Committee for Health, Social Services and Public Safety

Report on the Health and Social Care (Control of Data Processing) Bill

Together with the Minutes of Proceedings of the Committee Relating to the Report, Minutes of Evidence, Written Submissions and Other Papers

Ordered by the Committee for Health, Social Services and Public Safety
to be printed 18 November 2015

Report: NIA 274/11-16 (Committee for Health, Social Services and Public Safety)

Table of Contents

Membership and Powers

The Committee for Health, Social Services and Public Safety is a Statutory Departmental Committee established in accordance with paragraphs 8 and 9 of the Belfast Agreement, section 29 of the Northern Ireland Act 1988 and under Standing Order 48.

The Committee has the power to:

- Consider and advise on Departmental budgets and annual plans in the context of the overall budget allocation;
- Consider relevant secondary legislation and take the Committee stage of primary legislation;
- Call for person and papers;
- Initiate inquiries and make reports; and
- Consider and advise on any matters brought to the Committee by the Minister for Health, Social Services and Public Safety.

The Committee has 11 members including a Chairperson and Deputy Chairperson and a quorum of 5.

The current membership of the Committee is as follows:

Ms Maeve McLaughlin (Chairperson)
Mr Alex Easton (Deputy Chairperson)
Mrs Pam Cameron
Mrs Jo-Anne Dobson
Mr Thomas Buchanan
Mr Kieran McCarthy
Ms Rosaleen McCorley
Mr Michael McGimpsey
Mr Daithí McKay
Mr Fearghal McKinney
Mr Gary Middleton

---

[1] With effect from 23 January 2012 Ms Sue Ramsey replaced Ms Michaela Boyle
[2] With effect from 06 February 2012 Ms Sue Ramsey replaced Ms Michelle Gildernew as Chairperson
[3] With effect from 23 April 2012 Mr Conall McDevitt replaced Mr Mark Durkan
[4] With effect from 02 July 2012 Ms Michelle Gildernew is no longer a Member
[5] With effect from 10 September 2012 Ms Maeve McLaughlin was appointed as a Member
[6] With effect from 15 October 2012 Mr Roy Beggs replaced Mr John McCallister
[7] With effect from 04 September 2013 Mr Conall McDevitt resigned as a Member; his replacement has yet to be announced
[8] With effect from 16 September 2013 Mr David McIlveen replaced Ms Paula Bradley
[9] With effect from 16 September 2013 Ms Maeve McLaughlin replaced Ms Sue Ramsey as Chairperson
[10] With effect from 30 September 2013 Mr Fearghal McKinney was appointed as a Member
[11] With effect from 04 July 2014 Mrs Jo-Anne Dobson replaced Mr Samuel Gardiner
[12] With effect from 23 September 2014 Ms Paula Bradley replaced Mr Jim Wells as Deputy Chairperson

[13] With effect from 06 October 2014 Ms Rosaleen McCorley was appointed to the Committee

[14] With effect from 06 October 2014 Mr George Robinson replaced Mr David McIlveen

[15] With effect from 06 October 2014 Mr Michael McGimpsey replaced Mr Roy Beggs

[16] With effect from 01 December 2014 Mr Paul Givan replaced Mr Gordon Dunne

[17] With effect from 11 May 2015 Mr Alex Easton replaced Ms Paula Bradley as Deputy Chairperson

[18] With effect from 03 June 2015 Mr Mickey Brady resigned as a Member; his replacement has yet to be announced

19With effect from 14 September 2015 Mr Daithí McKay was appointed as a Member

[20] With effect from 5 October 2015 Mr Thomas Buchanan replaced Mr Paul Givan

[21] With effect from 9 November 2015 Mr Gary Middleton replaced Mr George Robinson

Executive Summary

The purpose of the Health and Social Care (Control of Data Processing) Bill is to provide a clear statutory framework with appropriate safeguards, to enable in certain circumstances the processing of health and social care information which identifies individuals.

The evidence from stakeholders on the Bill was in support of a statutory framework with robust and stringent safeguards. However, significant concerns were expressed about a number of issues including the use of the terms 'public interest' and 'social well-being'; the right of an individual to opt-out of having their identifiable data shared; and the robustness of the safeguards provided for within the Bill including the Code of Practice.

Clause 1

A number of key issues were raised in relation to Clause 1 which deals with the control of information of a relevant person:

The use of the term 'public interest' in Clause 1(1) attracted a considerable amount of comment. The Committee's main concern was that, as the Bill is currently drafted, identifiable information could be shared if it was found to be in the public interest whether or not it was connected to a medical or social care purpose. Initially, the Department indicated that the drafting of Clause1(1) reflected its intent. However, it later clarified that information sharing would not be permissible solely on the basis of public interest; all uses must be connected to a medical or social care purpose. In response to the issues raised by the Committee, the Department proposed an amendment that would allow the sharing of information in the public interest *only* if it was connected to a health or social care purpose.

The Committee was also concerned that individuals were unaware of their right to opt-out of having their information shared. Whilst acknowledging that an opt-out provision already exists in health and social care (under section 10 of the Data Protection Act 1998), the Committee was of the view that the protection of an individual's right to a private life and the potential for raising public awareness of the right to opt-out was of such importance that provision should be on the face of the

Bill. The Committee therefore agreed its own amendment to Clause 1(2) to place an ‘opt-out’ provision on the face of the Bill.

The Committee was clear in its view that the safeguards within the Bill should be made as robust as possible to better regulate the processing of health and social care information which identified individuals. To that end, it held the view that information should only be processed if authorisation is granted by the committee established by the Bill to authorise the processing of information. In response to the Committee’s concerns, the Department proposed an amendment to Clause 1(3) to this effect.

The use of the term ‘social well-being’ in Clause 1(11) to describe ‘a relevant person’ was also criticised because of its breadth and potential for wide interpretation. The Committee felt strongly that this term should be replaced with the term ‘social care’. The Department provided the wording of an amendment to address the Committee’s concerns and replace ‘social well-being’ with ‘social care’.

The Committee considered the wording of a proposed departmental amendment to Clause 1(14), which would remove the word ‘services’ from after ‘social care’, as the definition of ‘social care’ refers to the Health and Social Care (Reform) Act (NI) 2009 and means any services designed to secure improvement in the social well-being of people in Northern Ireland, thus making the word ‘services’ superfluous.

The Committee expressed concerns in relation to the open-ended definition of processing. It was of the view that prohibiting the selling of identifiable information was of such importance for the protection of individuals and public confidence in the Bill, that a Ministerial assurance should be sought that regulations made under this legislation will not make provision for the selling of information which identifies individuals. A Ministerial assurance to that effect was provided.

The Committee agreed that it was content with Clause 1 subject to the amendments proposed by the Department and the Committee.

Clause 2

The Committee was firmly of the view that the establishment of the committee to authorise processing of confidential information should be mandatory. It felt that this safeguard was of the utmost importance in ensuring that confidential information is protected and due process is followed when applications are received and considered. To address the Committee’s concerns, the Department proposed an amendment to redraft Clause 2(1) to this effect.

The Committee agreed that it was content with Clause 2 subject to the amendment proposed by the Department.

Clause 3

The Committee felt strongly that the Code of Practice had the potential to be a more robust safeguard against the unlawful processing of information, and was of the view that it should be strengthened. In response to the Committee’s view, the Department proposed an amendment to require health and social care bodies, and any other person who provides health and social care under arrangements made with a public body who exercises functions in relation to the provision of health and social care, to ‘have due regard’ to the Code of Practice as opposed to ‘have regard’.

To further strengthen the Code of Practice, the Committee agreed its own amendment to provide that a court or tribunal may take into account a breach of the code in any proceedings where it considers relevant.

The Committee agreed that it was content with Clause 3 subject to the amendments proposed by the Department and the Committee.

Clauses 4 to 6

The Committee agreed Clauses 4 to 6 as drafted.

Introduction

1. The Health and Social Care (Control of Data Processing) Bill (NIA 52/11-16) was introduced to the Assembly on 16 June 2015. At Introduction the Minister of Health, Social Services and Public Safety made the following statement under section 9 of the Northern Ireland Act 1998:

   a. "In my view the Health and Social Care (Control of Data Processing) Bill would be within the legislative competence of the Northern Ireland Assembly."

2. The Bill passed its Second Stage on 29 June 2015 and was referred to the Committee for Health, Social Services and Public Safety on 30 June 2015.

3. The stated purpose of the Bill is to make provision about control of data processing in relation to health and social care.

4. The Bill has 6 clauses: Clause 1 sets out the circumstances for which the Department may make regulations to make provision for the processing of Health and Social Care information; Clause 2 allows the Department to establish a body to authorise the processing of confidential information as defined in the Bill; Clause 3 places an obligation on the Department to publish a Code of Practice in respect of the processing of information; Clause 4 relates to control of regulations made under the Bill; Clause 5 sets out the definitions of specific terms used within the Bill; and Clause 6 sets out the title and commencement dates.

5. During the period covered by this Report, the Committee considered the Bill at 9 meetings. Details of the meetings can be found at Appendix 1.

6. At its meeting on 9 September 2015 the Committee agreed a motion to extend the Committee Stage of the Bill to 20 November 2015. The motion to extend was supported by the Assembly on 21 September 2015.

7. The Committee had before it the Health and Social Care (Control of Data Processing) Bill and the accompanying Explanatory and Financial Memorandum. On 3 July 2015, the Committee wrote to key stakeholders and inserted public notices in the Belfast Telegraph, Irish News, and News Letter seeking written evidence on the Bill by 7 August 2015.

8. A total of 23 organisations responded to the request for written evidence and details of the submissions received by the Committee are included at Appendix 3.

9. Following introduction of the Bill, the Committee took evidence from departmental officials on 17 June 2015, and from:

   a. The Privacy Advisory Committee and the Law Centre on 9 September 2015;

   b. The Northern Ireland Human Rights Commission, the Northern Ireland Rare Disease Partnership, Northern Ireland Fire and Rescue Service and Northern Ireland Cancer Registry on 16 September 2015; and

   c. The Information Commissioner's Office, the Royal College of Nursing and the Royal College of Psychiatrists on 23 September 2015.

10. The Committee sought advice from the Assembly Examiner of Statutory Rules in relation to the range of powers within the Bill to make subordinate legislation.

11. The Committee discussed the evidence received from stakeholders with the Department on 30 September and 21 October 2015.

12. The Committee carried out its clause-by-clause scrutiny of the Bill on 11 November 2015. At its meeting on 18 November 2015, the Committee agreed its report on the Bill and that it should be printed.

Consideration of the Bill

13. In response to its call for evidence, the Committee received 23 written submissions and took oral evidence from 9 organisations.

14. The organisations that provided written and oral evidence to the Committee outlined a range of views and raised a number of issues. The Committee explored these with the Department of Health, Social Services and Public Safety both in writing and in oral evidence sessions.

Clause 1: Control of Information of a relevant person

15. Clause 1 sets out the circumstances for which the Department may make regulations to make provision for the processing of health and social care information.

16. The Committee recognised and shared the views of organisations such as the Huntington's Disease Association, Genetic Alliance UK, Cancer Registry and the Rare Disease Partnership that there are numerous benefits of sharing data to help in the prevention of diseases and improving the quality of life, treatment of care, and service provision for sufferers of a wide range of conditions. It also recognised the significant benefits of information sharing in relation to participation in international research and audits.

17. The Committee was firm in its support for a clear statutory framework, and robust and stringent safeguards for sharing health and social care information which identifies individuals, in prescribed circumstances. However, a number of issues were raised by both the Committee and those who had responded to its call for evidence in relation to Clause 1.

Clause 1(1)

18. The Southern Health and Social Care Trust and the South Eastern Health and Social Care Trust were of the view that, to provide clarity on the purpose of the Bill at Clause 1(1), the term 'health or social care purposes' should be used rather than 'medical or social care purposes'.

19. The Privacy Advisory Committee expressed a view that Clause 1(1)(a) is redundant in that the interests are much broader than improvement of health and social care. It pointed out that the health and social care purposes that require to be addressed by this Bill cover a range of activities directed at enabling all health and social care organisations to carry out their tasks effectively and efficiently, including improvements where necessary and possible. It suggested that Clause 1(1)(b) is incorporated into Clause 1(1) to read: ‘The Department may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed information of a relevant person for medical or social care purposes and which are in the public interest.’

20. The Southern Health and Social Care Trust suggested that in addition to proving that the outcome of sharing information will be in the interests of health and social care or in the public interest, the Bill should state that applicants need to prove that: (i) the results cannot be obtained without the use of personal identifiable information; and (ii) it is not possible /practical to obtain consent from the individuals concerned.

21. The Committee questioned whether the Department’s intent in relation to the policy objective was reflected in the Bill; an issue which was also raised by the Privacy Advisory Committee in relation to Clause 1(1)(a) and Clause1(1)(b):

> “I think the Privacy Advisory Committee's concern was that the impression given by the draft Bill was that there were two separate issues going on. One was for a health and social care purpose, a medical and health care/social care purpose, or a public interest purpose. Clause 1(1)(a) and 1(1)(b), with the ‘or’ between them — either for improving the health service or for public interest — tended to convey that the public interest was a separate interest. As Dr Harper said, it might be other kinds of public interest, like public protection, police inquiries or whatever. That is a major source of confusion. That is not what I understand to be intended. Our committee was simply suggesting a form of words to try to make it clearer that the "and" is conjunctive, not disjunctive. It has to be for a health and social purpose and it has to be in the public interest.”

22. The Northern Ireland Human Rights Commission (NIHRC) noted in its written evidence that paragraph 19 of the Explanatory and Financial Memorandum states that the provisions of the Bill are compatible with the European Convention on Human Rights (ECHR). The NIHRC noted guidance from the

Westminster government to departments about disclosure of views regarding Convention compatibility in the Explanatory Notes that accompany a Bill. In order to discharge the government's commitment to provide a human rights assessment, departments should do one of the following: state that the department does not consider that the provisions of the Bill engage convention rights; or in a case where any ECHR issues arise but are not significant, deal with the issues in a short paragraph or paragraphs in the explanatory notes; or where significant issues arise, state that issues arising as to the compatibility of the Bill with convention rights are dealt with in a separate memorandum and provide a web address at which the memorandum can be accessed.

23. In its written evidence, the NIHRC referred to the Council of Europe Committee of Ministers Recommendation on the protection of medical data which provides that medical data may be collected and processed for specified purposes and if provided by law: for public health reasons; or subject to principle 4.8, the prevention of a real danger; the suppression of a specific criminal offence: or, another important public interest. It highlighted that Clause 1(1) states that regulations may be made providing for the processing of information for the purpose of 'improving health and social care' or 'in the public interest.' The NIHRC was initially of the view that the latter phrase is too broad and does not meet the requirements to be specific on the other 'important public interest' being covered. In light of its concerns, the NIHRC advised that the Bill could be made clearer on the specific purposes provided by law enabling the collection and processing of medical data. It suggested that Clause 1(1)(b) could be amended to specify 'in the interests of public safety' rather than 'in the public interest'. It felt that this would make it clear that the provision is tied to health, social care and public safety.

24. During its oral evidence to the Committee, the NIHRC stated that, after reflection, it would be content with 'in the public interest' provided the safeguards are clear and robust. It referred in particular to the Code of Practice being thorough, comprehensive and detailed and having a clear articulation of Article 8 of the European Convention on Human Rights, and the establishment of the committee. With those caveats, it felt that the Bill would meet the Article 8 test.

25. The Belfast Health and Social Care Trust highlighted that difficulties have arisen in the past where the risk of sharing data for beneficial purposes has been

refused as the public interest test is open to interpretation. The Trust wished to ensure that the Bill adequately covers some of the sharing and processing of information that currently exists, and projects which would have relied on the public interest test. It pointed out that the sharing of personal identifiable data with organisations such as the Cancer Registry has been of concern because of the ambiguity within the ‘public interest’ test.

26. The Royal College of Psychiatrists noted that one major aim of this legislation is to reduce the likelihood of public interest secondary uses being subject to legal challenge. However, it pointed out that this part of the Bill, read along with subsections (8) and (9) which refer to the Data Protection Act, seems almost to be a ‘get out of jail free card’, especially if there has been a breach in data security. It highlighted that the information which is being shared under this legislation is both private and sensitive to the individuals being identified by it, and were such information to be inadvertently or accidentally disclosed to unauthorised third parties (such as insurance companies or other bodies whose possession of the information may not be in the interest of the patient), then there should be appropriate penalties.

27. The Northern Ireland Cancer Network (lung sub-group) felt that the legislation should allow organisations such as the Northern Ireland Cancer Registry to handle, analyse and report on data. It stated that the Cancer Registry is a key partner in the processing and analysis of audit data for the national lung cancer audit and highlighted the audits’ positive impact in England on improvement in survival and care. It suggested that the Bill may need some rewording to facilitate this partnership.

28. In its written evidence, the Northern Ireland Fire and Rescue Service (NIFRS) highlighted that people who die in accidental fires in Northern Ireland are, almost without exception, known to health and social care because of existing health conditions. The NIFRS was of the view that it needs to take a risk-based approach to prevention, not a blanket one. It stated that by having access to information that tells it where vulnerable people live it can take a directed risk-based approach and meaningful steps to reduce risks where its actions have the most effect.

29. The NIFRS referred to its colleagues in Fire Services in England being able to gain access to GP data to help them to direct their prevention work. It was of the view that access to similar data for the NIFRS would allow it to transform its

prevention work and make a significant contribution to the health, safety and well-being of the public of Northern Ireland. These points were reiterated during its oral evidence.

30. The Rare Disease Partnership was of the view that the Department must be obliged to make the regulations and the word ‘may’ should be replaced with ‘shall’.

31. The Northern Ireland Cancer Registry questioned whether there will be a complaints process in cases of breaches.

32. Initially, the Department responded to the concerns raised in relation to ‘the public interest’ advising that the processing of information will be considered for medical or social care purposes which are in the interests of improving health and social care or are in the public interest. It later clarified, during the oral evidence session on 30 September, that,

    “… the public interest provision at clause 1(1)(b) does not stand alone. Information sharing would not be permissible solely on the basis of public interest. All uses must be connected to a medical or social care purpose, such as medical research, management of healthcare services or provision and management of social care services. It is, therefore, a rather narrower provision than some comments may have suggested.”

33. Officials acknowledged that there was a level of confusion that the public interest was not grounded in medical or social care interests because of the way Clause 1(1) is worded. Officials also acknowledged that the example it provided during the oral evidence session on 17 June 2015, in relation to the NIFRS being able to use the information for education and awareness of vulnerable people who have presented to A&E or hospital as a result of fire, added to the confusion; there is no expectation that if the NIFRS did make an application to the committee for education or awareness purposes that it would succeed.

34. It highlighted that the committee will be responsible for scrutinising each application and that processing will only be enabled if the committee authorises it; the Data Controller will then make the final decision to share or not to share. It noted that Clause 1(1)(b) places an evidential requirement on the requestor to clearly show the committee how the public interest is served where Clause 1(1)(a) does not apply and highlighted that its inclusion is expected to significantly reduce the use of the current common law approach.

35. In relation to the right to opt-out, the Department confirmed that where individuals opt-out of having their information shared their wishes will be respected. It pointed out that opt-out arrangements will be consulted upon as part of the process of developing the regulations which will be subject to draft affirmative procedure in the Assembly. The Department clarified that the ‘requirement’ provision will only be used to address unforeseen emergency circumstances and the exercise of this power will require regulations to be made by the Department which will be subject to draft affirmative procedure in the Assembly.

36. Addressing the Cancer Registry’s specific issue that it and similar organisations should be allowed to handle, analyse and report on data, the Department stated that it is anticipated that the Cancer Registry will receive specific support under the regulations to provide a statutory basis for its operation. It confirmed that this support will make provision for the handling, analysing and reporting of data.

37. In response to the Royal College of Psychiatrists’ concern that this legislation seems almost to be a ‘get out of jail free card’, especially if there has been a breach in data security, the Department pointed out that under the Data Protection Act, the decisions as to the purpose and manner of processing rests with the Data Controller. It highlighted that any processing of information under the Bill must comply with the provisions of the Data Protection Act (Clause 1(8)) and that Data Controllers must ensure that any processing of personal information for which they have responsibility complies with the Data Protection Act. It confirmed that failure to do so risks enforcement action and compensation claims from individuals.

38. The Department also confirmed that there will be a complaints process. It highlighted that Clause 1(2)(d) provides for the establishment of fines and penalties in regulations. It also pointed out that all processing must be compliant with the Data Protection Act and the Information Commissioner can impose fines of up to £500k for breaches of the Act.

39. Having considered the issues raised in the evidence, the Department’s initial response, and the further information/clarification provided by the Department, the Committee wrote to the Department on 15 October 2015, asking whether it would be prepared to make an amendment to Clause 1(1) to allow the sharing of information in the public interest only if it was connected to a medical or social care purpose.

40. The Committee also considered the possibility of completely removing reference to public interest and sought clarification from the Department of the implications of removing the reference.

41. The Department responded by proposing an amendment that would impose a mandatory duty upon the Department to make regulations; clearly link the purpose of the Bill with the general duties of the Department as set out in the Health and Social Care (Reform) Act (NI) 2009 by changing ‘medical and social care purposes’ to ‘health and social care purposes’ which, as defined in Clause 1(13) and (14), underpins the general duties of the Department; introduce consistency in the terminology used in the Bill; and make the link between ‘health and social care purposes’ and the ‘public interest’ clear and explicit.

42. The Department advised that the requirement for all processing to be in the public interest is a further safeguard in the process. It highlighted that the burden of evidence will be on the person applying to the committee for access to information to explain the expected benefit, for example that it will provide information which will help the HSC provide a better, more effective service to patients. The Department was therefore of the view that removing the reference to ‘public interest’ would remove an important safeguard in the Bill.

43. The Committee expressed concern about the open-ended direction of the introductory paragraph in Clause 1 ‘as it considers necessary or expedient’. In light of this concern, the Committee also requested clarification from the Department of the implications of removing ‘as it considers necessary or expedient’.

44. The Department’s response explained that the inclusion of the phrase ‘as it considers necessary or expedient’ means that everything must be either necessary or expedient for the purposes stated in Clause 1(1). It pointed out that if the phrase was removed the Department could still make regulations in connection with requiring or regulating processing of information in the public interest but would not have to consider them necessary or expedient for those purposes; by default this would impose fewer limitations on the Department. The Department was therefore of the view that removing the reference to ‘necessary and expedient’ would remove an important safeguard in the Bill.

45. After careful consideration of the Department’s rationale for the redrafting of Clause 1(1), the Committee agreed that it was content to support the

Department’s proposed amendment at Consideration Stage of the Bill. However, the Committee was of the view that clarity was required in relation to the phrase ‘as it considers necessary or expedient’ and expressed its expectation that such clarity would be provided in any subsequent regulations.

Clause 1(2)

46. The British Medical Association (BMA) stated that its primary care colleagues, as the guardians of their patients’ information, take significant care to promote the highest standards of confidentiality in their practices. The BMA stated its desire to see reference made to respecting patient objections to the disclosure of confidential information which would allow clinicians to act in accordance with their patients’ wishes.

47. The Royal College of Nursing (RCN) echoed this view by expressing concern that the committee could override the decision of an individual to opt-out from the disclosure of data, using the public interest criterion.

48. In its written evidence, the Law Centre NI (Law Centre) noted that one of the most important safeguards for the individual interests of service users is a right to opt-out of any processing of their confidential health and social care information which the committee has authorised. It stated that experience in England and Wales shows that opt-out tends to be a rare occurrence in practice, but such a right ensures proper respect for the decisions of individual service users. The existence of a right to opt-out of such processing of their confidential information would also serve to maintain and build confidence amongst service users about the proposed arrangements in the Bill.

49. It noted that in England and Wales, a right to opt-out is one of the ‘Standard Conditions of Approval’ of the Confidentiality Advisory Group which states that the approval of processing by the committee requires that the applicant ensure that: ‘The wishes of patients who have withheld or withdrawn their consent are respected’. However, the Law Centre was of the view that this does not provide adequate protection of individual rights and interests and nor is it sufficiently apparent to service users. It therefore recommended that the right to opt-out should be part of primary legislation and not a policy of the committee. This point was illustrated further during the oral evidence session:

> “I believe that that is a very important human rights safeguard, the individual's right to a private life. They can recognise the public good and it, quite rightly, recognises the public benefit from these secondary uses, but, when it comes down to it, individual patients and service-users should have a right to say, "No, I don't want my information to be used in that way". Whether that is for a good reason, bad reason or whatever reason, it should just be a protection. I think that having that right to opt-out would reassure patients and the public as to what this legislation is for.”

50. The Law Centre proposed that Clause 1 should be amended so that subsection (2)(c) does not apply for or in connection with the processing of prescribed information of a relevant person in circumstances where that person has expressly withheld or withdrawn their consent to such processing.

51. The Commissioner for Children and Young People (NICCY) was of the view that it will be essential to put in place robust safeguards, which replicate good practice from other jurisdictions. In particular, NICCY was of the view that the legislation should include a right for individuals to opt-out as is the case in England and Wales. Furthermore, it highlighted that consideration must then also be given to how children will be appropriately informed of this right, and whether children would have the right to opt-out or whether their right would be limited to having a say in the decision, with a parent or carer exercising the right to opt-out on their behalf.

52. The Information Commissioner’s Office pointed out that the Department acknowledged that there was a concern amongst some respondents to its consultation on the Bill, that an individual should have the right to ‘opt-out’ of secondary uses. In response, the Department explained that the proposals will establish a statutory basis which will allow for the sharing of information, and will not have the power to require it to be shared. The Commissioner’s Office noted however that in Clause 1(2)(a), regulations may make provision for ‘requiring or authorising’ the disclosure, to a relevant person involved with improving the physical or mental health of people in Northern Ireland, or, with the prevention, diagnosis or treatment of illness. It highlighted that this would suggest that in cases where the personal data may assist with either of these provisions that the data controller would be required to share the data.

53. During its oral evidence session the Law Centre also referred to this issue:

> ‘Although the English law has a similar phrase, I understand that it has never been used to require the processing of information. It is certainly our view that that is not appropriate; it is not clear why that was in the English legislation or why it is in this Bill. The provision should be permissive, making it possible to process confidential information rather than giving a power to anyone to require that‘

54. The Privacy Advisory Committee was of the view that any refusal to process prescribed information should be respected.

55. The BMA was also concerned by the reference to ‘requiring’ disclosure. It noted that this would place a legal requirement on providers to supply data. It stated that the Bill should not be used as a lever to compel extractions of confidential data and this is not consistent with the Control of Patient Information Regulations 2002 applicable in England and Wales which are of a permissive nature, and which it understood the Department intended to replicate. It was of the view that the Bill should permit lawful sharing of confidential information; however, if GPs (or others who hold data) do not wish to share in particular circumstances then they must not be legally mandated to do so.

56. The BMA recognised the importance of a legal framework in which clinicians and patients have confidence. Creating a statutory requirement to disclose which removes control from doctors and patients risks losing this trust which would be extremely difficult to regain; should patients lose trust in the confidential nature of the health service they may withhold information from the clinicians who are treating them. It pointed out that this would not only have a detrimental impact on the care they receive but it would also reduce the quality and usefulness of the data for the purposes envisaged under the Bill.

57. The Southern Health and Social Care Trust was of the view that the Bill does not make it clear how the balance between the committee, the Data Controller and the individual would work. It felt that the Bill should state that the Data Controller has the ultimate decision about whether the information can be shared or not and that this can override the committee’s decision.

58. The British Dental Association also sought confirmation that the committee has no power to compel the Data Controller to disclose information.

59. The Law Centre pointed out that Clause 1(2)(c) makes possible a lawful processing of confidential information which is not possible on the basis of the

existing options. The Law Centre was supportive of this, as for health and social care, there are significant public interests which cannot be securely and reasonably achieved using the existing options. It highlighted the need for a flexible and responsive process which is independent of those who would wish to process the confidential information and avoids the need to create an explicit statutory basis for every situation which arises. It was of the view that the arrangements proposed in the Bill will provide greater protection for service user confidentiality through requiring independent scrutiny and authorisation of such uses. It felt that this would address concerns that leaving judgement about the sufficiency of the public interest basis for disclosure to individual health and social care staff (who wish to process the information) does not provide a sufficiently clear legal basis to fully meet the requirements of Article 8 of the European Convention on Human Rights.

60. The NIHRC welcomed the proposed enabling power to create offences to ensure protections for rights holders. It noted that Clause 1(2)(d) contains a specific indication of a sanction (up to level 5 on the standard scale).

61. The Royal College of Psychiatrists was of the view that the establishment of new offences should not overrule existing offences, or if they do, they should provide similar protections.

62. The Northern Ireland Local Government Association (NILGA) acknowledged the importance of ensuring that contraventions of the Bill and associated regulations are prevented and discouraged through the enabling of a regulation specifying relevant offences.

63. The Department confirmed that the final decision to disclose information will rest with the Data Controller. It also highlighted that under the Data Protection Act, the decisions as to the purpose and manner of processing rests with the Data Controller and any processing of information under the Bill must comply with the provisions of the Data Protection Act (Clause 1(8)). It pointed out that the committee will only approve the sharing of information not compel it.

64. The Department stated that requiring the sharing of information would be done through the making of regulations. When asked by the Committee whether it would be better to have it spelt out on the face of the Bill when information could be required, officials explained that the regulation making approach had been

chosen because there are a number of specifics that need to be consulted upon at the next stage.

65. The Department clarified that there is no intention to override the decision of an individual to opt-out; where individuals opt-out of having their information shared their wishes will be respected. It advised that opt-out arrangements will be consulted upon as part of the process of developing the regulations.

66. However, the Committee did not fully accept the Department's position on opt-out and was concerned that individuals were unaware of their existing right to opt-out of having their information shared. Whilst acknowledging that an opt-out provision already exists in health and social care under section 10 of the Data Protection Act, it remained of the view that the protection of an individual's right to a private life and the potential for raising public awareness of the right to opt-out was of such importance that provision should be on the face of the Bill. The Committee therefore agreed the wording of a proposed Committee amendment to place an 'opt-out' provision on the face of the Bill.

67. During the course of its scrutiny, the Committee discussed the reported breach in England in relation to care data, where patient data was shared against their wishes. Although this data is protected by a different set of safeguards, Members wished to highlight this as an example of what can go wrong if the necessary processes or technical structures to protect data are not put in place or are not fit for purpose. The Committee supported the recommendation made by the Information Commissioner during oral evidence, that during the development process, a privacy impact assessment should be undertaken of any system that is being put into place to implement the Bill. The Commissioner outlined that a privacy impact assessment looks at the system in its entirety, tries to identify where the weaknesses are, such as where there may be potential for information being disclosed or mishandled, and puts in mitigating measures to counteract that.

Clause 1(3)

68. The NIHRC recommended that, to be an effective safeguard in the processing of confidential information, particularly sensitive health data, Clause 1(3) should be amended to specify that regulations must provide for authorisation by the

committee. The Southern Health and Social Care Trust and the Rare Disease Partnership shared this view.

69. The Committee was clear in its view that the safeguards within the Bill should be made as robust as possible to better regulate the processing of health and social care information which identified individuals. The Committee therefore wrote to the Department on 15 October 2015 to ask whether it would be prepared to make an amendment to the effect that information would only be processed if authorisation is granted by the Committee. The Department provided the wording of a proposed amendment to that effect. The Committee agreed that it was content to support the Department's proposed amendment at Consideration Stage of the Bill.

Clause 1(5)

70. The Belfast Health and Social Care Trust questioned whether the cost and technology available will form part of the basis for requesting information via this legislation.

71. The Health and Social Care Board was of the view that further clarity is needed to avoid differences that could potentially arise in the application of Clause 1(5).

72. The Royal College of Psychiatrists pointed out that all reasonable steps should be taken to ensure that if anonymous or pseudonymous information can be used that it is used, and that if the patients involved could give consent, that that option has been provided to them. It therefore welcomed Clause 1(5).

73. The Committee expressed a concern about the use of the phrase 'reasonably practical'.

74. The Department advised that this provision only relates to the situation where regulations may be made to require processing of health information. It provides that regulations may not be made for this purpose if it would be reasonably practicable to achieve the objective in other ways having regard to the cost of and the technology available. Any applications will therefore have to prove that, to achieve the purpose, the regulations are required.

75. Having considered the comments made, and the Department's response, the Committee was content with the Department's position that any applications will have to prove that, to achieve the purpose, regulations are required.

Clause 1(6)

76. The Royal College of Psychiatrists welcomed the requirement for an annual review of any disclosures to ensure that they were legal. However, it suggested that consideration should be given to tying this aspect into the work of the committee.

77. The Department advised that Clause 1(6) applies only if processing is required by regulations made by the Department. However, it stated its intention that all applications will be subject to annual review by the committee with a view to assessing whether support under the legislation should continue or be withdrawn. It stated that this will be considered under the process to develop regulations which will be subject to public consultation.

78. The Committee welcomed that all applications will be subject to annual review by the committee with a view to assessing whether support under the legislation should continue or be withdrawn. The Committee noted that relevant regulations will be subject to public consultation, scrutiny by the Health, Social Services and Public Safety Committee and the Assembly draft affirmative procedure.

Clause 1(7)

79. The Rare Disease Partnership questioned the purpose of Clause 1(7). It had concerns that it may operate to inhibit or prevent the identification of individuals who could benefit from new treatments. In particular, individuals affected by rare diseases who may currently have very little treatment available and may need to be tracked down to enable them to benefit from scientific and other advances.

80. In response, the Department advised that the output required from disclosure of information can, under Clause 1(13)(b), be used to inform individuals about their care and treatment.

81. The Committee was content with the Department’s response.

Clause 1(8)

82. The BMA welcomed the statement on the face of the Bill that that processing must be compliant with the Data Protection Act 1998 (DPA). It noted that this

will encompasses the DPA principle of ‘fair processing’ which means that patients should be made aware when their information is being disclosed and for what purpose.

83. In its written evidence, the Information Commissioner’s Office expressed the view that processing health and social care data without the consent of an individual where it is necessary in the interests of improving health and social care, or, where it is in the public interest, would satisfy the conditions for processing set out in Schedule 2 para 5(b) and Schedule 3, para 7(b) of the Data Protection Act 1998. However, whilst it appreciated that the proposals will provide a legal gateway for the Department to allow the disclosure of health and social care data in certain circumstances, thus satisfying a relevant condition for processing, it pointed out that the processing may still may not be compliant with the first data protection principle i.e. that information is processed fairly and lawfully and that certain ‘conditions’ are met.

84. During its oral evidence to the Committee, the Information Commissioner’s Office provided an update on its position:

> “When we started considering the Bill, we had a fairly major concern that it would contravene the Northern Ireland Act in view of the fact that data protection is a reserved matter. There is no problem at all with the Assembly legislating for the sharing and processing of information, but it seemed to us at first that this was introducing something called a "condition for processing", which is well established in schedules 2 and 3 to the Data Protection Act (DPA). However, we spoke to officials in the Department and they reassured us that they had spoken to Westminster and are satisfied that the Bill conforms and that there is no danger of intrusion into a reserved matter. That gives us comfort. If it had intruded, there would be a question of legality.”

85. The Information Commissioner’s Office also questioned in its written evidence whether the disclosure of data for secondary uses was compliant with the second data protection principle i.e. that personal data is to be obtained only for one or more specified purposes and shall not be further processed in any manner incompatible with that purpose. It pointed out that if an individual provides information about their health condition or social well-being to an organisation with the belief that it will only be used in relation to their own direct treatment/care, and that information is then processed further for secondary

purposes, then it may be arguable that this is not compatible with the second principle.

86. During oral evidence, the Information Commissioner’s Office again expressed concern about the fairness of the process. It highlighted that patients need to know what is happening or is likely to happen to their information, and stressed the need for proper guidance and proper awareness-raising activity at the implementation stage and when patient information is being collected. It pointed out that that requirement is far more stringent in the case of sensitive personal data in that the Act requires much more information to be provided to the patient at the point of collection about the purposes of collection and how it may be processed, both with and without their consent.

87. The Department highlighted that the Bill does not set aside the requirements of the Data Protection Act 1998. Any processing must fully comply with the provisions of the Data Protection Act; it will be the responsibility of the requestor to evidence to the committee that this is the case.

88. Regarding the Information Commissioner’s comments in relation to the fairness of the provisions, the Department advised that the proposals were subject to a public consultation and 94% of respondees were in favour of the proposals.

89. However, when the Committee considered the respondees to the Department’s consultation it discovered that a very small number of individuals, who were not identified as medical professionals, submitted responses. The Committee was of the view that robust engagement with the public on the secondary use of their health and social care data was absolutely essential. The Committee highlighted that any public consultations on subsequent regulations should specifically target the general public to raise awareness that information that can be shared, and ensure that views are listened to and acted upon.

Clauses 1(10) and 1(11)

90. The Northern Ireland Cancer Registry was of the view that the definition of information should also include basic sociodemographic facts such a name, date of birth, postcode, ethnic group, gender and marital status to enable comprehensive monitoring of disease at population level.

91. The BMA was concerned that the intention is that all information will fall under the scope of the Bill ‘whether or not the identity of the individual in question is ascertainable from the information’. The BMA was of the understanding that if the information is anonymous to the extent that an individual cannot be identified, then it would not be subject to common law obligations of confidence or the DPA. It was therefore of the view that it is unnecessarily restrictive to include such information within the scope of the Bill.

92. The Department advised that all information which is caught within the definition of information is included in the scope of the Bill. The definition of ‘confidential information’ is that the identity of the individual is ascertainable; the Bill does not deal with access to anonymised information.

93. The Committee was content with the Department’s response.

94. The Southern Health and Social Care Trust questioned whether Clause 1(11)(a)(i) should read ‘and/or’ to include both physical and mental health. It was also of the view that the term ‘social well-being’ should be replaced with ‘social care’ for consistency throughout the Bill.

95. The South Eastern Health and Social Care Trust highlighted that the introduction of the term social well-being is confusing and suggested reference to the definition supplied under Clause (11)(b).

96. The Rare Disease Partnership was of the view that it is impossible to create an exhaustive list of groups that receive services designed to secure improvement in social care. It suggested that thought might be given to specifying the Code of Practice as a suitable vehicle to give further explanation and guidance.

97. The Committee shared the concerns expressed about the introduction and breadth of the term ‘social well-being’ and wrote to the Department on 15 October 2015 to ask whether it would be prepared to make amendments to Clause 1(10) and 1(11) to replace ‘social well-being’ with ‘social care’. The Department indicated that it was prepared to make such an amendment to Clause 1(11). It highlighted that consequential amendments would also be required to Clause 1(2) (a) and (b), (5), (6) and (7) in relation to the definition of “relevant person” and to Clause 3 to move the definitions of “health care” and “social care” to Clause 5 to ensure those definitions apply to the entire Bill.

98. The Committee was content with the Department’s proposed amendment to Clause 1(11) and agreed to support the proposed amendment during

Consideration Stage of the Bill. The Committee noted that consequential amendments would be required.

99. The Department advised the Committee that, whilst redrafting Clause 1(11) to remove the term ‘social well-being’ is appropriate, redrafting Clause 1(10) (which defines ‘information’) to make a similar amendment would not be appropriate. It outlined that ‘social care’ is defined in the Bill by reference to section 2(5) of the Health and Social Care (Reform) Act (NI) 2009 (“the Reform Act”) as meaning any services designed to secure any of the objectives of section 2(1)(b) of the Reform Act. However, the social well-being of an individual is a state personal to that individual. Therefore, to replace a reference to a state with a reference to services in the definition of ‘information’ would not be appropriate.

100. The Committee was content with the Department’s rationale for not amending Clause 1(10) to replace ‘social well-being’ with ‘social care’.

Clause 1(12)

101. The Belfast Health and Social Care Trust noted that the Bill introduces the term ‘confidential information’ and uses a definition similar to that of personal data within the Data Protection Act (DPA). It was of the view that that the aligning of definitions would assist with the understanding of the legislation. It noted that ‘medical purposes’ uses an extended form of words defined in the DPA.

102. The Department advised that the definition of ‘personal data‘ in the DPA is similar to the definition in the Bill, but differs in that the DPA definition is restricted to the data controller whereas the Bill definition refers to the ‘person processing that information’. It highlighted that this was important as it extends to those who seek to access the information and should therefore remain. The Department also pointed out that the Bill defines confidential information as being generated in circumstances where an obligation of confidence was owed to an individual.

103. The Committee accepted that the definition should refer to a ‘person processing that information’ and welcomed that it extends to those who seek to access information.

Clauses 1(13) and 1(14)

104. The Law Centre was unclear about the purpose of Clauses 1(13)(b) and 1(14)(b). It noted that these clauses define ‘medical purposes’ and ‘social care purposes’ respectively as including provision of information to individuals. The Law Centre was unclear why a Bill which is essentially about facilitating the lawful secondary use of confidential information should include the possibility of ‘informing individuals’ with respect to their primary care. It also highlighted that these clauses also appear to be in contradiction to the intent of Clause 1(7): Regulations under subsection (1) may not make provision for requiring the processing of confidential information of a relevant person who is a recipient of services referred to in subsection (11)(a) solely or principally for the purpose of determining the care and treatment to be given to particular individuals.

105. The Department responded advising that whilst Clauses 1(13)(b) and 1(14)(b) make provision for informing individuals about their care and treatment, Clause 1(7) refers to determining care and treatment to be given to particular individual.

106. The Committee was of the view that it is reasonable that the outcome of any work undertaken, following a successful application, would be used to inform individuals if it would lead to an improvement in service provision. The Committee was therefore content with the Department’s response.

107. The Committee considered the wording of a proposed departmental amendment which would remove the word ‘services’ from after ‘social care’, as the definition of ‘social care’ refers to the 2009 Reform Act and means any services designed to secure improvement in the social well-being of people in Northern Ireland, thus making the word ‘services’ superfluous. The Committee agreed that it was content to support the Department’s proposed amendment at Consideration Stage of the Bill.

Clause 1(15)

108. The Royal College of Nursing’s (RCN) primary concern in relation to the Bill was ensuring that any personal confidential information accessed is done so securely and genuinely for purposes related solely to the commissioning and provision of health care services, rather than for any commercial activities. It pointed out that it will be essential for the Department to build confidence in this principle and overcome some of the negative perceptions and doubts that have

built up as a consequence of the indifferent track record of health and social care organisations in respect of their capacity to manage and store confidential personal data securely.

109. The RCN highlighted that stakeholder and public support for the Bill will be determined largely by an understanding of the controls that exist around the access and use of information and a general feeling that the Bill's primary purpose is to protect the security of confidential personal data, rather than to facilitate access to it. These controls relate to the security and confidentiality of the data, the fact that it must not be used to an individual's detriment, in either identifiable form or as a result of research conducted at the level of the group, and in relation to any potential commercial access to data. The RCN therefore welcomed the wording of paragraphs 8 and 9 in the Explanatory and Financial Memorandum

110. In response to the concerns raised, the Department reiterated that the use of the information requested must always be for a health or social care purpose which is necessary or expedient in the interest of improving health and social care and in the public interest.

111. In its written and oral evidence the Law Centre also expressed concern about the open-ended definition of 'processing' and it highlighted the obvious concern of 'selling'. It was of the view that service users are likely to be supportive of uses which are in the public interest such as improving health and social care and the efficiency and effectiveness of health and social care services generally. However, it felt that service user and public support for confidential health and social care information being sold to the benefit of private interests was not likely. It therefore recommended that the open-ended definition of processing should be tightened up.

112. The Department advised that there has never been an intention that information could be sold and confirmed that the selling of information will be prohibited in the regulations. It highlighted that even within the current process for anonymised information in the health and social care sector, information cannot be sold. The Department was therefore of the view that is not necessary to make an amendment to the Bill to prohibit the selling of information.

113. The Committee shared similar concerns to witnesses in relation to the open-ended definition of processing. The Committee was of the view that prohibiting

the selling of identifiable information was of such importance for the protection of individuals and public confidence in the Bill, that a Ministerial assurance should be sought that regulations made under this legislation will not make provision for the selling of information which identifies individuals. A Ministerial assurance to that effect was provided and can be found at Appendix 4.

Clause 2: Establishment of committee to authorise processing of confidential information

114. Clause 2 allows the Department to establish a body to authorise the processing of confidential information as defined in the Bill.

115. The Committee noted the Department's intention that a committee be established to authorise the processing of confidential information. However, it shared the view of those who called for the mandatory establishment of a committee, and some of the concerns expressed in relation to its operation and constitution.

Clause 2 (1)

116. The NIHRC, Privacy Advisory Committee, Law Centre, British Dental Association, Royal College of Psychiatrists, Rare Disease Partnership and the Belfast, South Eastern and Southern Health and Social Care Trusts all recommended that the establishment of a committee to authorise the processing of confidential information should be mandatory and the wording of the Bill should be amended to reflect this.

117. The Committee was also firmly of the view that the establishment of the Committee should be mandatory. It felt that this safeguard was of the utmost importance in ensuring that confidential information is protected and due process is followed when applications are received and considered. The Committee wrote to the Department on 15 October 2015 to ask whether it would be prepared to make an amendment to make the establishment of the committee mandatory. The Department provided the wording of a proposed amendment which provides that the Department must by regulations establish a committee. The Committee therefore agreed that it was content to support the Department's proposed amendment at Consideration Stage of the Bill.

Clause 2 (2)

118. The RCN was of the view that a key issue is establishing appropriate safeguards to ensure compliance with the legislation and the safeguarding of personal information. The RCN was unclear about how the proposed committee would discharge this function. It pointed out that the 2014 consultation document stated: “Under the proposals, applicants would have to demonstrate to the advisory group that the use of service user identifiable information is absolutely essential to the successful outcome of their work; that similar results could not be obtained by using anonymised or pseudonymised service user information; and that it is either impossible or impracticable to gain consent from every individual whose data may be used”.

119. The RCN questioned how or why the advisory group proposed in the consultation document had evolved into the committee proposed under the Bill. It noted that the defined purpose of the advisory group was to protect the security and interests of the service user from the non-authorised use of their personal data but pointed out that the Bill states that the purpose of the proposed committee lies in “… the processing of confidential information of a relevant person in prescribed circumstances and subject to compliance with prescribed conditions …”. It recognised that the proposed committee’s functions may well mirror those of the advisory group but, if this is the case, the RCN does not feel that this is readily apparent from the wording of the Bill. The RCN also noted a subtle change of emphasis from protecting the interests and security of the service user to ensuring compliance with the legislation. It felt that these two objectives should be synonymous but noted that they may not always be so.

120. The Department advised that the name of the body was changed in response to comments made during the public consultation. Consultees felt that ‘advisory group’ was a weak description considering the committee will make decisions on the authorisation of disclosure of information.

121. The Committee agreed with this view therefore accepted the Department’s position on the issue.

122. The BMA felt that it is important that, in releasing approved information, general practitioners, who are under immense pressure in caring for their patients, are

not expected to dedicate large and unfunded sections of work time to processing requests for information.

123. In response to the BMA’s concerns in relation to the resources required to process requests for information, the Department advised that the experience in Great Britain would strongly suggest that there is no significant impact on individual Data Controllers.

124. The Committee was content with the Department’s response.

Clause 2(3)

125. The NIHRC noted that the Commissioner for Public Appointments had expressed concern about the lack of diversity and specifically the underrepresentation of women, young people, persons with disabilities and ethnic minorities in public appointments in Northern Ireland. Therefore, the NIHRC recommended that consideration be given to how best to ensure diversity on the proposed committee.

126. The British Dental Association recognised that determining ‘public interest’ is a key responsibility and a critical aspect of the decision making process and highlighted the need to ensure for the committee’s organisational structure to be effective and the decision making processes robust and transparent. The Association also felt that greater clarity on how the committee will operate is needed and that any regulations should be subject to consultation. In relation to its make-up, the British Dental Association was of the view that it should include representation of healthcare professionals, clinicians, patient representatives and those with relevant expertise including clinical research and legal.

127. The Northern Ireland Cancer Registry and Genetic Alliance also thought that the authorising committee should have some representation of patients.

128. The BMA was of the view that the committee should include representatives of medical professions both from primary and secondary care. It also pointed out that membership from the public health community should be sought if the committee is to consider applications for data for public health purposes.

129. The Northern Ireland Cancer Network (lung subgroup) highlighted that the constitution of the committee will be key to its ability to function and deliberate on the diversity of applications while the Health and Social Care Board

emphasised the need for an independent, suitably empowered committee, not only to ensure robust decision making, but also to maintain strong public confidence.

130. The Rare Diseases Partnership felt that the Bill should provide greater clarity on the committee's composition and powers, and its relationship with bodies with similar functions elsewhere. In particular, it considered that the committee should include clinicians, ethicists and patient representatives, and that this should be made clear in the Bill.

131. The RCN felt that it was important, to command public confidence, that the committee must be truly independent in its composition, constitution and outlook, excluding anyone with a vested personal or professional interest in access to personal confidential data. It saw the committee as a guarantor of compliance with the legislation and as an advocate for the rights of service users in this respect.

132. The Royal College of Psychiatrists suggested that the make-up of the committee and the publication of its decisions should be established in the legislation.

133. NILGA pointed out that the committee will need to consider how it will deal with applications from councils or community planning partnerships in a strategic and efficient manner. NILGA requested that full consideration be given to the potential for a senior local government representative (e.g. a Chief Executive) to have membership of the committee. It was of the view that councils should be considered a governmental partner in tackling the public health issues faced in Northern Ireland.

134. The Department advised that, in relation to the operation and constitution of the committee, this would be dealt with in forthcoming regulations that would be subject to draft affirmative procedure.

135. The Committee agreed that it is appropriate for such detail to be included in regulations with the safeguard that they would be subject to scrutiny by the Committee for Health, Social Services and Public Safety and the Assembly draft affirmative procedure.

Clause 3: Code of Practice

136. Clause 3 places an obligation on the Department to publish a Code of Practice in respect of the processing of information.

137. There was broad support for a Code of Practice. However, the Committee, and some of those who responded to its request for evidence, raised a number of issues including the status of the document.

Clause 3(1) and 3(2)

138. The Belfast Health and Social Care Trust, BMA, NILGA and the Northern Ireland Cancer Registry Council all welcomed the requirement that the Department prepares a Code of Practice and the timeframe for review.

139. The Southern Health and Social Care Trust felt that it should be clear that the Code of Practice relates to the processing of information for ‘secondary purposes’ while the British Dental Association, the Rare Disease Partnership and NILGA shared the view that the Code of Practice should be subject to consultation.

140. The Department highlighted that it already has a statutory duty to consult under section 75 of the Northern Ireland Act 1998 and under section 19 of the HSC (Reform) Act (NI) 2009.

141. The Committee was content with the Department’s response.

Clause 3(4) to 3(5)

142. The NIHRC advised that in fulfilling the ‘in accordance with the law’ requirement, any interference with or restriction of Article 8 rights is clearly provided for in primary or secondary legislation and not left to non-binding codes of practice. In any event, the Commission recommended that Clause 3 (4) and 3 (5) are amended to specify ‘must comply with’ rather than must ‘have regard’ to the Code of Practice. The Privacy Advisory Committee was of the view that health and social care bodies must consciously consider the equality duty in section 75 of the Northern Ireland Act 1998 and have ‘due regard’ to the Code of Practice. The Law Centre also considered that ‘regard’ would be better replaced by ‘due regard’.

143. In its oral evidence, the NIHRC referred again to the Code of Practice commenting that it could be strengthened by stating that it must be complied with and, in particular, should address the specific Article 8 safeguards. It noted that there is case law on the issue of guidance and circulars and whether or not they are binding on public authorities and it often depends on the language and on how it is framed and used.

144. The Northern Ireland Cancer Registry and the Northern Ireland Cancer Registry Council pointed out that the Bill refers only to health and social care bodies. They both highlighted that some organisations are undertaking innovative and important work providing population based information for epidemiological research on disease causation and outcomes using health and care data. They were therefore of the view that the legislation should be phrased in such a way to ensure that it does not exclude such work.

145. In response to the comments made, the Department confirmed that the Code of Practice will be fully compliant with the Data Protection Act and Human Rights Act. It stated that the Code will be considered alongside other guidance and legislation and was of the view that the use of ‘must comply with’ would restrict consideration to the Code of Practice only.

146. The Committee did not accept the Department’s response to the concerns raised in relation to the status of the Code of Practice. The Committee felt strongly that the Code of Practice had the potential to be a more robust safeguard against the unlawful processing of information, and was therefore of the view that it should be strengthened. The Committee wrote to the Department on 15 October 2015 asking whether it would be prepared to make amendments to make the Code a compliance code; and insert words to the effect that ‘a court or tribunal may take into account a breach of the code in any proceedings where it considers relevant’.

147. The Department responded advising that a code of practice is guidance to be followed and not meant to be prescriptive or rules for every occasion. It highlighted that a House of Lords case explains the strength of the duty “to have regard to” in a code of practice; that even though an Act or regulation permits the issuing of a code relating to a duty of some kind but does not impose any specific obligation to comply with the code, a court may still decide to have regard to it when considering whether the duty has been fulfilled. A code of

practice is an officially sanctioned code and not a document issued on a voluntary basis without statutory authority.

148. The Department reiterated its point that the Code of Practice will only be one piece of guidance which will assist health and social care organisations to fulfil their functions with regard to processing information. In addition, the organisations will have developed their own policies and procedures to be followed, along with having regard to statutory requirements such as the Data Protection Act and Human Rights Act.

149. The Department did however provide the wording of a proposed amendment to strengthen the provision to require health and social care bodies, and any other person who provides health and social care under arrangements made with a public body who exercises functions in relation to the provision of health and social care, to 'have due regard' to the Code of Practice as opposed to 'have regard'.

150. The Committee was content that the proposed departmental amendment to replace 'have regard' with 'have due regard' would strengthen the status of the Code of Practice. The Committee therefore agreed that it was content to support the Department's proposed amendment at Consideration Stage of the Bill.

151. However, the Committee remained of the view that it should be on the face of the Bill that a court or tribunal may take into account a breach of the code in any proceedings where it considers relevant. The Committee therefore agreed the wording of a proposed Committee amendment to this effect.

Clause 3(6)

152. The Southern and South Eastern Health and Social Care Trusts felt that Clause 3(6) which provides the meaning of 'health care', 'health and social care bodies' and 'social care' should be included earlier in the Bill to provide clarity and limit use to these terms to avoid the introduction of other terms which are more open to interpretation, for example well-being.

153. In response to these concerns, the Department provided the wording of a proposed amendment to remove social well-being from Clause 1(10). It also proposed consequential amendments to move the definitions of 'health care'

and ‘social care’ to Clause 5 (Interpretation) to ensure that they apply to the entire Bill.

154. The Committee was content that the Department’s proposed amendments would address the issues raised in relation to the definitions used and their positioning within the Bill.

Clause 4: Regulations

155. Clause 4 relates to control of regulations made under the Bill.

156. The Law Centre and the Rare Disease Partnership welcomed the requirement that a draft of the regulations will be laid before and approved by resolution of the Assembly. The NIHRC viewed this as an additional protection for Article 8 of the ECHR.

157. The Committee was of the view that it is appropriate that the regulation-making powers are subject to draft affirmative procedure and therefore agreed Clause 4 as drafted.

Clause 5: Interpretation

158. Clause 5 sets out the definitions of specific terms used within the Bill.

159. The South Eastern Health and Social Care Trust recommended that a definition of ‘public interest’ be included whilst the Rare Disease Partnership recommended that the World Health Organisation’s definition of health should be included.

160. The Department highlighted in its response that public interest by its very nature is considered on a case by case basis. It stated that the committee will have the broad skills needed to stringently test this, and the existing case law will also assist. In relation to the definition of ‘health’, the Department confirmed that the current definitions reflect the general duties of the Department.

161. The Committee was content with the Department’s response to the issues raised and therefore agreed Clause 5 as drafted.

Clause 6: Short title and commencement

162. Clauses 6 sets out the title and commencement dates.

163. The Southern Health and Social Care Trust was of the view that the title could be interpreted as a Bill for the control of data processing for all health and social care information in all circumstances, including the purpose for which health and social care information is originally obtained i.e. direct care. It stated that the scope of the Bill could be improved by amending the title to read ‘control of data processing for secondary purposes’.

164. The Northern Ireland Cancer Registry and the Northern Ireland Cancer Registry Council were of the view that the legislation should apply retrospectively to health and social care data already collected.

165. In response to the comments made, the Department advised that the title of the Bill does not affect its scope, and the legislation will not apply retrospectively to health and social care data already collected.

166. The Committee was content with the Department’s response to the issues raised and therefore agreed Clause 6 as drafted.

Clause By Clause Consideration

The Committee conducted its clause-by-clause consideration of the Bill on 11 November 2015. Information on the Committee's deliberations on the individual clauses in the Bill, which sets out the context to the decisions reached by the Committee, can be found in the previous section of this report. Details of the Department's proposed amendments can be found in Appendix 4.

Clause 1 - Control of information of a relevant person

Agreed: the Committee is content with Clause 1 subject to the amendments proposed by the Department: to permit the sharing of information in the public interest only if it is connected to a health or social care purpose; to permit the processing of information only if authorisation is granted by the committee established under section 2(1); to replace 'social well-being' with 'social care' in Clause 1(11); and remove the superfluous word 'services' from Clause 1(14); and, the amendment proposed by the Committee to place an opt-out provision on the face of the Bill as follows:

Clause 1, Page 2, line 17

At end insert -

'(5A) Regulations under subsection (1) may not make provision requiring the processing of information of a relevant person who has notified the Department to cease, or not to begin, processing information in respect of which that person is the subject.'

Clause 2 – Establishment of committee to authorise processing of confidential information

Agreed: the Committee is content with Clause 2 subject to the amendment proposed by the Department to redraft Clause 2(1) to ensure the establishment of the committee to authorise the processing of information.

Clause 3 – Code of Practice

Agreed: the Committee is content with Clause 3 subject to the amendment proposed by the Department to redraft Clause 3(4) and (5) to require health and social care bodies, and any other person who provides health and social care under arrangements made with a public body who exercises functions in relation to the provision of health and social care, to have due regard to the Code of Practice; and, the amendment proposed by the Committee which provides that the Code of Practice may be taken into account by a court or tribunal in any case in which it appears to the court or tribunal to be relevant as follows:

Clause 3, Page 4, line 27

At end insert-

‘(5A) Failure to observe any provision of the code of practice does not of itself make a person liable to any criminal or civil proceedings.

(5B) A code of practice–

(a) is admissible in evidence in criminal and civil proceedings; and

(b) may be taken into account by a court or tribunal in any case in which it appears to the court or tribunal to be relevant.

Clause 4 – Regulations

Agreed: the Committee is content with Clause 4 as drafted.

Clause 5 – Interpretation

Agreed: the Committee is content with Clause 5 as drafted.

Clause 6 – Short title and commencement

Agreed: the Committee is content with Clause 6 as drafted.

Long Title

Agreed: the Committee is content with the Long Title of the Bill.

Links to Appendices

Printable version of Report can be accessed here

Appendix 1 - Minutes of Proceedings can be viewed here.

Appendix 2 - Minutes of Evidence can be viewed here.

Appendix 3 - Written submissions can be viewed here.

Appendix 4 - Correspondence from the Department and Other Papers here.

Correspondence from the Department and Other Papers

Table of Contents

1. Departmental Briefing Paper 11.06.15
2. Ministerial Response - Control of Data Processing Bill 18.08.15
3. Letter to DALO - Control of Data Processing Bill 17.09.15
4. Departmental Response - Summary of Evidence of the Bill 17.09.15
5. Ministerial letter - Evidence considered by Department 14.10.15
6. Departmental Response - Amendments to the Bill 30.10.15
7. Ministerial Letter - Ministerial Assurance 05.11.15
8. Research Paper - Key Provisions of the Control of Data Processing Bill 10.09.15

The information contained in this document is available online at:

www.niassembly.gov.uk

This document can be made available in a range of alternative formats including large print, Braille etc. For more information please contact:

Committee for Health, Social Services and Public Safety
Marie Austin
Northern Ireland Assembly
Parliament Buildings
Ballymiscaw
Stormont
Belfast BT4 3XX

Tel: 028 90 521947

Email: committee.hssps@niassembly.gov.uk

ISBN 978-1-78619-014-7

© Copyright Northern Ireland Assembly Commission 2015