

EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) (CORONAVIRUS) REGULATIONS 2021

2021 No. 891

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 The purpose of this instrument is to reduce the spread of COVID-19 in care homes, in order to protect care home residents, who are vulnerable to COVID-19.
- 2.2 This is achieved by amending the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (“the 2014 Regulations”), to provide that the registered person for nursing and personal care in care homes must secure that – subject to certain exceptions— a person does not enter the care home premises unless they provide evidence that they have been vaccinated with a complete course of an authorised vaccine against COVID-19.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 This instrument is laid under the draft affirmative procedure pursuant to section 162 of the Health and Social Care Act 2008.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.2 Not applicable.

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 set out in Section 3 under “Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)”.

5. European Convention on Human Rights

- 5.1 The Minister of State for Care, Helen Whately MP has made the following statement regarding Human Rights:

“In my view the provisions of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021 are compatible with the Convention rights.”

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 out 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 kinds of activities that are regulated activities for the purposes of Part 1 of the 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 CQC. Any person who carries on a regulated activity without being registered with the CQC commits an offence.
- 6.3 This instrument seeks to amend regulation 12 (safe care and treatment) of the 2014 Regulations. For the purposes of preventing, detecting and controlling the spread of infections, and specifically in response to the effects of the coronavirus pandemic, this instrument provides that a registered person of the regulated activity of providing accommodation for persons who require nursing or personal care (see paragraph 2 of Schedule 1 of the 2014 Regulations) in a care home, must not permit a person to enter the premises of that care home, unless that person meets one of the specific requirements listed in 7.4.
- 6.4 Where providers do not comply with the requirements set out in this instrument, CQC could consider taking regulatory action, for example through the issuing of a warning notice.
- 6.5 Regulation 7 sets out the requirement for the Secretary of State to carry out an annual review these regulations, taking into account clinical advice and the accessibility and availability of authorised vaccines, and publish a report setting out the conclusions of this review.

7. Policy background

What is being done and why?

- 7.1 The independent Scientific Advisory Group for Emergencies (SAGE) Social Care Working Group has highlighted that people living in care homes have been significantly impacted by the COVID-19 pandemic due to a combination of a heightened risk of severe outcomes following COVID-19 infection and the risk of outbreaks in these closed settings. They have advised that a vaccination uptake rate of 80% in staff and 90% in residents in each individual care home setting would be needed to provide a minimum level of protection against outbreaks of COVID-19, recognising that current or emergent variants may require even higher levels of coverage and/or new vaccines to sustain levels of protection and that higher coverage and both doses would result in more protection. Only 65% of care homes in England are currently meeting this dual threshold, and the proportion is only 44% of care homes in London. ¹
- 7.2 Research by Public Health England also shows that those who do become infected 3 weeks after receiving one dose of the Pfizer-BioNTech or AstraZeneca vaccine were

¹ [Statistics » Supplementary Information \(england.nhs.uk\)](#)

between 38% and 49% less likely to pass the virus on to their household contacts than those who were unvaccinated. This protection is on top of the reduced risk of a vaccinated person developing symptomatic infection in the first place, which is around 60 to 65% – 4 weeks after one dose of either vaccine.

- 7.3 A COVID-19 vaccine, like most vaccinations, also has benefits that go beyond the benefits felt by the vaccinated individual. By vaccinating the social care workforce, additional benefits to society include a reduction in the rate of transmission by the workforce among the remainder of the workforce, care home residents and the wider community. In addition, the vaccine will reduce the likelihood of social care workers falling ill as a result of COVID-19 and needing to isolate or be absent from work. Reducing the spread of the virus will have further positive impacts by reducing hospital admissions and the consequential cost of dealing with hospital treatments.
- 7.4 There remains a strong case for introducing a new requirement to make high-risk environments as safe as possible from the effects of COVID-19. Consequently, regulations will be amended to require all CQC-registered care homes, in England, providing accommodation for persons who require nursing or personal care, to only allow persons to enter a care home if they meet one of the following requirements:
- the person is a service user of the regulated activity in the premises used by the registered person;
 - the person has provided the registered person with evidence that satisfies the registered person they have been vaccinated with the complete course of an authorised vaccine;
 - the person has provided the registered person with evidence that satisfies the registered person that for clinical reasons they should not be vaccinated;
 - it is reasonably necessary for the person to provide emergency assistance in the premises;
 - it is reasonably necessary for the person to provide urgent maintenance assistance to the premises;
 - the person is a member of the emergency services in execution of their duties;
 - that a person is a friend or relative of the service user visiting the service user;
 - the person is visiting a dying service user;
 - it is reasonably necessary for the person to provide comfort or support to a service user in relation to a service user's bereavement following the death of a relative or friend; or
 - the person is under the age of 18.
- 7.5 The registered person must secure that the requirement is complied with and we will issue guidance setting out how they should do this.

What the Government has done to encourage uptake

- 7.6 The UK COVID-19 vaccination uptake plan, published on 13 February 2021 and published here [UK COVID-19 vaccine uptake plan - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/92222/uk-covid-19-vaccine-uptake-plan), sets out the significant programme of work underway to drive vaccine uptake, including actions to improve access and to address the concerns of those who may be hesitant to receive the vaccine.

- 7.7 We are also delivering a targeted programme of work to support vaccine uptake among adult social care staff. In order to build confidence in the vaccine among the workforce, we have delivered an extensive communications programme which includes:
- Bespoke communications materials (posters, videos, leaflets, and shareable social media assets) shared across our CARE App, weekly newsletter, and Adult Social Care and Department of Health and Social Care social channels.
 - A paid advertising campaign targeting social care workers with digital advertising to build vaccine confidence and encourage booking via the National Booking Service
 - A stakeholder toolkit (Q&As, guidance and communications materials) which is updated weekly
 - Positive messaging using influencers, leaders and care home workers who have already been vaccinated to boost confidence and tackle misinformation.
 - Content in different languages and briefings with different faith groups who have expressed interest in co-creating vaccine content and acting as ambassadors.
- 7.8 We have also provided direct support to managers of care homes for older adults that have lower vaccine uptake rates among their staff. This includes having conversations with care home managers to support them to access vaccinations for their staff and signpost resources that they can use to enable their staff to feel confident about taking the vaccine.
- 7.9 We continue to work closely with partners and stakeholders to identify and progress further actions at local, regional and national level to increase vaccine uptake among adult social care staff.
- 7.10 Despite the already existing non-regulatory options listed above, vaccine uptake amongst care home workers is not consistently at the level we know from SAGE advice is needed to minimise the risk of outbreak. It is imperative that together we now take every step necessary to reduce the risk of spreading the virus to those most at risk from COVID-19 and those who care for them.

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 18.

9. Consolidation

- 9.1 No consolidation is being undertaken.

10. Consultation outcome

- 10.1 The Department of Health and Social Care (DHSC) conducted a public consultation on the proposal to require older adult care home providers to deploy only those workers who have received their COVID-19 vaccination in line with government guidance (unless medically exempt) from 14 April 2021 until 26 May 2021. Over 13,500 responses were submitted through an online survey and 26 responses to the consultation were received outside of the online platform. Responses were received from care home providers, adult social care representatives, other adult social care

providers, members of the adult social care workforce, local government representatives, service users/ relatives of service users, health care providers and members of the public.

- 10.2 Overall, a majority (57%) of respondents did not support the proposal but the responses from the adult social care sector were mixed.
- 10.3 Respondents highlighted clearly issues with the initial scope of including only CQC-registered care homes with at least one older (65+) adult. There was also significant support for broadening the scope of the policy to include all those coming into close contact with residents or all those entering care homes in any capacity. There was also some support for broadening the policy to all health and social care staff, in any setting.
- 10.4 In response to the consultation DHSC will extend the scope of the policy to all CQC-registered care homes in England providing accommodation for persons who require nursing or personal and to include all persons who enter a care home, regardless of their role (excluding the exemptions listed in 7.4). The combination of consultation responses with public health evidence provides a strong foundation on which to proceed with the policy.
- 10.5 The consultation response document is available here: [Making vaccination a condition of deployment in care homes: government response - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/making-vaccination-a-condition-of-deployment-in-care-homes)

11. Guidance

- 11.1 The Government intends to publish operational guidance by the end of July.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies is that providers are likely to experience a short-term cost of dealing with staff absences, if workers chose not to get vaccinated as a result of the policy. Although the impact of this will be partially mitigated by the 16-week grace period for requiring staff to get vaccinated. In the long run however, having a fully vaccinated workforce reduces the likelihood of a high number of absent days, which would benefit the provider as it reduces the need and therefore cost of finding replacement work.

As the policy change also impacts visiting professionals who enter a care home, businesses who have unvaccinated staff may incur a cost. These businesses may need to reallocate staff to deal with this change or may suffer from lost business as care home providers are required to select from competing businesses who have staff that meet the requirements of the regulations. As some businesses may lose revenue from lost work in care homes if their staff are unvaccinated, other businesses with vaccinated staff will benefit from increased work and therefore revenue. This is likely to result in a zero to small net cost to businesses. An additional new cost that is likely to be incurred by businesses and providers is the cost associated with showing that staff are vaccinated. There may be a cost associated with implementing and maintaining a system to verify vaccine status among visiting professionals.

We can expect Local Authorities to proactively manage these risks given their knowledge of local provider and labour markets and, the ongoing work taking place regarding vaccine uptake. Contingency plans should already be in place to deal with workforce shortages and provider failures as set out in the Care Act.

- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 A full impact assessment has not been published with this instrument. An Impact Statement setting out the preliminary analysis of the impact of this instrument has been laid in Parliament and published at <https://www.gov.uk/government/consultations/making-vaccination-a-condition-of-deployment-in-older-adult-care-homes/outcome/statement-of-impact-the-health-and-social-care-act-2008-regulated-activities-amendment-coronavirus-regulations-2021> and available from the Department of Health and Social Care, 39 Victoria Street, London, SW1 0EU.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 To minimise the impact of the requirement on small businesses (employing up to 50 people) the approach taken is to work with Skills for Care to ensure that local authorities and providers will have access to guidance and resources to support workforce capacity and resilience. We have also taken on board the need for a suitable grace period for implementation of the policy and have included a 16-week grace period from when this instrument comes into force.
- 13.3 The basis for the final decision on what action to take to assist small businesses was public consultation as set out in paragraphs 10.1-10.5. Following this the decision was made to regulate small businesses, taking on board feedback that small care homes will find this policy more challenging to implement.

14. Monitoring & review

- 14.1 A statutory review clause is included in the instrument. This clause requires the Secretary of State to review the operation and effects of these Regulations and lay a report in Parliament within one year after the date on which these Regulations come into force, and within every year after that.

15. Contact

- 15.1 Martin Teff at the Department of Health and Social Care Telephone: 0113254 6304 or email: martin.teff@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Julie Laughton, Deputy Director for ASC Vaccines, Testing, and PPE, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Helen Whately MP, Minister of State for Care at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.