EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) REGULATIONS 2023

2023 No. 1402

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 The purpose of this instrument is to ensure that providers of care homes, hospitals and hospices facilitate visits to residents and patients, ensure that visits out of care homes are not discouraged and to enable patients to be accompanied when attending a hospital or hospice as an outpatient.

2.2 This is achieved by amending the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") to add 'visiting and accompanying in care homes, hospitals and hospices' as a new fundamental standard that applies in respect of certain activities carried on in care homes, hospitals and hospices.

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 The Health and Social Care Act 2008 ("the 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 on regulated activities, which is a term defined in section 8 of the Act. Providers of regulated activities are required to meet the standards imposed by the provisions of the Act and the regulations made under it.

6.2 The 2014 Regulations are made under the Act and prescribe the activities that are regulated activities for the purposes of Part 1 of the Act (see regulation 3 of the 2014

Regulations) and the requirements that apply in relation to the way in which those activities are carried on ('the fundamental standards'). Providers of regulated activities are required to register with the CQC. Any person who carries on a regulated activity without being registered commits an offence. Regulation 8 of the 2014 Regulations provides that the registered person (defined in regulation 2 of the 2014 Regulations as "in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity") must comply with the fundamental standards set out in regulations 9 to 20A of the 2014 Regulations in carrying on a regulated activity.

6.3 Before making regulations under section 20 the Act, section 20(8) requires the Secretary of State to consult such persons as the Secretary of State considers appropriate, except with respect to regulations which amend other regulations made under section 20 and which do not, in the opinion of the Secretary of State, effect any substantial change in the provision made by those regulations. In respect of the amendments being made by this instrument the Secretary of State has concluded that, in accordance with section 20, a consultation is required and, accordingly, one has been carried out.

6.4 This instrument inserts a new fundamental standard, namely new regulation 9A (visiting and accompanying in care homes, hospitals and hospices), into the 2014 Regulations. This fundamental standard requires that service users (defined in regulation 2 of the 2014 Regulations as "a person who receives services provided in the carrying on of a regulated activity") are, unless there are exceptional circumstances, facilitated to receive visits to care homes, hospitals and hospices and, in relation to service users who are provided with accommodation in a care home, are not discouraged from taking visits out of the care home. It also requires service users to be enabled to be accompanied at a hospital or hospice when attending as an outpatient.

6.5 "Exceptional circumstances" will be assessed on the circumstances of each case and will carry its ordinary, restricted meaning as interpreted by cases such as *R v Kelly* [2000] 1 QB 198 "We must construe exceptional circumstances as an ordinary, familiar adjective and not as a term of art. It describes a circumstance which is such as to form an exception, which is out of the ordinary course, or unusual, or special, or uncommon. To be exceptional, a circumstance need not be unique, or unprecedented, or very rare; but it cannot be one that is regularly, or routinely or normally encountered." The Department considers that an example of an exceptional circumstance might be where a visit would pose a significant risk to the health, safety or wellbeing of a service user or an employee of the provider.

6.6 In contrast with other fundamental standards set out in the 2014 Regulations which apply equally in respect of all CQC registered providers, this fundamental standard will only apply in relation to the registered person in respect of 'relevant regulated activities' carried on in care homes, hospitals and hospices. In particular, it will not apply to registered persons in respect of regulated activities carried out in other settings or in relation to residential units for substance misuse or detoxification services provided in a hospital.

6.7 The definition for 'relevant regulated activity' also excludes any services provided to a service user who is or is required to be, detained in a prison (or a similar institution) or who is detained under immigration legislation. However, this exclusion does not include any service user who is receiving services provided in the carrying on of the

regulated activity in paragraph 5 of Schedule 1 of the 2014 Regulations (assessment or medical treatment for persons detained under the 1983 Act).

6.8 As this instrument only applies in respect of 'relevant regulated activities' the reference to 'service user' in new regulation 9A will be limited to persons who receive services provided in the carrying on of a relevant regulated activity, rather than regulated activities generally.

6.9 As noted above, the registered person is responsible for compliance with all of the fundamental standards in carrying on a regulated activity, see regulation 8 of the 2014 Regulations. This includes, for example, a requirement in regulation 17 of the 2014 Regulations to establish systems and processes to ensure compliance with the requirements set out in the 2014 Regulations (which will include the new requirements in relation to visiting and accompanying). Where the registered person does not comply with the new requirements set out in this instrument, CQC could consider taking regulatory action using its existing civil enforcement powers, for example, through the issuing of a warning notice. It will not be a criminal offence to fail to comply with the requirements set out in this instrument.

7. Policy background

What is being done and why?

7.1 Contact with loved ones is a vital component of care and treatment. Research shows that it plays a crucial role in maintaining good health and wellbeing for people living in care homes or attending hospitals or hospices, enabling them to maintain relationships. Often the role of a visitor extends beyond companionship into provision of support, care and advocacy.

7.2 During the COVID-19 pandemic, restrictions on visiting were introduced in care homes and hospitals to help reduce the spread of the virus and keep those most at risk from adverse outcomes safe. This meant that many care home residents and hospital patients were unable to see loved ones for prolonged periods of time, including after lockdown restrictions were eased for the rest of the country. Concerns have been raised by campaigners, the public and in Parliament that these measures had a detrimental effect on the wellbeing of residents and patients, and that some settings are still not providing sufficient access for visitors.

Explanations

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

7.3 Currently, CQC assesses health and care providers against the fundamental standards and other requirements set out in CQC regulations. CQC carries out assurance regarding visiting as part of their regulation of health and care settings, which is implicitly covered by the fundamental standards of 'person-centred care' and 'dignity and respect'.

7.4 In their explanation of the fundamental standards, CQC describe the standard of 'person-centred care' as the requirement for an individual to have care or treatment that is tailored to them and meets their needs and preferences. The standard of 'dignity and respect' sets out that individuals must always be treated with dignity and respect, including being given support to remain independent and involved with their local community. While those standards are capable of including visiting, they do not set any explicit standard or expectation that relates specifically to visiting.

7.5 These standards are enforced by CQC using their civil powers, meaning that where a regulation is breached, CQC can enforce the standards by issuing requirement or warning notices, imposing conditions, suspending a registration, or cancelling a registration. However, as visiting is not specifically referred to in the regulations (nor is it its own standard), CQC do not currently specifically assess providers against any standardised requirements.

What is being changed?

7.6 The Government recognises how important visiting is for people who access care and treatment and their loved ones, and that this should be considered a fundamental part of the provision of good care. Regulation 2(2) of this instrument inserts a new regulation 9A into the 2014 Regulations. This will add visiting and accompanying in care homes, hospitals and hospices as a new fundamental standard for providers of relevant regulated activities. Providers who carry on relevant regulated activities will, unless there are exceptional circumstances, be required to facilitate visits for individuals who are receiving care or treatment in the course of the carrying on of those regulated activities in care homes, hospitals and hospices. In hospitals and hospices this also includes enabling a service user to be accompanied by another person to outpatient and diagnostic appointments or the emergency department.

7.7 New regulation 9A(2) also sets out a requirement that the taking of 'visits out' out of a care home must not be discouraged (unless there are exceptional circumstances). Though residents cannot legally be prevented from leaving care homes (except in certain cases such as where the person lacks the relevant capacity and is subject to the Deprivation of Liberty Safeguards), we understand that during the pandemic a range of restrictions were placed on residents wishing to leave the care home, particularly upon their return, and that these discouraged service users from taking visits out. The intention is that service users must not be discouraged from leaving the care home premises to support their wellbeing and participation in their community. In practice, this will mean, for example, that providers should not impose unreasonable rules on returning after a visit out that would discourage service users from taking a visit out and effectively act as a restriction.

7.8 New regulation 9A(3) sets out what a registered person must do to comply with regulation 9A(2). It emphasises the importance of the service user's needs and preferences in relation to visiting. It sets out that service users must be facilitated to receive visits in a way that is appropriate, meets the service user's needs and reflects their preferences.

7.9 The registered person (the person registered with the CQC as the registered manager or service provider) in a relevant setting will be responsible for ensuring that any necessary and proportionate precautions are put in place so that service users may receive visits or be accompanied safely.

7.10 New regulation 9A(4) makes it clear that a service user is not required to receive any visit, take a visit out of a care home, or be accompanied, if they do not wish to be. If a service user does not have capacity to consent, they are not required to receive a visit, or be accompanied, if it would not be in their best interests to do so.

7.11 In addition, this regulation will not require or enable a registered person to do anything that is not in accordance with any court or tribunal order or with any provision in, or made under, the Mental Health Act 1983, the Mental Capacity Act 2005 and so far as relating to high security psychiatric services, the National Health

Service Act 2006. The purpose of this is to ensure that the requirements in this instrument do not conflict with provisions made in or under the legislation listed and to avoid any unintended consequences.

7.12 New regulation 9A will not apply to a registered person in respect of the regulated activity of 'accommodation for persons who require treatment for substance misuse' or in respect of any detoxification services for substance misuse (which may take place in a hospital setting). This is achieved by excluding these services from the definition of 'relevant regulated activity' in new regulation 9A(6). These services are excluded because it is common for an individual in a substance misuse residential rehabilitation or inpatient detoxification service to go without visitors for a period while undergoing treatment or rehabilitation, to support their treatment. Limiting visits according to risk and being able to maintain a safe drug and alcohol free environment is fundamental to their operation. Other activities which the CQC regulates, such as personal care; management of blood and blood derived products and transport services; and triage and medical advice provided remotely, are also excluded from the definition of 'relevant regulated activity' as visiting and accompanying are not relevant in respect of these activities.

7.13 Similarly, the definition for 'relevant regulated activity' excludes any service user who is, or is required to be, detained in a prison (or another similar institution) or who is detained under immigration legislation. This reflects the policy intent for any existing rules or procedures in respect of visiting to continue to apply in respect of these persons (for example, the Prison Rules 1999). However, where a service user is receiving services provided in the carrying on of the regulated activity in paragraph 5 of Schedule 1 of the 2014 Regulations (assessment or medical treatment for persons detained under the 1983 Act), the policy intent is that the requirements in this instrument will apply (so far as it is in accordance with any court or tribunal order or with provisions made in, or under, the legislation listed in new regulation 9A(5)).

What will this mean?

7.14 The new regulation will impose duties on registered providers which relate to visiting and accompanying. It will also enable the Care Quality Commission (CQC) to specifically inspect relevant health and care settings against the standard, and more easily identify a breach of the visiting and accompanying requirement as the regulation sets out specific points regarding visiting and accompanying that a provider must comply with. CQC will be able to use their existing civil enforcement powers to take action against a breach. This could include issuing requirement or warning notices, imposing conditions, suspending a registration, or cancelling a registration. As noted above, it will not be an offence to fail to comply with this new standard.

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 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 A public consultation on introducing visiting (including accompaniment) as a new CQC fundamental standard was open from 21 June 2023 to 16 August 2023. An easy read translation of the consultation was available from 28 June 2023 to 23 August 2023. Over 1,400 responses were received from individuals responding in both personal and professional capacities, in addition to charities and organisations. The majority of respondents supported the proposal to introduce visiting as a new fundamental standard.

10.2 Some of the main themes about the current situation in relation to visiting included government guidance being unclear, and that strict visiting times and complicated complaints processes were some of the barriers to visiting in health and care settings.

10.3 Some respondents expressed concern that setting out 'exceptional circumstances' or 'reasonable explanations' (where a provider may restrict visiting) may actually make it easier for some providers to adopt restrictive practices, which is contrary to the intention of the policy. DHSC recognises that there will always be some, very limited, circumstances in which visiting cannot be facilitated by the provider, in order to maintain the safety and wellbeing of service users and staff. However, in response to this feedback, the new regulation has been drafted in a way that does not provide a list of exceptional circumstances.

10.4 While the majority of consultation respondents expressed clear support for a consistent approach across CQC registered settings, some concerns were raised by sector representatives about the requirements for some health and care settings potentially putting individuals at increased risk. For this reason, DHSC decided to exclude services for substance misuse and inpatient detoxification or rehabilitation services from the requirement. This reflects the complex circumstances and risk of relapse for a vulnerable person. Visiting is already carefully considered within care plans in these settings. Supported living settings and 'extra care' housing schemes will also not be in scope of the regulation. This is because CQC do not regulate the accommodation aspect of these settings, and therefore do not assess visiting in them. Both 'supported living' and 'extra care' housing generally exercise exclusive possession, wherein which the individual has a tenancy agreement and they can decide who visits and when.

10.5 The government considered whether for hospices, where visiting has historically not been an issue, legislation would be a disproportionate response. However, supported by the vast majority of consultation responses on this issue, we decided that legally enshrining the protection of visitation in the future was, on balance, the appropriate way forward and ensures consistency with care homes and hospitals.

10.6 Some campaigners have called for a specific right to a 'care supporter' for anyone accessing health and care settings. Given the support demonstrated in response to the consultation, and the role of the CQC as the regulator in England, DHSC believes that introducing visiting as a fundamental standard is the most proportionate and appropriate way in which to protect and enable visiting. This puts visiting on the same footing as other important factors in care provision.

10.7 A full consultation response is available here1 on GOV.UK.

[1] https://www.gov.uk/government/consultations/visiting-in-care-homes-hospitals-and-hospices/outcome/government-response-to-the-consultation-on-visiting-in-care-homes-hospitals-and-hospices

11. Guidance

11.1 CQC is required to issue statutory guidance about compliance with regulations made under section 20 of the Act (which includes the fundamental standards). Guidance to accompany the new regulation is being produced by CQC and is intended to be published before this instrument comes into force. The guidance will be subject to a further consultation process (required under section 24 of the Act).

12. Impact

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

12.2 Costs have been estimated for care home settings where the central estimate of the quantified cost to business is £526,000 in year 1 of the appraisal period. This figure is an estimate of the staff administration and familiarisation costs of facilitating visitors for the care home settings that are not currently accommodating visits in any circumstances. This annual figure is expected to decrease over time, as the number of care homes reporting not allowing visiting has been broadly decreasing.

12.3 We do not expect there to be any significant additional costs or benefits from the regulation in hospital settings or hospices. Independent hospitals should be set-up to permit visiting, they do not normally require additional staff, and are unlikely to need additional funding to comply with the regulation. Most hospices with inpatient units are largely independent charitable organisations which already permit and support visiting, and we do not anticipate that they will require additional staff or funding to facilitate this regulation. There is no evidence to indicate that restrictions to visits in hospices is a widespread issue.

12.4 There is no significant impact on the public sector. The regulation will apply to NHS hospitals, however, as above, there is already guidance in place across the NHS that requires hospitals to facilitate visiting and they should be equipped to do so, therefore it is unlikely that additional staff or funding is needed to comply with the regulation.

12.5 A full Impact Assessment has not been prepared for this instrument. This is because the expected cost on business is not expected to be significant and because we do not deem the regulation to be novel given existing visiting guidance, nor contentious given broad support for legislation on visiting. Instead, a De Minimis Assessment has been prepared for this instrument. This is a type of impact assessment that is appropriate to use when the costs or benefits to business are expected to be less than £5 million in any one financial year. This is undertaken when a full impact assessment is therefore not proportionate. This will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 We expect any additional administrative costs from visiting to be proportional to a setting's size. This means the costs of facilitating visits are expected to increase as the number of residents and size of the settings increase. The regulation will therefore not disproportionately affect 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 or 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 SBEE Act 2015, it is determined that it is disproportionate to include a provision to review the amendments made by this instrument to the 2014 Regulations. This is supported by the analysis which shows the costs to business are unlikely to be significant. With regards to paragraph 15(c) of the statutory guidance under section 31 of the SBEE Act 2015, there is an existing sunset provision contained in regulation 1(6) of the 2014 Regulations. The 2014 Regulations are due to expire after 31 March 2025 which is before any review provision in this instrument would be required to be completed. It is intended that a further amending instrument to implement any changes following a review of the 2014 Regulations will be made before the expiry date for the 2014 Regulations.

14.3 The approach to monitoring of this legislation is that the Department will carry out an evaluation of the regulatory change within two years after the date the new regulations come into effect to ensure no unforeseen policy consequences arise from this change and the policy intention underpinning the change is met. We will carry out this review through further engagement with CQC and other health and care stakeholders and monitoring of available data in health and care.

15. Contact

15.1 The Visiting and Health Protection Policy team at the Department of Health and Social Care, email: visiting@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Nichola Pitt and Richard Cienciala, Deputy Directors for Adult Social Care Operational Resilience at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Helen Whately MP, Minister for Social Care at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.