EXPLANATORY MEMORANDUM TO

THE MEDICAL PROFESSION (RESPONSIBLE OFFICERS) (AMENDMENT) REGULATIONS 2025

2025 No. 221

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 His Majesty.

2. Declaration

2.1 Karin Smyth, Minister of State at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Philip Harper, Deputy Director for Professional Standards and International workforce, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Stephanie Alderson at the Department of Health and Social Care (Telephone: 020 7972 5552 or email: PSIW@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the Medical Profession (Responsible Officer) Regulations 2010 ("the 2010 Regulations"). The 2010 Regulations establish arrangements for the role of responsible officers in the medical profession and set out the requirements and functions of the role, which is primarily concerned with the evaluation of doctors' fitness to practise.

4.2 The amendments will ensure that all doctors, including doctors who are themselves responsible officers, have a prescribed connection to an appropriate body for the purposes of revalidation, to be evaluated with regard to their fitness to practise. The instrument also provides for the Department of Health and Social Care and the General Medical Council to appoint a sufficient number of responsible officers.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England, Wales and Scotland.

4.4 The territorial application of the amendments in this instrument (that is, where the instrument produces a practical effect) is England, Wales and Scotland.

5. Policy Context

What is being done and why?

5.1 The amendments made by this instrument cover updates to ensure that the prescribed connections[1] are effective and enable the responsible officers of designated bodies to fulfil the duties associated with their roles as well as possible, to ensure public safety.

Appointment of a "sufficient number" of responsible officers- NHS England, the General Medical Council and the General Medical Council

5.2 Currently only NHS England is required to nominate or appoint a "sufficient number"[2] responsible officers; whereas other bodies, including the General Medical Council and the Department of Health and Social Care may only appoint one responsible officer. Previously the Department of Health and Social Care was able to appoint two responsible officers, but that provision was removed, possibly by omission, in the 2013 amendments to the 2010 Regulations.

5.3 The policy is to provide the General Medical Council and the Department of Health and Social care with the same flexibility as NHS England, to appoint a sufficient number of responsible officers necessary to ensure that each responsible officer has the ability to carry out their responsibilities under the Regulations. Where multiple responsible officers are nominated or appointed, the amendments also provide for the relevant body to determine the division of their responsibilities. It is considered necessary to provide these bodies with such flexibility to adapt to changing circumstances which may arise, in particular in light of the amended prescribed connections.

5.4 For example, within the Department of Health and Social Care, this flexibility will enable the Chief Medical Officer and the Deputy Chief Medical Officer, amongst others if necessary, to be appointed as responsible officers for the Department. It is anticipated that the Deputy Chief Medical Officer will be the responsible officer for medical practitioners such as public health specialists working for local authorities and cremation referees. While the Chief Medical Officer will be responsible officer for the Deputy Chief Medical Officer in the Department, amongst others if necessary, who are themselves responsible officers.

Amending the prescribed connections of medical practitioners

5.5 As part of reforms to the public health system in 2021, Public Health England was split into the UK Health Security Agency and the Office for Health Improvement and Disparities. In England, medical practitioners working for local authorities including cremation referees had their prescribed connections moved temporarily from Public Health England to the UK Health Security Agency. However, the UK Health Security Agency does not have oversight of the practise of doctors working for local authorities and so these doctors will now connect instead with the Department of Health and Social Care, with their responsible officer being the Deputy Chief Medical Officer who is the head of the Office for Health Improvement and Disparities. The

[1] Where a medical practitioner, including a practitioner who is a responsible officer has a "prescribed connection" to a designated body, the responsible officer for that body has responsibilities relating to evaluation of the medical practitioner.

[2] A "sufficient number" of responsible officers means the number required to ensure that each responsible officer has the capacity to carry out their responsibilities.

Office for Health Improvement and Disparities works with local government already, taking action on tackling health disparities and health risks.

Amending the prescribed connections of medical practitioners who are responsible officers

5.6 Under the current provisions, a responsible officer of any Government department or executive agency of a Government department in England and any non-departmental public bodies in England has a prescribed connection with the Department of Health and Social Care. This presents a potential safety risk as the Chief Medical Officer does not have the capacity to sufficiently fulfil all functions required, as well as it could be done. The amendments provide that the prescribed connections for a responsible officer of any Government department or executive agency of a Government department in England and any non-departmental public bodies in England (with the exception of the Department of Health and Social Care's Deputy Chief Medical Officers, and the responsible officers for the Medicines and Healthcare products Regulatory Agency and UK Health Security Agency) will be transferred to NHS England, which has greater capacity and the relevant expertise to oversee the additional responsible officers. All relevant parties have agreed with the amendments to the connections.

5.7 The connections for responsible officers of the Department of Health and Social Care (except for the Chief Medical Officer), and the responsible officers of the Medicines and Healthcare products Regulatory Agency and UK Health Security Agency remain unchanged. They will continue to have a prescribed connection to the Department of Health and Social Care.

5.8 Currently, a responsible officer of the Department of Health and Social Care, the Scottish Ministers and the Welsh Ministers (i.e. the Chief Medical Officers of England, Wales and Scotland) do not have a prescribed connection under the 2010 Regulations.

5.9 The Chief Medical Officers are the most senior medical leaders and role models of medical leadership and professionalism. The policy is that all doctors, particularly the most senior medical leaders should be brought within scope of the 2010 Regulations. To ensure consistency in the prescribed connections of these high-level doctors, the National Medical Director at NHS England, and the Chief Medical Officers of England, Scotland and Wales will all have a prescribed connection with the General Medical Council. The General Medical Council is the most suitable organisation for these high-level doctors to connect with, as it is the independent regulator of doctors in the UK. The role of National Medical Director at NHS England, and the Chief Medical Officers of England, Wales and Scotland are of a comparable seniority and equally key role models of medical leadership and professionalism. Therefore, the policy is that it is important to align the prescribed connection and ensure consistency in the management of senior medical connections and how they are supported for revalidation.

5.10 To maintain consistency of connections, the Deputy National Medical Director of NHS England will connect to NHS England, rather than the Faculty of Medical Leadership and Management. This allows the National Medical Director of NHS England to act as responsible officer for the Deputy National Medical Director.

What was the previous policy, how is this different?

5.11 The policy that doctors engage in the revalidation process, and the role of responsible officers has not changed. The amendments are required to improve and update the 2010 Regulations. The amendments do not seek to change the policy of the existing regime. Instead, the purpose of the amendments is to update the legislation to ensure that the arrangements for designated bodies and the responsible officers may continue to function effectively, with updates to address safety concerns associated with ineffective prescribed connections.

6. Legislative and Legal Context

How has the law changed?

6.1 The amendments to the 2010 Regulations will ensure the effective operation of prescribed connections and evaluation of doctor's fitness to practise.

6.2 Regulations 5 (duty to nominate or appoint responsible officers), 11 (responsibilities of responsible officers: prescribed connection under regulation 10) and 13 (responsibilities of responsible officer: prescribed connections under regulation 12) are amended such that NHS England, the Department of Health and Social Care and the General Medical Council will all have a duty to nominate or appoint a sufficient number of responsible officers, nominate replacements where a sufficient number are not already appointed and determine the division of responsibilities.

6.3 Regulation 10 (connection between designated bodies and medical practitioners) is amended to remove a prescribed connection for medical practitioners who are National Medical Director or National Deputy Medical Director of NHS England to the Faculty of Medical Leadership and Management and to replace a prescribed connection for medical practitioners who work for local authorities to the United Kingdom Health Security Agency with a prescribed connection to the Department of Health and Social Care.

6.4 Regulation 12 (connection between designated bodies and medical practitioners who are responsible officers) is amended such that, amongst other things, responsible officers for any non-departmental public body in England, or any Government department or executive agency of a Government Department in England (subject to the exceptions identified) have a prescribed connection with NHS England, rather than with the Department of Health and Social Care. A responsible officer for Department of Health and Social Care (except the Chief Medical Officer), the UK Health Security Agency and the Medicines and Healthcare products Regulatory Agency has a prescribed connection with the Department of Health and Social Care. The responsible officers specified (the Chief Medical Officers of England, Wales and Scotland and the NHS England Medical Director) have a new prescribed connection with the General Council.

6.5 The Schedule has also been amended so the General Medical Council (by virtue of being in Part 1 to the Schedule to the 2010 Regulations) is always required to have an RO.

Why was this approach taken to change the law?

6.6 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 The draft of this legislation was subject to a six-week consultation in March/April 2024 targeted at those stakeholders who would be affected. The following organisations were consulted: NHS England, The office of the Chief Medical Officer (the Department of Health and Social Care), the Ministry of Defence, the Civil Aviation Authority, the Medicines and Healthcare products Regulatory Agency, the Foreign, Commonwealth & Development Office, the Home Office – Pathology Delivery Board, the British Medical Association, the Medical Research Council, the Health and Safety Executive, the Care Quality Commission, the National Institute for Health and Care Excellence, the UK Health Security Agency.

7.2 The Scottish Ministers and the Welsh Ministers were consulted and both indicated they were content for the proposed amendments to be made. The consultation was also shared with Northern Ireland for information.

7.3 There were nine responses. The stakeholders, including the devolved governments, were broadly supportive of, or had no comments on the amendments and no changes were made as a result of the consultation.

8. Applicable Guidance

8.1 The General Medical Council and NHS England publish guidance on responsible officers (Responsible officer hub - GMC[3] and NHS England » Responsible officers[4]) and will update these as necessary.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the Statutory Instrument relates to the maintenance of existing regulatory standards. The amendments may have a low level of impact on the designated bodies and medical practitioners affected by the changed prescribed connections, for example. However, for most, the obligations associated with the regulations (the responsibilities of medical practitioners, responsible officers and designated bodies) remain the same. The Department of Health and Social Care and the General Medical Council are now required to nominate or appoint a sufficient number of responsible officers, so their obligations have changed. However, the benefit of this policy is that they may have multiple responsible officers.

Impact on businesses, charities and voluntary bodies

9.2 There is no significant, impact on business, charities or voluntary bodies. This instrument only impacts the designated bodies responsible officers for a small group of doctors and relates to the maintenance of existing regulatory standards. We anticipate that the benefits of improving clinical governance for doctors exceed possible costs.

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[3] https://www.gmc-uk.org/responsible-officer-hub

[4] https://www.england.nhs.uk/professional-standards/medical-revalidation/ro/

9.3 The legislation does not impact small or micro businesses.

9.4 There is no significant, impact on the public sector because of the same reasons described above for business, charities of voluntary bodies.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is that the Department of Health and Social Care will continue to engage and work with relevant organisations, to update the 2010 Regulations as required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").