EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) (CORONAVIRUS) (NO. 3) REGULATIONS 2022

2022 No. 206

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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 These Regulations amend the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") to remove provisions which were inserted into the 2014 Regulations for the purposes of preventing, detecting and controlling the spread of infections, specifically in response to the effects of the coronavirus pandemic.

2.2 Those provisions require;

(a) a registered person ("A") in respect of the regulated activity of providing residential accommodation together with nursing or personal care in a care home, to secure that a person ("B") did not enter any premises used by A unless B met specific requirements, as well as to have related governance arrangements in place.

(b) with effect from 1st April 2022, the registered person ("A") to 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, subject to specific exemptions.

2.3 Specifically, these regulations revoke the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021and the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Secretary of State for Health and Social Care has been clear in his intention to revoke the regulations, subject to consultation and parliamentary procedure, since 31 January 2022, when he updated Parliament on this policy[1]. Health and social care stakeholders have also been clear that they need certainty regarding the status of the legislation and its impact on unvaccinated workers as early as possible ahead of 1

[1] https://www.gov.uk/government/speeches/oral-statement-on-vaccines-as-a-condition-of-deployment

April 2022, in order to minimise both anxiety throughout the sector and subsequent workforce capacity pressures.

3.2 As such, due to necessity to provide clarity as soon as possible to the sector, the period between the SI being signed and coming into force will be shortened to 14 days, instead of the conventional 21 days.

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. 3) 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 the 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 came into force on 11th November 2021 and made provision in relation to the requirements on persons registered for the regulated activity of providing accommodation for persons who require nursing or personal care carried on in a care home. The requirement on the registered person was in effect a prohibition on persons entering a care home premise unless vaccinated against coronavirus, or otherwise exempt from the requirements.

6.4 The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 made further amendments to the 2014 Regulations. The general effect was to introduce requirements from 1 April on registered persons for 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). The regulations require that 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. The regulations also set out specific exemptions - the requirements would 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; or if the provision of the regulated activity is part of a shared lives agreement.

6.5 The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 also align the definition of "authorised vaccine" to that used in the the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021.

6.6 The core requirement of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 - that 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 been vaccinated with a complete course of doses an authorised vaccine - has an enforcement date of 1 April 2022.

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 social care sector has been to protect the workforce, patients, and people who receive care and support.

7.2 Following a public consultation which closed on 26 May 2021, the government laid regulations on 22 June 2021 requiring registered persons of all Care Quality Commission (CQC)-registered care homes to ensure that a person does not enter the premises unless they have been vaccinated, subject to specific exceptions, to protect at-risk residents. These regulations came into force on 11 November 2021.

7.3 The government launched a further consultation on making COVID-19 vaccination a condition of deployment in healthcare and the wider CQC-regulated social care sector in September 2021. The government's response to the consultation was published in November 2021, and regulations were laid to extend the vaccination as a condition of deployment policy to health and wider social care. The regulations required the CQC registered person to only deploy workers to undertake a regulated activity if they were fully vaccinated, subject to specific exemptions. The regulations were subsequently approved by Parliament in December 2021. Some provisions, amending the policy in care homes, came into force on 6 January 2022 and the remaining provisions, which extend the policy to health and wider social care, are set to come into force on 1 April 2022.

7.4 In taking these steps the government has always followed the best, and latest, clinical and scientific evidence and the principle of maximising the protection of public health while minimising intrusion into people's everyday lives.

Healthcare COVID-19 vaccine uptake

7.5 Data collected for the NHS shows that over 1.45 million (95%) NHS trust staff have received at least one dose, with 1.4 million (92%) staff having received 2 doses. The percentage of staff receiving a first dose is above 96% in all regions (2 doses above 93%), bar London, which is at 92% for first dose (88%, 2 doses). Over 1.24 million (78%) have received a booster. All data are as of 24 February 2022, covering vaccinations up to 20 February 2022.

Social care COVID-19 vaccine uptake

7.6 More than 1.3 million social care workers in England have now taken up at least one dose of the vaccine.

7.7 As of 20 February 2022, 96% of staff in care homes have received a first dose of the vaccine and 95% a second dose.

7.8 In wider social care settings, while the regulations have not yet come into force, providers were reporting that 89% of home (domiciliary) care staff and 76% of staff in other settings had received one dose of the vaccine, as of 20 February 2022. There is little regional variation in care home uptake, however there is some variation in domiciliary care staff uptake, which ranges from 85% in London, to over 92% in the North East and Yorkshire.

Uptake since September 2021

7.9 Since the government launched the consultation on vaccination as a condition of deployment in health and wider social care settings in September 2021, there has been a net increase of 208,000 people working in NHS trusts who have received a first dose of a COVID-19 vaccine, becoming part of the 19 out of 20 NHS workers who have done so.

7.10 During the same time, there has also been a net increase of 38,000 people working in social care getting vaccinated, including 19,000 people working in care homes and 19,000 people working in domiciliary care.

Vulnerable groups

7.11 As of 20 February 2022, 96% of all care home residents have received two doses of the vaccine and 87% have received a booster.

7.12 In the general population, 92% of adults aged 80 and over have received two doses of the vaccine and 88% have received their third dose or booster.

7.13 Of those identified as clinically extremely vulnerable, 94% have received two doses of the vaccine and 85% have received their third dose or booster.

Clinical evidence at the time regulations were laid

7.14 At the time government laid the regulations for both care homes and health and wider social care, Delta was the predominant variant.

7.15 In the face of the Delta variant, with a population that had immune systems that had never been exposed to COVID-19, the data provided strong evidence in support of ensuring as much of the population was vaccinated as possible, both to reduce the risk to individuals, as well as the risk of transmission to vulnerable people.

7.16 For the COVID-19 Delta variant, vaccine effectiveness against infection after two doses was estimated at around 65% with Oxford-AstraZeneca vaccine, and 80% with Pfizer-BioNTech vaccine. Studies reported 65% to 70% effectiveness against symptomatic disease with Oxford-AstraZeneca vaccine, and 80 to 95% with Pfizer-BioNTech (after two doses). Effectiveness against hospitalisation of over 90% was observed against the Delta variant with both vaccines (after two doses).

7.17 Several studies provided evidence that vaccines were effective at preventing infection. Uninfected individuals cannot transmit; therefore, the vaccines were also effective at preventing transmission.

7.18 Analysis from Public Health England indicates that the COVID-19 vaccination programme had directly prevented between 23.8 and 24.4 million infections, over 82,100 hospitalisations, and between 102,500 and 109,500 deaths.

The updated clinical evidence

7.19 The first cases of Omicron were reported on 27 November 2021, just over two weeks after the regulations for wider health and social care were laid. Very shortly after its discovery, Omicron became the dominant variant in the UK and now represents nearly all infections.

Severity of Omicron

7.20 While Omicron still presents a threat to public health, especially for those that are unvaccinated, relative to Delta it is intrinsically less severe. There is emerging evidence that Omicron may have lower virulence due to:

(i) preference to replicate in a different part of the respiratory system;

(ii) different cell entry mechanism compared to previous variants.

7.21 This has resulted in the risk of presentation to emergency care or hospital admission with Omicron being approximately half of that for Delta. When coupled with the high vaccination rate in the population, this has meant the impact of the circulation of Omicron has been less than initially feared.

Effectiveness of primary course of COVID-19 vaccine

7.22 Further data collected by UKHSA now shows that a full primary course of an approved vaccine does not provide the intended longer-term public health protection against the spread of COVID-19 on which the vaccination as a condition of deployment policy was originally decided.

7.23 Nonetheless, it remains a fact that a primary course is an important foundation to building up the resilience of the immune response. Each exposure to a vaccine teaches the immune system to respond to the virus reducing the risk of severe disease or death.

Coronavirus (COVID-19) booster vaccine effectiveness

7.24 Initial data from UKHSA shows that a booster increases protection against symptomatic and asymptomatic Omicron infections to 62% in those without a prior infection rising to 71% in those with prior infection. Protection against Omicron symptomatic infection after the booster, however, does decline, suggesting that protection against infection may also decline quite quickly; 2 to 4 weeks after a booster dose vaccine effectiveness against symptomatic infection ranged from around

65 to 75%, dropping to 55 to 65% at 5 to 9 weeks, 45 to 50% at 10 to 14 weeks, and 30 to 40% at 15 and over weeks after the booster.

7.25 For those in the general population who have had a booster dose, protection against hospitalisation with Omicron is higher and more durable than protection against infection. Protection against hospitalisation after the booster is above 90% initially dropping to around 75% after 10 to 14 weeks.

7.26 UKHSA has marked a subvariant of Omicron called BA.2 as a 'variant under investigation' (VUI), one level below a 'variant of concern' (VOC). While a VUI has mutations which are potentially concerning and UK or international community transmission, a VOC has demonstrated significant characteristics such as increased transmissibility, severity or ability to infect a person. However, an initial analysis of vaccine effectiveness against the BA.2 subvariant reveals a similar level of protection to symptomatic infection compared to BA.1, the original variant of Omicron. At least 25 weeks after two doses, vaccine effectiveness against symptomatic infection was reported as 9% and 13% respectively for BA.1 and BA.2, which increased to 63% for BA.1 and 70% for BA.2 at 2 weeks following a third booster dose. Receiving a full course of vaccination, and in particular a booster dose, therefore remains crucial in ensuring the level of protection that individuals can receive against COVID-19. JCVI will continue to review the booster programme and how frequently vaccination may be needed as part of our enduring response. It is possible that in the future this may include annual vaccination programmes for those who need additional protection.

Population exposure to Omicron variant

7.27 Omicron's increased infectiousness meant that at the peak of the recent winter spike, 1 in 15 people had a COVID-19 infection, according to the Office for National Statistics (ONS). Around 24% of England's population has had at least one positive COVID-19 test. The latest analysis shows that there is an additional incremental benefit from each vaccine exposure, even in those who have had prior infection, showing that if a person has had prior infection, they should still get all three vaccinations if they want the highest level of protection available.

The proposed way forward – announced on 31 January

7.28 Vaccination remains the very best line of defence against COVID-19 and all people working in health and social care settings have a professional duty to be vaccinated. However, in light of the latest clinical evidence and the views received in response to the consultation, the view of the government is that it is no longer proportionate to require vaccination as a condition of deployment through statute in health, care homes or other social care settings.

7.29 While the government's intention is to revoke the vaccination as condition of deployment requirements in the regulations, the importance of vaccination remains clear: vaccines save lives, and everyone working in health and social care has a professional duty to be vaccinated against COVID-19. The government is therefore taking the following steps:

- The Secretary of State for Health and Social Care has written to the professional regulators operating across health to review current guidance to registrants on vaccinations, including COVID-19, and to emphasise their professional responsibilities in this area.

- Engaging with the NHS to review its policies on the hiring of new staff and the deployment of existing staff, taking into account their vaccination status.
- Reviewing the Code of Practice on the prevention and control of infections with a view to strengthening the obligations providers must satisfy in meeting the required standard set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Department of Health and Social Care will seek views on this in a separate consultation.

7.30 In keeping with the Government's approach throughout the pandemic of following the latest clinical and scientific evidence, should there be another dramatic change in the virus, the government will not hesitate to review the policy again as necessary to safeguard the most vulnerable people in society.

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 2018.

9. Consolidation

9.1 No consolidation is being undertaken.

10. Consultation outcome

10.1 Between 9 February 2022 and 16 February 2022 DHSC conducted a public consultation on revoking regulations which require COVID-19 vaccination as a condition of deployment in health and social care. Over 90,000 responses were submitted through an online survey and 17 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 majority (90%) of respondents supported the government proposal to revoke the regulations. 9% did not support the government proposal citing the lead argument that those who are clinically vulnerable, such as the immunosuppressed, may be at risk from unvaccinated health and care workers.

10.3 The government has taken account of the latest clinical evidence and the views received in response to the consultation in coming to the decision to revoke the vaccination as a condition of deployment regulations. This instrument revokes the vaccination as condition of deployment requirements in the regulations.

11. Guidance

11.1 Guidance is not required for this SI. The Department for Health and Social care will continue to keep the health and social care sector updated as needed.

12. Impact

12.1 The impact on business, charities or voluntary bodies providing CQC-regulated activity is that they are unlikely to experience the short-term cost of replacing staff that may arise if the regulations are not revoked.

12.2 There is either none or no significant impact on the public sector.

12.3 In reducing regulatory burden, a further Impact Assessment has not been undertaken for this instrument.

13. Regulating small business

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

13.2 Revoking the vaccination as condition of deployment requirements in the regulations reduces regulatory burdens on businesses. No further specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 This instrument revokes the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021and the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 and does not contain provisions in relation to monitoring or reviewing. The government will keep this policy under review, and should there be a change in the scientific and clinical advice, the government will not hesitate in reviewing the policy again as necessary to safeguard the most vulnerable in society.

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 at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.