Briefing for the Health Committee – w/c 11 October 2021

The Health and Care Bill was introduced in the House of Commons on 6 July 2021. A link to the Bill as introduced in Parliament is available on the UK Parliamentary website:

https://publications.parliament.uk/pa/bills/cbill/58-02/0140/210140.pdf

The Bill contains 6 parts with 16 Schedules addressing a range of issues relating to health and social care and builds on recommendations for reform set out by NHS England in the NHS Long Term Plan published in 2019 and in the White Paper 'Integration and Innovation: Working together to improve Health and Social Care for all' published in February 2021.

The Bill aims to:

a. Promote local collaboration;
b. Reform the NHS Provider Selection Regime;
c. Improve accountability and enhancing public confidence in the health and care system; and
d. Deliver a range of targeted measures to support people at all stages of life.

The Bill also contains provisions to support social care, public health and quality and safety in the NHS. These are designed to address specific problems or remove barriers to delivery, maximise opportunities for improvement, and have, in most cases, been informed by the experience of the pandemic.

The Department of Health and Social Care has offered to carry four provisions in the Bill that touch on devolved matters on behalf of Northern Ireland, by way of the legislative consent process. These provisions include:-

- International Healthcare Arrangements (Reciprocal Healthcare),
- Medicines & Healthcare products Regulatory Agency (MHRA),
- Professional Regulations, and
- Arm's Length Bodies (ALBs) – Transfer of Functions

Minister Argar wrote to the Department of Health (DoH) on the 5 July offering to carry the above four provisions on behalf on Northern Ireland via the legislative consent process. Minister Swann responded to indicate agreement in principle, subject to scrutiny by the Health Committee, and agreement of both the Executive and Assembly. Minister Swann wrote to the Health Committee on the 8 July to inform of this approach, and the intention to progress the legislative consent process in September due to imminent Summer recess.

Minister Swann wrote to Health Committee on 27 September updating on the intention to progress the four legislative motions separately. An Executive Paper seeking approval for the four provisions to be carried, and four separate LCMs be progressed on 29 September was circulated An updated version taking account of comments received was recirculated on 5 October. The Department of Infrastructure (DfI) responded to indicate they welcomed discussing forward, with nil responses received from both the Departments of Agriculture, Environment and Rural Affairs (DAERA), and Justice (DoJ). It was proposed to include the Executive Paper on the Agenda for the Executive meeting on the 7 October.

The paper did not make the agenda on the 7 October, and Minister Swann raised an urgent procedure request on the 8 October to seek FM/dFM approval for the provisions to be carried and individual LCMs be progressed. As at the 11 October a formal response to this request had not yet been received, and confirmation of the response will be provided to the Committee on the 14 October.

Minister's correspondence to the Health Committee on 27 September expressed the intention that four separate Legislative Consent Motions (LCMs) would be taken forward. Individual briefing on each LCM is set out in the attached Annexes as follows:

Annex A – International Healthcare Arrangements
Annex B- Medicines & Healthcare products Regulatory Agency (MHRA)
Annex C - Professional Regulations
Annex D - Arm's Length Bodies (ALBs)-Transfer of Functions Power

Annex A

INTERNATIONAL HEALTHCARE AGREEMENTS

Background

- Reciprocal healthcare is a small and important element of general healthcare policy in the UK. Reciprocal healthcare agreements support people from the UK to obtain healthcare when they live in, work in or visit other countries (and vice versa for people from other countries who are in the UK).

- These normally involve the UK and the other country agreeing to waive healthcare charges for migrants, workers or visitors. Some agreements involve the UK and other countries reimbursing one another for the cost of healthcare—this approach underpins the EU reciprocal healthcare arrangements. Reciprocal healthcare agreements can facilitate cooperation on planned treatment or other areas of healthcare policy.

- In 2019 Parliament enacted the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (HEEASAA) to establish a legal basis for the Secretary of State to fund and implement reciprocal healthcare, and share necessary data, after the UK left the EU. The Act contained powers to implement new bilateral agreements with individual Member States and to establish detailed unilateral arrangements to support certain people to access healthcare in an EEA state or Switzerland if no bilateral arrangement was in place in the event of a no deal exit from the EU. During the Lords stages there were significant changes to limit the original global scope of regulations and to confine the Bill to arrangements with EEA countries and Switzerland.

- The UK agreed on 19 October 2019, the EU Withdrawal Agreement, EEA EFTA Separation Agreement (agreed 20 December 2018 and signed 28 January 2020) and the Swiss Citizens' Rights Agreement (announced 20 December 2018 and signed 25 February 2019), which all provide for legacy reciprocal healthcare rights for citizens who used their right to free movement before the end of transition.

- On 20 December 2020, the UK signed the Trade and Cooperation Agreement (TCA) with the EU. The TCA contains a Protocol on Social Security Coordination which provides UK Nationals with access to a range of social security benefits, including reciprocal healthcare cover when they are in the EU.

- The UK/Ireland Common Travel Area Enduring Healthcare Agreement was signed by officials on 18 December 2020 and the UK-Switzerland Convention on Social Security Coordination has been signed on 9 September 2021 and is due to come into operation in November 2021.

- NHS Business Services Authority (NHSBSA) manages reciprocal healthcare, including administering payments for healthcare costs for which the UK is responsible, on behalf of England, Scotland, Wales, and Northern Ireland. However, decision making for planned care under the SSC Protocol rests with the Health and Social Care Board and Trusts have a function to report EHIC use to enable reclamation of funds.

- Currently, the Secretary of State only has powers under HEEASAA to implement comprehensive reciprocal healthcare agreements within the EEA and Switzerland. The limited territorial scope of the powers in HEEASAA mean that the Secretary of State does not have the necessary powers to implement reciprocal healthcare agreements with Rest of World (ROW) countries, including, for example, British Overseas Territories and Crown Dependencies, other than the ability to exempt individuals from charges for relevant healthcare charges.

- The UK has a number of reciprocal healthcare agreements with countries outside the EU which are; Anguilla, Australia, Bosnia and Herzegovina, British Virgin Islands, Falkland Islands, Faroe Islands, Gibraltar, Isle of Man, Israel, Jersey, Kosovo, Montenegro, Montserrat, New Zealand, North Macedonia, Norway, Serbia, St Helena and Turks and Caicos Islands.

- They are limited in scope because of the absence of financial reimbursement or data sharing powers. For example, under the terms of reciprocal healthcare agreements the UK has with ROW countries, UK nationals are able to access emergency treatment should they require it, however, access to haemodialysis

for kidney patients is restricted or not included within the scope of these agreements.

- The Bill, at Part 5: Miscellaneous, seeks to amend HEEASAA to enable the Secretary of State to implement comprehensive bilateral healthcare arrangements with ROW, to pay for treatments outside the UK and facilitate the necessary data processing by expanding the scope to countries, territories and international organisations outside the EU, EEA and Switzerland.

- The draft clauses also allow the Secretary of State to make regulations to implement the international arrangements by conferring functions on public authorities across the UK by an amended regulation making power at Section 2 of HEEASAA.

- Having UK-wide legislation for international healthcare arrangements will ensure a consistent framework for the negotiation and implementation of these arrangements. However, as international relations are an excepted matter, but health is devolved any future regulations taken forward that would have a devolved implication is subject to a statutory duty to consult the devolved administrations before regulations are made. Section 5; *Requirement for consultation with devolved authorities*, of HEEASAA sets out this duty.

- This duty is underpinned by a Memorandum of Understanding (MOU) which sets out the mechanisms by which the UK nations will work together to deliver on international healthcare arrangements from negotiation to implementation.

- Building on the working practices established in preparation for the UK's exit from the EU, departmental officials are working with the Department of Health and Social Care and the other devolved administrations to developed a revised comprehensive MOU to HEEASAA to set out how the UK regions will work together to develop and implement any future international healthcare agreements and to ensure where functions are conferred on public authorities in Northern Ireland they can be legislated for by the Assembly where possible.

Annex B

MEDICINES INFORMATION SYSTEM(S)

Introduction

1. The Health and Care Bill is being used as the legislative vehicle to make an amendment to the Medicines and Medical Devices Act 2021 (MMDA).

2. The draft motion, be tabled by the Minister of Health in respect of this amendment is:

> ***"That this Assembly endorses the principle of the extension to Northern Ireland of the provisions within the Health and Care Bill dealing with medicine information systems, that will allow an amendment to the Medicines and Medical Devices Act 2021, to enable information systems in relation to human medicines to be established and managed by the Health and Social Care Information Centre, and will align section 19 of the Medicines and Medical Devices Act 2021 that deals with Medical Devices Information Systems with the new provisions for a Medicines Information System"***

3. In terms of the relevant policy objective, the Health and Care Bill provides for an enabling power within the MMDA to allow for a UK wide medicines information system (or systems) to be established and managed by NHS Digital.

4. The Committee will recall they gave support to a legislative consent motion last autumn to be considered by the Assembly for a similar power to establish and operate one or more information systems in relation to medical devices. This enabling power was included in the then Medicines and Medical Devices Bill and the Assembly motion was agreed on 30th November 2020. The Bill was enacted in February 2021.

Medicines Information Systems

<u>Why is this provision necessary?</u>

5. UK-wide obligations to capture data, potentially through a registry, to address specific gaps in knowledge regarding the use, safety, and/or effectiveness of

their products can already be placed on Marketing Authorisation Holders (MAHs) for medicines in the UK by the MHRA through post-authorisation commitments detailed in a medicine's approved Risk Management Plan.

6. However, MAH designed and controlled registers and registries have not consistently delivered the required evidence in reasonable time frames partly due to a lack of trust from clinicians and patients but also partly due to the way in which they are set up, placing burdens on healthcare providers for additional data entry, meaning that they have often failed to recruit sufficient patients to meet the required objectives.

7. Furthermore within the Independent Medicines and Medical Devices Safety Review chaired by Baroness Julia Cumberlege (IMMDS Review) (published on 8 July 2020), that review explicitly states that "We also want to see a registry for all women on antiepileptic drugs who become pregnant, to include mandatory reporting of data relating to them and their child(ren) collated over lifetimes. This should not be limited to sodium valproate but should include all antiepileptic drugs." (para 4.91). The report also adds that "This registry could potentially be expanded to collect data on paternal and transgenerational effects (i.e. effects in children of those who were exposed to valproate in utero), both issues which have been raised by those affected as being of great concern" (para 4.92)

8. Although Section 3(1)(h) of the MMDA enables regulations made under clause 1(1) to amend or supplement the requirements around recording information about the supply of human medicine, this section does not go far enough to allow the breadth of data related to the practices around prescribing nor to allow the collection of the breadth of information on patient outcomes that would make a UK wide registry a valuable resource for all stakeholders. Furthermore there is currently no provision for a registry for monitoring medicines prescribed to patients in the Human Medicines Regulations 2012. Therefore MHRA need an explicit power to establish such a registry.

9. In order to develop a Medicines Information System on a statutory basis an amendment to the MMDA is being proposed. This statutory basis will ensure

that, for the issues where there are the most significant known or potential risks to patient safety, MHRA as the UK Regulator will be able to build fit for purpose registries, and that in turn will improve the ability to reduce harm.

How will this provision be used?

10. This, similar to the Medical Devices Information System (MDIS) provision, is an enabling provision to allow regulations to be developed to establish a Medicines Information System (MIS). The Regulations once drafted, will contain the full details on how the MIS will be established and how it will operate.

11. It is envisioned that a two-stage approach will be adopted for collection of information about medicines:-

    i. Requirements about information relating to medicines to be provided to NHS Digital who will combine the data from various sources and hold this in an information system; and

    ii. MHRA to use the data compiled by NHS Digital to establish specific medicine registries.

12. A registry would only be set up by the MHRA through this power when alternative approaches to capturing sufficient data are not feasible and there is sufficient public health need. The intention is that a registry could only be initiated where one of the following criteria apply:

    i. There are known risks associated with a medicine that can result in serious adverse health outcomes and where adherence to effective risk minimisation measures is critical to ensuring the benefits associated with the medicine outweigh the risks

    ii. There are substantive unknowns about the safety or effectiveness of a medicine in a population in whom prescribing may occur that mean that urgent evidence is required to build the evidence base on the benefit

risk balance and inform the need for and feasibility of risk minimisation measures.

13. Further, it must be clear that a MAH would not be able to deliver a registry that would provide the strength of evidence the MHRA, and the wider healthcare system require. This may be because the proposed objectives of the registry are such that full UK national coverage of the registry is preferred or necessary and/or that the incorporation of data routinely captured through the health service would be required to support a successful registry.

What are the benefits of having UK wide medicine information system

14. A comprehensive, UK-wide medicines registries can be a potentially important tool in improving patient safety through better post marketing surveillance of the use of medicines. The proposed registries will support the MHRA's regulatory functions and a UK-wide registry is more robust for pharmacovigilance reasons. This is particularly important with regards to high risk medicines as there is the potential by having these registries mandatory, the ability to reduce harm will be improved.

What safeguards are in place to protect the sharing of patient data with regards this enabling provision to establish a Medicines Information System?

15. This enabling power is restricted to purposes related to the safe and effective use of human medicines and a number of safeguards are in place on its use.

16. Northern Ireland has in place strong information governance arrangements and a code of practice on the sharing of patient identifiable information both for direct care and secondary use. Patient's data shall be held securely, controlled and processed in compliance with data protection laws and General Data Protection Regulation (GDPR) that will ensure patient information will be protected.

17. No regulations can be taken forward on the MIS without the consent of the Department, as when regulations are to be made under the new section 7A for the MIS, the Department will be the appropriate authority either alone or jointly with the Secretary of State and therefore the Department's consent is necessary.

18. The situation is different for MDIS where the Secretary of State has sole authority, as the subject matter of medical devices is a reserved matter, but Committee will recall last year the devolved administrations negotiated a statutory consultation clause to the Medicines and Medical Devices Bill and no regulations can be made without proper consultation with the devolved administrations, and this means that the DAs can legally challenge the Secretary of State if there is a failure to consult properly.

<u>What other amendments are being taking forward under this clause in the Health and Care Bill under the heading of Medicines Information System?</u>

19. In order to align provision for an offence of disclosing information that is already included in the MMDA for MDIS, provision is also now made for the MIS. This provision was shared with the Department of Justice and advice was received from officials that this new offence of disclosure of information is consistent, proportionate and will not have a detrimental impact on the justice system in Northern Ireland.

Medical Devices Information System (MDIS)

20. Clause 85 of the Health and Care Bill also makes technical amendments to section 19 of the MMDA dealing with the Medical Devices Information System (MDIS), which are intended to align with the new provisions for the MIS and which will enable NHS Digital to share information they receive which comes from data linkage, and to contain commercially sensitive technical information about devices.

21. Furthermore in order to align provision for an offence of disclosing information that is already included in the MMDA for MDIS, provision is also now made for the Medicines Information System. This provision was shared

with the Department of Justice and advice was received from officials that this new offence of disclosure of information is consistent, proportionate and will not have a detrimental impact on the justice system in Northern Ireland.

22. Clause 85 of the Health and Care Bill also makes technical amendments to Section 43 of the MMDA to allow for technical elements of the Health and Social Care Act 2012 that establish and constitute NHS Digital to be amended, in order that secondary legislation taken forward for MIS and MDIS is coherent and consistent. This power will only be exercisable when making regulations under the new section 7A of MMDA dealing with MIS, or under section 19 of the MMDA dealing with MDIS, and therefore subject to the safeguards as discussed in paras 17 and 18 above,

Conclusion

23. It is hoped the above briefing note will help the Committee with writing their report for the Assembly and to enable Assembly debate to take place on the legislative consent motion as outlined in para 2 above.

Annex C

PROFESSIONAL REGULATION

Introduction

1. Thank you for the opportunity to brief the Committee today on the Health and Care Bill 2021, which was introduced in Parliament on 6th July 2021, with particular reference to the provisions of the Bill (Clause 123) that deals with the regulation of healthcare professionals.

Background and context

2. The need for reforming the regulation of healthcare professionals has been acknowledged for many years, not least since the Law Commissions Report on the Regulation of Healthcare Professionals in 2015. It is considered that the UK model of regulation for healthcare professionals is rigid, complex and needs to change to better protect patients, support our health services and to help the workforce meet future challenges. In doing so, it needs to be faster, fairer, more flexible and minimise costs to registrants.

3. Regulation of healthcare professionals is a devolved matter in Northern Ireland. The policy approach of the Department of Health, and that of the Health Departments in England and the other Devolved Administrations, is to work on a four country basis regarding healthcare profession regulatory matters. This reflects the practical reality that the vast majority of the regulation of healthcare professions is performed by regulatory bodies which operate UK-wide, thereby ensuring a consistent approach across the wider NHS.

4. The powers sought through this provision of the Health and Care Bill form part of a wider reform programme aiming to create a more flexible and proportionate regulatory framework for the healthcare professions that is better able to protect patients and the public. The proposals will enable the

regulators to achieve more responsive and accountable regulation including putting in place modern and efficient fitness to practise processes which will better support professionals.

5. The UK wide consultation “Promoting Professionalism, Reforming Regulation”, published October 2017, set out the high-level principles for reform. These were widely welcomed by stakeholders, including in Northern Ireland. The subsequent joint response of the four UK Governments, published in July 2019, set out plans to modernise the legislation of all the nine UK-wide regulators using the Westminster secondary legislative route provided under Section 60 of the Health Act 1999.

6. The White Paper: “Integration and Innovation: Working Together to Improve Health and Social Care for All”, published in February 2021, included a proposal to widen the scope of Section 60 of the Health Act 1999 to assist taking forward delivery of the reform agenda. This is taken forward by this provision.

7. This proposal therefore supports the UK-wide agenda to reform the regulation of healthcare professionals. The objectives of reform are to ensure that the level of regulatory oversight of healthcare professions is proportionate to the risks to the public, now and in the future; the bureaucracy of healthcare regulation is reduced; and that the professions protected in law are the right ones.

8. Given the UK-wide reach of the relevant healthcare regulatory bodies, and policy framework within which they operate, it is essential that the scope of these provisions extends to Northern Ireland. Legislative divergence in this area may seriously disrupt the movement of regulated healthcare professionals across the UK for training and career advancement with potential negative consequences on the delivery of care.

9. Section 60 of the Health Act 1999 provides powers to make changes to the UK-wide professional regulatory landscape through secondary legislation.

This provision - Clause 123 of the Bill (Part 5 - Miscellaneous) - Regulation of health care and associated professions - will widen the scope of Section 60 and enable the Secretary of State to make additional changes. These are: close a regulator whose professionals have been moved to another regulator or have been deregulated; take professions out of the regulation where this is no longer required for the protection of the public; and enable the delegation of previously restricted functions to other regulators. It also provides for potential future expansion of the use of Section 60 to include Senior NHS Managers and Leaders.

10. Secondary legislation made using the new powers would be subject to the existing provision in Schedule 3, namely, a public consultation and the affirmative parliamentary procedure.

11. Any use of the Section 60 Order can only extend to Northern Ireland with prior approval from Northern Ireland's Minister for Health. Any use of this Section 60 legislative route would, as stated in Schedule 3, be subject to a three month statutory consultation and the affirmative procedure at Westminster. In addition, any Section 60 Order that would amend the Northern Ireland statute book, for example in respect of the Pharmaceutical Society of Northern Ireland, would also require a Legislative Consent Motion of the Northern Ireland Assembly.

The provisions of Clause 123

12. This Clause will provide:

- **the power to remove a profession from regulation**
  The removal of a profession from statutory regulation through secondary legislation will make it easier to ensure that the protections and regulatory barriers that are in place remain proportionate for all health and care professions.

- **the power to abolish an individual health and care professional regulator**
  There is inevitable duplication in having nine regulatory bodies (10 including Social Work England) performing similar functions in relation to different professions. It may be assessed in the future that reduction in the number of regulators would deliver public protection in a more consistent way, while also delivering financial and efficiency savings. Powers under Section 60 already allow for the creation of a new regulators through secondary legislation. However, it is not possible to use these powers to close a regulator.
  This change would allow the Secretary of State to exercise this power and enable Parliament to abolish a regulator using secondary legislation, where its regulatory functions have been merged into or subsumed by another body or bodies, or where the professions that it regulates are removed from regulation.

- **The power to remove restrictions regarding the power to delegate functions through legislation**
  Regulators are currently restricted from delegating to another body some of their core functions. This includes the keeping of a register of persons permitted to practise; determining standards of education and training for admission to practice; giving advice about standards of conduct and performance; and administering procedures relating to misconduct and unfitness to practise.
  The removal of these restrictions would enable a single regulator to take on the role of providing a function across some or all regulators. This will help to deliver public protection in a more consistent fashion and may also increase efficiency. Where a function is delegated, a regulator would retain responsibility for that function.

- **Clarifying the scope of section 60 to include senior NHS managers and leaders**
  Expanding the definition of professions covered by Section 60 to include senior managers and leaders and other groups of worker would enable the

government to extend regulation to those groups in the future should it be decided to do so.

Other amendments

13. The Bill also contains provisions to support social care, public health and quality and safety in the NHS. These are designed to address specific problems or remove barriers to delivery, maximise opportunities for improvement, and have, in most cases, been informed by the experience of the pandemic.

14. The Bill contains 6 parts with 16 Schedules addressing a range of issues relating to health and social care. Part 1 deals with the health service in England regarding integration, collaboration and other changes.

15. Part 2 of the Bill deals with health and adult social care information.

16. Part 3 of the Bill provides a new primary power to allow the Secretary of State (SoS) to transfer functions to and from specified Arm's Length Bodies (ALBs), and to delegate the SofS's functions to them.

17. Part 4 of the Bill covers The Health Services Safety Investigations Body including the Establishment of the HSSIB, Investigations and reporting.

Why a Legislative Consent Motion is needed

18. Health is a transferred matter and, as such, falls within the legislative competence of the Northern Ireland Assembly. The Bill contains a number of clauses which form part of a wider programme of reform to professional regulation which is being taken forward by the UK Government and the devolved administrations.

It is intended to bring each provision forward as an individual Legislative Consent Motion (LCM). This is based on a balance of efficiency. If amendments are taken forward by Westminster in respect to any of the devolved NI provisions, and in turn the NI provisions are linked on one LCM motion, this amendment change will impact on the entire LCM motion, potentially resulting in repeating previously cleared steps up to, and including the possibility of a 2nd, separate LCM being required to cover amendments not scoped within the original LCM, thereby generating unnecessary repetition work for all, and time delays.

Action taken to date

19. Following introduction of the Health and Care Bill on 6 July 2021, Westminster offered to carry four provisions on behalf of Northern Ireland which deal with transferred matters. These provisions include Arms Length Bodies (ALBs) – Transfer of Functions. Minister Swann responded 8 July to indicate agreement in principle to take forward the legislative consent process, subject to scrutiny from Health Committee and agreement from the Executive and Assembly, and advised both Executive Colleagues and Health Committee of these developments. Due to impending Summer recess, DoH officials continued to engage with DHSC and DSO over the Summer on this work.

Minister Swann circulated an Executive Paper seeking approval for the four provisions to be carried, and four separate LCMs be progressed on 29 September. An updated version taking account of comments received was recirculated on 5 October. The Department of Infrastructure (DfI) responded to indicate thy welcomed discussing forward, with nil responses received from both the Departments of Agriculture, Environment and Rural Affairs (DAERA), and Justice (DoJ). It was proposed to include the Executive Paper on the Agenda for the Executive meeting on the 7 October.

The paper did not make the agenda on the 7 October, and Minister Swann raised an urgent procedure request on the 8 October to seek FM/dFM approval for the provisions to be carried and individual LCMs be progressed. As at the

11 October a formal response to this request had not yet been received, and confirmation of the response will be provided to the Committee on 14 October.

Current position with the Health and Care Bill 2021

20. The Westminster Parliament introduced the Health and Care Bill on 6 July 2021. The Bill has completed its First and Second Stages in the House of Commons and commenced its Committee Stage on 14 September 2021, which is currently ongoing and due to finish on 28 October 2021. At Committee Stage proposed amendments to the Bill are submitted and tabled for debate by Parliament at Report Stage. Amendments must be tabled before 2 November 2021, a final report on amendments will be prepared for circa 9 November 2021 (before parliamentary recess). It is expected that Report Stage of the Bill, when amendments will be debated and voted upon, will take place circa 17 November 2021.

That concludes our briefing. Thank you Chair and Committee members for your time. We are happy to answer any questions you may have.

Annex D

ALB TRANSFER OF FUNCTIONS POWER

Background and context

1. The underpinning policy aim is to improve health outcomes by way of increases in efficiency, effectiveness and economy.

2. The ALB Transfer of Functions provision introduces a new primary power to allow the Secretary of State (SoS) to transfer functions to and from specified England Arm's Length Bodies, and to delegate the SofS's functions to them. Secondary legislation will be required to progress any proposed transfers.

Bodies within the Bill that provide function in respect of Northern Ireland

3. Five relevant bodies and one Special Authority within the Bill provide functions to Northern Ireland. An overview of this position is as follows:

Health Education England (HEE), Hosts the UK Foundation Programme Office (UKFPO)

None of the proposals as they relate to HEE, appear to have any implications for Northern Ireland.

Health and Social Care Information Centre, known as NHS Digital, may collect data on behalf of Devolved Administrations via non-mandatory requests

Health Research Authority (HRA), has a statutory requirement to work with Devolved Administrations. Some powers for some research UK-wide. Where the research relates to a devolved subject area, then the HRA has no remit. IT systems are UK-wide. Acts for UK Ethics Committee Authority (UKECA)

Research is very much a collaborative process and is delivered through large-scale studies with multiple sites in more than one UK nation or sometimes also internationally. Northern Ireland is represented at the 4 Nations Research Governance Policy meetings by the Assistant Director of R&D, PHA.

Research governance infrastructure in Northern Ireland is built around compatible processes developed in partnership with the Health Research Authority and the other Devolved Administrations for a UK-wide approach to ensure the UK remains an attractive and competitive research location. This includes recently approved re-structuring of HSC staff and recruitment of new staff around these agreed processes, and in line with longer term planning for UK-wide research approvals.

A re-allocation of the HRA function would need to take account of the impact of changes in process that might be introduced, on the planning within the Devolved Administrations. Long term working and development of the relationship with HRA has ensured that these impacts are now taken into account through 4-Nations discussion.

This will also be important in the post-EU exit context where close working will be required to ensure there is mutual understanding of any potential legislative differences between GB and NI that might emerge.

Human Fertilisation and Embryology Authority (HFEA) , This matter is reserved to Westminster. HFEA is the UK's statutory independent regulator of fertility treatment and research using human embryos.

Functions in Northern Ireland include licensing, monitoring and inspection of fertility clinics including to public and private fertility centres.

Human Tissue Authority (HTA), regulates activities concerning the removal, storage, use and disposal of human tissue and bone marrow and peripheral blood stem cell donation. The HTA produces various clinical codes of practice in line with the statutory requirements set out in the Human Tissue Act 2004. The role of the HTA includes regulation of activities by UK healthcare providers related to the donation of organs and tissues for transplantation, on which the HTA works in conjunction with the Special Authority NHS Blood and Transplant.

Clause 88(2)(b) of the Bill allows the Secretary of State to transfer any functions of a Special Health Authority to any of the relevant bodies listed at Clause 86. NHS Blood and Transplant (NHSBT) is a Special Health Authority which manages blood donation services in England, and organ and tissue donation and transplantation services for all parts of the UK, including NI. This includes managing the donation, storage and transplantation of organs, tissues, bone marrow and stem cells, managing the UK-wide NHS Organ Donor Register, and researching new treatments and processes. This work is underpinned by the Human Tissue Act 2004 and various Codes of Practice developed by the Human Tissue Authority. Whilst the Minister of Health is not aware of any proposed changes to the UK-wide functions of NHSBT at the present time, the Committee should note the potential for future changes to be introduced under these powers. Any proposed changes in respect of NHSBT's functions outside of England would be subject to appropriate consultation with devolved Health Departments and their Arm's Length

Bodies, and would only be taken for the purposes of enhancing and improving current service provision in line with the UK Government's strategic objectives to increase organ donation and transplantation.

Memorandum of Understanding

4. Officials are working with the Department of Health and Social Care and the other Devolved Administrations to develop a memorandum of understanding (MoU) setting out the commitment to consult in respect of any future secondary legislation.

5. Ministerial confirmation has been provided that the MoU will include a commitment to early engagement with officials from devolved administrations, before a formal consultation process, in order to clarify the impact of a proposed transfer on all areas of the UK and seek input in policy development from those affected. Assurance has been provided of the commitment to effective and collaborative engagement on any such transfer in the future.

Current Financial Commitments

6. This Bill provides the enabling power to transfer functions and amend funding models via future secondary legislation, therefore the committee should note the position in respect of current financial commitments in respect of the relevant bodies within the Bill.

7. The Human Tissue Authority currently receives approximately £25k per annum.

8. The Health Research Authority currently receives £54k although this is expected to rise to £61k in 2021/22. This reflects the shared payment of costs for new IT infrastructure for UK wide use.

9. Approximately £2.1m per annum is provided to NHS Blood and Transplant for the provision of its service to the NI population.

10. Although it is not possible to identify positive or negative implications within the current Bill, any future proposals enacted by secondary legislation would need to consider financial safeguards for Northern Ireland.

Why a Legislative Consent Motion is needed

11. Health is a transferred matter and, as such, falls within the legislative competence of the Northern Ireland Assembly. The ALBs and Special Agencies contained within the Bill are not Northern Ireland Bodies but they do carry out functions on behalf of Northern Ireland in areas of transferred competence.

12. It is noted that fertility is a reserved matter and, as such future changes in respect of HFEA, lie outside the legislative competence of the Northern Ireland Assembly.