Item 55 Appointment of the CEO

This item provides that the CEO is to be appointed by the Board following consultation with the Health Minister and all State/Territory Health Ministers (sub-item (1)).

The appointment is to be made by written instrument (sub-item (2)) and will be on a full-time basis (sub-item (3)). Sub-item (4) specifies that the CEO is not to be appointed for a period exceeding five years, and that the CEO is not permitted to be a Board member (sub-item (5)).

The note to this item makes reference to section 33AA of the *Acts Interpretation Act 1901* in order to clarify arrangements for the re-appointment of the CEO.

Item 56 Acting CEO

This item provides for the Board to appoint an acting CEO, after consulting the Health Minister (sub-item (1)), during vacancies or absences in the office of the CEO, or where the CEO cannot fulfil his/her duties for a period of time.

The note to this item assists the reader by providing a reference to the appointment provisions in the *Acts Interpretation Act 1901*.

Item 57 Outside employment

This item specifies that the CEO is not to engage in paid employment outside the CEO role without the Board Chair's approval (sub-item (1)) and that the Board Chair must notify the Health Minister of any such approval (sub-item (2)).

Item 58 Disclosure of interests

This item specifies that a disclosure made under section 29 of the Act by the CEO regarding disclosure of interests must be made to the Board.

Item 59 Remuneration of the CEO

This item provides that the remuneration of the CEO is to be determined by the Remuneration Tribunal. If no determination by the Tribunal is in operation, the member is to be paid remuneration and allowances which are determined by the Health Minister by legislative instrument made under sub-item (4).

Sub-item (3) makes clear that this provision is subject to the *Remuneration Tribunal Act 1973*.

Item 60 Leave for the CEO

This item provides for the CEO's recreation leave entitlements to be determined by the Remuneration Tribunal (sub-item (1)). It also provides that the Board Chair may grant, and determine the conditions of, other leave of absence (sub-item (2)) and requires the Board Chair to notify the Health Minister if granting the CEO leave of more than one month (sub-item (3)).

Item 61 Resignation of the CEO

This item provides for the CEO to resign by giving a written resignation to the Board Chair (sub-item (1)). Such resignation is effective from either the day the Board Chair receives the written notice or a later date specified in the resignation (sub-item (2)). The Board Chair is required to notify the Health Minister if the CEO resigns (sub-item (3)).

Item 62 Termination of appointment of the CEO

This item provides for the Board to terminate the appointment of the CEO due to specified circumstances. The Board **may** terminate the appointment of the CEO for reasons including misbehaviour, physical or mental incapacity, for unsatisfactory performance as determined by the Board, or if the CEO becomes bankrupt, initiates

bankruptcy procedures, compounds with one or more creditors, provides an assignment of his or her remuneration for the benefit of one or more of his or her creditors, is absent except on leave for the specified periods, fails to comply with section 29 of the Act or section 16 of the *Public Governance, Performance and Accountability Rule 2014*, or engages in paid employment outside the duties of his or her office without the approval of the Board Chair (sub-item (1)).

The Board is required to notify the Health Minister and each State/Territory Health Minister if it is considering terminating the appointment of the CEO (sub-item (2)), and if it proceeds with the termination, the Board must notify the Health Minister and each State/Territory Health Minister (sub-item (3)).

Item 63 Other terms and conditions of the CEO

This item provides for the Board to determine other terms and conditions of the CEO's employment that are not covered in the instrument.

PART 8—STAFF AND CONSULTANTS

Item 64 Staff of Agency etc.

This item provides for the engagement of two categories of employees, including:

- staff engaged as public servants under the *Public Service Act 1999*; and
- other persons who may be employed by the Agency under written agreements.

Sub-item (1) provides that the staff of the Agency are to be engaged as public servants under the *Public Service Act 1999*.

Sub-item (2) specifies that the CEO and Agency staff engaged as public servants under the *Public Service Act 1999* constitute a Statutory Agency, and the CEO is the Head of that Statutory Agency for the purposes of the *Public Service Act 1999*.

Sub-item (3) provides that, in addition to staff engaged as public servants under the *Public Service Act 1999* (sub-item (1)), the Agency may employ other persons outside the *Public Service Act 1999* through written agreements where the Agency considers it necessary for the performance or exercise of the Agency's functions or powers. The terms and conditions of these persons are such as the Agency determines from time to time (sub-item (4)). The Board may choose to establish a policy under item 14 of this Rule to inform the Agency of when employing staff under this provision is appropriate.

Item 65 Services of other persons to be made available to the Agency

This item provides that the Agency may arrange for the services of employees of Commonwealth Agencies or employees of State/Territory governments to assist the Agency in the performance of its functions.

Item 66 Consultants

This item provides that the Agency may engage consultants to assist in the performance of its functions and the exercise of its powers. Sub-item (2) provides that the terms and conditions of the consultant's engagement are to be determined in writing by the Agency.

PART 9—REPORTING

Item 67 Sharing information with other jurisdictions

This item sets out a comprehensive framework for the sharing of information with all States and Territories, which reflects the inter-jurisdictional nature of the governance arrangements of the Agency. It allows State/Territory Health Minister to request access to a range of prescribed reports, documents or information to ensure full transparency and accountability of the Agency's activities and operations to all jurisdictions. The Commonwealth Health Minister has equivalent powers to request reports, documents and information under section 19 of the Act.

Sub-item (1) prescribes the Agency for the purposes of paragraph 82(a) of the Act, and each State/Territory Health Minister is prescribed as a State/Territory Health Minister for the Agency for the purposes of paragraph 82(b) of the Act (sub-item (2)).

Sub-item (3) prescribes the range of reports, documents and information which relate to the Agency's activities for the purposes of paragraph 82(c) of the Act. These include a range of reports, documents and information that the Agency will be required to prepare under the Act, and also reports and recommendations prepared by a standing advisory committee for consideration by the Board (sub-item (3)(g)). It is intended that the reports and recommendations that would fall within the scope of sub-item (3)(g) would include final versions of reports and recommendations prepared by a standing advisory committee for consideration by the Board, and would not include less substantive documents or advice, or other documents or information of a deliberative nature.

Sub-item (4) prescribes the circumstances for the purposes of paragraph 82(d) of the Act in which in which a prescribed State/Territory Health Minister may request prescribed reports documents and information.

Item 68 Board must advise State/Territory Ministers of availability of reports, documents and information

This item provides that the Board must, as soon as practicable, inform each State/Territory Health Minister that he or she may request the prescribed report, document or information referred to in item 67.

Item 69 Board must provide reports, documents and information if requested

This item provides that if a prescribed report, document or information is requested by the State/Territory Health Minister it must be given to the State/Territory Health Minister within 30 days of the State/Territory Health Minister's request.

Item 70 Board must prepare a national digital health work program

This item provides that the Board must prepare a national digital health work programme for each financial year (sub-item (1)). The work programme must be prepared within 3 months during the financial year in which the Board is first appointed, and for each following financial year, before 31 March of that year (sub-item (2)). However, the Ministerial Council may approve a later date for the preparation of a national digital health work programme (sub-item (3)).

The national digital health work programme will comprise activities to deliver, operate, maintain and evolve the national digital health architecture, infrastructure, services, foundations, solutions design and development to facilitate digital information sharing across the Australian health care system. These include, but are not limited to, the *My Health Record*, the Healthcare Identifiers Service, the National Authentication Service for Health, the National Health Services Directory, the Clinical Terminology and Health Informatics Service, eHealth Reference and Testing Platform Service, Supply Chain Services, Secure Messaging Delivery and National Product Catalogue.

The Ministerial Council will be responsible for approving the national digital health work programme prepared by the Agency.

PART 10—FINANCE

Item 71 Application of money by the Agency

This item provides that the money of the Agency is only to be applied in payment or discharge of the costs, expenses and other obligations incurred or undertaken by the Agency in the performance of its functions and the exercise of its powers or in payment of any specified remuneration or allowances.

Sub-item (2) provides that sub-item (1) does not prevent investment, in accordance with section 59 of the Act, of any money that is not immediately required for the Agency's purposes.

PART 11—TRANSITIONAL

Division 1 – Preliminary

Item 72 Definitions

This item sets out definitions of terms that are relied upon in Part 11.

Item 73 Transfer day

This item provides that the Health Minister may, by notifiable instrument, specify a day (after the day on which the instrument commences) to be the transfer day for the purposes of Part 11.

Division 2 – Transfer of assets and liabilities of NEHTA Limited

Item 74 NEHTA Limited assets and liabilities

This item provides that the assets and liabilities of NEHTA Limited will cease to be assets and liabilities of NEHTA Limited and will become the assets and liabilities of the Agency on the transfer day.

The note to this item states that any liability, including any actual, contingent or prospective liability to pay a Commonwealth tax that arises at the time with the transfer of assets and liabilities from NEHTA Limited to the Agency on transfer day under item 74, is, in addition to liabilities that arose before transfer day, transferred to the Agency.

Item 75 Transfer of custody of records or documents of NEHTA Limited

This item applies to a record or document that was in the custody of NEHTA Limited immediately before the transfer day.

Sub-item (2) provides that if the record or document relates to an asset or liability that becomes an asset or liability of the Agency then the record or document is to be transferred into the custody of the Agency on or after the transfer day.

Item 76 Certificates relating to vesting of land

This item applies to any land that would vest in the Agency under Part 11 and there is a certificate lodged with a land registration official that is signed by the Health Minister, identifies the land and states that the land has become vested in the Agency.

Sub-item (2) provides that the land registration official may register the matter in a way in which dealings of that kind are registered and give effect to the certificate.

Item 77 Certificates for vesting of assets other than land

This item applies to an asset other than land that vests in the Agency under Part 11 and there is a certificate lodged with an assets official that is signed by the Health Minister, identifies the asset and states that the asset has become vested in the Agency.

Sub-item (2) provides that the assets official may deal with the certificate as if it were a proper and appropriate instrument for transactions in relation to assets of that kind, that is, as if it was registered, and make such entries in the register in relation to assets of that kind.

Division 3 – Transfer of other matters relating to NEHTA Limited

Item 78 Acts of NEHTA Limited to be attributed to the Agency

This item provides that anything done by NEHTA Limited before the transfer day has the effect, at and after that day, as if it has been done by, or in relation to, the Agency.

Item 79 Legal proceedings of NEHTA Limited

This item relates to any proceedings that were pending in a court or tribunal immediately before the transfer day and to which NEHTA Limited was a party. Sub-item (2) provides that on and after the transfer day, the Agency is substituted for NEHTA Limited as a party to the proceedings.

Sub-item (3) provides that, without limiting subsections (1) and (2), the Agency is substituted for NEHTA as an opponent in opposition proceedings before the Commissioner of Patents, despite regulation 5.15 of the *Patents Regulations 1991*. Regulation 5.15 deals with the circumstances in which an opponent in opposition proceedings may be transferred to a new opponent.

Item 80 References in instruments to NEHTA Limited

This item relates to instruments that are in force immediately before the transfer day and contain a reference to NEHTA Limited.

Sub-item (2) provides that an instrument relating to an asset or liability containing a reference to NEHTA Limited has effect, at and after the transfer day, as if it were a reference to the Agency.

Sub-item (3) provides that this item does not prevent the instrument from being varied or terminated on or after the transfer day.

Division 4 – Other matters

Item 81 Exemption from stamp duty and other State or Territory taxes

This item specifies that the Agency is not subject to taxation under any State or Territory law in respect of an exempt matter, or anything connected with an exempt matter.

An exempt matter is the vesting of an asset or liability under Part 11, or the operation of the Rule in any other respect (sub-item (2)). The Health Minister may certify that a matter is exempt in writing or that a specified thing was connected with an exempt matter (sub-item (3)).

Item 82 Certificates taken to be authentic

This item provides that a certificate provided in items 76, 77 or 81 is authentic unless the contrary view is established.

Item 83 First appointments to standing advisory committees

This item provides for the Health Minister to appoint the first members of each standing advisory committee (sub-item (1)) after consulting all the State/Territory Health Ministers (sub-item (2)). Sub-item (3) provides that the member is appointed on a part-time basis and for a period no greater than three years.

Item 84 Compensation for acquisition of property

This item specifies that the Commonwealth is liable to pay a reasonable amount of compensation if the operation of Part 11 results in an acquisition of property (sub-item (1)). If the Commonwealth and the person do not agree on the amount of compensation, the person may institute proceedings for the recovery of reasonable compensation as the court determines (sub-item (2)).

Regulatory Impact Statement

The Office of Best Practice Regulation has advised that a Regulation Impact Statement is not required (OBPR Reference 16442). A Regulation Impact Statement was prepared which supported the establishment of new governance arrangements, and is available at http://ris.dpmc.gov.au/2015/07/21/proposed-changes-to-the-personally-controlled-electronic-health-record-system/.

Statement of Compatibility with Human Rights

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

Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016

Overview of the Legislative Instrument

The *Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016* (the Rule) will establish the Australian Digital Health Agency (the Agency) as a body corporate which will be legally separate from the Commonwealth.

The Rule is made by the Commonwealth Minister for Finance under section 87 of the *Public Governance, Performance and Accountability Act 2013* (the Act). This section provides for rules to be created to establish a new corporate Commonwealth entity.

The Rule provides for the Agency's purpose, functions, powers, Board and advisory committee arrangements, accountability and transparency mechanisms, staffing arrangements, reporting obligations, funding mechanisms, and consultation requirements.

The Rule also provides for membership of the Agency's Board to be skill-based with an appropriate balance of skills, experience or knowledge in fields such as medical practice, healthcare delivery, delivery of private health services and consumer health advocacy. A person will be eligible for appointment as a Board member only if the Health Minister is satisfied that the person has the necessary skills, experience or knowledge.

The Rule outlines the Agency's functions, which include:

- coordinating, and providing input into, the ongoing development of the National Digital Health Strategy (sub-item 9(1)(a));

- implementing aspects of the National Digital Health Strategy as directed by the Ministerial Council (sub-item 9(1)(b));

- developing, implementing, managing, operating and continuously innovating and improving specifications, standards, systems and services in relation to digital health, consistent with the national digital health work programme (sub-item 9(1)(c));

- developing, implementing, and operating comprehensive and effective clinical governance, using a whole of system approach, to ensure clinical safety in the delivery of the national digital health work program (sub-item 9(1)(d));

- developing, monitoring and managing specifications and standards to maximise effective interoperability of public and private sector digital health systems (sub-item 9(1)(e));

- developing and implementing compliance approaches in relation to the adoption of agreed specifications and standards relating to digital health (sub-item 9(1)(f));

- liaising and cooperating with overseas and international bodies on matters relating to digital health (sub-item 9(1)(g));

- undertaking such other functions as are conferred on the Agency by the Rule or by any other law of the Commonwealth (sub-item 9(1)(h)); and

- undertaking anything incidental to or conducive to the performance of any of the functions conferred on the Agency (sub-item 9(1)(i)).

Human Rights Implications

The Governance arrangements of the Agency have been developed with significant industry and community stakeholder consultation. Consultation with a broad spectrum of stakeholders in developing the governance structure of the Agency limits the likelihood that individuals will be negatively impacted by the establishment of the corporate Commonwealth entity.

The Rule supports the right to health by ensuring that the My Health Record system becomes an integral part of the Australian health system leading to more effective healthcare and a more sustainable health system.

The Rule is compatible with human rights to the extent that it promotes certain rights, such as:

- right to health, by facilitating the sharing of information between healthcare providers and placing the individual at the centre of their healthcare needs (Article 12(1) of the *International Covenant on Economic, Social and Cultural Rights*);
- rights of people with a disability, by establishing a governance model which will take into account the interests of the disabled and other minority groups (Article 12 of the *Convention on the Rights of Persons with Disabilities*); and
- freedom of expression, by reducing health information fragmentation and allowing individuals to more readily access their own health information (Article 19 of the *International Covenant on Civil and Political Rights*).

The Rule is likely to only have a limited impact on individuals' rights as it does not impose restrictions on individuals.

Minister for Finance, Senator the Hon Mathias Hubert Paul Cormann