EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (LIABILITIES TO THIRD PARTIES SCHEME) (ENGLAND) (AMENDMENT) REGULATIONS 2023

2023 No. 634

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 This instrument amends the National Health Service (Liabilities to Third Parties Scheme) (England) Regulations 2018 ("the 2018 Regulations") to add the Commissioner for Patient Safety ("the Commissioner") as a body that is eligible to be a member of the "NHS Liabilities to Third Parties Scheme". This would then enable the Commissioner to apply to become a "member" and a participant of the scheme.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

6. Legislative Context

6.1 Section 71 of the National Health Service Act 2006 ("the 2006 Act") enables the Secretary of State to establish indemnity schemes to cover the liabilities to third parties of specified bodies and other persons providing NHS services.

6.2 The 2018 Regulations provide for such an indemnity scheme. Regulation 4(1) of the 2018 Regulations sets out the bodies that are eligible to apply for membership of the scheme. A body may only be added to regulation 4(1) if it is specified in section 71 of the 2006 Act.

6.3 Section 1(1) of the Medicines and Medical Devices Act 2021 ("the 2021 Act") provides that the Secretary of State is required to appoint a Commissioner for Patient Safety. Paragraph 5(4) of Schedule 1 to that Act amended section 71 of the 2006 Act to add the Commissioner to the list of specified bodies and other persons that may covered by indemnity schemes.

6.4 This instrument adds the Commissioner as an "eligible body" within regulation 4(1) of the 2018 Regulations. Once an eligible body, the Commissioner could then apply to become a "member" and participant of the scheme.

7. Policy background

What is being done and why?

7.1 The Commissioner's core duties are to "promote the safety of patients with regard to the use of medicines and medical devices" and to "promote the important of the views of patients and other members of the public in relation to the safety of medicines and medical devices".

7.2 The Commissioner has the statutory duty to publish annual reports which may include criticism and recommendations regarding certain medicines and medical devices. This could lead to public liability claims against the Commissioner from members of the public and commercial organisations. This could incur significant personal financial loss for the Commissioner if they are not indemnified.

7.3 Adding the Commissioner as a body that is eligible to be a member of the "NHS Liabilities to Third Parties" indemnity scheme allows the Commissioner to apply to become a member of the scheme. Membership of the scheme would provide the Commissioner with cover for public liability claims that could arise from members of the public and commercial organisations.

7.4 This protection was envisaged by Parliament when it passed the 2021 Act, which amended the 2006 Act to give the Secretary of State the power to include the Commissioner in indemnity schemes.

Explanations

What did any law do before the changes to be made by this instrument?

7.5 Regulation 4(1) of the 2018 Regulations sets out the bodies which are eligible to apply to become members of the "NHS Liabilities to Third Parties" indemnity scheme. The Commissioner was not specified in regulation 4(1) and so was unable to apply to become a member of the scheme.

Why is it being changed?

7.6 To add the Commissioner as an eligible body so they can apply to become a member of the scheme.

What will it now do?

7.7 The Commissioner will be eligible to apply to become a member of the "NHS Liabilities to Third Parties" scheme.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act

9. Consolidation

9.1 Consolidation is not being done.

10. Consultation outcome

10.1 A consultation did not take place as there is no wider impact.

10.2 This instrument requires consent from HM Treasury which has been sought and received.

11. Guidance

11.1 Guidance is not required.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because no impact on business is foreseen.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is to review as appointments are reviewed.

14.2 The instrument does not include a statutory review clause.

15. Contact

15.1 Lizzie Roff at the Department of Health and Social Care Telephone: 020 7972 4415 or email: lizzie.roff@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Adam McMordie, Deputy Director for Quality, Patient Safety, and Maternity at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister Caulfield at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.