Clause 1(1)

The Committee expressed concern about the breadth of the term 'in the public interest'. The Committee considered the possibility of sharing information in the public interest only if it was connected to a medical or social care purpose.

- The Committee agreed to ask whether the Department would be prepared to make an amendment to allow the sharing of information in the public interest only if it was connected to a medical or social care purpose.

The Department agrees that this amendment would make the link between "medical and social care purposes" and "public interest" clear and explicit. The sharing of information in the public interest will only be permitted if it is connected to a medical or social care purpose.

The Department further proposes to change "<u>medical or social care purposes</u>" to "<u>health or social care purposes.</u>"

This amendment would -

- **more visibly 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 ("the 2009 Reform Act"). "Health and social care purposes" (as defined in Clause 1(13) and (14)) will underpin the general duties of the Department which are to promote an integrated system of health care services designed to secure improvement in the physical and mental health of people in Northern Ireland and in the prevention, diagnosis and treatment of illness and social care services designed to secure improvement in the social well-being of people in Northern Ireland, and**
- **introduce consistency to the terminology used in the Bill.**

  To ensure that the scope of the Bill remains unchanged the name of the definition of "medical purposes" in Clause 1(13) would be changed to

read "health care purposes". The substance of the definition will remain unchanged.

The Committee also considered the possibility of completely removing reference to public interest.

- The Committee agreed to request clarification of the implications of removing reference to public interest and whether the Department would be prepared to make such an amendment.

The requirement for all processing to be in the public interest is a further safeguard in the process. The burden of evidence will be on the person applying to the committee for access to information to prove what good will this do – eg will it provide information to feed into research, will it provide information which will help the HSC provide a better, more effective service to patients, will it help ensure that a specific intervention or treatment is effective. The Department would contend that removing the reference to "public interest" would remove an important safeguard in the Bill.

The Committee expressed concern about the open-ended direction of the introductory paragraph in Clause 1 'as it considers necessary or expedient'.

- The Committee agreed to seek confirmation of the implications of removing 'as it considers necessary or expedient' and whether the Department would be prepared to make such an amendment.

The wording of this clause means that everything must be either necessary or expedient for the purposes stated in clause 1(1). If the phrase "as it considers necessary or expedient" 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 would contend that removing the reference to "necessary and expedient" would remove an important safeguard in the Bill.

The Department proposes that Clause 1(1) be redrafted as follows:

1.—(1) The Department must by regulations make such provision for and in connection with requiring or regulating the processing of prescribed information of a relevant person for health or social care purposes as it considers necessary or expedient in the public interest.

Clause 1(2)

The Committee acknowledged that an opt-out provision already exists in health and social care; under section 10 of the Data Protection Act, and that this Bill is compliant with the Act. It also acknowledged that putting 'opt-out' on the face of the Bill would be duplicating an existing provision. However, the Committee was of the opinion that the right to opt-out, and the potential for raising public awareness of the right to opt-out, was of such importance that it should be on the face of the Bill.

- The Committee agreed to ask the Department whether it would be prepared to make an amendment to put 'opt-out' on the face of the Bill.

Given the provision for opt out which already exists, the Department would contend that is not necessary to include a provision for "opt out" on the face of the Bill.

By virtue of clause 1(8) of the Bill all applications for access to information will be subject to the provisions of the Data Protection Act 1998 (DPA).

Section 10 of the DPA already provides that an individual has the right to object to processing of their personal information if it would cause unwarranted and substantial damage or distress.

Furthermore the Bill will establish a statutory basis which will *allow* for the sharing of information. The committee will not have the power to compel the data controller to share information. For any approved application, it will ultimately be for the data controller to decide what information is released. In this way the wishes of those who do not want their information used for purposes beyond the immediate provision of care will be respected.

The DPA also places an obligation on data controllers to ensure that information is fairly processed. Fairness requires data controllers to be transparent – clear, honest and open with individuals about how their information will be used. This enables people to make informed decisions.

At recent evidence sessions the Department gave a commitment that, at the appropriate time, it will undertake an awareness campaign which will provide information about "opt out".

Clause 1(3)

The Committee was of the view that information should only be processed if authorisation is granted by the Committee.

- The Committee agreed to ask the Department 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 is prepared to make this amendment and proposes that clause 1(3) be redrafted as follows:

1.- (3) Regulations under subsection (1) which make provision in relation to the authorisation of the processing of confidential information of a relevant person must provide that such information may only be processed if authorisation is granted by the committee established under section 2(1).

Clause 1(10) and Clause 1(11)

The Committee expressed concern about the breadth of the term 'social well-being' in Clause 1(10) and Clause 1(11). It was suggested that it should be replaced with the term 'social care'. The Committee however was unclear about the implications of replacing "social well-being" with 'social care'.

- The Committee agreed to seek clarification of the implications of replacing 'social well-being' with 'social care' and ask whether the Department would be prepared to make such an amendment.

The Department is prepared to make this amendment to clause 1(11) and proposes that the clause be redrafted as follows:

1.--(11) For the purposes of this Act, "a relevant person" means an individual who is a recipient of—
(a) health care; or
(b) social care.

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.

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.

"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 objects 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.

Clause 1(15)

The Committee expressed serious concerns about the open-ended definition of processing, including the obvious concern of selling. The Committee noted that the Department intended to make it clear in regulations that selling is prohibited, however it felt strongly that it should be on the face of the Bill.

- The Committee agreed to ask the Department whether it would be prepared to make an amendment to the Bill to make provision to prohibit the selling of information.

"Prescribed" is defined in Clause 5 of this enabling Bill as "prescribed in regulations made by the Department".

By virtue of clause 4(2) these regulations will be subject to draft affirmative procedure in the Assembly, along with public consultation and scrutiny by the Health Committee.

The Department would contend that is not therefore necessary to make an amendment to the Bill to prohibit the selling of information.

Clause 2(1)

The committee felt strongly that the establishment of a committee to authorise the processing of confidential information should be mandatory.

- The committee agreed to ask the department whether it would be prepared to make an amendment to make the establishment of the committee mandatory.

As a committee will have to be established and authorisation for processing will have to be given by this committee to ensure the process operates as intended the Department is prepared to make this amendment and proposes that Clause 1(3) be redrafted as follows:

2.—(1) For the purposes of subsection (2), the Department must by regulations establish a committee.

Clause 2(3)

The Committee referred to the Assembly Examiner of Statutory Rules' recommendation that, if Clause 2(1) is amended to make the establishment of the committee mandatory, the regulation-making power in Clause 2(3) might be slightly recast to contain a regulation-making power setting out the detailed matters mentioned in that provision as drafted on introduction.

- The Committee agreed to ask the Department whether it would be prepared to make amendments to address the Examiner's recommendation if the establishment of the committee is made mandatory.

The Department proposes to make the establishment of a committee mandatory (see amendment to clause 2(1) above). Regulations, which will be made under the power in Clause 2(3), will then set out the detail of the process. These regulations will be subject to draft affirmative procedure along with public consultation and Committee scrutiny.

The Department would therefore contend that it is not necessary to redraft clause 2(3) in the manner suggested by the Examiner.

Clause 3(4) and Clause 3(5)

The Committee was of the firm view that the Code of Practice could be strengthened as a safeguard and recommended that it 'must be complied with'. The Committee also expressed a view that the insertion of words to the effect of 'a court or tribunal may take into account a breach of the code in any proceedings where it considers relevant' should be included in the Bill.

- The Committee agreed to ask the Department 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'.

A code of practice is guidance to be followed and not meant to be prescriptive or rules for every occasion. However 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.

The Code of Practice which will be prepared and issued by the Department will only be one piece of guidance which will assist HSC organisations to fulfil their functions with regard to processing information. 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.

The Department has previously indicated that it is prepared to strengthen this 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.

The Department contends that this amendment would address the Committee's concerns and proposes that clause 3(4) and (5) be redrafted as follows:

3-- (4) Health and social care bodies must have due regard to the Code of Practice in exercising their functions in relation to the provision of health and social care.

3-- (5) 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, must, in providing such care, have due regard to the Code of Practice.

Clause 3(6)

The Committee questioned whether the definitions 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 e.g. well-being.

The Committee agreed to consider this issue further when the Department's response to issues raised in relation to social well-being had been received.

The Department will await further communication from the Committee on this issue.