Dear Cathy

Thank you for the opportunity to comment on the targeted consultation draft Section 95AA Guidelines (dated 13 February 2009). The Office's comments are attached.

There have been substantial changes to the draft Guidelines since the last comprehensive review by the Office in June 2008. Our comments on this draft are quite extensive as the Office is unsure about the reasoning behind some of these changes. We note that our recent preliminary comment on the 'pre-consultation' draft were cursory in nature given the timeframe and that we have now had sufficient time to complete a comprehensive review of the draft.

The Office understands that the NHMRC anticipates that the Guidelines will be completed by the end of June and will then be forwarded to the Privacy Commissioner for approval. In order to brief the Commissioner at that time it will be important that staff have a clear understanding of the rationale for the inclusion (or exclusion) of content in the Guidelines that the attached comments relate to.

The Office looks forward to receiving feedback on the targeted consultation process. In the context of understanding the rationale for whether our suggestions are incorporated or other changes are made it would be useful for the Office to receive copies of all submissions to help us to gain an understanding of any further changes made to this consultation draft of the Guidelines.

I also note that the issue regarding NPP10 (whether contact details of genetic relatives may be collected in a manner envisaged by the guidelines) which was the subject of discussion
between the Privacy Commissioner and the CEO of the NHMRC in May 2008 does not appear to have been resolved. This matter may need to be resolved by a Public Interest Determination (PID), or in the longer term, by an additional exception to the NPPs (or proposed UPPs).

Once again, the Office appreciates having the opportunity to review the targeted consultation draft guidelines.

Yours sincerely

Andrew Solomon
Director, Policy
Office of the Privacy Commissioner

www.privacy.gov.au

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Andrew Solomon

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OFFICE OF THE PRIVACY COMMISSIONER

COMMENTS ON THE CONSULTATION DRAFT OF THE GUIDELINES FOR THE
DISCLOSURE OF GENETIC INFORMATION TO A PATIENT’S GENETIC RELATIVES
UNDER SECTION 95AA OF THE PRIVACY ACT 1988 (CTH)

23 February 2009

Thank you for the opportunity to comment on the Targeted Consultation draft (13 February 2009) of the section 95AA guidelines.

The Office notes and appreciates the incorporation of many of our recent comments (2 February 2009) into this draft, such as the inclusion of a consolidated statement of the Guidelines and giving more prominence to the general disclaimer relating to the scenarios.

We look forward to the feedback on the targeted consultation draft, particularly any privacy issues that may be raised.

The contact for this matter is Toni Beauchamp, (02) 9284 9720 or toni.beauchamp@privacy.gov.au.

1) Guideline 6
In our comments of 23 May 2008 (page 8), the Office noted that (then) guidelines 6 and 7 effectively repeated the obligations set out in NPP 2.1(ea) and suggested:

It seems unnecessary to purport to create obligations in the guidelines which are already enacted in legislation. ...Put another way, a provider would only need to refer to the guidelines if the requirements of NPP 2.1(ea) have already been met, seemingly making it redundant to repeat the guidelines. The Office suggests that the document could (and in places, does) usefully provide guidance on how these various tests should be interpreted.

Additionally, the Office notes that (to the extent that these guidelines are necessary at all), they don’t align with the requirements of the enabling legislation, which refers to the organisation having a “reasonable belief” that the use or disclosure is necessary etc...

The Office reiterates these comments. Guideline 6 is currently drafted as:

Decision-making about use and disclosure without consent must take into consideration the nature of the threat to the genetic relatives, the potential for the threat to be lessened or prevented, and whether disclosure is required to achieve this outcome.

The phrase ‘take into consideration’ does not align with the requirements of NPP 2.1(ea). If this Guideline is retained, the Office suggests that it be modified to:
Use or disclosure of genetic information without consent may proceed only when the authorising medical practitioner has a reasonable belief that this is necessary to lessen or prevent a serious threat to the life, health or safety of a genetic relative.
2) Notifying patients of disclosure

The second last paragraph of section 3.2.4 (page 20) states: ‘If disclosure without consent is to take place, the authorising medical practitioner should consider notifying the patient of this decision. Similarly, the last sentence of section 3.3.1 (page 22) states: ‘If disclosure without consent takes place, consideration should be given to notifying the patient of this decision.’ No further guidance is provided on this matter.

This text has been changed from the June 2008 draft, which stated (page 38) ‘If disclosure without consent is to take place, the patient should be notified of this decision and advised when the disclosure has taken place.’

The Office is unclear about the reason for this change. In the Office’s view, the patient should generally be notified of the decision to disclose their genetic information without consent. While this would not necessarily be required by the Privacy Act it is consistent with good privacy practice (as discussed at item 12, NPP 1 does require that providers inform patients of certain matters at the time of collecting personal information).

The Office recognises that disclosing genetic information after the patient has expressly refused consent may pose challenges to the patient-clinician relationship. However, if the provider does not tell the patient, it is likely that they will find out elsewhere (i.e. from their relative).

The Office suggests that the text in section 3.2.4 be modified as follows: ‘If disclosure without consent is to take place, in general, the patient should be notified of this decision and advised when the disclosure has taken place’ (with similar changes to section 3.3.1).

Guidance could then be provided on any extenuating circumstances where it may not be appropriate to notify the patient.

3) Explanation of terms used in these guidelines (page vii-vii)

Authorised representative

The Office notes that the term ‘authorised representative’ has replaced the term ‘surrogate decision maker’ used in earlier drafts.

In our comments of 23 May 2008 (page 6) the Office suggested that it may be useful to clarify that being a ‘close relative, for example, a spouse, does not automatically convey surrogate decision making status on the individual. This point was included in the subsequent draft (6 June 2008) but has been taken out of the current draft. The Office suggests that this point be reinserted at the end of the explanation.
It is important that the term ‘authorised representative’ is used consistently throughout the document (rather than ‘representative’). In particular, the word authorised should be inserted before each occurrence of ‘representative’ in section 3.1.3 (‘Involving the authorised representative in decision-making’ and in the ‘Statement of Acknowledgement’ (sample materials, page 44).

Confidentiality
The Office reiterates our comments of 23 May 2008 (page 7). Unless it is necessary for a clear purpose, the Office suggests that this text be deleted.

Lessen
The Office suggests that:
- the word ‘significantly’ be replaced by ‘noticeably’; and
- the phrase ‘there is some doubt’ is modified to ‘it is doubtful.’

Necessary
The Office suggests that the explanation of the term ‘necessary’ be omitted. Section 3.2.3 provides guidance on how the term should be interpreted. The current explanation is not entirely consistent with the discussion in that section.

Privacy
The Office reiterates our comments of 23 May 2008 (page 7) regarding the inclusion of a definition of Privacy. The Parliament has chosen not to define the meaning of ‘privacy’ in the Privacy Act so it seems unlikely that the Privacy Commissioner could approve a definition of privacy. The Office considers that the explanation is unnecessary and suggests it be deleted.

Reasonable belief
In the Office’s view, the current explanation of ‘reasonable belief’ is unhelpful. The Office suggests the following form of words:

‘Reasonable belief’ is a belief that results from the exercise of sound judgement. If a health service provider sought to rely on ‘reasonable belief’ they would need to be able to explain, drawing on their experience, training, and expertise, the basis on which they formed that belief.

4) ‘What are these guidelines for?’ (page 1)
The Office suggests that the first sentence is modified to: ‘These guidelines were developed in response to changes to the Privacy Act and NPP 2 that provide for use or disclosure of genetic information to genetic relatives without the consent of the patient in certain circumstances.’

The second sentence states ‘Such disclosure differs from procedures currently in place for notifiable diseases in that there is no obligation on the patient to
provide consent'. In the Office's view, this statement is unnecessary and may cause confusion.

It seems more relevant to explain that NPP 2.1(ea) is more permissive than the general requirements of NPP 2.1(e) for use or disclosure of personal information, as the threat need not be 'imminent' (as that is the reason why the use or disclosure must be conducted in accordance with the guidelines). The Office suggests that this could be explained in the Introduction as it may detract from the flow of this section.
5) ‘When is disclosure without consent permissible?’ (page 3-4)
The Office is concerned that the discussion in the second last paragraph could undermine the intent to reassure practitioners that there is no legal obligation to disclose the information. The Office suggests that the last two sentences be moved to a new paragraph and modified to:

As the legislation does not compel a medical practitioner to disclose information to a genetic relative, the question may be asked whether an aggrieved relative, who has not been notified about a risk for a serious genetic condition, can take legal action against the medical practitioner. As the law currently stands, there is no valid basis to suggest that a doctor could be liable for non-disclosure.

In the Office’s view, the suggested text is a better reflection of the legal advice provided to the NHMRC by the Australian Government Solicitor on this matter, as well as the conclusion reached by Margaret Otlowski (2007) in her article ‘Disclosure of genetic information to at-risk relatives: recent amendments to the Privacy Act 1988 (Cwlth)’.

The fourth paragraph begins ‘Health practitioners have an obligation to advise the patient ...’ The Office suggests that inserting the word ‘ethical’ before obligation. The same change should then be made to the second paragraph at the top of page 21.

The Office also suggests that the first sentence of the first paragraph be modified to: ‘When consent is withheld, the authorising medical practitioner will first need to determine whether there is a “serious” threat to genetic relatives, taking into consideration:....’

6) ‘How does disclosure take place?’ (page 4)
As stated in the Office’s previous comments (see for example, 23 May 2008, page 18), the steps that the provider takes to obtain the contact details of genetic relatives must, by definition, not be unlawful.

Therefore, it does not seem appropriate to refer to this requirement as ‘good practice’. Perhaps this ‘tip for compliance’ could be moved to precede the paragraph starting ‘Many ethical concerns’ and modified to reflect the discussion in section 3.3.1 as follows:

The collection of contact details must accord with the Privacy Act particularly NPPs 1 and 10. Health practitioners are generally not permitted to obtain contact details, without consent or lawful authority, from other databases or records to which they may have access.

7) ‘Framework for Legal and Ethical Use and Disclosure of Genetic Information’ (page 5)
(dit point 3)
For clarity, the Office suggests reversing the order of the two last sentences (as well as inserting the word ‘authorised’ before representative). It would also be useful to include a footnote to refer the reader to the explanation of ‘authorised representative’ in the Explanation of Terms Used in These Guidelines.
8) 'Australian Privacy Legislation' (section 1, page 6)
In the last paragraph, the phrase ‘hold health information as a result of’ is unnecessary and may cause confusion. Generally, any personal information held by a health service provider is likely to be ‘health information’ as defined under section 6 of the Privacy Act. This may also include information which is not of a clinical nature. The Office suggests that this phrase be deleted.

9) 'Cultural competency' (section 2.1.2, page 8)
The Office has some concerns about the sentence 'Some cultural groups do not welcome the involvement of non-family members and health practitioners need to be sensitive to this possibility.' This could be taken as implying that it is generally acceptable to use family-members as interpreters. The Office notes the guidance provided on this issue in the NHMRC's publication, Communicating with Patients: Advice for medical practitioners (2004).

10) 'The Ethics of Disclosing without consent' (section 2.3.3, page 12)
For clarity, the Office suggests inserting the phrase 'In addition to ensuring that use or disclosure meets the requirements of NPP 2.1(ea)' in front of 'The Decision involves consideration of:....'

11) 'Providing information about implications for genetic materials' (section 3.1.1, page 14)
The last sentence refers to suggested inclusions for a patient privacy information leaflet in the sample materials in Appendix 3. It seems important to draw the reader’s attention to the requirement under NPP 1 that health providers inform their patients of certain matters when they first collect personal information. The Office suggests the following from of words:

The Privacy Act requires that providers give notice to their patients about certain matters when they first collect health information. These matters include why the information is being collected, how it may be used and to whom it may be disclosed. The full notice requirements are set out in NPP 1.3, and NPP 1.5. It is therefore important that patient privacy information leaflets are updated to include possible use or disclosure of genetic information without consent.

This text could include a footnote reference with a link to NPP 1.3 and NPP 1.5 at: http://www.privacy.gov.au/publications/npps01.html#q1

12) 'Seeking consent for use and disclosure of information concerning children and young people' (section 3.1.3, page 16)
The second sentence of the third paragraph states 'Other children may be mature enough to make their own decisions, but still be vulnerable and warrant additional consent by adults.'

Where a child has the maturity to make their own decisions under the Privacy Act there is no requirement to gain the consent of parents. The Office suggests that the sentence be deleted.
It may also be useful to add the following guidance to the end of the second paragraph:

A child or young person can give or withhold consent if he or she has sufficient understanding and maturity to understand what is being proposed. The responsibility for exercising a child or young person’s rights under the Privacy Act falls to a parent or guardian, until the child reaches a level of maturity where they are able to make decisions independently.

13) ‘When the genetic relative is a child’ (section 3.1.3, page 16)
This paragraph states ‘Issues of competency are also relevant when determining whether the genetic information should be disclosed to a child. In such situations, disclosure to the child’s parent or guardian is permitted.’

The Office suggests that the second sentence be modified to ‘In situations where the child does not have the maturity to make their own decisions under the Privacy Act, disclosure to the child’s parent or guardian is permitted.’

14) ‘Decision-making about use and disclosure without consent’ (section 3.2.3, page 18-19)
Please see the suggested wording for the first sentence under ‘When is disclosure without consent permissible?’ above.

The first sentence of the last paragraph states ‘Before making a non-consensual use or disclosure, a medical practitioner must form a reasonable belief ...’ It would be useful to include a footnote to refer the reader to the explanation of ‘reasonable belief’ in the Explanation of Terms Used in These Guidelines.

15) ‘When the medical practitioner is unwilling to disclose’ (section 3.2.5, page 21)
As noted in our comments on item 5, ‘When is disclosure without consent permissible?’, the Office considers that the discussion in the third paragraph could undermine the intent to reassure practitioners that there is no obligation to disclose the information. The Office suggests that the third paragraph be amended exactly as suggested at item 5.

16) Comments on the scenarios

Scenario 3 (page 25)
The Office considers that the last sentence in the first dot point is unnecessary and should be deleted.

The third dot point under Points for Consideration, asks ‘What information could be given to the patient or authorised representative of the person’. However, the discussion refers only to the process of assessing whether the patient has the capacity to make an informed decision. It seems particularly important to include some discussion of the information that could be given
to the authorised representative, given that the scenario is designed to illustrate the importance of ongoing provision of information.

Scenario 4 (page 26)
The Office considers that the last sentence in the first dot point is both unclear and unnecessary.

Scenario 6 (page 28)
The last sentence of the first paragraph states 'In general clinical practice, the medical practitioner in this scenario would most likely disclose to the mother, explain the risk and provide the opportunity for DNA testing of the adolescent.' This presumes that the disclosure is necessary to lessen or prevent a serious threat, which has not been established at this point. The Office suggests the sentence be deleted. The guidance could be incorporated into the last dot point ‘How might disclosure take place’.

Third dot point – the phrase ‘Further discussion of the process of use and disclosure...’ is unclear. The Office suggests that the information provided under this dot point should reflect the guidance provided in section 3.2.4. For clarity, the Office also suggests inserting the words ‘without consent’ after ‘Use and disclosure...’ in the last sentence of this dot point.

Scenario 7 (page 31)
The Office suggests that the phrase ‘from both disclosure and non-disclosure’ be omitted from the first sentence.

Third dot point – the Office suggests inserting the sentence ‘The implications for the man’s genetic relatives and benefits of notifying the sister have been explained.’

Fifth dot point – the last sentence states ‘In a situation where he continues to withhold consent, informing the sister and other close relatives would be appropriate.’ This wording does not seem appropriate as a decision has not been made if disclosure without consent can proceed.

Scenario 8 (page 30)
The third paragraph states ‘The paediatrician sought advice about the most appropriate mechanism for providing information to the woman’s siblings.’ The Office suggests that this be amended to ‘The paediatrician sought advice from practitioners with appropriate expertise on the seriousness of the threat to the life, health or safety of genetic relatives.’

The last sentence in the sixth dot point states ‘If this does not occur, the risk of further affected children being born should be considered and a decision taken as to whether disclosure without consent would be justifiable’. This does
not seem appropriate given that situations concerning genetic information that present a serious threat to an unborn child are outside the scope of the guidelines. The Office suggests that it be modified to: 'If this does not occur, the paediatrician will need to make a decision on whether disclosure without consent is necessary to lessen or prevent a serious threat to the life, health or safety of genetic relatives.'
17) Sample materials – Points about genetic information for a privacy leaflet

In our comments of 30 May 2008, the Office provided suggestions for revising the draft privacy leaflet. At that stage, the proposed text was not confined to points about genetic information but provided a sample leaflet for patients on health privacy more generally. The Office is unclear why the more general information about health privacy has now been deleted.

It is acknowledged that providers are likely to have an existing privacy brochure. Nonetheless, it seems useful to provide a sample of a complete health privacy brochure, so that providers can see how the paragraphs on genetic information might be positioned in relation to other information in the brochure.
ATTACHMENT A: OTHER COMMENTS

Please see the table below which outlines further suggestions that may assist to strengthen the accuracy and clarity of the guidelines.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Page 4, Who is Responsible for Decision Making and Disclosure</td>
<td>• The Office suggests breaking the 4th paragraph into two sentences.</td>
</tr>
<tr>
<td>Page 8, Privacy Legislation Amendment Act 2006 - Health information and sensitive information</td>
<td>• The Office suggests changing ' (see page iv)' to 'see meaning of &quot;genetic information&quot;, page iv'</td>
</tr>
<tr>
<td>Page 8, Privacy Legislation Amendment Act 2006 – Inclusion of Section 95AA</td>
<td>• The Office suggests rewording the second paragraph to: ‘NPP 2.1(ea) requires that use or disclosure of genetic information by a health practitioner without the consent of the patient is conducted in accordance with these Guidelines.’</td>
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<tr>
<td>Page 9, Diagnostic and predictive testing</td>
<td>• The last sentence (beginning 'For example, a diagnostic test') is very lengthy and difficult to follow. Perhaps the sentence could be broken up.</td>
</tr>
<tr>
<td>Page 19, Providing further information to a patient who has withheld consent</td>
<td>• The Office suggests that the first sentence be revised to: 'If the authorising health practitioner believes that the disclosure is necessary to lessen or prevent a serious threat to the life, health or safety of a genetic relative, a further discussion should be held with the patient.'</td>
</tr>
<tr>
<td>Page 27, Scenario 5 - Points for consideration, 3rd</td>
<td>• The Office suggests replacing the words 'and the implications for his genetic relatives' with 'and the benefits of informing genetic relatives'.</td>
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