EXPLANATORY MEMORANDUM TO

THE NATIONAL MEDICAL EXAMINER (ADDITIONAL FUNCTIONS) REGULATIONS 2024

2024 No. 494

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 Maria Caulfield, Minister for Mental Health and Women's Health Strategy at the Department of Health and Social Care, confirms that this Explanatory Memorandum meets the required standard.

2.2 William Vineall, Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Jenny Smith at the Department of Health and Social Care, Telephone: 0113 254 5020 or email: deathcertification@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 confers functions on the National Medical Examiner in addition to the one set out in Section 21(2)(a) of the Coroners and Justice Act 2009 ("the Act"). These additional functions require the National Medical Examiner to provide prescribed information, to issue guidance on the qualifications, functions and training required of medical examiners, and to provide reports on the exercise of functions by the National Medical Examiner, medical examiners and attending practitioners.

4.2 This information will enable monitoring of the medical examiner system as set out in paragraph 10.1 below.

Where does the legislation extend to, and apply?

4.3 The territorial extent of this instrument is England and Wales.

4.4 The territorial application of this instrument is England and Wales.

5. Policy Context

What is being done and why?

5.1 These regulations are part of the wider reform of the death certification process. The reforms change the way in which deaths are scrutinised and certified in England and

Wales with the introduction of a statutory medical examiner system. This was announced in a written ministerial statement on 27 April 2023 HCWS750[1].

5.2 The importance of death certification reform and the introduction of medical examiners has been underlined in numerous reports and inquiries including the 'Shipman Inquiry third report 2003[2]', 'Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry - Vol 2 - 2013[3]', 'Morecambe Bay Investigation 2015[4]' and 'Learning from Gosport 2018[5]'.

5.3 Currently, following a death, the case will either follow the path of medical certification by a medical practitioner or investigation by a coroner. This will remain the case in the new system, but additionally all deaths will be subject to either a medical examiner's scrutiny or a coroner's investigation.

5.4 Currently, medical examiner scrutiny of a death in England and Wales is not mandated – it operates on a non-statutory basis. However, once the new death certification process comes into force, there will be an independent review of all deaths in England and Wales, without exception.

5.5 The National Medical Examiner is integral to the smooth operation of the new system as they provide set standards of performance for medical examiners and keep these under review. The National Medical Examiner is also responsible for providing advice to bodies responsible for employing medical examiners on the qualification requirements for medical examiners, the functions of medical examiners, and the appropriate training to be undertaken by medical examiners.

5.6 The National Medical Examiner is also required to provide reports to the Secretary of State and Welsh Ministers on the way in which the National Medical Examiner, medical examiners, and attending practitioners have exercised their functions.

What was the previous policy, how is this different?

5.7 Previously, following a death, the case will either follow the path of medical certification by a medical practitioner or investigation by a coroner.

5.8 In its Third Report, the Shipman Inquiry examined the process of death certification and the coroner system. The Inquiry concluded that the previous arrangements for scrutinising Medical Certificates of Cause of Death (MCCDs) were confusing and provided inadequate safeguards. The Government of the day accepted the Shipman Inquiry's conclusions, and its action programme in response to the inquiry's key recommendations led to the design and piloting of a new rigorous and unified system of certification and independent scrutiny for all deaths in England and Wales that do not require investigation by a coroner (regardless of whether they are followed by burial or cremation).

5.9 The reforms to the death certification process introduce a unified system of scrutiny by independent medical examiners of all deaths in England and Wales that are not investigated by a coroner. The aims are to strengthen safeguards for the public, make the process simpler and more open for the bereaved, and improve the quality of certification and data about causes of death.

[1] https://questions-statements.parliament.uk/written-statements/detail/2023-04-27/hcws750
[2] The Shipman Inquiry third report: death certification and the investigation of deaths by coroners - GOV.UK (www.gov.uk)
[3] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry - GOV.UK (www.gov.uk)
[4] Morecambe Bay Investigation: Report - GOV.UK (www.gov.uk)
[5] Gosport Independent Panel report: government response - GOV.UK (www.gov.uk)

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument is made under powers contained in Section 21(2)(b) of the Act.

6.2 Section 21 of the Act provides that the Secretary of State may appoint a National Medical Examiner on terms and conditions considered appropriate by the Secretary of State. It also confers upon the National Medical Examiner the function of issuing guidance to medical examiners with a view to securing that they carry out their functions in an effective and proportionate manner.

6.3 This instrument changes the law by conferring additional functions on the National Medical Examiner which relate to further guidance functions, reporting to the Secretary of State and Welsh Ministers, and providing relevant advice.

Why was this approach taken to change the law?

6.4 This is the only possible approach to introducing the necessary provisions.

7. Consultation

Summary of consultation outcome and methodology

7.1 In accordance with section 21(3) of the Act, the Secretary of State has consulted with Welsh Ministers before making this instrument. Welsh Ministers indicated their support for the introduction of the medical examiner system and the proposed timetable.

7.2 Furthermore, a full consultation on the proposed changes to the death certification process and accompanying draft regulations was carried out between March 2016 and June 2016. The Government's response was published in March 2018 at Death certification reforms - GOV.UK (www.gov.uk)[6]. The consultation response sets out the government's analysis of responses received and addresses the issues raised.

7.3 The regulations were published in draft, for information, on 14 December 2023. While comments were welcomed, this was not a formal consultation and, as such, no formal response will be published. No substantive comments on the policy were received.

8. Applicable Guidance

8.1 Detailed guidance on the new medical examiner system, including the role of the national medical examiner, and the new medical certificate of cause of death will be published to coincide with the coming into force of regulations.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment on the introduction of the medical examiner system was prepared in 2018[7] and updated in 2022[8]. The Department of Health and Social Care

[6] https://www.gov.uk/government/consultations/death-certification-reforms
[7] Introduction of medical examiners and death certification reform in England: impact assessment (publishing.service.gov.uk)
[8] health-and-care-act-2022-summary-and-additional-measures-impact-assessment.pdf (publishing.service.gov.uk)

(DHSC) considers the 2018 and 2022 impact assessments remain sufficiently accurate. As such, a full impact assessment has not been prepared for this instrument.

9.2 However, a document has been prepared which provides an updated summary of the potential impact of the introduction of medical examiners and death certification reform in England and Wales and this is published at Death certification reform and the introduction of medical examiners: updated summary of impact - GOV.UK (www.gov.uk)[9]. The summary document builds upon the two previous impact assessments (2018 and 2022) and should be read alongside those. This summary document seeks to provide updates, where appropriate.

Impact on businesses, charities and voluntary bodies

9.3 There is no, or no significant, impact on business, charities or voluntary bodies as the role of the National Medical Examiner relates only to the functions of medical examiners and the provision of information and advice to the Secretary of State and Welsh Ministers.

9.4 The legislation does not impact small or micro businesses.

9.5 There is no, or no significant, impact on the public sector because of the reasons set out in 9.3 above.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is through the provision of reports and information by the National Medical Examiner to the Secretary of State and Welsh Ministers. This instrument places a requirement on the National Medical Examiner to produce reports and information on the exercise of functions by the National Medical Examiner, medical examiners and attending practitioners.

10.2 The instrument does not include a statutory review clause.

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").

[9] https://www.gov.uk/government/publications/medical-examiners-and-death-certification-reform-summary-of-impact/death-certification-reform-and-the-introduction-of-medical-examiners-updated-summary-of-impact