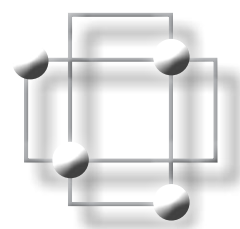


**Proposed Regulations  
for the  
Healthcare Identifiers Service**



**CONSULTATION PAPER**

**MARCH 2010**

Issued by the



**Australian Health Ministers' Advisory Council**

**Proposed Regulations for the Healthcare Identifiers Service  
Consultation Paper  
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# 1. Executive Summary

The Healthcare Identifiers Bill 2010 ('the Bill') was introduced into Parliament on 10 February 2010 by the Minister for Health and Ageing, the Hon. Nicola Roxon MP.

The Bill outlines the framework for a national Healthcare Identifiers Service (HI Service) which is required to provide a reliable means for identifying healthcare providers and consumers to improve information management and facilitate electronic communication between healthcare providers, and to support national e-health infrastructure.

The Bill supports these activities by:

- allocating functions to the Service Operator to assign, collect and maintain identifiers for individuals, healthcare providers and healthcare organisations;
- authorising the use of existing Medicare Australia infrastructure; and
- prescribing permitted uses and disclosures of healthcare identifiers.

The Bill provides the authority for regulations to be issued to support the operation of the HI Service.

The key areas in which regulations are being developed are to prescribe the classes of healthcare providers who can be assigned identifiers and to ensure appropriate security and access requirements are established for the HI Service.

This paper sets out proposals for draft regulations for public consultation, along with an indication of how these requirements are intended to be implemented in practice by the HI Service Operator.

## 2. Introduction and background

The HI Service is being developed to implement and maintain a national system for identifying individuals and healthcare providers.

This initiative was agreed to by the Council of Australian Governments (COAG) in February 2006, and is being designed and developed by NEHTA on behalf of all Australian Governments.

A more reliable and consistent identification system will improve the way information is shared and managed for patients and their providers, across a range of health services.

Unique healthcare identifiers will minimise the likelihood of information being sent to the wrong healthcare provider or being assigned to the wrong patient. It is expected that there will be reduced adverse events and inefficiencies associated with mismatching of patient information. This will bring about significant improvements in the safety and efficiency of the current health system.

In 2007, NEHTA contracted Medicare Australia to scope, design, build and test the HI Service. The design of the HI Service draws on existing elements of Medicare Australia infrastructure including trusted personal information about individuals, consumer Medicare cards, information policies, and customer services such as shop front and online services. For these reasons it has been agreed that Medicare Australia will be the initial Service Operator for the HI Service for the first two years of operation.

In order to implement the HI Service, specific legislative authority is required, both to establish the Service and to permit the use and disclosure of healthcare identifiers in the delivery of healthcare.

In 2008, COAG affirmed its commitment to a national system of healthcare identification and agreed to universally allocate healthcare identifiers for individuals and conduct public consultation on national health privacy legislative proposals, including protections for healthcare identifiers.

On 7 December 2009, COAG agreed to a *National Partnership Agreement on E-Health*, setting out national arrangements to support implementation of healthcare identifiers.

### 3. Consultation on legislative proposals

In July 2009, a *Discussion Paper: Legislative Proposals for Healthcare Identifiers and Privacy* was released seeking comments on proposals to support the establishment and implementation of unique identifiers for healthcare purposes and arrangements to protect the privacy of health information. Over 90 submissions were received from stakeholders, the outcomes of which informed the drafting of the exposure draft Healthcare Identifiers Bill 2010.

From November 2009, further consultation on legislative proposals, including the release of exposure draft legislation was undertaken. Consultation closed on 7 January 2010 with over 50 submissions received. This round of consultation was supported by the release of a paper *Building the Foundation for an E-Health Future— Update of legislative proposals for healthcare identifiers* and feedback informed the final content of the Bill.

Further information on these earlier rounds of consultation, including copies of the submissions received, is available from [www.health.gov.au/ehealth/consultation](http://www.health.gov.au/ehealth/consultation) or the eHealth Branch of the Department of Health and Ageing (see contact details below).

This document has been released to support public consultation on the proposed draft regulations which are proposed to be issued as subordinate legislation to the Healthcare Identifiers Bill 2010. Feedback is sought on the draft regulations (available from the above website) and on any issues for stakeholders that may be raised by the implementation of these proposals. **The closing date for comments is 9 April 2010.**

**Please forward comments on the draft regulations to:**

Draft Regulations for the Healthcare Identifiers Service  
eHealth Branch  
Primary and Ambulatory Care Division (MDP1003)  
Department of Health and Ageing  
GPO Box 9848  
CANBERRA ACT 2601  
  
or [ehealth@health.gov.au](mailto:ehealth@health.gov.au)

If you lodge comments by email, there is no need to send a separate copy by post.

Comments received will be published on the Department of Health and Ageing website, except where confidentiality is requested. Please indicate clearly if you wish all, or part, of your comment to be treated as confidential or anonymous. All confidential material should be clearly marked as 'confidential and not for publication'. Any request under the *Freedom of Information Act 1982* for access to a comment marked 'confidential' will be determined in accordance with that Act.

## 4. The Healthcare Identifiers Service— an overview

There will be three types of healthcare identifiers assigned by the HI Service:

- Individual Healthcare Identifier (IHI)—for individuals receiving healthcare services.
- Healthcare Provider Identifier—Individual (HPI-I)—for healthcare professionals involved in providing patient care.
- Healthcare Provider Identifier—Organisation (HPI-O)—for organisations (such as the hospital or health clinic) where healthcare is provided.

Healthcare identifiers will be provided to all individuals receiving healthcare in Australia. They will be automatically allocated to all individuals that are eligible to receive a Medicare Card or who receive treatment benefits through the Department of Veterans' Affairs (DVA). Individuals not associated with Medicare Australia or the Department of Veterans' Affairs may be issued with a temporary number when they next seek healthcare.

Individual healthcare providers, who meet one of the prescribed classes of providers set out in the regulations, will be able to be assigned a healthcare provider identifier either via their health registration body or directly by the HI Service.

For healthcare organisations, such as hospitals, clinics or individual practices, a healthcare provider identifier may be obtained direct from the HI Service.

The introduction of healthcare identifiers will not change the way individuals currently receive or have access to healthcare services or how information is shared by providers. Any sharing of personal health information will still need to be undertaken in accordance with existing privacy and health information laws in Australia.

Healthcare identifiers have been designed for use within the health sector, with the use being specifically limited to supporting the communication and management of health information as part of:

- Provision of healthcare to an individual
- Management, funding, monitoring or evaluation of healthcare
- Provision of medical indemnity cover for a healthcare provider
- Conduct of research that has been approved by a Human Research Ethics Committee

These permitted uses, and other legislative protections, are set out in more detail in the next section.



## 5. Legislation

The regulatory framework to establish and maintain a national healthcare identifier system consists of a number of key elements:

- Primary legislation—the Healthcare Identifiers Bill 2010
- Secondary legislation—Regulations issued under the Bill

The legislation will be supported by operational procedures and guidelines issued and maintained by the Service Operator.

In addition, a *National Partnership Agreement on E-Health* was agreed by COAG in December 2009, and sets out an over-arching governance framework to support the implementation of healthcare identifiers across Australian jurisdictions.

A summary of the key elements of the Bill is provided in this section of the paper, while the next section outlines the proposed regulations and the types of issues that may be addressed in operational guidelines.

The Bill comprises seven parts and includes provisions to allow specific regulations to be made. In summary:

### Part 1—Preliminary

This part of the Bill provides for commencement of the legislation on the day after Royal Assent, outlines the purpose of the HI Service, confirms that the Bill (once enacted) will bind the Crown in right of the Commonwealth and each of the states and territories and Norfolk Island, and contains key definitions.

Section 8 of the Bill provides for regulations to prescribe a registration authority as a 'national registration authority'.

### Part 2—Assigning healthcare identifiers

This part of the Bill authorises the Service Operator to assign healthcare identifiers, and specifies the types of healthcare identifiers that it is able to assign. Part 2 also requires the service operator to establish and maintain accurate records in relation to the HI Service.

Sections 9(1) and 9(5) provide for regulations to prescribe classes of healthcare providers that may be assigned an identifier by the Service Operator, and the requirements for assigning identifiers to these classes.

### **Part 3—Use and disclosure of identifying information for assignment of healthcare identifiers**

Part 3 of the Bill deals with the use and disclosure of healthcare identifiers and contains a number of provisions setting out penalties for unauthorised use or disclosure of healthcare identifiers.

Regulations provided for in this Part include:

- requirements for information that may need to be provided to the Service Operator by a healthcare provider who has been assigned an identifier (Section 14);
- rules that apply to healthcare providers requesting identifiers from the Service Operator (Section 21); and
- information that the Service Operator may request about any disclosures it makes to healthcare providers (Section 22).

### **Part 4—Interaction with the Privacy Act 1988**

Part 4 of the Bill outlines how the legislation interacts with the *Privacy Act 1988*, including the Privacy Commissioner's role in monitoring, compliance, enforcement and reporting activities associated with the HI Service.

### **Part 5—Healthcare Provider Directory**

Part 5 of the Bill requires the service operator to establish and maintain a healthcare provider directory which will list the details of all providers who have been assigned a healthcare identifier and who have consented to having their details included in the directory. The aim of the directory is to facilitate communications between healthcare providers by providing a reliable source of identifying and contact information about other participating healthcare providers.

### **Part 6—Oversight of the Role of the Ministerial Council**

Part 6 of the Bill outlines the role of the Australian Health Ministerial Council in providing oversight of the HI Service, and provides for a review of the legislation to occur before 30 June 2013 and for a report on the review to be tabled in Parliament. Further details on the role of the Ministerial Council in overseeing the HI Service and governance arrangements are contained in the *National Partnerships Agreement (NPA) for e-Health* agreed by COAG in December 2009.

## Part 7—Miscellaneous

Part 7 of the Bill contains a number of miscellaneous provisions, including the scope of authorisation under the legislation, the relationship between the legislation and state and territory laws and provisions designed to ensure that the Constitutional heads of power supporting the legislation are as wide as possible. Finally, Part 7 enables the Governor-General to make regulations which are required, necessary or convenient for the operation of, or giving effect to, the legislation.

## 6. Proposals for Regulations and supporting guidelines

Draft regulations have been developed by the Commonwealth in consultation with state and territory health authorities, NEHTA and Medicare Australia. They are based on policies set out in [the Bill](#), [the Explanatory Memorandum](#) and the NEHTA [Concept of Operations of the Healthcare Identifiers Service](#) (December 2009).

At this stage, regulations will not be made in all the areas identified in the Bill where regulations can be made. Further regulations may be required in the future to address issues that arise following the commencement of the HI Service.

### Overview of the Regulations

#### *a. National registration authorities*

The legislation has been drafted so that identifiers might be assigned to a healthcare provider by either a national registration authority or the Service Operator.

Section 8 of the Bill allows national registration authorities to be prescribed by regulation, which in turn permits those authorities to assign healthcare identifiers to individual healthcare providers under Section 9(2) of the Bill.

It is envisaged that the majority of healthcare providers will be assigned a healthcare identifier as part of their professional registration through the national registration scheme.

To support these arrangements, Regulation 4 prescribes the following national registration authorities:

- a National Health Practitioner Board established under the model Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld), or, in the case of WA, legislation it enacts that corresponds to that National Law; and
- the Australian Health Practitioner Regulation Authority (AHPRA) established by the National Law, if it is authorised to assign identifiers under the National Law.

The *Health Practitioner Regulation National Law Act 2009* is the model law to create a single national registration and accreditation system for the Australian health workforce. It will deliver a range of benefits to the Australian community by:

- Providing for the protection of the public by ensuring that only practitioners who are suitably trained and qualified to practice in a competent and ethical manner are registered;

- Facilitating workforce mobility across Australia and reducing red tape for practitioners;
- Facilitating the provision of high-quality education and training and rigorous and responsive assessment of overseas-trained practitioners;
- Having regard to public interest in promoting access to health services; and
- Having regard to the need to enable the continuous development of a flexible, responsive and sustainable Australian health workforce

Ten health professions will be included in the national system as of 1 July 2010. These are: chiropractors, dental care practitioners, medical practitioners, nurses and midwives, optometrists, osteopaths, pharmacists, physiotherapists, podiatrists and psychologists. A further 4 professions (Aboriginal and Torres Strait Islander health practice, Chinese medicine, medical radiation practice and occupational therapy) have been identified to be covered by 2012.

To give effect to the 'national legislation', each State and Territory must enact its own legislation to recognise the model laws.

It is envisaged that Western Australia will enact legislation that is consistent with the model laws. Regulation 4 is drafted to reflect this.

### ***b. Classes of healthcare providers***

Section 9(1)(a) of the Bill permits the Service Operator to assign healthcare identifiers to certain classes of healthcare providers, as prescribed in the regulations.

The draft regulations describe the classes of providers who may be assigned an identifier by the Service Operator. Regulation 5 prescribes the classes of individual healthcare providers, while regulation 6 prescribes classes of organisation healthcare providers.

It is proposed that the following two classes of individual healthcare providers be prescribed under Regulation 5:

- individuals who are registered by a registration authority as members of a health profession.  
This includes professionals who are registered through state and territory registration arrangements not captured by the national registration processes. A registration authority is defined in the Bill as an entity responsible under a law for registering members of a particular health profession. The regulation would also allow technical arrangements to be established with national registration authorities for the issue of identifiers to professionals under the National Law as part of their professional registration.  
AND
- individual healthcare providers who are members of a professional healthcare association which meets certain criteria outlined in the regulations.

For this class of providers, it is proposed that the professional association's members practice in a profession that relates to the delivery of healthcare, and that the association has admission requirements, standards of practice and ethical conduct, maintains a standing in the profession, has sets of rules and regulations and an ability to impose sanctions and the association has uniform national membership arrangements.

This class has been included to ensure that any health provider not registered under a state or territory law may still be assigned a healthcare identifier provided that they are involved in the delivery of health services and the association he or she belongs to is credible and appropriate. It is expected that a list of professional healthcare associations that meet the prescribed criteria will be developed and maintained for the HI Service.

Regulation 6 prescribes a class of organisation healthcare providers. Under the definition of 'healthcare provider' in section 5 of the Bill, a healthcare provider that is not an individual must be an entity, or a part of an entity, that has conducted, conducts, or will conduct, an enterprise that provides healthcare (including healthcare provided free of charge).

Regulation 6 requires a healthcare provider organisation to:

- employ or contract an individual who is an identified healthcare provider (ie. someone who has been assigned an individual healthcare provider identifier) and provides healthcare as part of his or her duties with the organisation; and
- employ or contract an individual who is a 'responsible officer' and one or more 'organisation maintenance officer'.

A responsible officer is the individual authorised by an organisation to act on its behalf in relation to its dealings with the Service Operator. Organisation maintenance officers maintain information associated with the healthcare provider organisation held by the Service Operator. The same individual may perform the role of responsible officer and organisation maintenance officer for an organisation, as well as being the identified healthcare provider. A self employed healthcare provider would undertake both roles.

### ***c. Information that may be requested before assigning healthcare identifiers***

In addition to prescribing classes of healthcare providers that may be assigned an identifier, the Bill (under Section 9(5)) also permits the regulations to prescribe certain requirements for assigning identifiers.

This requirement is needed to allow the Service Operator to request certain information in order to make a decision on whether it is appropriate to issue a healthcare identifier. As an example, a healthcare provider may be required to provide evidence that they fit one of the prescribed classes outlined above before an identifier is assigned.

Regulation 7 outlines the types of information that may be required before the service operator will assign a healthcare identifier, including:

- **for individual healthcare providers**—information that accurately identifies the individual healthcare provider and shows that the individual falls within one of the classes mentioned in regulation 5.

Documentation to meet these requirements might include evidence that the individual is a health professional registered, permitted or approved under state or territory law to supply a healthcare service, or where there is no relevant state or territory law, is a member of a professional association that has uniform national membership requirements relating to the supply of healthcare services.

- **for organisation healthcare providers**—information that accurately identifies the organisation and shows that it falls within one of the classes mentioned in regulation 6 and details of the responsible officer and organisation maintenance officer.

Documentation to meet these requirements might include accreditation details (for example, for hospitals where mandatory accreditation requirements apply), proof of qualifications and professional registration (where the organisation is a sole trader) and/or a statutory declaration from the organisation stating that it provides a health service.

If required, information must be provided in writing—this may include providing certified copies of original documents, where this is considered necessary. If the service operator or national registration authority requesting the information is not satisfied, the body does not have to assign a healthcare identifier to a healthcare provider.

#### ***d. Information that may be requested after assigning identifiers***

There may be situations where a healthcare provider who has been assigned an identifier by the Service Operator experiences a change of circumstances. It is important that the Service Operator is notified of any such changes, particularly where the change might mean that a healthcare provider no longer falls within one of the prescribed classes of healthcare providers set out in the regulations.

Section 14 of the Bill permits regulations to be made about the information that a healthcare provider who has an identifier may need to provide to the service operator.

Regulation 9 will oblige a healthcare provider who has been assigned an identifier to inform the Service Operator of any change in circumstances, including where this change might mean they no longer fall within a prescribed class of healthcare providers. For example, this obligation will apply to circumstances where a healthcare provider is no longer registered or qualified to act as the type of health professional under which they were issued a healthcare identifier, or for organisations, where the organisation is no longer providing a health service.

A penalty will apply where a healthcare provider fails to inform the Service Operator of any significant changes (such as those outlined above).

***e. Requirements for healthcare providers requesting disclosure of healthcare identifiers***

A healthcare provider who has been issued with an identifier may request healthcare identifiers from the Service Operator for specified purposes set out in the Bill.

To ensure healthcare providers maintain appropriate security measures, including an audit trail of access to the service, Section 21 of the Bill provides that regulations may prescribe rules about requests by healthcare providers to obtain identifiers from the Service Operator.

The key safeguards set out in Regulation 10 place an obligation on healthcare providers to ensure that:

- only individuals acting on behalf of an organisation that are specifically authorised will have access to healthcare identifiers in connection with the provision of healthcare services;
- appropriate security arrangements are in place to protect the information exchanged with, and received from, the Service Operator and that all relevant staff are aware of their obligations under the Bill and regulations; and
- full and accurate records of each person the provider has authorised to access healthcare identifiers from the Service Operator are retained for a specified time period.

It is anticipated that these regulations will be supported by guidelines issued by the Service Operator, on access to and disclosure of healthcare identifiers, based on relevant national standards of data security for the healthcare sector.

Regulation 10 includes a number of penalty provisions. Stakeholder feedback is sought on whether the provision set out in this Regulation are appropriate, including whether they raise any implementation issues for healthcare providers.

***f. Information requested after disclosure of healthcare identifiers***

In certain situations, the Service Operator may need to request information from a healthcare provider; for example, to assist in the investigation of a complaint or enquiry from an individual about access to the individual's records held by the Service Operator.

Section 22 of the Bill allows regulations to require a healthcare provider to make available to the Service Operator certain information about the disclosure of a healthcare identifier to that provider.

Regulation 11 provides that, on request from the Service Operator, a healthcare provider must provide sufficient information to identify the person who accessed the Service, in relation to the disclosure of a healthcare identifier to that provider.



It is recognised that healthcare providers currently work with a wide range of IT and identity management systems that may not at present be able to record details of every individual who requests healthcare identifiers from the HI Service on the organisation's behalf. However, to ensure sufficient certainty for consumers that access to information held about them by the Service Operator will be able to be subject to enquiry and investigation in the event of a suspected unauthorised access, it will be necessary for healthcare providers to make changes to systems and practices that will record all requests to the HI Service at the individual employee level.

In practice, many healthcare providers may be transitioning to an improved state of identity management and security over the next couple of years as uptake of e-health and electronic records systems becomes more widespread. During this period it is important that expectations around standards on rules for interaction with the Service Operator are clearly established from the outset. A penalty has been provided for in Regulation 11 to make clear that these standards will be enforceable.

Consideration is being given to allowing a period of transition for the enforcement of this penalty provision. During this period, the specified penalties would not be actively enforced, except in exceptional circumstances. The focus of this transition period (with a suggested period of 2 years) would be educative, helping providers to incorporate improved identity management standards in their systems. After this period penalties would be enforced.

If such a transition period were in place, this would not remove the requirement from a healthcare provider to make available to the Service Operator on request as much detail as they have on their records about a particular request for a healthcare identifier to assist in any enquiry or investigation. In addition, the transition period is only being proposed in relation to the requirements in Regulation 11. All other penalties provided for in the Bill and the regulations would be enforced from the commencement of the legislation.

Stakeholder feedback is sought on whether a transition period for enforcement of penalties in relation to Regulation 11 is an appropriate way to achieve a balance between ensuring appropriate security and identity management practices are in place to support a healthcare provider's interaction with the HI Service, while at the same time allowing sufficient time for providers to transition IT systems and day to day procedures to reflect these standards.