EXPLANATORY MEMORANDUM TO

THE MEDICAL EXAMINERS (ENGLAND) REGULATIONS 2024

2024 No. 493

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 makes provision in relation to medical examiners appointed by English NHS bodies.

4.2 The instrument sets out mandatory terms to be included in the terms of appointment of medical examiners and, permits appointing bodies to set the level of remuneration, expenses, fees, compensation for termination of appointment, pensions, allowances or gratuities, makes provision as to training, sets procedures relating to independence and confers some additional functions on medical examiners.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument is England and Wales.

4.4 The territorial application of this instrument is England only.

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 Medical examiner scrutiny of a death in England and Wales has been operating on a non-statutory basis since 2019. This instrument puts the role of the medical examiner on a statutory basis and means that there will now be an independent review of all deaths in England and Wales.

5.3 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]'.

5.4 Prior to the introduction of the medical examiner system, following a death, the case followed 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.

5.5 This instrument makes specific provision relating to the appointment and functions of medical examiners. These include, setting out mandatory terms to be included in their terms of appointment, permitting appointing bodies to set the level of remuneration, making provision as to training, and conferring some additional functions on medical examiners. These additional functions include providing advice to registered medical practitioners and senior coroners, reporting to the National Medical Examiner and other bodies, and reporting any serious concerns identified in respect of clinical governance, patient safety or public health surveillance.

5.6 The regulations include provisions to ensure the independence of medical examiners. Where a medical examiner is asked by an appointing body to exercise a relevant function, the regulations state they should not carry out those functions if they had one of the defined connections to the deceased person, to the relevant attending practitioner, or to any other relevant medical practitioner at the time of the death.

5.7 The regulations require medical examiners to provide certain advice and information in relation to the carrying out of their functions.

What was the previous policy, how is this different?

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

5.9 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 ("MCCD") 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

[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)

not require investigation by a coroner (regardless of whether they are followed by burial or cremation).

5.10 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.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument is made under powers contained within section 19(4) of the Coroners and Justice Act ("the Act").

6.2 Section 18A of the Act sets out that medical examiners are to be appointed by English NHS Bodies and section 19 provides minimum requirements for their appointment. This instrument sets out provision as to their terms of appointment, training, independence and functions in addition to those set out in the Medical Certificate of Cause of Death Regulations 2024 (made under section 20 of the Act).

6.3 This instrument is made alongside regulations made under the same power in Wales and under sections 20 and 21 of the Act which make provision relating to the preparation and delivery of the MCCD and the National Medical Examiner, applying to England and Wales.

Why was this approach taken to change the law?

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

7. Consultation

Summary of consultation outcome and methodology

7.1 There is no statutory requirement or pre-condition to consult before making these regulations.

7.2 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.

7.4 All government departments directly affected were consulted on the content of the instrument on 25 March 2024 and were supportive of the system and the legislative timetable.

[6] https://www.gov.uk/government/consultations/death-certification-reforms

8. Applicable Guidance

8.1 Detailed guidance on the new medical examiner system 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 has not been prepared for this instrument as impact assessments were prepared in 2018[7] and in 2022[8]. The Department of Health and Social Care (DHSC) considers the 2018 and 2022 English impact assessments, and Welsh impact assessment, are sufficiently accurate.

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.

9.4 The legislation does not impact small or micro businesses.

9.5 The impact on the public sector is costs have been estimated by NHS England to be £56.5m for 2024/25 (in 2024 prices). Funding for the medical examiner system in England and Wales will be provided centrally.

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.

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.

[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)
[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

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”).