

EXPLANATORY MEMORANDUM TO
THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES)
(AMENDMENT) REGULATIONS 2022

2022 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 Her Majesty.

2. Purpose of the instrument

- 2.1 The purpose of this instrument is to amend the expiry date of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (2014 Regulations) so that they cease to have effect after 31 March 2025. This would ensure that providers who carry on regulated activities continue to be required to register with the CQC and comply with the fundamental standards. The extension will also allow time for the Department to carry out a full review of the 2014 Regulations to determine whether their scope is still proportionate and ensure that regulated activities are delivered safely to a high standard. The 2014 Regulations are currently due to expire after 31 March 2022.

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 territorial extent of this instrument is England and Wales.
4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

- 5.1 Maria Caulfield MP, Parliamentary Under Secretary of State (Minister for Primary Care and Patient Safety) 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 2022 are compatible with the Convention rights.”

6. Legislative Context

- 6.1 The Health and Social Care Act 2008 (“the 2008 Act”) established the Care Quality Commission (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 provisions of the 2008 Act and the regulations made 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 is currently underway. Regulation 1(6) provides that the 2014 Regulations will cease to have effect after 31 March 2022.
- 6.4 This instrument seeks to amend regulation 1(6) to extend the expiry date of the 2014 Regulations for a further three years, so that the 2014 Regulations cease to have effect after 31 March 2025.

7. Policy background

What is being done and why?

- 7.1 The 2008 Act requires all providers who carry on 'regulated activities' in England to register with the Care Quality Commission (CQC), and to comply with the requirements and fundamental standards set out in regulations made under that Act. The 2014 Regulations sets 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 2022.
- 7.2 This instrument seeks to extend the expiry date of the 2014 Regulations for a further three years to ensure health and care providers continue to be required to register with the CQC and comply with the fundamental standards. The fundamental standards are the standards below which care must never fall and ensure that everyone receives safe, high-quality care.
- 7.3 The extension of the expiry date will allow the Government to review the 2014 Regulations to determine whether their scope is still proportionate to ensure that regulated activities are delivered safely to a high standard. Following the review, it is intended that a further instrument will be made to implement any changes.

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 No consolidation is being undertaken.

10. Consultation outcome

- 10.1 DHSC conducted a public consultation on the proposal to extend the expiry date of the 2014 Regulations from 15 July 2021 to 02 September 2021. The consultation did not attract a lot of interest, possibly due to the proposal not amending policy or how the CQC regulates providers. 32 responses were received. Responses were received from health and care provider organisations, individuals and the CQC.
- 10.2 19 responses supported the proposal and 13 responses did not support the proposal. Overall, a majority (59%) of respondents supported the proposal.

- 10.3 There was support for the certainty the extension will provide to health and social care providers and those who use the services by allowing the CQC to continue to ensure safe, effective, and high-quality services. Respondents not in support of the proposal suggested that the 2014 Regulations be amended, rather than extended, to reflect changes in the health and care sector since 2014.
- 10.4 The consultation response document is available here:
<https://www.gov.uk/government/consultations/the-health-and-social-care-act-2008-regulated-activities-regulations-2014-extension-of-expiry-date/outcome/the-health-and-social-care-act-2008-regulated-activities-regulations-2014-consultation-response>

11. Guidance

- 11.1 Operational 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 A full Impact Assessment has not been prepared for this instrument because the SI relates to the extension of existing regulatory standards (the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and no, or no significant impact, on the private, voluntary or public sector is foreseen.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses. However, the amendment to extend the expiry date of the 2014 Regulations does not change the current policy of the 2014 Regulations. Therefore, the amendment to extend the expiry date of the 2014 Regulations will have no additional impact on small business.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

- 14.1 Sections 28 to 32 of the Small Business, Enterprise, and Employment Act 2015 (SBEE Act 2015), which came into force on 1 July 2015, place a statutory duty on UK Government Ministers to either include review provisions in secondary legislation that regulates business or voluntary and community bodies or else publish a statement that it is not appropriate in the circumstances to do so.
- 14.2 For the purposes of section 31(2)(b) of the SBEE Act 2015, it is determined that it would be disproportionate to include a provision to review the amendments made by this instrument to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (2014 Regulations). This instrument does not change the current policy of the 2014 Regulations, and therefore, the amendment to extend the expiry date of the 2014 Regulations will have no additional impact on health and care providers. With regards to section 14(c) of the statutory guidance under section 31 of the SBEE Act 2015, an existing statutory review clause is contained in regulation 27 of the 2014 Regulations, to which a full review is currently underway. It is intended that a further amending instrument to implement any changes following the review will be made and come into force before the amended expiry date of the 2014 Regulations on 31 March 2025.

15. Contact

- 15.1 Matt Johnson at the Department of Health and Social Care. Email: 2014Regulations@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Verity Prime/Laura Lucking, Deputy Director (job share) 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 Maria Caulfield MP, Parliamentary Under Secretary of State for Primary Care and Patient Safety at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.