Explanatory Memorandum to The Medical Examiners (Wales) Regulations 2024

This Explanatory Memorandum has been prepared by The Department of Health and Social Services and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Medical Examiners (Wales) Regulations 2024. I am satisfied that the benefits justify the likely costs.

Eluned Morgan MS
Cabinet Secretary for Health and Social Care

15 April 2024

PART 1

1. Description

1.1 This instrument makes provision in relation to medical examiners appointed by a Welsh NHS body.

1.2 The instrument sets out mandatory terms to be included in the terms of appointment of medical examiners and about termination of appointment and permits the inclusion of such other terms as may be agreed between the appointing body and medical examiner. The instrument permits the appointing body to pay remuneration, expenses, fees, compensation for termination of appointment, pensions, allowances and gratuities to medical examiners.

1.3 This instrument also sets out requirements for medical examiners in relation to training, steps to follow in circumstances where the medical examiner is insufficiently independent in relation to a death, and confers functions on medical examiners, as outlined in section 4 below.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2.1 None.

3. Legislative background

3.1 Section 19(4) of the Coroners and Justice Act 2009 (“the Act”) gives the Welsh Ministers powers to make regulations about various matters relating to medical examiners in Wales, including in relation to their terms of appointment, training, procedures, and the conferral of additional functions on medical examiners.

3.2 Regulations made under this section are subject to the negative procedure under section 176(4) of the Act.

3.3 The subject matter of Part 1 of the Act is reserved under paragraph 167 of Schedule 7A to the Government of Wales Act 2006, but the Welsh Ministers have been given some limited executive functions in this area, including as set out in paragraph 3.1 above.

3.4 This instrument is made alongside regulations made by the Secretary of State under the same power in relation to England (the Medical Examiners (England) Regulations 2024) and under sections 20 and 21 of the Act which make provision in relation to the preparation and delivery of the Medical Certificate of Cause of Death (the Medical Certificate of Cause of Death Regulations 2024) and the National Medical Examiner (the National Medical Examiner (Additional Functions) Regulations 2024).

4. Purpose and intended effect of the legislation

4.1 These Regulations form 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 examiners system. This was announced by the UK Government's Parliamentary Under Secretary of State, Maria Caulfield, in a written ministerial statement on 27 April 2023 ***HCWS750.***

4.2 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.

4.3 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', the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry – Vol 2 – 2013', 'Morecambe Bay Investigation 2015' and 'Learning from Gosport 2018'.

4.4 Prior to the introduction of the medical examiner system, a death 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 not subject to a coroner investigation will be subject to medical examiner scrutiny.

4.5 Following appointment by an appointing body, this instrument requires medical examiners to undertake training to ensure they have the experience and skills necessary to carry out their functions. Medical examiners are also required to identify training needs of registered medical practitioners in relation to death certification.

4.6 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 a specified connection to the deceased person, to the relevant attending practitioner or to any other relevant medical practitioner at the time of the death. The regulations specify circumstances in which a medical examiner is considered insufficiently independent in relation to a death.

4.7 The Regulations require medical examiners to provide certain advice and information to specified persons in relation to the carrying out of their functions.

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

4.9 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.

5. Consultation

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

5.2 However, 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 by the UK Government. The UK Government's response was published in March 2016 at Death certification reforms - GOV.UK (www.gov.uk). The consultation response sets out the government's analysis of responses received and addresses the issues raised. The Welsh Government's consultation took place over the ten-week period from 7 November 2016 and 13 January 2017. The summary of responses was published at Introduction of the medical examiner role and reforms to death certification | GOV.WALES. The development of the Welsh model for the medical examiners service has been based on responses to the consultation and the outcome of the consultation undertaken by the UK Government.

5.3 The Medical Examiners (Wales) Regulations 2024 were also published alongside regulations to be made by England 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 requiring amendments to the regulations.

PART 2 – REGULATORY IMPACT ASSESSMENT

This programme of work is a reserved area led by the UK Government with some regulation making powers conferred on the Welsh Ministers in relation to Wales as described above.

An impact assessment (IA) was published by the Department of Health and Social Care (DHSC) in 2018 as part of their response to their consultation on death certification reforms in 2016 and this forms the core of the cost-benefit analysis for England and Wales. Updates to this IA have been made from time to time to reflect policy changes.

Introduction of medical examiners and death certification reform in England: impact assessment (publishing.service.gov.uk)

As a supplement to DHSC's cost-benefit impact assessment, Welsh Government published their estimated costs alongside their response to the Welsh Government's associated consultation held in 2017. These estimated costs were developed to the same methodology as the impact assessment for England.

estimated-medical-examiner-costs-for-wales.pdf (gov.wales)

There is no difference in substance between England and Wales to the way that medical examiners are expected to operate so the impact can be considered as the same on all death certification stakeholders.

Following the Welsh Government consultation, in line with responses received an All-Wales Medical Examiner Service was set up in Wales. Examiners are appointed by and the service managed by NHS Shared Services Partnership (part of Velindre University NHS Trust). This is different to the English model whereby medical examiners are appointed by individual trusts. Within the Welsh model medical examiners will not operate as such within the health board or trust within which they work as medical practitioners, and they are assigned to scrutinise deaths on a peripatetic basis adding an additional layer to their independence beyond that required by the regulations. The medical examiner service has been operating on a non-statutory basis in England and Wales since 2019.

The Welsh model is no more costly than the model operated in England, there may in fact be some efficiencies of scale.

An update to the impact assessments referenced above, was provided as part of additional measures introduced via the Health and Care Act 2022. This made changes to the Coroners and Justice Act 2009 whereby the appointment of medical examiners in England was changed from Local Authorities to English NHS bodies and in Wales from Local Health Boards to a Welsh NHS body. The section relating to medical examiners and the legislative changes made can be found at pages 26 to 29 of the impact assessment accompanying the Health and Care Act 2022 linked below. While some figures were revised to meet the costs current in 2022, it was considered that the previous assessment of the costs and

benefits of the medical examiner (ME) system published in 2018 remained sufficiently accurate for the purposes of estimating the costs and benefits of establishing a statutory scheme in England and Wales.

health-and-care-act-2022-summary-and-additional-measures-impact-assessment.pdf (publishing.service.gov.uk)

The most significant policy change since 2018, as discussed in the 2022 update above, was in relation to funding. The initial proposal for medical examiners included the charging of a fee. Section 20(5) of the Coroners and Justice Act 2009 provides a power enabling regulations prescribing a fee to be payable in respect of certain medical examiner functions to be made in both England and Wales. The UK Government's 2018 impact assessment (at page 1) in setting out 'option 3' as the preferred option, stated 'The system will initially be funded through cremation form fee revenues sourced from efficiencies in the system and DHSC. Following the interim period (2019/20 and 2020/21), the ME system would be primarily funded through a fee for cremations and burials.'

At the start of the pandemic in 2020, cremation form 5 (the cremation form completed by the second doctor) was suspended, and funding for the non-statutory ME system was provided by UK central government for England and Wales. In March 2022, the suspension of cremation form 5 was made permanent, and from that point forward funding for the ME system in England and Wales was, and will continue to be, provided centrally by UK government, rather than from a public fee. This means that it is not necessary to make regulations to prescribe for a fee to be payable at this time.

The updated costs of the statutory system in Wales for 2024/25, based on the actual costs of operating the service since 2019, are expected to be £4.3 million, based on 2023/24 prices. The current delivery model for the ME service in Wales is thought to be the most cost effective.

In terms of economic impact, it is anticipated that any new net cost to business from implementing the statutory system will be minimal or zero. These included potential familiarisation costs for doctors employed in both the NHS and private sector to understand new procedures and establish contacts with new medical examiners. These costs are mitigated to a large extent as DHSC is not proposing significant changes to the Medical Certificate of Cause of Death (MCCD) itself. Notably, a non-statutory national system of medical examiner offices has been established from 2019 within the NHS in Wales therefore moving from the non-statutory system to the statutory system is unlikely to result in further ME offices being established, thus resulting in minimal further set up costs. The non-statutory arrangements currently in place reflect the arrangements that would be in place in the statutory scheme.

As set out in the update provided in the Health and Care Act 2022 impact assessment and the latest impact assessment now provided for the England and Wales regulations below, the removal of the option of a fee and its collection means that there will be zero impact on the funeral director sector.

In addition, since the 2022 impact assessment update, a policy solution was required to address the issue of increased numbers of uncertified deaths due to the lack of timely availability of the medical practitioner to certify deaths. DHSC is introducing for England and Wales, as part of the Medical Certificate of Cause of Death Regulations 2024, a medical examiner certification for the exceptional circumstances where either:

- there is no attending practitioner, or
- an attending practitioner is not available within a reasonable time.

In either of these circumstances, the death will be referred to the senior coroner by a referring medical practitioner (not a medical examiner) and where the senior coroner decides not to investigate, in those circumstances only, the senior coroner should refer the case to a medical examiner to certify the death by completing a Medical Examiner MCCD.

The Updated Summary Impact of Medical Examiners and Death Certification Reform in England and Wales dated March 2024 below informs that the benefits of the scheme are not monetised and remain the same as outlined in the 2018 IAs for England and Wales. These costs and benefits are for the statutory system as a whole and relate to the set of primary and secondary legislation which underpins it.

The summary update is published at: Changes to the death certification process - GOV.UK (www.gov.uk)

In summary, the costs and benefits of the medical examiner system published in the 2018 England and Wales impact assessments remain sufficiently valid and accurate for the purposes of estimating the expected costs and benefits of establishing a statutory scheme in Wales. Taken together with the updates to that impact assessment provided since that time, these provide a full description of the expected impacts of the statutory scheme once it is commenced in Wales.

Post implementation review

This instrument does not include a statutory review clause.

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.