EXPLANATORY MEMORANDUM TO

THE MEDICAL CERTIFICATE OF CAUSE OF DEATH REGULATIONS 2024

2024 No. 492

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 for the role of attending practitioners and the circumstances in which they must issue a medical certificate of cause of death (MCCD). The regulations also set out the information the attending practitioner should provide to the medical examiner who will scrutinise the cause of death, and the circumstances in which a death should be referred to a coroner.

4.2 It introduces scrutiny of all non-coronial deaths by a medical examiner. The role includes discussing the proposed cause of death with the attending practitioner, and obtaining information to inform their decision, and the circumstances in which the medical examiner should refer a death to the senior coroner.

4.3 The regulations also set out the role of medical examiners where a case is referred to them by a senior coroner, the actions to be taken and the preparation, and signing, of a medical examiner's certificate.

Where does the legislation extend to, and apply?

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

4.5 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 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.

Role of attending practitioner

5.4 The regulations set requirements on attending practitioners for establishing a cause of death prior to completion of an attending practitioner's MCCD. They also require the attending practitioner to pass information to a medical examiner, the circumstances in which the attending practitioner may refer a death to a senior coroner, and processes to be followed.

Role of medical examiner

5.5 The regulations introduce mandatory scrutiny by medical examiners of all non-coronial deaths. Provisions also include the procedures to be followed by medical examiners when reviewing and confirming the cause of death. Where a medical examiner is unable to confirm the cause of death, the regulations set out the procedure for referring to a senior coroner.

5.6 Where a cause of death is confirmed by a medical examiner, they are required to sign the MCCD and notify a registrar that the cause of death has been confirmed which will allow the death to be formally registered and a death certificate issued.

5.7 There are also provisions for the informant registering the death to provide information not previously considered to the registrar and for that information to be passed to the relevant medical examiner with a view to reconsidering the proposed cause of death.

5.8 In circumstances where there is not an available attending practitioner, the regulations also allow a case referred to a senior coroner by a registered medical practitioner to then be referred by the senior coroner to a medical examiner. The process to be followed by medical examiners in these circumstances is set out in the regulations including the requirement for completion of a medical examiner's MCCD.

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[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)

5.9 As part of the reforms of the death certification process, the instrument introduces four new medical certificates of cause of death and the circumstances in which each should be used when certifying a death. The certificates are contained in Schedules 1 to 4 of the regulations and include a bilingual version of each form.

5.10 The main benefits of the new forms are to improve efficiency in the death certification system and in mortality data.

What was the previous policy, how is this different?

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

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

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument is made pursuant to powers contained within section 20 of the Coroners and Justice Act 2009 ("the Act"). By conferring duties on attending practitioners, medical examiners, registrars and coroners, it prescribes the entire process of certificating the medical cause of death in non-coronial cases.

6.2 The principal legal changes are that medical examiners are now under a duty to scrutinise the medical certificates of the cause of death prepared by attending practitioners in all non-coronial cases; and seek to establish the cause of death in non-coronial cases where there is not an available attending practitioner.

6.3 The instrument prescribes new medical certificates of the cause of death which reflect the new role of the medical examiners.

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 In accordance with section 20(3) of the Act, Welsh Ministers, the Registrar General and the Statistics Board have been consulted in respect of the content of this instrument and the prescribed forms and are generally supportive.

7.2 Furthermore, 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 also 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 Guidance was published alongside the draft regulations in December 2023. Detailed guidance on the new medical certificate of cause of death and on the new medical examiner system and 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, as 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 **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 there are no significant changes to the medical certificate of cause of death (MCCD). As such, the impact for medical practitioners completing an MCCD is likely to be the short-term need to understand the new procedures and establish key contacts with medical examiners.

9.4 The legislation does not impact small or micro businesses.

9.5 The impact on the public sector is costs of introducing the medical examiner system have been estimated by NHS England to be £56.5m for 2024/25 (in 2024 prices). The estimate for costs in Wales is £4.3m for 2024/24 (in 2023 prices). Funding for the medical examiner system in England and Wales will be provided centrally.

[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)
[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

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is through ongoing stakeholder engagement, to ensure that this instrument meets the policy objectives set out in section 5 of this Explanatory Memorandum.

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").