

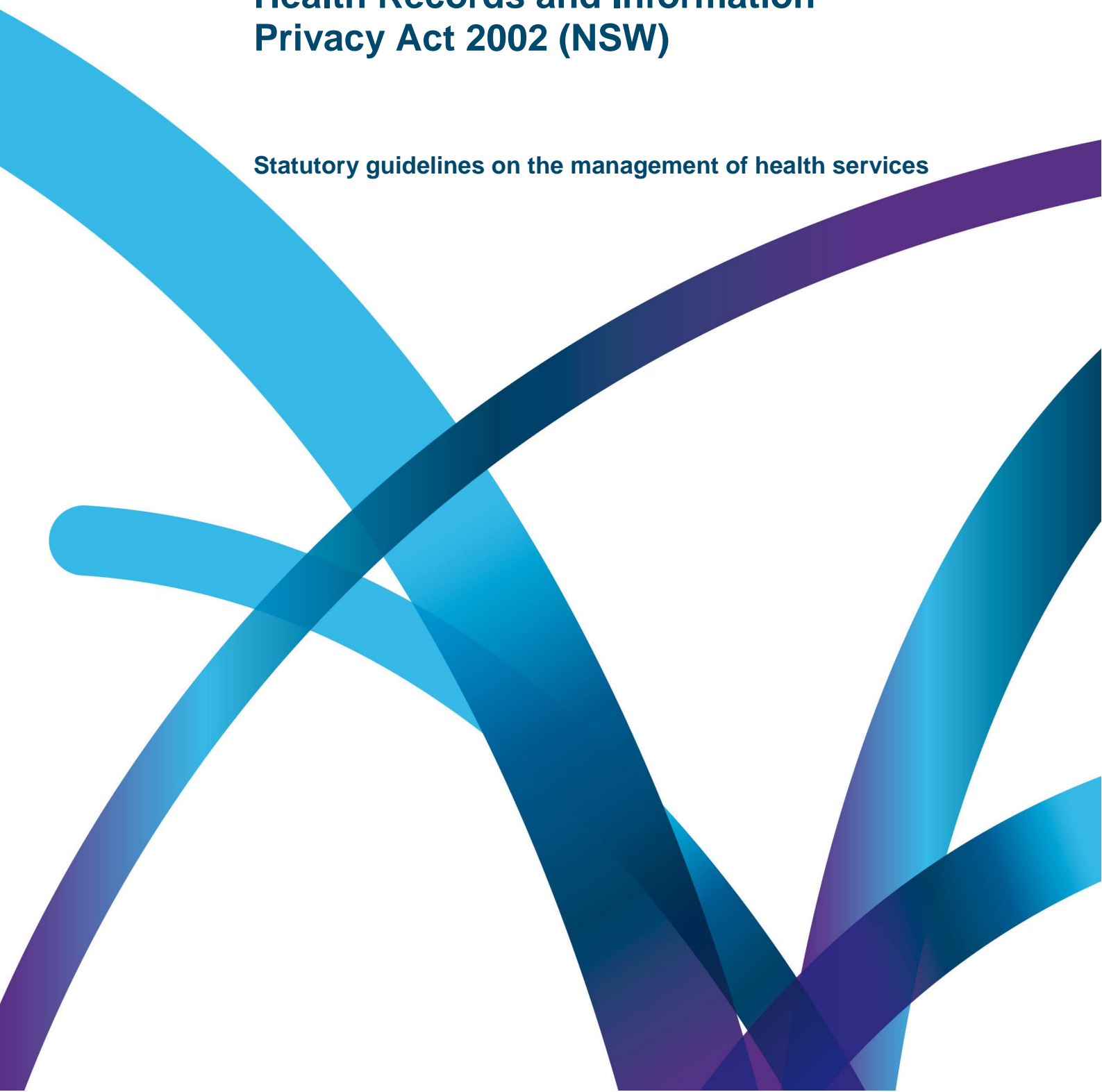


information
and privacy
commission
new south wales

statutory guidelines

Health Records and Information Privacy Act 2002 (NSW)

Statutory guidelines on the management of health services



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The statutory guidelines were issued in 2004 by former NSW Acting Privacy Commissioner John Dickie.

From the NSW Privacy Commissioner

The *Health Records and Information Privacy Act 2002 (NSW)* (the HRIP Act) creates a scheme to regulate the collection and handling of health information by public and private sector organisations in New South Wales. It applies to every organisation that is a health service provider or collects, holds or uses health information.

The HRIP Act will be fully operational from 1 September 2004. It aims to promote fair and responsible handling of health information by:

- protecting the privacy of an individual's health information held in the public and private sectors
- enabling individuals to gain access to their health information
- providing an accessible framework for resolving complaints about the handling of health information.

The objects of the HRIP Act are to:

- balance the public interest in protecting the privacy of health information with the public interest in the legitimate use of that information
- enhance the ability of individuals to be informed about their health care
- promote the provision of quality health services.

The HRIP Act contains 15 Health Privacy Principles (HPPs). These HPPs are the key to the HRIP Act. They are legal obligations that describe what organisations must do when they collect, store, use or disclose health information.

This publication outlines the requirements for the use and disclosure of health information for the management of health services. You should read it in conjunction with the HRIP Act and the Office of the Privacy Commissioner NSW 'User Manual: Handbook to Health Privacy'. If you are from the public health system, you should also read it in conjunction with the NSW Health Department's 'Privacy Manual'.

Part 1 explains some of the issues you need to consider when using and disclosing health information for the management of health services. It also includes a checklist and examples to help you decide what you should do in different circumstances.

Part 2 contains the statutory guidelines on the management of health services. You must comply with these statutory guidelines on the management of health services if you are seeking to use or disclose health information relying on the 'management of health services exemption' in HPP 10(1)(d) or 11(1)(d). These statutory guidelines on the management of health services have been prepared after consultation with stakeholders and are issued under section 64 of the HRIP Act.

If you need any further information, please contact Office of the Privacy Commissioner NSW on (02) 8019 1600.

JOHN DICKIE, ACTING PRIVACY COMMISSIONER 1 September 2004

PART 1: USING AND DISCLOSING HEALTH INFORMATION FOR THE MANAGEMENT OF HEALTH SERVICES

1.1 When can I use or disclose health information for the management of health services?

This checklist will tell you when you can use and disclose health information for the management of health services, and whether you need to comply with the statutory guidelines on the management of health services. The checklist assumes that:

- the information you are proposing to use or disclose is 'personal information' – that is, information about an individual whose identity can reasonably be ascertained from the information
- the information you are proposing to use or disclose is 'health information'
- you are covered by the HRIP Act

1. Could the purpose of the management of health services activity be served by using or disclosing de-identified information?

Yes	<input type="checkbox"/>	You should use or disclose de-identified information only. If you de-identify the information then you do not need to read any further, and you do not need to comply with the statutory guidelines on the management of health services. [Note: although the process of de-identifying health information is a use of the information by the organisation for the purposes of the management of health services, it does not need to be conducted in accordance with the statutory guidelines on the management of health services]
No	<input type="checkbox"/>	Go to question 2.

2. Are you proposing to use or disclose the health information with the consent of the individual(s) concerned?

Yes	<input type="checkbox"/>	You can use or disclose the health information relying on the 'consent exemption' in HPP 10(1)(a) or 11(1)(a). You do not need to read any further, and do not need to comply with the statutory guidelines on the management of health services.
No	<input type="checkbox"/>	Go to question 3.

Best practice tip: Wherever possible, you should seek the consent of the person. Use or disclosure authorised by the person is almost always to be preferred to relying on one of the other exemptions, provided the consent is freely given and informed. It is important that the person does not feel pressured to participate.

3. Was the health information collected for the primary purpose of the management of health services activity?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the management of health services activity relying on HPP 10(1) or 11(1). You do not need to read any further, and do not need to comply with the statutory guidelines on the management of health services.
No	<input type="checkbox"/>	Go to question 4.

4. Is the management of health services activity directly related to the primary purpose for which the health information was collected and would the person reasonably expect you to use or disclose their health information for the management of health services activity?

Yes	<input type="checkbox"/>	You can use or disclose the health information for the management of health services activity relying on the 'direct relation exemption' in HPP 10(1)(b) or 11(1)(b). You do not need to read any further, and do not need to comply with the statutory guidelines on the management of health services.
No	<input type="checkbox"/>	Go to question 5.

Examples of uses that may fall within the 'direct relation exemption' in HPP 10(1)(b) include uses for:

- *providing ongoing care to patients*
- *investigating and managing adverse incidents or complaints about care or patient safety*
- *some quality assurance activities carried out by the organisation such as monitoring, evaluating, auditing the provision of the particular product or service the organisation has or is providing the person*
- *managing the provision of the service or product*
- *following up complaints about the service or product*
- *recalls of a product*
- *administrative activities associated with providing, following up on or receiving payment for the service or product*
- *reminders where a person receives a service on a regular basis.*
- *managing a legal claim made by the person.*

Examples of disclosures that may fall within the 'direct relation exemption' in HPP 11(1)(b) include disclosures for:

- *providing information to a person or organisation involved in the ongoing care of the patient*
- *following up on an overdue payment (this would allow disclosures to a debt collector)*
- *disclosing information to an auditor or quality assessor for the purposes of monitoring, evaluating, auditing the provision of a particular product or service the organisation has provided or is providing to the person (as long as the individual reviewing the records understands and agrees to be bound by the HPPs or their equivalent).*
- *managing a legal claim made by the person.*

Best practice tip:

You should make the person aware that these activities are carried out as part of the normal functioning of your organisation. If you make it clear to the person that their information may be used or disclosed for these purposes, then there is a more persuasive argument that the person would 'reasonably expect' you to use or disclose their information in these ways.

5. Is the use or disclosure for the management of health services activity authorised, required, permitted or reasonably contemplated under another law?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the exemption in HPP 10(2) or 11(2). You do not need to read any further, and do not need to comply with the statutory guidelines on the management of health services.
No	<input type="checkbox"/>	Go to question 6.

For example: You may be required to disclose health information involving notifiable diseases pursuant to the Public Health Act 1991 (NSW), or in accordance with another statutory direction under Commonwealth law or court order or other subpoena.

6. Is the use or disclosure reasonably believed to be necessary to lessen a serious and imminent threat to an individual or prevent a serious threat to health or welfare?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the 'serious threat to health or welfare exemption' in HPP 10(1)(c) or 11(1)(c) You do not need to read any further, and do not need to comply with the statutory guidelines on the management of health services.
No	<input type="checkbox"/>	Go to question 7.

For example: The investigation and monitoring of confirmed or suspected cases of infectious diseases, and provision of information to police or agencies necessary to prevent death or serious harm to a person.

7. Can you rely on the 'management of health services exemption' to use or disclose the health information?

Yes	<input type="checkbox"/>	You can use or disclose health information relying on the 'management of health services exemption' in HPP 10(1)(d) or 11(1)(d) if you: <ul style="list-style-type: none">• meet the four exemption criteria in Part 1.2 of this publication and• comply with the statutory guidelines on the management of health services in Part 2 of this publication You should read on.
No	<input type="checkbox"/>	You cannot use or disclose the health information for the management of health services. (Unless you have identified another exemption in the HRIP Act that permits you to do so)

1.2 When can I rely on the ‘management of health services exemption’ and the statutory guidelines on the management of health services?

Under the ‘management of health services exemption’ you can use or disclose health information, without the consent of the person, for the secondary purpose of the management of health services if **all** the following four criteria are met.

Criteria 1

The use or disclosure is reasonably necessary for the funding, management, planning or evaluation of health services.

Criteria 2

You have taken reasonable steps to de-identify the information, or the purpose of the management of health services activity cannot be served by using or disclosing de-identified information and it is impracticable to seek the consent of the person to the use or disclosure.

Criteria 3

If the information could reasonably be expected to identify individuals, the information is not published in a generally available publication.

Criteria 4

The use or disclosure of the health information is in accordance with the statutory guidelines on the management of health services.

Please note that you must meet **all four** criteria to use or disclose health information relying on the ‘management of health services exemption’. The key terms in the criteria are explained in Part 1.3.

These four criteria are a summary of the requirements of the ‘management of health services exemption’. Please see Appendix A for the full text of the exemption.

1.3 Key terms in the ‘management of health services’ exemption explained

To help you decide whether you can rely on the ‘management of health services exemption’ to use or disclose information, the key terms contained in the ‘management of health services exemption’ are explained below.

Is the use or disclosure ‘reasonably necessary’?

When deciding whether the use or disclosure is ‘reasonably necessary’, consider to what degree the health information is needed for the management of health services activity.

What is meant by the ‘funding, management, planning, or evaluation of health services’?

‘Health service’ is defined in section 4 of the HRIP Act.

Activities which fall within the ‘funding, management, planning or evaluation of health services’ include activities for the purpose of undertaking, monitoring, assessing, or improving clinical practices and health service delivery.

Some of these will be routine activities carried out as part of the normal functioning of the organisation. If this is the case, they are likely to be considered activities for a ‘directly related secondary purpose within the reasonable expectation of the person’ and come within the ‘direct relation exemption’ in HPP 10(1)(b) or 11(1)(b). Please see question 4 of the checklist in Part 1.1 for examples.

Other activities which go beyond a routine management of health services activity will not come within the ‘direct relation exemption’. They may need to be considered under this ‘management of health services exemption’. For example the activity may involve a clinically significant departure from the routine clinical care provided to patients. It may involve developing a systematic investigation of possible innovations in technique, process or intervention. Sometimes such activities are difficult to distinguish from research, and may form a continuum with it.

Could de-identified information be used?

If the management of health services activity could be undertaken by using or disclosing de-identified information, then you should proceed this way. This may involve you converting ‘identifiable’ information (information that allows identification of a specific individual) into ‘de-identified’ information. De-identified information is information from which identifiers have been permanently removed, or where identifiers have never been included. De-identified information cannot be re-identified.

However sometimes de-identified information cannot achieve the purpose of the management of health services activity. This could be, for example, where an activity involves linking information about individuals from two or more sources and you need identified information to correctly link records from each data source.

What are ‘reasonable steps to de-identify’?

When de-identifying information, you should consider the capacity of the person or organisation receiving the information to re-identify it or re-link it to identifiable information. Removing the name and address may not always be enough, particularly if there are unusual features in the case, a small population, or there is a discussion of a rare clinical condition. Reasonable steps to de-identify might also include removing other features, such as date of birth, ethnic background, and diagnosis that could otherwise allow an individual to be identified in certain circumstances.

When is it ‘impracticable to seek consent’?

The fact that seeking consent is inconvenient or would involve some effort or expense is not of itself sufficient to warrant it ‘impracticable’. Some examples of where it might be impracticable to seek consent include if:

- the age and / or volume of the information is such that it would be very difficult or even impossible to track down all the individuals involved
- there are no current contact details for the individuals in question and there is insufficient information to get up-to-date contact details
- a complete sample is essential to the integrity and success of the management of health services activity and the activity would not be possible if any persons refused to allow their information to be used.

What is a ‘generally available publication’?

A ‘generally available publication’ is defined in section 4 of the HRIP Act to mean a publication that is generally available to members of the public, either in paper or electronic form.

What does ‘in accordance with the statutory guidelines on the management of health services’ mean?

The statutory guidelines on the management of health services are legally binding. You must comply with them to lawfully use or disclose health information relying on the ‘management of health services exemption’. They are contained in Part 2 of this publication.

PART 2: STATUTORY GUIDELINES ON THE MANAGEMENT OF HEALTH SERVICES

1. Application of the statutory guidelines on the management of health services

- 1.1 Organisations seeking to use or disclose health information relying on the 'management of health services exemption' in Health Privacy Principle 10(1)(d) or Health Privacy Principle 11(1)(d) must do so in accordance with these statutory guidelines.
- 1.2 The 'management of health services exemption' and these statutory guidelines on the management of health services regulate the situation where the purpose of the management of health services activity cannot be served by using or disclosing de-identified information and where it is impracticable to seek the consent of the person to the use or disclosure of their health information for the management of health services activity.
- 1.3 Failure to comply with these statutory guidelines constitutes a breach of the Health Privacy Principles and the HRIP Act.

2. Respect for dignity and personal privacy

- 2.1 An overriding obligation for those who seek to use or disclose health information for the management of health services is at all times to respect the dignity and privacy of the individual to the greatest extent possible.

3. Procedure to be followed before using and disclosing

- 3.1 Before using or disclosing health information for a management of health services activity, organisations must consider the questions set out in section 4 of these statutory guidelines.¹
- 3.2 If **all** of the questions are answered in the **negative**, organisations are permitted (although not required) to use or disclose health information for the purpose of the management of health services activity.
- 3.3 If **any** of the questions are answered in the **positive**, a proposal for the activity must be approved by a Human Research Ethics Committee as set out in section 5 of these statutory guidelines, before an organisation can use or disclose health information for that purpose.

¹The questions incorporate some of those contained in the NHMRC document *When does quality assurance in health care require independent ethical review (2003)*? The NHMRC document can be downloaded at: <http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>

4. Questions to be considered

1. Does the proposed activity pose any risks or burdens for patients beyond those of their routine care?

Risks include not only physical risks, but also psychological, spiritual and social harm or distress, for example stigmatisation or discrimination. Burdens may include intrusiveness, discomfort, inconvenience or embarrassment.

2. Is the proposed activity to be conducted by a person who does not normally have access to a patient's records?

Activities conducted by an auditor or quality assessor for the purposes of monitoring, evaluating, auditing the provision of a particular product or service the organisation has provided or is providing to the person will come within the 'direct relation exemption' in HPP 10(1)(b) or 11(1)(b) (as long as the individual reviewing the records understands and agrees to be bound by the HPPs or their equivalent.) If this is the case, these statutory guidelines on the management of health services do not apply.

3. Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the patients?

Where the activity involves an analysis of current practice and / or service delivery (examining what is being done and whether it is being done well), and / or the development and implementation of accepted responses to those practices, this question can be answered in the negative.

Activities involving the application and evaluation of a new technology not previously used in the health service should be considered by a Human Research Ethics Committee. Similarly, activities involving the development of a systematic investigation of possible innovation in technique, process or intervention should be considered by a Human Research Ethics Committee.

4. Does the proposed activity seek to gather information beyond that collected in routine clinical care?

Depending on what constitutes routine clinical care in each case, information that goes beyond 'routine' might include observations, blood samples, additional investigations or genetic studies that touch upon information about relatives or contacts as well as the individual patient.

5. Does the proposed activity involve the linkage of health records?

Where the linkage of health information is undertaken within an organisation using only information lawfully collected by the organisation in the course of providing a health service to the person, and the linkage is used to produce information for the funding, management, planning or evaluation of health services, this question can be answered in the negative.

Activities involving the linkage of health information held by different organisations (and hence involving a disclosure of health information by at least one organisation), should be considered by a Human Research Ethics Committee.

5. Written proposal to be submitted to Human Research Ethics Committee

5.1 Where any of the questions in section 4 are answered in the positive, a proposal for the activity must be approved by a Human Research Ethics Committee in accordance with this section, prior to the organisation using or disclosing health information for the purpose of the activity.

5.2 In such circumstances, the statutory guidelines on research (contained in Part 2 of the publication: 'Statutory guidelines on research' and able to be downloaded at: www.lawlink.nsw.gov.au/privacynsw) are to be applied to the 'funding, management, planning and evaluation of health services activity'. The procedures contained in the statutory guidelines on research must be followed. Accordingly the Human Research Ethics Committee will weigh the public interest in the activity against the public interest in the protection of privacy.

5.3 For the purposes of applying the statutory guidelines in such circumstances, the following amendments should be made to the statutory guidelines on research:

Omit "research or the compilation or analysis of statistics" and / or "research", wherever occurring and insert instead "management of health services";

Omit "HPP 10(1)(f)" wherever occurring and insert instead "HPP 10(1)(d)";

Omit "HPP 11(1)(f)" wherever occurring and insert instead "HPP 11(1)(d)".

Appendix A

Health Privacy Principle 10

Limits on use of health information

(1) An organisation that holds health information must not use the information for a purpose (a "secondary purpose") other than the purpose (the "primary purpose") for which it was collected unless:

(d) Management of health services

The use of the information for the secondary purpose is reasonably necessary for the funding, management, planning or evaluation of health services and:

(i) either:

(A) that purpose cannot be served by the use of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the use, or

(B) reasonable steps are taken to de-identify the information, and

(ii) if the information is in a form that could reasonably be expected to identify individuals, the information is not published in a generally available publication, and

(iii) the use of the information is in accordance with guidelines, if any, issued by the Privacy Commissioner for the purposes of this paragraph.

Health Privacy Principle 11

Limits on disclosure of health information

(1) An organisation that holds health information must not disclose the information for a purpose (a "secondary purpose") other than the purpose (the "primary purpose") for which it was collected unless:

(d) Management of health services

the disclosure of the information for the secondary purpose is reasonably necessary for the funding, management, planning or evaluation of health services and:

(i) either:

(A) that purpose cannot be served by the disclosure of information that does not identify the individual or from which the individual's identity cannot reasonably be ascertained and it is impracticable for the organisation to seek the consent of the individual for the disclosure, or

(B) reasonable steps are taken to de-identify the information, and

(ii) if the information could reasonably be expected to identify individuals, the information is not published in a generally available publication, and

(iii) the disclosure of the information is in accordance with guidelines, if any, issued by the Privacy Commissioner for the purposes of this paragraph.