



Northern Ireland
Assembly

Committee for Health

Report on Legislative Consent Memorandums on the UK Government Health and Care Bill

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Introduction

1. The **Health and Care Bill** was introduced in the House of Commons on 6 July 2021. It is currently at Committee stage in the House of Commons and has been from 7 September 2021.
2. The purpose of the Bill is to give effect to the policies that were set out as part of the NHS's recommendations for legislative reform following the **Long Term Plan** and in the White Paper '**Integration and Innovation: Working together to improve Health and Social Care for all**' published in February 2021.
3. There are 135 clauses and 16 schedules in the Bill addressing a range of issues relating to health and social care. The Bill makes changes to a number of existing Acts, most notably the National Health Service Act 2006 and the Health and Social Care Act 2012.
4. The Department of Health and Social Care has offered to carry four provisions in the Bill that touch on devolved matters on behalf of NI, by way of the legislative consent process. These provisions were:
 - International Healthcare Arrangements (Reciprocal Healthcare)
 - Medicines and Healthcare Products Regulatory Agency (MHRA)
 - Professional Regulation
 - Arm's Length Bodies (ALBs) – Transfer of Functions
5. The first three legislative consent motions have been laid. The LCM for the Arm's Length Bodies – Transfer of Functions has not yet been laid. This report will only cover the three LCMs that have been laid. However, the Committee did receive evidence and briefing on the fourth LCM and it will be referenced throughout this Report and the Appendices.

International Healthcare Arrangements

6. In 2019, Parliament enacted the Healthcare (European Economic 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.

7. 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.
8. 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.
9. NHS Business Services Authority manages reciprocal healthcare, including the administration of payments for healthcare costs on behalf of England, Scotland, Wales and NI. The UK has a number of reciprocal healthcare arrangements with countries outside the EU. These 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.
10. The Bill seeks to amend the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 to enable the Secretary of State to implement bilateral healthcare arrangements with the rest of the world. This ensures there is a consistent framework for the negotiation and implementation of these arrangements.

Medicines and Healthcare Products Regulatory Agency (MHRA)

11. The Bill provides for an enabling power within the Medicines and Medical Devices Act 2021 to allow for a UK wide medicines information system to be established and managed by NHS Digital.
12. Obligations to capture data and to address specific gaps in knowledge regarding the use, safety, and/or effectiveness of their

products can already be placed on Marketing Authorisation Holders for medicines in the UK. However, these have not consistently delivered the required evidence in reasonable time frames due to a lack of trust from clinicians and patients and the way they are set up.

13. This Bill proposes placing a Medicines Information System on a statutory basis which 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.
14. The Department outlines that a registry would only be set up by the MHRA when alternative approaches to capturing data are not feasible and there is a sufficient public health need. There are criteria for when registry could be initiated.
15. 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.

Professional Regulation

16. The regulation of healthcare professionals is a devolved matter. The approach by the Department of Health, is to work on a four country basis regarding healthcare profession regulatory matters. This reflects the reality that the vast majority of regulation is performed by bodies which operate UK-wide. This ensures a consistent approach across the wider NHS.
17. The powers sought in the Bill seeks to implement a wider reform programme creating a more flexible and proportionate regulatory framework for healthcare professionals. The proposals seek to achieve more responsive and accountable regulation.
18. The Department has outlined that this LCM is needed as it is essential that these provisions extend to NI as divergence may seriously disrupt the movement of regulated healthcare professionals across the UK.

19. The provision will widen the Scope of Section 60 of the Health Act 1999 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 public.
 - Enable the delegation of previously restricted functions to other regulators.
 - Provide for the future expansion of the use of Section 60 to include Senior NHS Managers and Leaders.

Committee Consideration

20. The Committee was first aware of these LCMs when the Minister wrote to the Committee on 8 July to inform the Committee that he intended to write to the Minister of State for Health to note agreement, in principle, to take forward the legislative consent process, subject to scrutiny by the Committee and agreement of the Executive. The Minister advised in that letter that officials would take forward a 'deferred' legislative consent approach after summer recess.
21. The Minister then wrote to the Committee on 27 September to advise that he would be progressing the four legislative motions separately. Copies of correspondence from the Department can be found at Appendix 3.
22. The Committee was briefed prior to the laying of the LCMs on 14 October, a copy of the briefing paper provided by the Department can be found at Appendix 3 and a copy of the Hansard of the briefing can be found at Appendix 2.
23. At the briefing, the Committee was advised that a paper was circulated to the Executive on 29 September seeking approval for the four provisions to be carried, and four separate LCMs be progressed. The Committee was advised in the briefing paper that 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).

24. The Committee was advised that an Executive Paper did not make the agenda of the Executive meeting on the 7 October, and that the Minister raised an urgent procedure request on the 8 October to seek the First Minister's and deputy First Minister's approval for the provisions to be carried and individual LCMs be progressed.
25. Departmental officials briefed the Committee on the four separate LCMs and a number of issues were discussed with officials during that session. Issues that were raised re outlined below:

International Healthcare Arrangements

- The Committee sought clarity on the scope of the arrangements and the links to cross-border healthcare and healthcare provision within the Trade and Co-operation Agreement (TCA). The Committee were assured that this had no impact on cross-border health and the TCA.
- The Committee sought assurances that this LCM does not restrict the Minister of Health from making healthcare arrangements with particular regions. The Committee was advised that this would not prevent that from happening and that the only limit was that the Minister could not come to agreements with states.
- The Committee sought clarity on the European Health Insurance Card (EHIC) and were advised that travellers could make use of the Global Health Insurance Card (GHIC). The Committee highlighted that the Department should consider how it can promote the use of GHIC with NI travellers when the EHIC becomes invalid.

Medicines and Healthcare Products Regulatory Agency (MHRA)

- The Committee sought clarity on whether the registry has any potential impact on the movement of medicines from the EU in to NI. The Committee was advised there was no impact.
- The Committee sought assurances that the systems in NI are adequate for collecting data and that the systems feed into UK-wide processes. The Committee was advised that the data held on systems will be looked at to see what information is there, what gaps there are and what improvements can be made.

Professional Regulation

- The Committee sought assurances on the use of Section 60 by the Secretary of State to wind up NI based regulators, such as the Pharmaceutical Society. The Committee were assured that if the use of any section 60 Order of the 1999 Act extends UK-wide to the extent that it impacts on Northern Ireland's devolved competence, a new legislative consent motion of the Assembly has to be granted. This would give the Assembly the opportunity to consider any decision that impacts on NI.
 - The Committee asked for further information on what consultation had taken place.
 - The Committee also sought further information on the power to extend Section 60 to include Senior NHS Managers and Leaders.
26. Following the briefing, the Committee wrote to the Department seeking further information on a number of issues that were brought up by Members during the briefing. These included:
- A copy of the revised Memorandum of Understanding in relation to North/South co-operation on provision of healthcare;
 - Further information on how the Department plans to communicate changes in relation to the EHIC and GHIC changes and in relation to replacement certificates;
 - A written briefing providing the Department's views on the UK Health and Care Bill; and
 - Detail of what local consultation and engagement has been undertaken by the Department on these four LCMs.
27. A copy of the response from the Department to these issues and other queries raised during the briefing is included at Appendix 3. The Committee considered this response at its meeting on 4 November.
28. The Committee was advised on Friday 15 October that the three LCMs had been laid and that the fourth LCM on Arm's Length Bodies had not been laid.

Conclusion

29. At its meeting on 4 November, the Committee agreed that it was content with these LCMs. However, the Committee would like to highlight that the Department needs to ensure that there is better local engagement and consultation during the LCM process, both in recommending that UK Department of Health and Social Care engage with NI organisations during the drafting of the Bill and that the Department undertakes consultation during the LCM process.
30. The LCM process within Committees is very limited, with Committees only having 15 working days to report on LCMs, this makes it difficult for the Committee to undertake consultation. Therefore, it is important that the Department undertake as much consultation as possible to take the views of those that will be impacted by LCMs.
31. The Committee for Health agreed this report to be published on 11 November 2021.

Appendix 1: Minutes of Proceedings

- [14 October 2021](#)
- [4 November 2021](#)

Appendix 2: Minutes of Evidence

- 21 October - [A briefing from the Department of Health on the Department's amendments](#)

Appendix 3: Papers from the Department of Health

- 8 July 2021 - [Letter from Minister advising of deferred legislative consent approach](#)
- 27 September 2021 - [Letter from Minister advising that he would be progressing with four separate Legislative Consent Motions](#)
- 11 October 2021 - [Briefing paper from Department on the Legislative Consent Motions](#)
- 1 November 2021 - [Response from Department to issues raised at briefing session](#)

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