Privacy Commissioner
Te Mana Matapono Matatapu

Proposed

Amendment No. 7

to the

Health Information Privacy Code 1994

Information Paper

Submissions

Submissions may be emailed to code@privacy.org.nz or mailed to:

Submissions on Amendment 7 to HIPC
Office of the Privacy Commissioner
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Closing date for submissions is 13 April 2012. Any enquiries may be addressed to Sebastian Morgan-Lynch, Senior Policy Adviser (Health) on (04) 474 7593.

29 February 2012

Proposed Amendment No. 7 to the Health Information Privacy Code 1994
Information Paper

Introduction

This paper provides the background to, and the reasoning, behind proposed amendments (Amendment No. 7) to the Health Information Privacy Code (HIPC).

Amendment No. 7:

1. Amends the definition of 'serious threat' to harmonise it with the forthcoming Privacy (Information Sharing) Amendment Bill
2. Permits Medic Alert to use the National Health Index (NHI) number as a unique identifier
3. Permits health agencies to identify health practitioners by their Common Practitioner Number
4. Creates a regulatory regime for information derived from Newborn Metabolic Screening Programme blood spot samples ("Guthrie Cards")

1. Amending the definition of 'serious threat'

Under information privacy principles 10(d) and 11(f) of the Privacy Act 1993, agencies may use or disclose health information where there is a "serious and imminent" threat to a person's life or health or to public health or public safety. This wording is mirrored in rules 10(1)(f) and 11(2)(d) of the HIPC.

The Privacy (Information Sharing) Amendment Bill was introduced to Parliament on 16 August 2011. It will, if it is enacted, modify the "serious and imminent" exception to refer simply to a "serious threat". It will provide that such a threat must be one which "an agency reasonably believes to be a serious threat having regard to all of the following:

(a) the likelihood that the threat will occur; and
(b) the severity of the consequences if the threat occurs; and
(c) the time at which the threat may occur"

This change, which the Privacy Commissioner supports, was based upon a recommendation of the Law Commission after it made a detailed study of the issues.[1]

This Bill has not passed yet. However, if Parliament makes the amendment, it is the Commissioner's view that a similar change should be made to the HIPC.

This change is important to both patients and practitioners. The significance of the phrase "serious and imminent threat" in a clinical context is that it marks the point at which sensitive information may be disclosed in spite of a relationship of confidentiality.

This proposed change is being notified ahead of the Bill's passage through parliament. This will enable the Commissioner to complete a public submission process in order to be in a position to be ready to make the change if, and when, the bill is enacted without undue delay. However, the Commissioner does not intend to issue this part of the amendment to

[1] The Law Commission's report may be read at http://bit.ly/rvilr0. A summary of its recommendations is available at http://bit.ly/vfHMnd.

the code before Parliament has passed the Bill. If the Bill is substantially delayed in the parliamentary process the Commissioner will consider splitting this part of the code amendment off to pass at a date later than the rest of the amendment.

2. Permitting health agencies to identify health practitioners by their Common Practitioner Number

Unique identifiers in the health sector are regulated in various ways by rule 12. Specifically, rule 12(1) prohibits a health agency from 'assigning' (using), a unique identifier that has already been assigned by another agency.

For example, a doctor could not list her patients by IRD number as that unique identifier would have previously assigned to them by the IRD.

Rule 12 contains exceptions to this general prohibition. Rule 12(4) allows a health agency such as a hospital to identify a health practitioner by the identifier assigned them by their professional body. This allows a General Practitioner to be legitimately identified in hospital records by their Medical Council registration number, for example.

The Health Practitioner Index is a national register of health practitioners being developed by the Ministry of Health. When it is fully implemented health practitioners will all have a Common Practitioner Number (CPN) assigned to them by the Ministry and used to identify them for payment and service monitoring purposes.

The CPN indicates with a high degree of certainty when a health professional has provided services, transferred or received medical records. The use of the CPN also allows patients who obtain their own records to see exactly who has been involved in their care.

Under the law as it stands, the use of the CPN by a hospital, surgical practice or other health agency to uniquely identify a health practitioner would breach rule 12(1). This amendment changes that by permitting health agencies to assign a practitioner's CPN for their own purposes.

3. Permitting Medic Alert to use the National Health Index (NHI) number as a unique identifier

Rule 12(3) holds the other major exception to the prohibition on assignment of unique identifiers. Rule 12(3) allows any agency or class of agency listed in Schedule 2 to assign the National Health Index number to any person, as long as that person's identity has been clearly established and the assignment is necessary for the agency to carry out its functions.

Schedule 2 includes nearly all agencies that might be considered part of the health sector, including District Health Boards, hospitals, health practitioners, ACC as well as any agency that has a government contract to provide health services.[2]

MedicAlert Foundation – New Zealand Incorporated (MedicAlert) is the local branch of an international non-profit organisation that operates an emergency health care service.

MedicAlert maintains a database of members' medical information that is made available to medical authorities in the event of an emergency. Members supply critical medical data to

[2] Specifically a contract with the Ministry of Health, ACC or a DHB

the organization and receive a metal bracelet or necklace tag which is worn at all times. It can be used by law enforcement or emergency medical personnel to access their medical history and special medical needs.

Currently, MedicAlert is not listed on Schedule 2 of the HIPC. Because the Ministry of Health does not share information from its national collections with agencies that are not listed on Schedule 2, MedicAlert is unable to verify identity information provided to it by its members with the National Health Index.

Medic Alert is seeking to be added to Schedule 2 so it can access the NHI and the national Medical Warnings System. This access is intended to improve the accuracy of the information it provides to emergency services.

4. Creating a regulatory regime for information derived from Newborn Metabolic Screening Programme blood spot samples

The Guthrie test is a blood test for newborn babies developed in 1962, conducted on blood spots obtained from a heelprick. The Newborn Metabolic Screening Programme (NMSP) detects rare but life-threatening metabolic disorders with a blood test done at 48 hours old or as soon as possible after this. Early diagnosis means that treatment can start quickly, before the baby becomes sick. Each year about 45 New Zealand babies are found to have a metabolic disorder. Although these disorders cannot be cured, early treatment with medication or a special diet can help a baby stay well and prevent severe disability or even death.

The blood spots are attached to a card holding identifying information about the mother and baby, the "blood spot card". After all testing has been completed, some residual blood remains on the blood spot cards, which are stored in secure storage in Auckland.

There are currently around 2 million bloodspot cards in storage. In 2003 the Privacy Commissioner of the time, Bruce Slane, published a report outlining privacy concerns around the residual blood samples held on the cards.[3]

In summary, those concerns were that an enormous and ever-growing collection of DNA-bearing bodily samples was being held indefinitely without any clear purpose for its retention. Given inevitable advances in power and reductions in cost of DNA technology, it was almost certain that if the cards were retained then new purposes would be found for them that differed widely from the initial purpose of collection. This could well jeopardise the trust between parents of newborns and the agency conducting screening of newborns.

Given the importance of the programme, any threats to parents' trust in the NMSP should be taken very seriously as it could lower the very high uptake level of the programme and pose a risk for newborn babies.

The recommendations of the report were:

> 1. That the Ministry of Health allocate clear responsibility and authority for the operation of the newborn metabolic screening programme.

[3] http://privacy.org.nz/guthrie-tests

2. That the body appointed move urgently to develop clear rules for retention of the samples and any further use or third party access to those samples, consulting widely with stakeholders and with the Privacy Commissioner.
3. That these rules, and any permission-granting structures they involve, be incorporated in legislation in such a way that they are clear, robust and enforceable.

The first item of the list has been addressed - the NMSP is currently administered by the National Screening Unit (NSU), part of the Ministry of Health. Following a consultation process the second item has also been resolved, by the NSU publishing a policy framework for governance of the collection.[4]

However, the blood spot card collection is not likely to be regulated by additional legislation in the foreseeable future.

Since the collection is to be retained permanently, and policy frameworks can change, there will be the ongoing potential for information to be derived from the residual blood spot samples and used for purposes unrelated to the original screening programme. Some form of additional protection is needed to protect the collection into the future.

Accordingly, this amendment regulates all information derived from blood spot samples held on blood spot cards (derived information) by adding a new Schedule 3 and adding provisions to rules 10 and 11 to require any health agency using or disclosing derived information to comply with that Schedule.

Schedule 3 requires any agency using or disclosing derived information to either obtain the authorisation of the individual concerned, a close available relative, or to ensure that the use or disclosure complies with a list of permitted primary and secondary purposes.

This means that if a new purpose were to be proposed for derived information in the future (and the consent of the individual or their close available relative was not able to be obtained) then Schedule 3 would have to be amended for the new purpose to be permitted.

The regime outlined in Schedule 3 is intended to allow new uses in the future by way of public consultation and formally notified amendment to the Schedule. It will also reflect the existing acceptable uses outlined in the NMSP policy framework.

Close available relative

This definition is taken from the Human Tissue Act 2008. The Human Tissue Act sets out a method of deciding who may make decisions about the disposition of a person's bodily parts of substances when they are unable to make the decision for themselves. The definition is set out in the Appendix.

Derived information

The Privacy Act regulates information about identifiable individuals, rather than their bodily substances. The samples by themselves do not present any privacy risk, though there are cultural issues around their use and storage which are beyond the scope of this paper. However any use which might present privacy concerns would inevitably require the analysis

4 http://www.nsu.govt.nz/files/ANNB/Newborn_Metabolic_Screening_Programme_Policy_Framework_June_2011.pdf

of the samples, and the collection of information about them. This derived information will fall within the ambit of the Privacy Act, the HIPC and the new Schedule 3.

Permitted primary purpose

These purposes include any use or disclosure that is directly connected to the NSU or other governing agency carrying out the NMSP and are not intended to be exclusive.

Permitted secondary purpose

These permitted secondary purposes reflect, in a summarised form, the purposes outlined in the NMSP Policy Framework that was developed by the NSU after consultation with stakeholders. Detailed guidelines about use of bloodspots may be found in the Framework.

Use and disclosure of derived information

This section requires that any health agency's proposed use or disclosure of derived information complies with both the NMSP policy framework and either the list of primary and secondary purposes or the authorisation of the individual concerned or their close available relative.

Appendix

Human Tissue Act 2008

10 Close available relative defined

(1) A **close available relative** means, in relation to an individual who was 16 years old or older at the time when he or she died,—

(a) a person who was a spouse, civil union partner, or de facto partner of the individual immediately before his or her death; or

(b) if the individual, immediately before his or her death, had no spouse, civil union partner, or de facto partner, or if no person who was then the individual's spouse, civil union partner, or de facto partner is available, a son or daughter—

(i) of the individual; and

(ii) who is 16 years old or older; or

(c) if no person referred to in paragraph (a) or (b) is available, a parent of the individual; or

(d) if no person referred to in paragraphs (a) to (c) is available, a brother or sister—

(i) of the individual; and

(ii) who is 16 years old or older.

(2) A **close available relative** means, in relation to an individual who was under 16 years of age at the time when he or she died,—

(a) a parent of the individual; or

(b) if a parent of the individual is not available, a person who was a guardian of the individual immediately before his or her death; or

(c) if no person referred to in paragraph (a) or (b) is available, a brother or sister—

(i) of the individual; and

(ii) who is 16 years old or older.