EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) (CORONAVIRUS) (NO. 2) REGULATIONS 2022

2022 No. 15

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 reduce the spread of COVID-19 in health and social care settings, including in an individual's own home, in order to protect persons receiving care who are vulnerable to COVID-19, and also to protect our valuable health and social care workforce.

2.2 This instrument amends the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations"), to provide that the registered person in respect of the regulated activity of providing accommodation for persons who require nursing or personal care in a care home must secure that – subject to certain exceptions— a person only enters the care home premises if they provide evidence that they have been vaccinated with a complete course of an authorised vaccine against COVID-19 or, if otherwise vaccinated against coronavirus is also, within a specified time period, vaccinated with a single dose of an authorised vaccine, subject to certain exceptions.

2.3 This instrument also amends the 2014 Regulations, to provide that the registered person can only employ or otherwise engage a person in respect of any other regulated activity, if the person provides evidence that they have been vaccinated with a complete course of an authorised vaccine against COVID-19 or, if otherwise vaccinated against coronavirus is also within a specified time period, vaccinated with a single dose of an authorised vaccine, subject to specific exemptions.

2.4 This instrument, for both care homes and wider health and social care, provides those that have been part of a clinical trial an exemption from COVID-19 vaccination. Additionally, this instrument for both care homes and wider health and social care also provides, for those who have not previously been employed or otherwise engaged by the CQC registered person, a specific timeline in which to become fully vaccinated.

2.5 The section on legislative context provides more information as to when the different provisions of this instrument comes into force.

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 The Secretary of State for Health and Social Care, the Rt Hon Sajid Javid 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) (No. 2) Regulations 2022 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. For the purposes of preventing, detecting and controlling the spread of infections, specifically in response to the effects of the coronavirus pandemic, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") were amended by the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021 ("the Care Home Coronavirus Regulations").

6.3 The Care Home Coronavirus Regulations come into force on 11th November 2021 and make provision in relation to the requirements on registered persons registered for the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home.

6.4 This instrument makes additional amendments to regulation 12 of the 2014 Regulations.

6.5 Regulation 3 of this instrument makes further provision in relation to the requirements placed on registered persons registered for the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home. Specifically in relation to circumstances where a person has participated or is participating in a clinical trial; and where a person has not previously been employed or otherwise engaged by the registered person in respect of that regulated activity.

6.6 Regulation 4 of this instrument makes further amendments to regulation 12 of the 2014 Regulations and comes into force after a period of 12 weeks beginning with the day after the day on which this instrument is made. Regulation 4 amends regulation 12 with respect to the requirements placed on registered persons with respect to any regulated activity.

6.7 With respect to the regulated activity of providing accommodation for persons who require nursing or personal care in a care home, a registered person must secure that a

person is only permitted entry into the premises used by the registered person if certain conditions are met. These conditions are that, subject to certain exemptions, the person has provided evidence to the registered person that they have been vaccinated with a complete course of doses of an authorised vaccine or for clinical reasons should not be vaccinated, or that they have been otherwise vaccinated against coronavirus. This instrument also provides for an alternative option for a person that has not previously been employed or otherwise engaged for the purposes of the provision of that regulated activity.

6.8 With respect to all other regulated activities other than the provision of accommodation for persons requiring nursing or personal care (except care provided under a shared lives agreement), a registered person must secure that a person is only employed or otherwise engaged for the purpose of a regulated activity if, subject to certain conditions, they have similarly been vaccinated with a complete course of doses of an authorised vaccine or for clinical reasons should not be vaccinated, or that they have been otherwise vaccinated against coronavirus. This instrument also provides for alternative options for a person that has not previously been employed or otherwise engaged for the purposes of the provision of that regulated activity – both where that person was first employed or engaged during the period that this instrument was made and regulation 4 comes into force, and also where that person was first employed or engaged after regulation 4 comes into force.

6.9 For the purposes of the amendments made by regulation 4 only, the definition of "authorised vaccine" is defined with reference to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021.

6.10 Regulation 5 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.

6.11 It may be helpful in understanding the requirements to consider 3 categories:

1) **Employed or otherwise engaged prior to date regulations are made.** Subject to certain conditions, a registered provider could only employ or otherwise engage a worker after the enforcement date if they have provided evidence that they have been vaccinated with a complete course of an authorised vaccine, or, if vaccinated with unauthorised vaccine, have received a top-up dose if required (as set out in the schedule 4A)

2) **Employed or otherwise engaged after the enforcement date (i.e. new starter after the grace period has ended).** Subject to certain conditions, a registered provider could only employ or otherwise engage a worker 21 days after their first dose of an authorised vaccine. Subsequently, after a period of 10 weeks from the first dose of an authorised vaccine, the registered person would not be able to employ or otherwise engage a worker until they had received a complete course of an authorised vaccine.

   If vaccinated with an unauthorised vaccine and more than 10 weeks had passed since their last vaccination, the registered person would not be able to employ or

otherwise engage a worker after the coming into force date until they had received a top-up dose, if required (as set out in schedule 4A).

3) **Employed or otherwise engaged after regulations are made but before enforcement date (i.e. a new starter during the 12 week grace period).** Subject to certain conditions, a registered provider could only continue to employ or otherwise engage a worker, after the grace period, if the worker has had a first dose of an authorised vaccine. The worker would need a second dose within 10 weeks of the first dose to continue to be employed or otherwise engaged.

   If vaccinated with an unauthorised vaccine and more than 10 weeks had passed since their first vaccination, the registered person would not be able to employ or otherwise engage a worker after the coming into force date until the worker had received a top-up dose, if required (as set out in schedule 4A)

6.12 In respect of care homes, the Care Home Coronavirus Regulations require that a new starter has received two doses of an authorised vaccine before they can be deployed (subject to certain conditions). These further regulations would amend the requirements relating to Care Homes so that there is consistency in approaches with respect to new starters. The grace period for Care Home Coronavirus Regulations relating to care homes has already passed. Therefore, when the further regulations are made, care home registered persons will be able to deploy a worker 21 days after their first dose of an authorised vaccine. Subsequently, after a period of 10 weeks from their first dose of an authorised vaccine, the registered person would not be able to deploy a worker until they had received a complete course of an authorised vaccine.

6.13 The Code of Practice relating to health care associated infections (see section 21 of the Health and Social Care Act 2008) to this instrument will be updated to supplement this instrument, providing guidance about compliance with this instrument. In particular, the Code of Practice will provide guidance as to other types of vaccines considered reasonably appropriate for the purposes of being otherwise vaccinated against coronavirus and the types of evidence considered reasonably appropriate for demonstrating a person's vaccination status.

7. Policy background

What is being done and why?

7.1 During the course of the pandemic the overriding concern for government, the National Health Service (NHS) and the care sector has been to protect the workforce, patients, and the users of services. Whether in care homes, at home, in hospitals or in general practice, everyone working in health and social care with vulnerable people would accept a first responsibility to avoid preventable harm to the people whom they are there to care for.

7.2 The vaccination uptake for NHS staff shows 93.5% have had at least one dose (90.7% two doses) (data published 2 December). However, uptake rates still vary from 84.0% to 97.2% for first dose (79.0% to 94.9% for two doses) amongst NHS trusts (data published 11 November).

7.3 The vaccination uptake for domiciliary care staff shows 84.7% have had at least one dose (77.0% two doses) (data published 2 December). However, as of 2 December,

uptake rates still vary from 62.8% to 100.0% for first dose (46.8% to 96.3% for two doses) amongst Local Authorities.

7.4 For patients, social care recipients, and their families and friends, there remains uncertainty on whether they are afforded the added protection of vaccinated staff. The impact of the COVID-19 pandemic in both hospitals and care homes raises the questions as to whether this should continue to be accepted as the norm.

7.5 During the pandemic, following the development of COVID-19 vaccines, there has been a substantial and sustained effort to enable access to vaccines. This has resulted in high COVID-19 vaccine uptake in the population, including across health and social care staff.

7.6 To further increase uptake levels, regulations have already come into force which will mean that from 11 November 2021, registered persons in care homes must ensure that, subject to limited exceptions, only those persons who can provide evidence that they have been vaccinated against COVID-19 or that they are clinically exempt, can enter the premises of the care home. A number of social care stakeholders have called for parity in approach across the health and social care sectors, so that the most vulnerable are protected in every setting.

7.7 The Government is not alone in bringing in requirements for vaccinations in health and care settings. Similar requirements have been introduced in France, Greece and New Zealand as well as parts of Canada, Australia and the US.

7.8 The Joint Committee on Vaccination and Immunisation (JCVI) has advised that vaccination against COVID-19 is a critical step in protecting vulnerable people as well as the wider health and social care sector.

7.9 Analysis from PHE indicates that the COVID-19 vaccination programme has directly prevented an estimated 24.1 million infections, over 261,500 hospitalisations, and 127,500 deaths.

7.10 For the COVID-19 Delta variant vaccine effectiveness against infection has been estimated at around 65% with Oxford-AstraZeneca vaccine and 80% with PfizerBioNTech vaccine. Studies have reported 65% to 70% effectiveness against symptomatic disease with Oxford-AstraZeneca vaccine, and 80 to 95% with PfizerBioNTech. Effectiveness against hospitalisation of over 90% is observed with the Delta variant with both vaccines.

7.11 For the Alpha and Delta COVID-19 variants there is clear evidence that vaccines are effective at preventing infection. Uninfected individuals cannot transmit the virus – this helps protect those that are most vulnerable in our society.

7.12 With the emergence of the new variant Omicron, and the early signs of increased transmissibility, vaccination is more important than ever. Although there is limited scientific evidence of vaccine efficacy at this time, JCVI has been clear that even if the vaccines are less effective, they are not ineffective, and will help reduce the risk of infection and severe disease.

7.13 A COVID-19 vaccine, like most vaccinations, also has benefits that go beyond the benefits for the vaccinated individual. Additional benefits to society include a reduction risk of transmission by the workforce among the remainder of the workforce, patients and the wider community. In addition, the vaccine will reduce the likelihood of health and 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.

7.14 Despite the unprecedented action to encourage vaccine uptake there remains, for example over 95,000 NHS workers who are unvaccinated. As such, 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 providers, both public and private, to only employ or otherwise engage those persons who have provided evidence that they have been vaccinated with a complete course of authorised COVID-19 vaccine, or if, otherwise vaccinated against coronavirus, have received a "top-up" dose of an authorised vaccine (subject to UKHSA guidance).

Exemptions

7.15 The requirements placed upon registered providers will not apply in the event that the person employed or otherwise engaged does not have direct, face-to-face contact with service users; is under the age of 18; is clinically exempt; is participant in a clinical trial; the provision of the regulated activity is part of a shared lives agreement.

7.16 The terms 'face to face' and 'otherwise engaged' should be given their plain, ordinary meaning. 'Otherwise engaged' means those workers that are deployed for the provision of the regulated activity but are not directly employed. They may be working under a contract for services or they may be students or volunteers with no contractual arrangement with the registered person.

7.17 Further detail to support planning and implementation, including examples of applying the requirements to roles, is available in the guidance that has been published by NHS England.

7.18 The majority of respondents agreed with our proposal in the consultation to grant exemptions from COVID-19 vaccination based only on medical grounds. As such, in line with the Green Book on immunisation against infectious disease, a registered persons will be able to continue to use workers for whom vaccination is not clinically appropriate. The worker will need to provide evidence of their exemption.

7.19 In relation to pregnancy, clinicians have been clear that vaccines are safe for the majority of pregnant women. The JCVI has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group. The Royal College of Obstetricians, Royal College of Midwives and the UK Tetralogy Service consider COVID vaccination to be safe. There is no evidence that COVID-19 vaccines have any effect on fertility or chances of becoming pregnant.

7.20 However, we recognise that in some circumstances, vaccination may not be appropriate during pregnancy. There are already arrangements in place for demonstrating COVID-19 vaccination status with short-term exemptions available for those with short-term medical conditions and as an option that some pregnant women may choose to take. For pregnant women the exemption expires 16 weeks post-partum. This will allow them to become fully vaccinated after birth.

7.21 We have not included exemptions on religious grounds. We are aware that some members of religious groups could refuse vaccination due to their beliefs. We recognise these are sensitive issues for people but also that views and guidance on uptake of the vaccine has been provided by religious organisations. For example, the Catholic Church has confirmed that it believes COVID-19 vaccinations are morally

acceptable regardless of how they have been manufactured, and can be "used in good conscience". The Muslim Council of Britain has recommended both the AstraZeneca and Pfizer vaccine to protect eligible patients from coronavirus, and the Hindu forum of Britain has set out there is no prohibition from Hindu scriptures to use COVID-19 vaccines for one's health.

7.22 It is also important that Government balances remaining concerns on religious grounds with ensuring that the scope of any exemptions do not undermine the public health benefits of the policy or create a system that can be used by individuals wrongly to circumvent the requirements. This type of exemption would be difficult to implement or prove and we do consider it likely therefore that this type of exemption may lead to tension between religious and non-religious members of the workforce who are unvaccinated or when they are taking the decision to become vaccinated.

7.23 Guidance to support implementation continues to set out the need to further engagement with targeted communities where uptake is the lowest, including extensive work with BAME and faith networks to encourage workers to receive the vaccine.

What the Government has done to encourage uptake and mitigate workforce risks

7.24 The Government recognises that there are concerns about the potential impacts of the regulations on workforce pressures and the pressures on services, particularly over winter. We are taking action, in collaboration with the NHS and adult social care sector, to mitigate these risks and continue to encourage workers to take up the vaccine. This includes:

- the 12-week grace period, allowing time for both workforce planning, and for those colleagues who are not yet vaccinated, to make the positive choice to protect the people they care for, as well as themselves.
- committing to an enforcement date of the 1 April 2022 to assist providers over the winter period and help minimise workforce pressures.
- reducing the time employers have to wait in order to deploy a new worker – now a worker can be deployed 21 days after their first dose, rather than having to wait 8 weeks.
- Increasing engagement with health and care workers on vaccinations and the opportunities for vaccination, as set below. To further reduce the size of the unvaccinated workforce ahead of requirements coming into force.
- Additional funding for health and care services to support service delivery during winter.

Encouraging uptake

7.25 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), set out the significant programme of work undertaken to drive vaccine uptake, including actions to improve access and to address the concerns of those who may be hesitant to receive the vaccine.

7.26 The NHS has focused in recent months on a targeted approach to improve uptake in hesitant groups by undertaking campaigns directed towards midwifery workers, black, Asian, and minority ethnic (BAME) groups and students, as well as using the booster

campaign as an opportunity to reengage workers. In order to maximise uptake over the winter months, the NHS's plan includes the following:

- Further increase engagement with targeted communities where uptake is the lowest, including extensive work with BAME and faith networks to encourage workers to receive the vaccine.
- Use Chief Professional Officers to encourage staff vaccination uptake for all NHS staff in a communications push.
- The use of 1-2-1 conversations for all unvaccinated NHS staff with their line manager, with clear guidance on how to do this. This was associated with an increase in vaccine uptake by 10% in phase 1.
- Increasing number and diversity of opportunities to receive the vaccine. Using the booster campaign to make the most of walk-ins, pop-ups, and other ways to make getting the vaccine as easy as possible.

7.27 We have also delivered a targeted programme of work to support vaccine uptake among 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.

7.28 In both health and social care we will continue to encourage as many people as possible to take up the vaccine and will work closely with the NHS ahead of the regulations coming into force. We believe those that have not yet had the vaccine will take the positive step towards protecting themselves, and vulnerable people, following the example already set by that vast majority of health and social care workers.

7.29 These steps sit alongside other key interventions that we have made to support services such as:

- Bolstering capacity across urgent and emergency care and the wider NHS, including with a £250 million investment in general practice, £55 million for the ambulance service, and £75 million for NHS111;
- publishing an adult social care winter plan, including £388 million to support infection prevention control and £162.5 million for workforce recruitment and retention; and

- investing £478 million for support services, rehabilitation and reablement care following discharge from hospital, and ensuring health and social care services are joined up.

7.30 There are now record numbers of doctors and nurses working in the NHS, as well as record numbers of professionally qualified clinical staff overall. The Government is are committed to recruiting and retaining more talented staff, including an additional 50,000 nurses by the end of this parliament.

7.31 Although NHS workforce figures are dynamic (as people join and leave the workforce), since Government consulted on vaccination as a condition of deployment in wider health and social care in September, the latest published figures show an overall net increase of staff vaccinated with a first dose of over 50,000.

7.32 We have already seen the impact of introducing vaccination requirements in care homes. Throughout the development and implementation of the policy vaccination rates have continued to rise steadily. Contrary to what some feared we are not aware of any care home closures where vaccination as a condition of deployment has been the primary cause.

7.33 Through each part of the development of the policy government has taken onboard lessons learnt from the earlier implementation of vaccination requirements in relation to care homes settings. This includes ensuring there is an appropriate grace period, reducing the time employers have to wait in order to deploy a new worker; and reducing the complexity of the exemptions process as well as recognising mixed doses and vaccines received abroad.

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 DHSC conducted a public consultation on making vaccination a condition of deployment in wider health and social care from 9th September 2021 until 22 October 2021. Over 34,900 responses were submitted through an online survey and 42 responses to the consultation were received outside of the online platform. Responses were received from front line staff, managers, representative organisations, local government representatives, service users / care recipients and their relatives, providers and members of the public.

10.2 Overall, the consultation showed that, while a majority 64% of respondents did not support the proposal, the responses from the health and social care sector were mixed, with some groups (e.g. managers of healthcare or social care services) mostly supporting the proposed legislative change while others (e.g. service users / care recipients and their relatives) were mostly opposed.

10.3 Regarding policy scope, the consultation showed some support for the proposed scope of those deployed to undertake direct treatment or personal care as part of a CQC-regulated activity in a healthcare or social care setting.

10.4 One of the main areas of concern was the timing of the changes and the impact on workforce this winter. Many representative bodies called for a longer period of preparation and implementation, to take effect after winter.

10.5 The majority of respondents agreed with our proposal to provide exemptions on medical grounds. There was a call for ensuring that the system for demonstrating vaccination status or exemption from vaccination is simple and clear.

10.6 The consultation showed that respondents were concerned about the potential for disproportionate impact on those with protected characteristics, such as pregnant women and people from particular ethnic minority backgrounds. We have published a Equality Impact Assessment which provides further information.

10.7 The government has considered the concerns raised in relation to introducing flu vaccination requirements. The flu programme runs between October and March with most flu vaccinations happening October and January. Due to the need to balance this with the time necessary for health and social care to implement the regulations, the government has chosen not to introduce vaccination requirements for flu at this time.

10.8 Following the consultation DHSC will extend the scope of the policy to all those deployed to undertake a CQC regulated activity, this includes non-clinical ancillary staff that may have social contact with service users and care recipients.

10.9 The combination of consultation responses with the public health evidence and protection of vaccinations as set out above, provides a strong foundation on which to proceed with the policy.

10.10 This policy is not a first step in introducing wider vaccination requirements for the general population, the Government has been clear that is not the intention.

11. Guidance

11.1 Further guidance to support planning and implementation has been published by NHS England. The Government will also publish further guidance to support the adult social care sector.

12. Impact

12.1 The impact on business, charities or voluntary bodies where they are providing CQC-regulated activity 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 12-week grace period. 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.

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

12.3 A full Impact Assessment has been laid in Parliament and 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 Further guidance will be published to help support health and social care providers in implementing and complying with the regulations.

13.3 The basis for the final decision on what action to take to assist small businesses is taken from the responses received to the consultation.

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. As part of the review the Secretary of State must consider whether the objectives of the Regulations remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

15. Contact

15.1 Charles Watson at the Department of Health and Social Care can be contacted with any queries regarding the instrument: charles.watson@dhsc.gov.uk

15.2 Matthew Henry, Deputy Director, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Rt Hon Sajid Javid MP, Secretary of State for Health and Social Care at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.