

Regulations requiring compulsory Covid-19 vaccination of care home workers and others entering settings will come into force this month. **Duncan Astill**, regulatory partner at Mills & Reeve, and **Sandesh Singh**, barrister at Crown Office Chambers, examine the implications and the CQC's proposed approach to enforcement



# Rock and a hard place?

**Regulation 12(3) of the Health and Social Care Act (Regulated Activities) Regulations 2014 (regulations) will require that a service provider or registered manager of a care home must ensure that a person does not enter the premises unless they can demonstrate that: (a) they have received a complete course of an authorised Covid-19 vaccination (Oxford/Astra-Zeneca, Moderna, Janssen or Pfizer/BioNTech) or, alternatively, (b) they are exempt from vaccination for clinical reasons.**

The new requirement will extend to all agency staff, volunteers, health-care workers, hairdressers and other tradespeople who might be engaged in the normal operation of a care home. However, there will be some exceptions. For example, it will not apply to those under the age of 18, friends and family visiting a service user or people entering the care home to assist with an emergency or carry out urgent maintenance assistance.

Further, as the requirement will apply to the regulated activity specified in schedule 1, para. 2 of the regulations (care homes providing residential accommodation together with nursing or personal care), it will not cover senior living, retirement living or other similar care facilities.

## Vaccine exemption

Updated guidance from the Department of Health and Social Care (DHSC) has set out how care home staff will be able to apply for official proof that they are unable to be vaccinated for clinical reasons. This will also be relevant to the NHS and other

organisations that deploy their staff to enter and provide services in care homes.

The new process will, from 24 December, require care staff to complete an application for an exemption, which will be clinically reviewed. This will replace the temporary self-certification scheme introduced on 15 September.

While the further DHSC guidance is welcome, there is a continued lack of clarity as to what will constitute a valid clinical exemption; whether staff are required to share the outcome of their formal application before 24 December and whether staff who have previously self-certified, but do not obtain a clinical exemption, will be able to work until that date. In addition, it is not clear whether, in reality, clinical staff will have sufficient capacity to review all applications for exemption by 24 December.

## Judicial review

The new requirement has raised a number of serious concerns within the sector. A report published by Skills for Care in October estimated that there are 105,000 vacancies being advertised each day, with employers expecting this to increase by between 17,000 and 70,000 as staff choose not to take up the vaccine.<sup>1</sup>

An additional concern is that the new requirement will essentially create a 'two-tiered system'. Care staff working in care homes who refuse to be vaccinated and are dismissed are likely to transfer into homecare, supported living or the NHS.

In that context, it will be interesting to see how the government responds to the DHSC's recent consultation (which

closed on 22 October) on making vaccination a condition of deployment in the NHS and the wider social care sector.<sup>2</sup>

As many commentators predicted, a judicial review challenge has been launched against the secretary of state for health and social care.

The challenge will be brought on a number of grounds, including that the regulations are incompatible with laws prohibiting mandatory vaccines; interfere with the right to 'bodily integrity'; will disproportionately impact women and those who identify as Black/Caribbean/Black British; and are irrational and will lead to shortages in both front line and non-front line care workers.

Will the judicial review be successful? That is impossible to answer at this stage. Therefore, registered persons should ensure that they are fully compliant with the new requirement by 11 November.

## The role of the CQC

As the DHSC's operational guidance makes clear, the requirement for compulsory vaccination forms part of the fundamental standards set out in the regulations. Therefore, compliance with it will be monitored and, in appropriate cases, enforced by the CQC.

The CQC will follow up any information of concern received, and will seek evidence to confirm that systems and processes are in place to comply with the new requirement. Therefore, it is essential that care providers have robust systems and processes in place by 11 November to demonstrate compliance.

While registered persons will not be required to show a record of the



evidence seen to support the vaccination or exemption status of people entering the care home, they will need to be able to provide reassurance that systems and processes are in place.

Registered persons should ensure that a record is kept of, at least, the vaccination or exemption status of staff members and those entering the care home, and the date that the status was last checked.

## The CQC's approach to enforcement

During a DHSC webinar, Alison Murray, head of inspection at the CQC, explained that the regulator will not be prescriptive about the systems and processes that should be implemented to meet the new requirement. However, she suggested that registered persons should:

- Carry out a risk assessment process
- Talk to their team and any regular visiting professionals
- Decide how they are going to 'make this work in practice'
- Make a record of their discussions
- Review any actions they are going to take regularly

She confirmed that, in the event of non-compliance with the new requirement, the CQC could take enforcement action against registered persons in the form of a fixed penalty notice or prosecution. However, she suggested that 'this would happen in very, very, very rare cases' and would 'more likely

to form part of wider concerns about the service'.

Rather, the CQC is 'much more likely' to use its civil enforcement powers (requirement notices, warning notices and conditions) in the event of non-compliance and would only take action which was 'reasonable and proportionate'.

She also touched on the potential for there to be a 'short term tension between deploying vaccinated staff and the requirement to have sufficient staff to provide safe care and treatment'.

She suggested that, if such a situation arose, if there was a 'nice risk assessment and a risk mitigation plan' in place then the CQC is 'not likely to go down a heavy enforcement line'. Rather, any enforcement action is 'much more likely to fall somewhere around the lower end of our actions'.

## Due diligence defence?

Murray's comments might be interpreted as suggesting that the CQC will look to take some enforcement action, albeit at the lower end of the scale, in the event of a breach – even if this arises as the result of a tension between the need to deploy vaccinated staff and the requirement to deploy sufficient staff to provide safe care.

If that is correct, it is not clear how this approach takes into account the potential for a registered person to be able to establish the due diligence defence contained in 22(4) of the regulations, which provides as follows (emphasis added): (4) *But it is a defence for a registered person . . . to prove that they took **all reasonable steps and exercised all due diligence** to prevent the breach of any of those regulations that has occurred.*

What if, on a particular day, a care provider is short staffed and feels forced

to rely on an unvaccinated member of agency staff (with suitable risk mitigation measures) in order to provide safe care? Can they argue that they took all reasonable steps and exercised all due diligence to avoid a breach of the new requirement and that, essentially, use of an unvaccinated staff member was unavoidable in the circumstances? In principle, yes.

But what is required in any particular case will depend on the facts, including the size and resources of the care provider's operation, and it will inevitably be extremely difficult to rely on the defence if staff shortages arise due to a failure to prepare adequately during the 16-week 'grace period' provided by the new regulations.

Providers will need to be able to demonstrate that significant advance thought has been given to what steps it would be reasonable to take in order to comply with the requirement and that all due diligence was exercised to ensure that the necessary steps identified were actually implemented – both generally, in terms of preparation, and specifically, in the event of an unavoidable staff shortage on a particular day.

Hopefully the new requirements (and the signalled intention to extend the requirement across the sector) will have the desired effect of nudging up vaccination rates rather than nudging carers into other professions.

## NOTES

1 <https://www.laingbuissonnews.com/care-markets-content/news/staff-turnover-rate-remains-high-skills-for-care-reports/>

2 <https://www.laingbuissonnews.com/care-markets-content/news/mandatory-covid-and-flu-vaccines-for-all-care-staff-to-be-considered/>