EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) REGULATIONS 2025

2025 No. [XXXX]

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. Declaration

2.1 Baroness Gillian Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Adam McMordie, Deputy Director for Quality, Patient Safety & Investigations, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Jamie Samuel at the Department of Health and Social Care email: 2014Regulations@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The purpose of this instrument is to remove the expiry date provision of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (2014 Regulations) and amend the review clause, so the 2014 regulations are reviewed every 5 years from 13 July 2023. This will ensure that providers who carry on regulated activities continue to be required to register with the Care Quality Commission (CQC) and comply with the fundamental standards.

Where does the legislation extend to, and apply?

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

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

5. Policy Context

What is being done and why?

5.1 The Health and Social Care Act 2008 (2008 Act) requires all providers who carry on 'regulated activities' in England to register with the CQC, and to comply with the requirements and fundamental standards set out in regulations made under that Act. The 2014 Regulations set out these regulated activities, and the fundamental standards

that all registered providers must comply with. The 2014 Regulations are currently due to expire after 31 March 2025. This statutory instrument removes the expiry date provision from the 2014 Regulations and amends the review provisions to provide for a five-yearly review.

What was the previous policy, how is this different?

5.2 In March 2022, the 2014 Regulations expiry date of 31 March 2022 was extended to 31 March 2025 pending a post implementation review of whether the 2014 Regulations had met their original objectives. The responses to the review were limited and there was not sufficient evidence to suggest the 2014 Regulations did not meet their original objectives. The outcome of the Post Implementation Review can be found at https://www.gov.uk/government/consultations/post-implementation-review-of-regulations-relating-to-the-care-quality-commission

6. Legislative and Legal Context

How has the law changed?

6.1 The Health and Social Care Act 2008 ("the 2008 Act") established the CQC and gave it the function of maintaining a registration system for providers of health and adult social care who carry out regulated activities, which is a term defined in section 8 of the 2008 Act. Providers of regulated activities are required to meet the standards imposed by the provision of the 2008 Act and the regulations under it.

6.2 The 2014 Regulations are made under the 2008 Act and prescribe the activities that are regulated activities for the purposes of Part 1 of the 2008 Act, and the requirements that apply in relation to the way in which those activities are carried on. Providers of regulated activities are required to register with the CQC. Any person who carries on a regulated activity without being registered with the CQC commits an offence.

6.3 Regulation 27 of the 2014 Regulations requires the Secretary of State to carry out a review of the 2014 Regulations before 1 April 2020. This review took place in July 2022. Regulation 1(6) provides that the 2014 Regulations will cease to have effect after 31 March 2025. Regulation 3(2) of these Regulations removes regulation 1(6). Regulation 3(3) amends the review clause in the 2014 Regulations so the next review and report is due by 13 July 2028 (which is 5 years after the previous review report of the 2014 Regulations was laid before Parliament on 13 July 2023). It also inserts a requirement for there to be 5 yearly reviews following this date, save that that period may be abridged by the early publication of the review.

Why was this approach taken to change the law?

6.4 Removing the expiry date to the 2014 Regulations will reduce the burden on Parliamentary time by no longer needing to routinely extend the expiry date of 2014 Regulations. It will ensure that providers who carry on regulated activities continue to be required to register with the CQC and comply with the fundamental standards for providing health and care services. Inserting a requirement to review the 2014 Regulations will provide a check and balance that the 2014 Regulations continue to meet their original objectives and evolve with the changing landscape of the health and social care sector.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Department of Health and Social Care conducted a public consultation to replace the expiry date of the 2014 Regulations with a review clause from the 26th April 2024. The consultation process ended 21 June 2024. DHSC also conducted an easy read consultation from 3 July to 27 September.

7.2 There were 187 responses to the main consultation document and 32 responses to the easy read consultation document. There were 219 responses to the question on whether the expiry date should be removed – 187 from the main consultation and 32 from the easy read. 70% of respondents agreed with the proposal to remove the expiry date of the 2014 Regulations replacing it with a five yearly review. While 9% disagreed.

7.3 In response to the question "what alternatives, if any should DHSC consider" of the 222 responses, 63% did not respond to this question. Of the respondents that did answer this question 65% felt the alternative should be a 3-year extension and 33% felt an alternative could be a 5-year extension of the 2014 Regulations.

7.4 The full consultation response document can be found here: https://www.gov.uk/government/consultations/changes-to-regulations-relating-to-the-care-quality-commission/outcome/government-response-to-the-results-of-the-consultation-on-changing-regulations-relating-to-the-cqc

8. Applicable Guidance

8.1 There is no applicable guidance to accompany this statutory instrument.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because there is no significant impact as the instrument does not make any significant change to current policy.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies because the instrument does not make any significant change to current policy.

9.3 The legislation does not impact small or micro businesses.

9.4 There is no, or no significant, impact on the public sector because the instrument does not make any significant change to current policy.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 A statutory review clause is included in this instrument to review the 2014 regulations after a five-year period from 13 July 2023. The next review point will be 13 July 2028 and then every five years after this date.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Baroness Gillian Merron, Parliamentary Under-Secretary of State for Patient Safety, Women's Health and Mental Health at the Department of Health and Social Care has made the following statement regarding Human Rights:

"In my view the provisions of the Health and Social Care Act 2008 (Regulated Activities (Amendment) Regulations 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").