The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021

Lead department	Department of Health and Social Care
Summary of measure	The measure requires all care home workers or visiting professionals to be fully vaccinated against COVID-19, unless exempt, before entry to the premises of Care Quality Commission (CQC) regulated providers of nursing and personal care.
Submission type	Impact assessment (IA) – 18 August 2021
Legislation type	Secondary legislation
Implementation date	11 November 2021
Policy stage	Final
RPC reference	RPC-DHSC-5085(1)
Opinion type	Formal
Date of issue	20 October 2021

RPC opinion

Rating[1]	RPC opinion
Fit for purpose	The regulations were made on 22 July 2021. However, the Department did not submit an IA for RPC scrutiny until 18 August 2021. The RPC issued an initial review notice (IRN) to the Department. The Department resubmitted the IA, which is now fit for purpose, as it addresses the RPC's main points of concern and clearly outlines the rationale for intervention, the modelling assumptions and methodology. It also includes a monitoring strategy, and sufficiently tests uncertainties through sensitivity analysis. The IA's discussion of the measure's impacts on labour market shortages should discuss any competition effects and the consequences for providers, residents and others.

[1] The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the Better Regulation Framework. The RPC rating is fit for purpose or not fit for purpose.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying provision	Qualifying regulatory provision - IN
Equivalent annual net direct cost to business (EANDCB)	£88.1 million	£88.1 million *(2019 prices, 2020 pv)*
Business impact target (BIT) score	£88.1 million	£88.1 million
Business net present value	£88.1 million	
Overall net present value	£90.8 million	

RPC summary

Category	Quality	RPC comments
EANDCB	**Green**	The EANDCB calculation is fit for purpose. The IA monetises the direct impacts of recruitment, including training and productivity loss. The IA now also identifies other direct costs such as transitional and familiarisation costs but concludes that these appear to be immaterial and do not alter the EANDCB estimate.
Small and micro business assessment (SaMBA)	**Green**	The SaMBA is now fit for purpose. The IA approximates the number and market share of small and micro businesses (SMBs), including civil society organisations (CSOs), in the care home sector. The IA notes that, although disproportionately affected, SMBs cannot be exempt. The IA now provides further detail of the resources and programmes available to support staff recruitment and retention in order to mitigate these impacts.
Rationale and options	**Good**	The IA presents a clear rationale for intervention, which is supported by evidence. It shows consideration of non-regulatory options based on the current vaccination strategy.
Cost-benefit analysis	**Satisfactory**	The IA clearly presents the assumptions and methodology used to derive workforce estimates and estimate impacts. The IA uses breakeven analysis to estimate the required level of benefits and provides sensitivity analysis of the percentage of staff that may be replaced and the cost of recruitment. However, it should provide further evidence to support the decision to use a 50% midpoint for the central estimate of staff recruitment.
Wider impacts	**Weak**	The IA considers the impacts on equality and human rights and explores regional variations in the sector. It should include analysis of the measure's impact on low-income communities. The IA discusses the operational risk of staff shortages; this must be extended to consider any competition effects and the consequences (for providers, residents and others) of such shortages, and how these impacts could be mitigated.
Monitoring and evaluation (M&E) plan	**Satisfactory**	The IA identifies the most important quantitative and qualitative metrics to monitor the measure's impacts and notes the statutory requirement to review the measure every 12 months. The Department could consider how the measure's M&E plan fits in with M&E plans for other measures included in the Health and Care Bill 2021-2022 (the Bill).

Response to IRN

As originally submitted, the IA was not fit for purpose as it did not consider mitigations to support SMBs that are not exempt from the measure but would be disproportionately affected by the costs identified in the IA. In response to the IRN, the Department has now addressed this point by providing further detail, which we note in the SaMBA section below.

In the IRN, we also recommended further clarifications in the presentation of the direct and indirect costs to support the EANDCB validation, which the Department has addressed. In doing so, the RPC notes and accepts that the direct transitional and familiarisation costs, appear to be immaterial and do not alter the EANDCB.

Summary of measure

The Government has regulated to introduce a requirement, for all care home staff, volunteers or visiting professionals, such as healthcare workers, tradespeople, CQC inspectors and other ancillary services to be fully vaccinated before being deployed to any CQC-registered care home in England (15,000 in total), unless the individual is exempt. These requirements will come into effect on 11 November 2021, following a sixteen-week grace period from the date the regulations were made.

The IA estimates the net present value (NPV) of the proposal at -£90.8 million over a one-year appraisal period. The main monetised costs are associated with the direct incremental costs to social care providers of replacing people who do not fulfil the vaccination requirements of the regulations within the grace period but would otherwise still be available.

EANDCB

The Department's EANDCB estimate is based on care home providers needing to recruit extra staff at a unit cost of £2,500 for employees who do not fulfil the vaccination requirements within the grace period. The figure includes the extra costs of agency workers, recruitment costs, training costs and accounts for initial lower productivity of new staff. To apportion these costs between the private and public sectors, the IA estimates that local authorities run three per cent of care homes and excludes those homes from the EANDCB.

The IA notes several other non-monetised direct costs to care home providers, including transitional costs to cover staff absences due to vaccination side effects and familiarisation costs related to the vaccination requirements. Although it describes attempts to monetise these costs. The Department excludes them on the basis that these costs appear to be immaterial to the calculation of the EANDCB and overall NPV for this measure, but we believe The Department should still include these figures. Also, as discussed below, the IA should consider the indirect impacts of the failure to maintain the necessary staffing levels due to labour market shortages.

The EANDCB does not include any monetised direct benefits, which the IA attributes to the difficulty of separating the proposal's impacts from those of wider vaccination policy implementation. Instead, the Department includes break-even analysis, as discussed below.

SaMBA

The IA approximates SMBs in the sector by using the total number of staff and beds in the sector as a proxy to identify the number and market share of care home providers who could be classified as SMBs. The IA classifies 3,785 care home providers (serving 58 per cent of the market) as SMBs.

Given the significant proportion of SMBs in the sector, the IA notes that it would not be possible to exempt SMBs or CSOs while ensuring that all care users are equally protected. The IA acknowledges that the administrative burden of verifying that staff are vaccinated and recruitment costs for replacing staff may fall disproportionately on SMBs. The IA outlines the mitigations to support care home providers such as working with the independent 'Skills for Care' charity to ensure easy access to resources, including guidance and best practice on recruitment and retention. The IA would benefit from additional detail on these schemes. The IA discusses wider policies to support staffing for the adult social sector such as the National Recruitment Campaign and a three-year investment of £500 million to provide qualifications, progression pathways and wellbeing and mental health support.

Rationale and options

The IA provides a clear rationale for intervention based on the findings of the Scientific Advisory Group for Emergencies (SAGE) Social Care Working Group, which has advised that a vaccination uptake rate of 80 per cent in staff and 90 per cent in care home residents in each individual care home setting is needed, in order to provide the minimum level of protection against COVID-19 outbreaks. The IA also refers to studies such as SIREN and Vivaldi 1 whose findings support the need to vaccinate care home staff to reduce transmission. The IA appropriately applies market failure concepts such as internalising the positive externality created when an individual is vaccinated with respect to the wider benefits to society.

Given the advice on uptake rates, the IA considers the various non-regulatory options that the Government has used so far to encourage the voluntary uptake of the COVID-19 vaccination, such as communications, stakeholder engagement and the prioritisation of care home staff to be vaccinated. Despite these efforts, the IA acknowledges vaccinations still remain below the desired level – this is accentuated further at the regional level, where evidence indicates a weaker uptake in London. The IA also highlights the existing precedent for mandatory vaccinations (e.g. Hepatitis B) for healthcare workers in the UK to support this intervention to move from a voluntary to mandatory vaccination regime.

Cost-benefit analysis

The RPC agrees with the IA's cost-benefit analysis (CBA) approach, which covers a one-year appraisal period; the Department will review the proposal annually and update the CBA. The IA clearly presents its assumptions and methodology, including the derivation of upper and lower scenarios with respect to recruitment needed to replace employees who may not meet the requirements within the grace period. the IA estimates the staff replacement level due to this measure at between 3% and 11%; this provides a range of NPVs (-£149 million to -£38 million, 2019 prices, 2021 pv year). The IA then takes a midpoint of 50% to form the central estimate. However, further the IA should provide further discussion on the reason for choosing this percentage. The IA also would benefit from further clarity on the assumptions or costs related to the dismissal of non-compliant members of the existing workforce or any contract changes that may result.

The IA provides break-even analysis to quantify the benefits of the regulations, which concludes that at least 1,547 additional quality-adjusted life years are required for the measure to have a net positive social impact under the central scenario.

Following the RPC's recommendations, the IA now includes further sensitivity analysis of the cost of recruitment and illustrates an increase from £2,500 to £3,600 in recruitment costs, which would push the central estimate to £137 million.

Wider impacts

The IA considers the equality impacts of the proposal, noting the workforce is disproportionately comprises ethnic minorities and females. It identifies a risk of the regulations imposing a disproportionate negative impact on these groups. The IA should extend its assessment to examine the regulations' socio-economic impacts, for care home employment, and the impacts on CSOs involved in the care home sector. In addition, the IA notes that the regulations will not impinge on civil liberties.

The IA also discusses regional variations in the current uptake rate of the COVID-19 vaccination programme, particularly in London, and the possible causes of hesitancy. These variations are used as a fundamental assumption in the modelling, as discussed in the CBA and are important in understanding the scale of impacts that the regulations may have regionally.

The IA acknowledges the operational risks that providers face if the sector faces labour market shortages from staff losses and the difficulties in attracting new workers. The IA notes that the risks to the provision of care will be managed by local authorities, with oversight by CQC and support from DHSC and Skills for Care. However, the Department should consider whether there are any competition effects and the consequences for providers (especially, SMBs, due to the high fixed costs of recruitment), residents and others of such shortages and the possible failure to recruit staff to adequate levels quickly enough to maintain adequate cover continuously as required by the terms of CQC registration.

Monitoring and evaluation plan

The IA notes that the Secretary of State is required, by statute, to review the regulations, and publish a report, annually. Further, the IA identifies the metrics with which the Department will monitor the measure's impacts including data on vaccine uptake rates and workforce size, absences and vacancies as well as qualitative intelligence and surveys to track sentiment and experience of stakeholders with respect to retention, recruitment and indicators of strain. This data should help to fill the evidence gap with respect to the uncertainties identified in the IA. The RPC commends the Department for including this level of detail in the IA. The Department should consider how the M&E plan for this measure will interact with the M&E plan for the package of measures included the Bill.

Other comments

The Department should also consider the possible impacts of staff receiving booster vaccinations during the appraisal period (e.g., staff absences due to side effects) in the development of the IA for vaccination as a condition of deployment for all health workers and in the annual review of this policy.

Regulatory Policy Committee

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