



Department
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Introduction of Medical Examiners and Reforms to Death Certification in England and Wales: Policy and Draft Regulations

Consultation

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Registration Services

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Introduction of Medical Examiners and Reforms to Death Certification in England and Wales:

Consultation on Policy and Draft Regulations

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Chapter 1: Introduction

The consultation

- 1.1 The reforms to the death certification process proposed in this document will, for the first time, 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.
- 1.2 The improved process has been informed by the findings of the Shipman Inquiry and by discussions with a wide range of organisations, groups and individuals. It has also been tested and refined by pilot sites which have implemented the new process in both hospital and community settings (to the extent that this was possible whilst complying with existing legislation). The pilot sites have shown that where the new process is implemented effectively it delivers the aims of the reforms and provides value to all concerned.
- 1.3 The new process has been developed with input and guidance from a wide range of organisations and individuals and we are most appreciative of the contributions we have received and of the time and commitment that so many people have provided to the work.
- 1.4 This document describes how the Government sees the new medical examiner system working in practice, and includes draft regulations that will provide the detailed legal framework within which local medical examiners' services will operate. We intend to provide more detail in guidance.
- 1.5 The intention of this consultation is to identify any gaps in the death certification process and to seek views on some specific proposals. It is aimed both at the professionals involved in the process and at the wider general public who might need to become involved at some points during their lives.
- 1.6 For deaths followed by cremation, the medical examiner service will end the need for bereaved families to pay cremation form fees; currently around £184.00 (about 75 per cent of deaths in England and Wales are followed by cremation rather than burial). A single medical examiner fee will be introduced for deaths scrutinised by a medical examiner irrespective of whether the body of the deceased is cremated or buried.
- 1.7 This consultation builds on the earlier *Consultation on Improving the Process of Death Certification* (Department of Health, July 2007). The responses to

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that document shaped the medical examiner system and we are now asking about details of its operation - we are not asking whether or not there should be such a system.

- 1.8 Also within this document the Ministry of Justice (MoJ) is consulting on draft regulations that will require doctors to notify deaths to a coroner in certain circumstances, and broadly on changes to the cremation regulations which are needed as a result of the new medical examiner role. The MoJ intend to undertake a more detailed consultation at a later date on the proposed amendments to the Cremation (England and Wales) Regulations 2008.

Background to the changes

- 1.9 The death certification system in England and Wales is overdue for reform. It has remained largely unchanged for over fifty years, despite repeated criticism: The *Fundamental Review of Death Certification and Investigation in England, Wales and Northern Ireland*, published in 2003, noted that “During the last three-quarters of a century, the Government has twice commissioned reviews on these subjects, in 1936 and 1965. Very little happened in response to these reports. The services are showing the consequences of this neglect.”
- 1.10 In its *Third Report*,¹ the Shipman Inquiry examined the process of death certification and the coroner system. The Inquiry concluded that existing arrangements for scrutinising Medical Certificates of Cause of Death (MCCDs) were confusing and provided inadequate safeguards.
- 1.11 The Government of the day accepted the Shipman Inquiry’s conclusions, and its action programme in response to the inquiry’s key recommendations² 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).
- 1.12 More recently, the Francis³ Inquiry report, published in February 2013, made a number of observations about certification and inquests relating to hospital deaths. Seven of the inquiry’s recommendations are directly relevant to the proposed medical examiner process (numbers 275 – 281) and in almost all cases we believe that they are matched by the reforms we are proposing. In the draft regulations though, we are putting forward an alternative approach to assuring the independence of medical examiners than that suggested by

¹ Third Report – Death Certification and the Investigation of Deaths by Coroners (TSO, 2003)

² Learning from Tragedy, Keeping Patients Safe (TSO, February 2007)

³ Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (TSO, February 2013)

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recommendation 275 – “It is of considerable importance that independent medical examiners are independent of the organisation whose patients’ deaths are being scrutinised.” The alternative approach to assuring the independence of medical examiners can be found in regulation 5 of The Death Certification (Medical Examiners) (England) Regulations.

- 1.13 The medical examiner system will benefit the public, the health service and local authorities in a number of significant ways:
- **It will be fair** - all deaths will be scrutinised in a robust, and proportionate way regardless of whether they are followed by burial or cremation;
 - **It will be independent** - a medical examiner will scrutinise all medical certificates of cause of death (MCCD) prepared by the attending doctor;
 - **It will be transparent** - families will have the cause of death explained to them, including clarification of medical terms, and be able to ask questions or raise concerns;
 - **It will be robust** – there will be a protocol that recognises different levels of risk depending on the circumstances and stated cause of death;
 - **It will be accurate** - the medical examiner will be an experienced doctor, capable of ensuring that the MCCD is completed fully and accurately, providing the NHS, the Office for National Statistics, local authorities and wide range of other users with better quality cause of death statistics to inform health policy, the planning and evaluation of health services and international comparisons;
 - **It will be efficient** - it will help to make sure that the right cases are reported to coroners; and
 - **It will improve safety** – the new system will allow easier identification of trends, unusual patterns and local clinical governance issues and make malpractice easier to detect.

The legal basis for the reforms

- 1.14 The legal basis for the new system is set out in Chapter 2 of Part 1 of the Coroners and Justice Act 2009 *Notification, certification and registration of deaths*, which has yet to enter into force.
- 1.15 When in force, section 19 of the 2009 Act, as amended by the Health and Social Care Act 2012, will require medical examiners to be appointed and

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monitored by upper tier and unitary local authorities in England and by Local Health Boards in Wales. In addition, section 20 of the 2009 Act will enable regulations to be made setting out the procedures and requirements for the preparation, scrutiny and certification of MCCDs. Section 21 of that Act will also enable regulations to be made setting out the functions of the National Medical Examiner.

- 1.16 Although this primary legislation provides the fundamental legal framework for the reforms in both England and Wales, it also allows Ministers in Wales to develop their own regulations in respect of key aspects of the new system, including the terms for the appointment of medical examiners and, additional functions of medical examiners. The Welsh Government will consider what regulations would be appropriate in respect of Wales only and consult on these separately.
- 1.17 The Ministry of Justice and the Home Office will change the Cremation (England and Wales) Regulations 2008 and the Registration of Births and Deaths Regulations 1987 respectively to enable the new system to be introduced.

This consultation

- 1.18 There are a number of questions in this document on which we would welcome comment and views. They are available as a questionnaire for on-line submission.
- 1.19 The impact assessment that we have published as part of this consultation indicates that the new arrangements are unlikely to lead to either significant costs or savings for businesses, charities, or the voluntary sector. Copies of the consultation impact assessment and equality analysis are available on the Department of Health's pages on the Gov.uk website at:
www.dh.gov.uk/consultations.
- 1.20 Copies of this consultation paper have been sent to the organisations listed at Annex F and is published on the Department of Health's Gov.uk pages as above.

Consultation principles

- 1.21 The principles underpinning this consultation are available on the Cabinet Office's website at:
<http://www.cabinetoffice.gov.uk/resource-library/consultation-principles-guidance>

How to respond

- 1.22 You can respond in writing, by e-mail or by completing an on-line questionnaire. There is more information on page 36.

Comments on the consultation process itself

- 1.23 If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
2E08, Quarry House
Leeds
LS2 7UE

consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality

- 1.24 We will manage the information that you provide in response to this consultation in accordance with the Department of Health's Information Charter. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 1.25 If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.
- 1.26 The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

- 1.27 We will aim to make available a summary of the response to this consultation within three months of the end of the live consultation, at:

www.dh.gov.uk/consultations

Chapter 2: The improved process of death certification – an overview

2.1 The improved process of death certification in England and Wales is designed to:

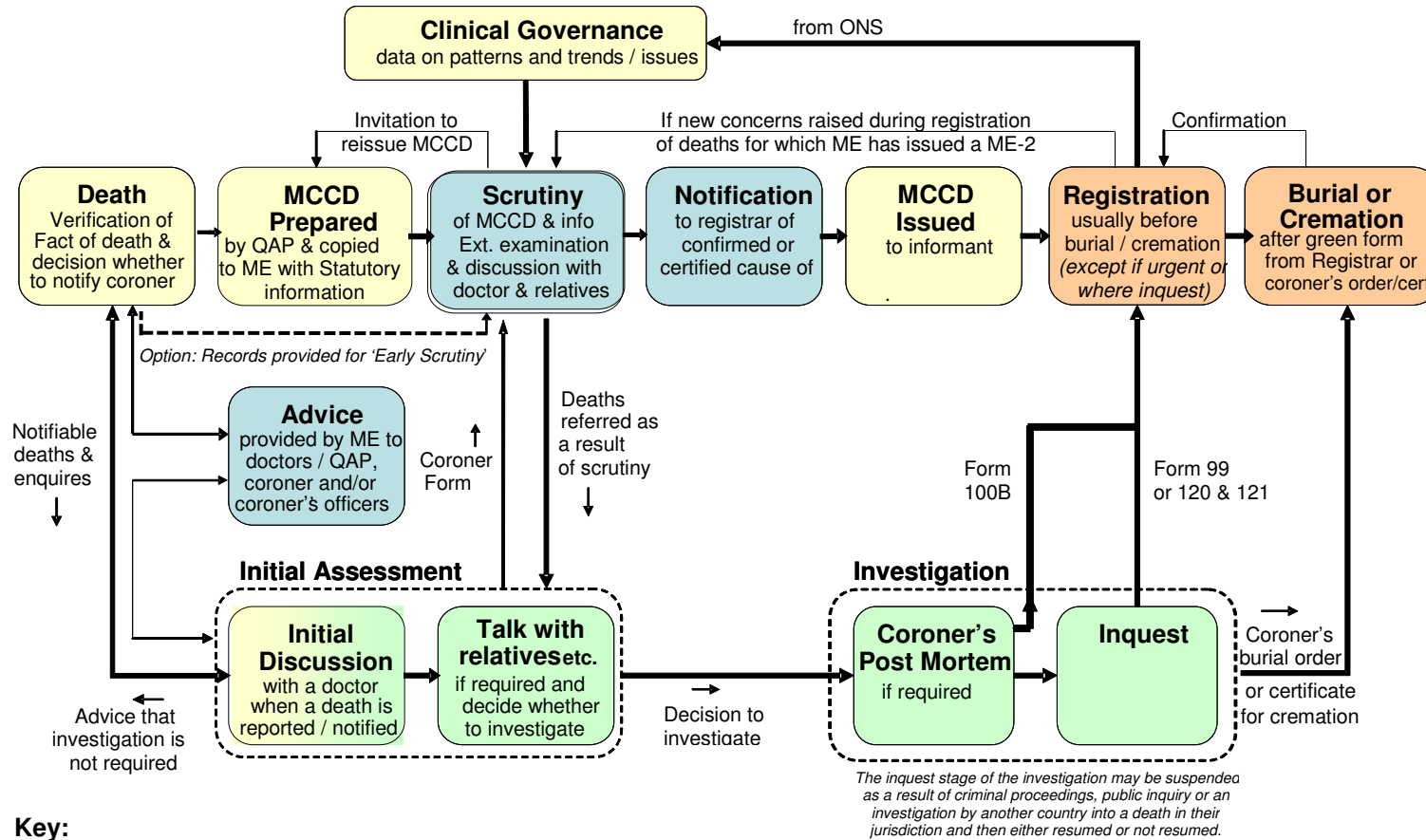
- **Strengthen safeguards for the public** by providing robust and independent scrutiny of the medical circumstances and cause of deaths, and ensuring that the right deaths are referred to a coroner;
- **Improve the quality of certification** by providing expert advice to doctors based on a review of the relevant health records; and
- **Avoid unnecessary distress for the bereaved** that can result from unanswered questions about the certified cause of deaths or from unexpected delays when registering a death.

2.2 Under the new system, the cause of all deaths that do not need to be investigated by a coroner will be confirmed by a medical examiner before a medical certificate of cause of death is issued, or will be established by a medical examiner. As we explain later, we do not expect the time required for doing this to lead to any undue delay or unnecessary distress for the bereaved.

2.3 Where the deceased is cremated, the scrutiny provided by medical examiners will replace the current arrangements for the completion of cremation forms (forms 4, 5 and 10) which, despite being improved in 2009, are often still seen as an administrative requirement or a supplementary check rather than as a valuable part of the death certification process.

2.4 Whilst the reforms are mainly concerned with the certification, scrutiny and confirmation of the cause of death, they will affect other parts of the wider system of which death certification is a key part. In designing and testing the new process we have taken care to use a 'whole-systems' approach – that is, one which has taken account of the impact on services and organisations responsible for other parts of the wider process. These wider processes (applicable in England and Wales when the reforms are implemented) are illustrated in the flowchart on the next page.

Overview of Process for Death Certification



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- 2.5 The medical examiner system will augment existing systems and processes to detect clinical governance issues, including clusters of unexpected deaths.
- 2.6 Medical examiners would very likely add significant value to NHS England's Retrospective Case Record Reviews work when introduced given they would be an ideal mechanism for identifying which deaths should be subject to in-depth case record review. In this way efforts to learn from problems in care would be much more efficiently and effectively directed. Without medical examiners it is less likely that the case record review work could be delivered comprehensively.
- 2.7 Medical examiners could also provide a valuable insight in areas of healthcare that might benefit from investigations undertaken by the Healthcare Safety Investigation Branch (formerly IPSIS) when it is established. For these reasons alone, medical examiners would add huge value to national and local efforts to tackle avoidable mortality.

The new process ⁴

- 2.8 Under the new process, when someone dies, and the death is apparently natural, a doctor who attended the person in the previous days will be required to prepare a medical certificate of cause of death (MCCD). If this doctor decides that the death needs to be notified to a coroner, or if the doctor is unable to establish the cause of death, he or she will contact the coroner's office. Medical examiners will be able to provide advice to a doctor in preparing an MCCD.
- 2.9 Where a death is not notified to a coroner, or it is notified but the coroner decides that it does not need to be investigated, the doctor will prepare a MCCD and provide a copy to the medical examiner together with the relevant medical records and other information.⁵
- 2.10 The medical examiner will scrutinise the deceased person's medical records and may choose to carry out a thorough (non-forensic) external examination of the body (or arrange for it to be carried out by someone else) to determine

⁴ The new process outlined here can be contrasted with the description of the current process provided in Annex d, which has been copied with slight modification from section 2 of the 2007 Consultation on Improving the Process of Death Certification.

⁵ The statutory information that needs to accompany the copy of the MCCD and relevant medical records is less than that required in the Cremation 4 form in the current system and can also be provided as part of the records rather than written out on a separate form. In some areas / settings, the medical records may be made available to the medical examiner before the MCCD is prepared / provided; this will allow 'early scrutiny' of the records and enable any pre-certification advice requested by the doctor to be given following independent review of the death.

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whether or not he or she agrees with the cause of death that the attending doctor certified.

- 2.11 If the medical examiner disagrees with what the attending doctor has written on the MCCD there will be a discussion and the medical examiner will either invite the doctor to prepare a new MCCD or conclude that the death needs to be referred to a coroner. If the medical examiner otherwise believes that the death needs to be notified to a coroner, the medical examiner must do so in accordance with regulations made under section 18 of the Act.
- 2.12 After scrutinising the deceased person's medical records and the results of any external examination, the medical examiner (or an officer acting on his or her behalf) will speak with a member of the bereaved family (or a prospective informant where there is no family member), usually by telephone, to discuss the cause of death with them and to offer them the opportunity to raise any concerns they may have. If concerns are raised, the medical examiner will usually discuss them with the attending doctor and then if necessary refer the death to a coroner. If, as a result of the discussion the death is not subsequently referred to a coroner, the person with whom the death is discussed will be asked to sign a form confirming the discussion. This can be done prior to or at the same time that the 'informant' provides the MCCD to the local registrar of births, deaths and marriages. The 'informant' may also sign this form, even where the informant wasn't a party to the discussion providing he or she is aware that it has been held. The informant is the person who informs the local registrar of births, deaths and marriages that the death has occurred and gives the information for the registration. This process will ensure it has been confirmed to the registrar that the death has been discussed and that no concerns were raised that might require the death to be investigated by a coroner.
- 2.13 If at the end of the process the death does not need to be investigated by a coroner and an agreed MCCD has been seen and checked by the medical examiner, the medical examiner will sign a Notification of Confirmed Cause of Death as soon as practicable and on the same day arrange for a copy to be sent to the registrar for the district where the death occurred.⁶ A copy will also be sent to the attending doctor (or the ward staff, practice staff or bereavement service acting on the doctor's behalf). The medical examiner pilots suggest that copies should be transmitted electronically to avoid delays. Within two days of receiving that notification, the original MCCD must be finalised and issued to a person who intends to be the informant in registering the death.

⁶ In cases where the medical examiner has been asked by a coroner to certify the cause of death, the medical examiner sends the registrar a Notification of Certified Cause of Death.

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- 2.14 When the confirmed MCCD is given to a registrar and matched to the notification provided by the medical examiner it can be used to register the death unless, in exceptional circumstances, the informant provides new information to the registrar that suggests the confirmed cause of death may be incorrect or the death may be unnatural. In these exceptional cases, the registrar will speak with a medical examiner's officer first and if necessary, invite the attending practitioner to prepare a new MCCD. There might be other reasons where the registrar might first need to contact the medical examiner's office, for example, the informant refuses to sign part B of the ME-2 form which confirms that a conversation about the cause of death between a member of the bereaved family and the medical examiner had taken place.
- 2.15 The Ministry of Justice intends to make amendments to the Cremation (England and Wales) Regulations 2008 to dovetail with the death certification reforms. These will deal with the issuing of information on implants, medical devices and communicable infections prior to a cremation taking place. Currently, it is proposed that this information could be provided when the confirmed MCCD is issued and can then be given to a funeral director or passed directly to a crematorium. The Ministry of Justice's future consultation on these amendments will provide further details on this process.
- 2.16 The pilot sites that have tested the new system have found that the process - from the medical examiner being notified of a death to the provision of a copy of the statutory notification confirming a cause of death - can usually be completed within one working day, and that in many cases this time can be absorbed within the one to two days taken for a MCCD to be prepared and issued in the existing process.
- 2.17 Where additional time is required, the experience of the pilot sites is that this need not cause unnecessary distress to the bereaved if there is a shared understanding of when the MCCD will be available and if there are local procedures for prioritising the process, without any loss of safeguards, in cases where there is a need for urgent certification
- 2.18 The most frequent reason for urgent death certification is to allow relatives to comply with faith and cultural practices that require burial as soon as possible after the death. Other reasons include:
- Expected deaths of organ donors, where retrieval of the organs needs to take place without delay;
 - Expected deaths of children in hospitals, where parents may want to take their child home or closer to home;

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- The need to accommodate long-distance travel arrangements of close relatives;
- Limited time for compassionate leave from work, or limited time away from a young family or from caring for a dependent person; and
- A cultural obligation to act as a host for a large number of people until a funeral has taken place.

2.19 The feedback from the pilot sites is that the demand for urgent certification is manageable within the new process, and that in areas where it is a significant requirement it can be met by arranging for medical examiners to be available for extended hours during the week and for specified periods during the weekend and on bank holidays.

The effects of the new process

2.20 The previous section described some of the benefits of the new system for bereaved families. This section summarises the impact on doctors, coroners and their staff, bereavement services, registrars, funeral directors and crematoria.

Effect on doctors

2.21 The current arrangements for attending doctors to report deaths to a coroner⁷ will be replaced by a statutory duty to notify deaths to a coroner in certain cases and circumstances. This duty will be set out in the Death Notification Regulations described in Chapter 5.

2.22 Attending doctors will continue to certify causes of death where they are able to do so but will need to be 'qualified attending practitioners' (QAPs). The draft regulations prescribe what is meant by this term. Currently, the medical practitioner issuing the MCCD must have attended the deceased during the deceased's last illness. In addition, under regulation 41 of the Registration of Births and Deaths Regulations 1987, the registrar must report a death to the coroner if the practitioner who completed the MCCD has not attended the deceased after death or within 14 days before death. Under the new regulations, with a limited exception, the practitioner completing the MCCD

⁷ The current practice under which doctors report deaths to a coroner is intended to pre-empt the death being reported by a registrar under regulation 41 of The Registration of Births and Deaths Regulations 1987 or under coroner's local reporting criteria.

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must have attended the deceased within 28-days before the death. This is explained further in Annex A.

- 2.23 In respect of deaths followed by cremations, doctors will no longer need to complete the cremation forms 4 and 5 and will therefore no longer receive the associated fees.
- 2.24 This means that it will no longer be a requirement for a doctor to have seen and examined the deceased person's body in the 75 per cent of deaths (not investigated by a coroner) where a cremation is being arranged. Instead, whether a body is examined by the doctor or subsequently the medical examiner will be subject to the discretion of the doctor/examiner in light of their assessment of risks of stated cause and circumstances. This will be the case, whether the death is followed by cremation or burial. Doctors may ask another doctor to examine the body on their behalf. Likewise, medical examiners may instruct another person to undertake such an examination, provided the person has sufficient qualifications and is sufficiently independent.
- 2.25 Attending doctors will need to provide a copy of the MCCD to a medical examiner for the cause of death to be confirmed (and the certificate checked) before it is issued.
- 2.26 The copy of the MCCD provided to a medical examiner will be accompanied by additional information set out in the regulations, including relevant health records. Where necessary, this information can be provided electronically and, if it is already documented clearly in health records, there will be no need to copy it onto a new form.⁸
- 2.27 Doctors will be able to obtain advice from a medical examiner (or from a medical examiner's officer using information documented by a medical examiner) on medical circumstances and causes of apparently natural deaths for which the cause is known but not clear. This will reduce doctors' reliance on discussions with hospital bereavement officers and coroner's officers which, in many cases, focus on ensuring that the certified cause is acceptable for registration rather than on whether it accurately reflects the medical history and circumstances documented in the records.
- 2.28 Doctors will be responsible for finalising the MCCD after the cause of death has been confirmed by a medical examiner, but they may delegate that task

⁸ See website with consultation documents for a copy of national exemplar forms that can be used to provide the statutory information, if it is not already recorded elsewhere in a format acceptable to a medical examiner. There are two 2-page national exemplar forms: one for administrative information and one for clinical information.

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to others such as ward or practice staff, or to bereavement services in hospitals and hospices. This finalisation will involve writing the date of confirmation on the original MCCD and we expect that it will be added to the existing procedure for issuing the MCCD.

Impact on coroners and their staff

- 2.29 The experience of the pilot sites suggests that the new process will reduce the number of deaths reported, notified or referred to coroners but increase the number of deaths that need to be investigated. This is because more of the cases referred are referred appropriately. If that experience is replicated nationally and consistently then the net effect would be to increase investigations as a proportion of reported deaths.
- 2.30 This is based on feedback from the death certification pilots and validated by a small study carried out in Sheffield.⁹ The changes in caseload are likely to differ in each area depending on current practice and other local factors. The actual impact on coroners' workload, and the additional cost that represents, will be kept under review as the reforms progress.
- 2.31 Coroners' officers will continue to talk directly to attending doctors when they carry out an initial assessment of the deaths that have been referred to the coroner and will only involve medical examiners and their officers where additional information or advice is required. Where a death is referred after it has been scrutinised by a medical examiner, the medical examiner's office can provide a copy of the medical examiner's records to the coroner.
- 2.32 Medical examiners should speak to a coroner (directly or via a coroner's officer) about any death where there is an unusual interplay of circumstance and medical factors. The nature and extent of these discussions will depend on coroners and medical examiners collaborating closely and developing the mutual trust and respect that is essential for the new system to work most effectively.
- 2.33 Where a coroner decides that a death referred to him or her does not need to be investigated, he or she will provide a copy of the information used to make this decision to the medical examiner's office. In the new process we propose to develop a good practice, (non-statutory) form to replace the coroner's Form 100 A (non-statutory form) that is sent to the registrar in the current process. The new form will include more information than the old form, but all the relevant information should be available from the coroner's case management system without the collection of any additional details.

⁹ A briefing note on the findings of the study carried out in Sheffield will be published separately.

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- 2.34 Where a natural death of known cause is notified to a coroner because there is no 'qualified attending practitioner' (or none is available in a reasonable period to prepare a MCCD) the coroner may use the good practice form to refer it to a medical examiner for certification. This will provide an alternative to the current arrangement in which in these cases a coroner needs to make preliminary inquiries to ascertain whether he / she has a duty to investigate a death, or must open an investigation in order to provide a certificate that can be used to register the death or provide a notification that allows the death to be registered as uncertified.
- 2.35 Coroners may ask medical examiners for general medical advice about deaths that are referred in order to assist the coroner's decision on whether to conduct an investigation. They may also ask for advice on what type of investigation would be appropriate.
- 2.36 Once a coroner has started to conduct an investigation into a death under section 1 of the 2009 Act, medical examiners will have no further role.

Effect on hospital and hospice bereavement services

- 2.37 In the new process, bereavement service officers in hospitals and hospices will no longer need to provide advice to doctors about causes of death that are acceptable for registration, or need to be the first to discuss the certified cause of death with the next of kin. However, where they currently provide the service they will continue to arrange for attending doctors to review the records and prepare a MCCD (with advice, where necessary, from a medical examiner or medical examiner's officer), make arrangements for the MCCD to be issued once it has been confirmed, conduct a bereavement appointment where one is requested, return property and make arrangements for release and collection of the deceased person by a funeral director or other authorised person. In the new system, they may also be asked to collate and provide the administrative information required by a medical examiner and to ensure that when the MCCD is issued it is accompanied by separate statutory information provided by the medical examiner on implants, medical devices and any communicable infections.¹⁰
- 2.38 In relation to deaths followed by cremation, bereavement service staff will no longer need to co-ordinate the completion of the Cremation 4 and 5 forms or to act as an intermediary for the payment of the associated fees as these will no longer exist.

¹⁰ A national exemplar of a form that can be used to provide statutory information on implants, medical devices and communicable infections is included on the consultation website.

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- 2.39 Centralised bereavement services at large acute hospitals may be able to provide the medical examiner's officer function alongside their existing work. However, this is only feasible where the people carrying out this function have the expertise and independence to confidently delegate responsibilities for key activities.

Effect on registrars

- 2.40 In the new process, for all deaths not investigated by a coroner, registrars will receive a statutory notification from a medical examiner that is fully completed and matches a MCCD delivered by an informant. Following this, they will register a death and /or issue a Certificate for Burial and Cremation (also known as the Green Form). This notification will also take the place of the Form A that registrars currently receive from a coroner and it will apply to all deaths where the cause is certified by an attending doctor and confirmed by a medical examiner, or certified by a medical examiner following referral from a coroner. Depending on local arrangements, the medical examiner will be able to provide the notification by secure e-mail or fax.
- 2.41 In most cases, registrars will need to ask the informant to complete and sign Part B of the notification when they deliver the MCCD. This part of the notification provides a written confirmation that the informant, or another person to whom the informant has spoken, has discussed the circumstances and cause of the death with the medical examiner, or with someone acting on behalf of the medical examiner, and has been offered an opportunity to raise any matters that might require the death to be notified or referred to a coroner.
- 2.42 At present registrars act as a safety net because there is no system for the scrutiny of MCCDs other than where a death has been referred to the coroner. In future, registrars will not be required to fulfil this role. The General Register Office intends to remove the duty on registrars under regulation 41 of the Registration of Births and Deaths Regulations 1987 to refer certain deaths to the coroner. Instead, if an informant raises any concerns about the cause of death at the time of registration the registrar will discuss that with the medical examiner that scrutinised the death (or, in practice, with the medical examiner's office) and, if necessary, invite the attending practitioner or medical examiner to prepare a fresh certificate to be issued.

Effect on funeral directors

- 2.43 In the new process, in relation to deaths followed by cremation, it is intended that funeral directors (or others arranging a funeral) will no longer need to facilitate the completion of the Cremation 4 and 5 forms, which, together with the Cremation 10 form, will be withdrawn through amendments intended to be

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made by the Cremation (England and Wales) Regulations 2008. The removal of form 4 will leave a gap in information about implants, and medical devices. The Ministry of Justice intends to undertake separate detailed consultation on these amendments.

Collection of bodies from hospitals

- 2.44 In the current process, hospitals with a mortuary or equivalent facility require an MCCD to be prepared and signed before the deceased person's body is released in order to be assured that the death does not need to be referred to the coroner. In the new process hospitals will need to wait until the MCCD has been confirmed by a medical examiner, but in many cases that confirmation will be provided within the current timescales.
- 2.45 Some hospitals have required sight of the registrar's Green Form before authorising release of a body. While it is reasonable for a hospital to want to be assured that releasing a body is appropriate, there is no legal basis for insisting on a Green Form, which can lead to unnecessary delays and distress for the bereaved. In January 2015, we consulted on a non-statutory form for the collection of a body of the person who has died from a hospital mortuary. The body collection form has been revised in light of responses to the consultation for use in the existing death certification process. In future, a slightly revised form will be made available to support collection of the body of the person who has died as part of the medical examiner process.

Effect on crematoria

- 2.46 In the new process, it is intended that crematoria will be able make the arrangements for a cremation on receipt of the documents listed below, and will not require any review or confirmation by a medical referee.
- Application for Cremation (Cremation 1 form)
 - Registrar's certificate for burial or cremation (Green Form) or Coroner's certificate for cremation (Cremation 6 form)
 - Information issued at the same time as the MCCD (or by or on behalf of the coroner) on the existence or removal of any implants or medical devices and on the transmission route and hazard group of any communicable infection
- 2.47 There is no requirement for crematoria to see the medical examiner's signed, notification to the registrar forms. This is because registrars will not issue a Green Form until they have received a statutory notification from a medical examiner. It is also anticipated that the current requirement for cremation

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forms 4 and 5 to be completed and available for inspection at a crematorium 48 hours prior to a cremation will be withdrawn by the Ministry of Justice and other requirements put in place by amending the Cremation (England and Wales) Regulations 2008.

Chapter 3: Funding local medical examiners' services in England

- 3.1 The Coroners and Justice Act 2009 (as amended by the Health and Social Care Act 2012) provides for medical examiner services to be funded by a fee payable to a local authority in England, or local health board in Wales. This was based on the preferred option set out in Section 6 of the 2007 consultation document '*Improving the Process of Death Certification*'. Under the medical examiner system, Cremation Forms 4, 5 and 10 and the associated fees will be removed.
- 3.2 Our preferred option is a single fee paid by families (in most cases) for certification of all deaths (irrespective of whether death is followed by burial or cremation, but excluding cases referred to coroners). The 2009 Act provides for separate regulations to set the fees in England and Wales. The draft regulations for England are included in this consultation – the Welsh Government will consult separately on its own regulations.
- 3.3 The fee needs to cover the cost of providing the service. In practice there may be minor local variations in costs, but we do not consider these to be significant enough to justify a variation of the fee across local authorities. We have used the pilot medical examiner services to establish some of the cost assumptions and what costs the fee will need to cover. This is set out in the impact assessment published with this document and suggests a national fee in England of around £80 to £100.
- 3.4 At present, families who choose cremation (the large majority in England and Wales) are required to pay about £184 in fees for the cremation forms.¹¹ Those forms, that process and those fees are being replaced under the new system with a fee for all deaths that are not referred to a coroner. The new service will cost less than the current system for most people, but will introduce a new fee for the minority who choose burial. Families opting for burial also deserve the same degree of assurance about the circumstances surrounding the death before the burial takes place as those choosing cremation. We believe there are significant benefits of the new system and that it is fairer that the fee will apply to all non-coronial deaths, as outlined in Chapter 1.

¹¹ Cremation forms 4 and 5 are completed by doctors for a fee, which is recommended by the British Medical Association, from April 2015, of £82 for each form (<http://www.bma.org.uk/support-at-work/pay-fees-allowances/fees/fee-finder/fee-finder-cremation>). The medical referee at the crematorium will normally charge about £20.

Who should be responsible for paying the fee?

- 3.5 There needs to be a simple way for families and local authorities to understand who is responsible for paying the fee, or for ensuring that it is paid. There are various ways in which this person might be identified but we believe the main choices are:
- The person who collects the MCCD; or
 - The person who registers the death at a register office.
- 3.6 In the new system an individual will collect the MCCD from the bereavement service or medical examiner's office and someone will be required to act as the informant for the death registration. Very often this will be the same person, but it does not need to be. For example, if the deceased person had no family or no one who can take on this role within the time limit for registration, a member of staff from the hospital or care home where they died will collect the MCCD or act as the informant.
- 3.7 As it may not always be convenient or sensitive to deal with the payment immediately – for example, a different family member may be dealing with the financial issues following the death – we propose that the time limit for payment should be three months from the medical examiner's confirmation date on the MCCD or, when the certifier is a medical examiner, the date of the MCCD. The Local Government Association has suggested that the burden on local authorities would be reduced if the time limit was 28 days rather than three months.
- 3.8 The draft fee regulations do not exempt an official or employee who collects the MCCD or acts as informant from paying the fee. We are seeking views as to whether there should be such an exception, for example to allow for hospital staff or local authority officials to register the death when no one else comes forward to do so without incurring charges. Under the current system, where there is no one available to arrange a funeral either the council or the hospital would deal with it. The obligation on a local authority to arrange for disposal of the body is set under the Public Health and Control of Disease Act 1984. Local authorities recover costs of a public health or community funeral from the deceased's estate under section 46(5) of the Act and this will continue to be the case.

Question 1: Do you agree that an individual should be prescribed in legislation as being responsible to pay, or to arrange to have paid, the medical examiner fee?

Question 2: Should the person prescribed be the individual that collects the MCCD from the medical examiner, or the death registration informant?

Question 3: Should the regulations exempt an official or employee who acts as an informant, from being responsible to pay, or to arrange to have paid the medical examiner fee?

Question 4: Should there be a 28 day or three month period for payment of the medical examiner fee?

How should councils collect the fee?

- 3.9 In the current system, fees are due to doctors who complete cremation forms 4 and 5 where the coroner has not undertaken an investigation. Normally, funeral directors contract with doctors to collect these fees on their behalf, and these costs are generally shown as a separately itemised cost on both the funeral director's estimate and final account.
- 3.10 In the new system, cremation forms 4 and 5 will no longer be required, and there will be no fees due to doctors. The new fee for the Medical Examiner scrutiny and confirmation of cause of death will apply to all deaths – cremations and burials. This fee will be payable to the Local Authority, who will have the discretion to determine the local process for payment. Local Authorities will need to ensure that bereaved families receive the right communications that explain the purpose and amount of this fee and the local collection method.
- 3.11 It will be up to local authorities what approach they choose. If they wish to work with third parties, such as funeral directors, they would need to let contracts. Representatives of local government and of funeral directors are considering what support could be put in place nationally to facilitate that process. In planning their approach, local authorities will need to be mindful that the bereaved will be going through a period of grieving and requiring immediate payment of the fee by the medical examiner office or the registration service, would not be appropriate. DH and the LGA are proposing and consulting on suitable periods within which the medical examiner fee might be collected.
- 3.12 We recognise that some families will not be in a position to pay this fee. For those who qualify for help from the Social Fund, the Funeral Expenses Payments scheme may be able to make a contribution towards the cost. Funeral Expenses Payments are made via the funeral director if one is used. Help may also be available in the form of a loan from the Social Fund Budgeting Loan scheme for qualifying applicants.

Question 5: As a local funeral service would you be willing to collect the medical examiner fee on behalf of a local authority, for a small administrative charge? The bereaved would see the fee itemised in the funeral director's bill. YES/NO

Chapter 4: Death certification regulations

Introduction

4.1 While the basic structure of the new system is provided for by the Coroners and Justice Act 2009, we intend to set out much of the important detail in three sets of regulations. These have been published in draft form for consultation alongside this document, and there are detailed descriptions in Annex A. They are:

- The Death Certification Regulations
- The Death Certification (Medical Examiners) (England) Regulations
- The National Medical Examiner (Additional Functions) Regulations

The Death Certification Regulations

4.2 These would apply to both England and Wales and cover much of the detailed process for death certification under the new system.

Question 6: Do you believe the provision of “administrative and clinical information” set out in schedule 1 is necessary and sufficient for all deaths, either for a medical examiner’s scrutiny or for a coroner’s investigation? If not, what would you add or delete and why?

Question 7: Do you agree that the medical examiner should have discretion about whether an independent non-forensic external examination of the body is necessary?

Question 8: In your view, are there sufficient safeguards if a person without a medical qualification but with suitable expertise and sufficient independence carries out a non-forensic external examination of the body on behalf of the medical examiner?

Question 9: Under regulation 26, do you agree that the medical examiner process should be suspended during a period of emergency?

Question 10: Do you agree that during a period of emergency any registered medical practitioner could certify the cause of death in the absence of a qualified attending practitioner?

Question 11: Are the proposed certificates and medical examiner forms set out in schedules 2- 7 fit for purpose? If not, please say why.

The Death Certification (Medical Examiners) (England) Regulations

These would make provisions for the terms of appointment of medical examiners, their remuneration and their additional functions. They also make provisions for ensuring an appropriate level of independence for English medical examiners. These apply to England only.

The National Medical Examiner (Additional Functions) Regulations

- 4.3 These would apply to England and Wales and set out additional functions of the National Medical Examiner. This would include setting standards for medical examiners and issuing guidance to local authorities in England and local health boards in Wales. They apply in England and Wales.
-

Question 12: In relation to regulation 5 of the NME regulations, what other aspects should standards cover for monitoring medical examiners' levels of performance?

Chapter 5: Notification of deaths to coroners' regulations

Regulations and guidance made under section 18 of the Coroners and Justice Act 2009

Introduction

These draft regulations are described in detail in Annex B.

- 5.1. Under section 18 of the Coroners and Justice Act 2009 (“the 2009 Act”), the Lord Chancellor may make regulations that require a doctor, in prescribed cases or circumstances, to notify a senior coroner of a death. Before making regulations the Lord Chancellor must consult the Secretary of State for Health and the Chief Coroner.
- 5.2. The Chief Coroner is a post created by the 2009 Act to provide leadership of coroners and national oversight of the coroner system. The Lord Chief Justice appointed His Honour Judge Peter Thornton QC as the first Chief Coroner of England and Wales in May 2012, and HHJ Thornton took up post in September 2012.
- 5.3. The 2009 Act contains a number of other reforms to the coroner system and the Ministry of Justice brought the majority of these into force on 25 July 2013, ahead of the new system of death certification. The Ministry of Justice consulted on its proposals, including draft coroner regulations and rules (made under sections 43, 45 and Schedule 7 of the Act), in March 2013. The new rules and regulations were laid in Parliament on 4 July and came into force on 25 July 2013.

Background

- 5.4. In March 2010 the Ministry of Justice issued the consultation paper titled *“Reform of the Coroner System; Next Stage”*¹² which sought views on (amongst other things) secondary legislation deaths to be reported to a senior coroner under section 18 of the 2009 Act.
- 5.5. The consultation established nine cases or circumstances in which doctors would be required to refer deaths to a senior coroner (a new post also introduced by the 2009 Act). These are when:

¹² www.justice.gov.uk/consultations/docs/coroner-reform.pdf

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- There is no attending practitioner or the attending practitioner(s) is unavailable within a prescribed period.
 - The death may have been caused by violence, trauma or physical injury, whether intentional or otherwise.
 - The death may have been caused by poisoning.
 - The death may be a result of intentional self-harm.
 - The death may be a result of neglect or failure of care.
 - The death may be related to a medical procedure or treatment.
 - The death may be due to an injury or disease received in the course of employment, or industrial poisoning.
 - The death occurred whilst the deceased was in custody or state detention, whatever the cause of death.
 - The cause of death is unknown.
- 5.6. The consultation paper also suggested draft guidance based on those categories that would give doctors more information to help them in determining whether a death was notifiable. For example, the guidance stated that deaths caused by poisoning include any deliberate or accidental intake of poisoning including illicit drugs, medical drugs (deliberate or accidental overdoses) and toxic chemicals.
- 5.7. The Ministry of Justice response to the consultation, published in October 2010¹³, showed that there was broad agreement to the circumstances in which coroners should be notified of deaths and to the accompanying guidance.
- 5.8. This Chapter and Annex B build on the first consultation as well as discussions since then with interested parties including members of the Death Certification Steering Group, the Coroner's Society, the Department of Health and the General Register Office. The purpose of this stage in the consultation is to further refine the draft regulations and guidance before the formal making of the regulations.

¹³ www.justice.gov.uk/consultations/docs/reform-of-coroner-system.pdf

The duty to notify a senior coroner of a death

- 5.9. The draft regulations made under section 18 require a registered medical practitioner to notify a senior coroner of a death. A registered medical practitioner means a person on the General Medical Council's List of Registered Medical Practitioners, and in practice one of the following would be responsible for referring a death to the coroner:
- The attending practitioner, including a hospital consultant, who would otherwise complete the medical certificate of cause of death (MCCD).
 - The registered medical practitioner, including a hospital consultant, who attends the deceased shortly after the time of death.
 - The medical examiner.
- 5.10. Medical practitioners, medical examiners and coroners will need training and guidance to enable them to carry out this duty. Written guidance will be available for medical practitioners alongside the certification forms issued by the Department of Health and will be based on the proposed guidance attached to this consultation.
- 5.11. The Ministry of Justice and the Department of Health will consider what other forms of training and guidance should be available. The training for medical examiners on this will be included in an e-learning package being developed by the Department of Health. One option would be to make this more widely available.
- 5.12. Regulation 41 of the Registration of Births and Deaths Regulations 1987 requires a relevant registrar to inform a coroner of the death of a person under certain circumstances (for example where the registrar has been unable to obtain a duly completed certificate of cause of death). There is currently an overlap of circumstances in which the notification should be made, so we therefore intend to remove the duty on registrars to refer certain deaths to the coroner contained in regulation 41 of the Births and Deaths Registration Regulations 1987.

Failure to comply with regulations

- 5.13. It is important to make sure that doctors comply with the new regulations and guidance, so that deaths are reported to the coroner appropriately and consistently. There are two situations where failure to comply might occur:
- Poor practice, due to a lack of knowledge or understanding.
 - Deliberate and wilful failure to report a death.

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- 5.14. Coroners and medical examiners will be expected to work closely together in future. Jointly, they will be able to identify those doctors who routinely fail to report deaths to the coroner or, equally, who report deaths to the coroner unnecessarily. It may also be appropriate for medical examiners to offer or arrange further training for the practitioner to address the problem.
- 5.15. If the doctor in question continues to fail to report deaths to the coroner, the medical examiner or the coroner should report the matter to the local authority or medical director. If it cannot be resolved locally it should be reported to the General Medical Council (GMC) who may conduct a full investigation and assess the appropriate action to take depending on the circumstances.
- 5.16. Suspected deliberate or wilful failure to report a death should also be reported to the relevant local authority or medical director who will involve the GMC and/or the police as necessary – or reported directly to the GMC and/or the police if that is more appropriate. If there is found to be criminal activity then existing criminal sanctions will apply. We do not believe it is necessary to create a new, separate offence.

Consultation

- 5.17. There are some areas that we would like further input on in relation to these regulations, and we would be grateful for responses to the following questions.

Question 14: Do you agree that a death should be notifiable if it is “otherwise unnatural”?

Question 15: Do you believe there is sufficient understanding between members of the medical and coronial professions as to the meaning of “unnatural” and that further definition is not required? If not, we would be grateful for suggestions as to what the guidance may include.

Question 16: Do you agree that provision needs to be made with regard to poisoning, given that cases of poisoning are rare?

Question 17: Do you believe that “poisoning, the use of a controlled drug, medicinal product or toxic chemical” sufficiently covers all such circumstances of death? If not, should the guidance be broadened?

Question 18: Do you believe there is a sufficient understanding of “neglect”? If not, should this be made clearer in the draft regulations rather than guidance?

Question 19: Do you agree that regulation 3(2)(e) - “occurred as a result of an injury or disease received during, or attributable to, the course of the deceased person’s work” - is clear that it includes any death that has occurred as a result of current or former work undertaken by the deceased, including cases such as mesothelioma or other asbestos related cases? If not, we would be grateful for alternative suggestions.

Question 20: Do you agree that it should be possible to make notifications orally, but that where an oral notification is made the information must be recorded in writing and confirmed?

Question 21: Do you agree that regulation 3(6) should prevent duplication of notification? We would be particularly grateful for views on how this would work in a surgical environment.

Question 22: Do you have any other comments about the draft Regulations?

Question 23: In relation to the guidance, do you agree with the examples used under each category of death? If not, we should be grateful for further examples or suggestions for definitions.

Question 24: Also in relation to the guidance, do you agree that no specific reference is needed as to whether certain deaths will be subject to jury inquests or not (such as those that have occurred under state detention)?

Question 25: Do you have any other comments about the guidance?

Chapter 6: Cremation regulations

Cremation Regulations made under Cremation Act 1902

Background

- 6.1 The Secretary of State for Justice has responsibility for cremation law and policy in England and Wales. Under section 7 of the Cremation Act 1902 the Secretary of State for Justice has powers to make regulations; currently they are the Cremation (England and Wales) Regulations 2008 (“the Cremation Regulations”). These Regulations, together with the Cremation Act 1902, provide the statutory regulatory framework for the running of crematoria and the cremation process.
- 6.2 Any cremation conducted outside of the scope or in breach of the provisions of the Cremation Act and Regulations is illegal. Broadly, as set out in regulation 16 of the Cremation Regulations, no cremation can take place unless:
- an application for cremation has been received in accordance with regulation 15 (Cremation Form 1)
 - a medical certificate giving the cause of death has been given by a registered medical practitioner who has attended the deceased, as set out in regulation 17 (Cremation Form 4)
 - a confirmatory medical certificate giving the cause of death has been given by a doctor of five years’ standing, who is not in any way related to the first doctor, as set out in regulation 17 (Cremation Form 5)
 - written authority has been given by the medical referee for the cremation to take place, as set out in regulation 23 (Cremation Form 10).
- 6.3 Regulation 14 provides for the forms at Schedule 1 to the Cremation Regulations to be used during the application, certification and authorisation process for cremation. Regulations 16 and 18 provide for the coronial certificate authorising cremation, should the death be investigated by the coroner, but we do not propose to cover instances where the coroner investigates here.
- 6.4 A similar process less the two medical certificates pertains for application and authorisation for cremation of stillborn babies and body parts. Different application and authorisation forms are used.

Impact of introduction of medical examiner on medical referees system

- 6.5 Currently, a medical referee (and deputy medical referee) must be appointed to each crematorium to scrutinise cremation forms and authorise cremations. The medical referee is responsible for checking all the cremation forms thoroughly, querying any inconsistencies (especially between Cremation Forms 4 and 5) and then providing authority for the cremation to take place by completing Cremation Form 10.
- 6.6 A cremation must not take place unless the medical referee is satisfied that adequate inquiries have been made by the medical practitioners completing the certificates and that the fact and cause of death have been definitely ascertained, or if not that the coroner has investigated the death and has released the body. A medical referee may perform or direct a post-mortem examination (with appropriate consent) if the cause of death has not been definitely ascertained. They also have a duty, where appropriate, to refer a case to the coroner.
- 6.7 The medical referee should not allow the cremation if there are other suspicious circumstances connected to the death of the deceased, whether revealed in the medical certificates or otherwise, unless a coroner has completed form Cremation Form 6.
- 6.8 When the medical examiner scheme is introduced, it is intended that the Cremation Regulations will be amended so that the role of the medical referee will cease to exist. There will need to be significant amendments to the Cremation Regulations to remove the scrutiny and authorisation roles of the medical referee, as well as to remove the role of the certifying doctors who fill in Cremation Forms 4 and 5. It will also be necessary to remove the related medical referee and certifying doctor statutory forms. A Statutory Instrument repealing and creating new cremation regulations will need to be in place to coincide with the introduction of the role of the medical examiner.
- 6.9 There are some aspects of the current cremation regulatory framework that will need to remain under the new death certification reforms. These are the current regulatory requirements for maintenance and inspection of crematoria, the conditions for cremation (including application), incineration; disposal of ashes and registration of cremations.
- 6.10 However, there are aspects of the current cremation authorisation process as currently held by the medical referee that will no longer remain after the medical examiner scheme is introduced, but will also not transfer to the medical examiner. These are the roles of scrutiny and final authorisation for the cremation of stillborn babies and of body parts.

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- 6.11 The introduction of the medical examiner system also presents us with an opportunity to consider the form that the residual cremation regulations may take and we would therefore welcome any further views you have on the regulations.

Questions on amendments to the Cremation (England and Wales) Regulations 2008 to enable the introduction of medical examiners

Authorisation for cremation of body parts by medical referee under current Cremation Regulations

- 6.12 Under regulation 25, the medical referee currently authorises, if appropriate, the cremation of body parts upon scrutiny of Cremation Form 2 and all the relevant documentation (see regulation 25 and Cremation Form 12).
- 6.13 As we have set out, the role of the medical referee will cease to exist when the death certification reforms are implemented and the medical examiner scheme is introduced. The medical examiner will scrutinise all deaths that are not investigated by a coroner and certify that disposal can take place by burial or cremation.
- 6.14 However, there is no provision in the legislative framework for medical examiners to be involved in the certification of body parts. As such, medical examiners will not certify their disposal. This represents a change in the current level of scrutiny in place prior to the cremation of body parts.

Question 26: After the changes are brought in, there will be no provision for medical examiners to be involved in the certification of the cremation of body parts. Do you agree that the requirement to complete a statutory application form and provide a registration document and a certificate from the hospital trust or other authority holding the body parts will provide sufficient scrutiny prior to the cremation of body parts? If not, what further scrutiny do you think would be needed, in the absence of medical referees?

Authorisation for cremation of stillborn babies by medical referee under current Cremation Regulations

- 6.15 Under regulation 26, the medical referee currently authorises, if appropriate, the cremation of stillborn babies upon scrutiny of Cremation Form 3 (Application for cremation of a stillborn baby), the certificate of registration of a stillborn baby issued by the registrar, and Cremation Form 9 (Certificate of stillbirth) (see regulation 26 and Cremation Forms 3, 9 and 13).
- 6.16 Again, there is no provision in the legislative framework for medical examiners to become involved in the certification of stillborn babies for cremation. The functions of medical examiners are limited to scrutinising those who have

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died. Stillborn babies are not legally classified as having died because they are not regarded as having been alive or showing signs of independent life after birth.

- 6.17 The Department of Health and the Ministry of Justice recognise that the birth of a stillborn baby is a very traumatic event for parents, and that the handling of the stillborn baby will be a sensitive issue for the parents and others who may be affected¹⁴. Whilst both Departments acknowledge that the introduction of medical examiners will alter the current level of scrutiny prior to cremation, there will remain robust review mechanisms in place regarding stillborn babies.
- 6.18 In particular, in April 2008 processes were introduced for stillborn babies in hospitals which involve review by multi-disciplinary teams. All stillborn baby cases are presented at perinatal mortality meetings and are reportable to Mothers and Babies: Reducing Risks through Audits and Confidential Enquiries across the UK on the Perinatal Death Notification form. As such, unusual trends are investigated, if necessary, by an independent team.
- 6.19 An application form for cremation (Cremation Form 3) will still be required and informants or doctors/midwives will still be required to register the stillborn baby in line with the Births and Deaths Registration Act 1953. However, there will be no medical referee based at the crematorium and the medical examiner will not authorise cremation. It is proposed that it will still be a requirement for doctors or midwives to fill in a certificate that the baby was stillborn prior to cremation.

Question 27: Do you agree that this proposal will provide a sufficient level of scrutiny in stillbirth cases? If not, what further scrutiny do you think would be needed, in the absence of medical referees?

- 6.20 Under the existing system medical referees currently authorise on Cremation 10 cremation where a coroner has certified – on Cremation 6 that there is no need for further examination of the body. Under the future system, while there would still be an equivalent of the coroner's certificate (currently Cremation 6), this would not be subject to further medical scrutiny as Cremation 10 is to be withdrawn.

Question 28: Do you agree that investigation and clearance for cremation by a coroner provides sufficient assurance for cremation to take place without a further check by a medical referee based at the crematorium? If not, what

¹⁴ The Ministry of Justice has recently carried out a consultation focusing on infant cremations, 'Consultation on cremation following infant cremation inquiries', (16 December 2015 – 9 March 2016; <https://consult.justice.gov.uk/digital-communications/consultation-on-cremation>)

further scrutiny do you think would be needed, in the absence of medical referees?

6.21 The Ministry of Justice plans to consult fully on a draft set of Cremation Regulations in late 2016. You will therefore have another opportunity to feed in any comments that you might have during that consultation exercise.

Responding to this consultation

Here we outline the consultation period, the deadline for submitting your responses and how to respond.

There are three ways to respond: online, by e-mail or by post. There is also a contact address in Chapter 1 to use if you have a complaint or wish to submit any comments about the consultation process.

The consultation begins on 10 March 2016 and will close on 15 June 2016.

Responding on the web

If you wish to respond online the questionnaire can be found at:

www.dh.gov.uk/liveconsultations

The online questionnaire will be available for the whole consultation period.

Responding by e-mail

If you wish to respond by e-mail please use the questionnaire at the back of this document. Once it is completed please e-mail to:

deathcertificationconsultation@dh.gsi.gov.uk

Responding in writing

If you wish to respond in writing, it would be helpful if you could do so by completing the consultation response form and sending it to the address below. If you do not want to use the consultation response form or are unable to do so, then please write with your answers and comments to:

Consultation on Introduction of Medical Examiners and Reforms to Death
Certification in England and Wales: Policy and Draft Regulations
Department of Health
2N15, Quarry House
Quarry Hill
Leeds
LS2 7UE

Annex A

The Death Certification Regulations

- 7.1 The Death Certification Regulations will apply to England and Wales and are divided into four parts:
- **Part 1** (Regulation 1-3): citation, commencement, application, interpretation and qualified attending practitioner.
 - **Part 2** (Regulations 4-16): preparation, scrutiny, confirmation and issue of an attending practitioner’s certificate and, where required, the referral of the death to a coroner¹⁵.
 - **Part 3** (Regulations 17- 23): preparation and issue of a medical examiner’s certificate following scrutiny of a death referred by a coroner in prescribed circumstances or, where required, referral of the death back to a coroner.
 - **Part 4** (Regulations 24-28): miscellaneous provisions including requirements during a period of emergency.
- 7.2 Part 2 of the regulations applies in all cases where an attending practitioner who has been made aware of a death is qualified under regulation 3 to certify the cause.
- 7.3 Part 3 of the regulations applies in specific cases where the coroner refers the death to the medical examiner to certify after deciding not to conduct an investigation under section 1 of the Coroners and Justice Act 2009 (“the Act”). This is where there is no attending practitioner qualified to certify the cause of death or, in the opinion of the coroner, no such practitioner is available within a reasonable period.
- 7.4 Part 3 of the regulations should not be used as a default for deaths where a qualified attending practitioner (QAP) defined in Regulation 3 is not contactable or available following a death that occurs outside usual working hours. We propose to issue guidance to help coroners decide what is “*within a reasonable period*”, which will specify that this is where:

¹⁵ All references to “coroner” in this chapter should be read as “senior coroner” or a coroner acting on behalf of the senior coroner.

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- Completion as soon as reasonably practicable before the end of the current working day or, if there are less than eight working hours to the end of the day, before 3:00pm on the next working day; or
- Where there is a known need for urgency and relevant local provision has been made, completion as soon as reasonably practicable within 24 hours.

Regulation 3: Who is a qualified attending practitioner?

- 7.5 Under the Registration of Births and Death Regulations 1987, a death (even an apparently natural death) can only be registered without reference to a coroner if the attending doctor who has certified the cause of death has seen the deceased either after death or within 14 days before the death. Otherwise, the registrar must refer the death to the coroner. The Ministry of Justice sought views in earlier consultations on whether this 14 day rule was necessary and should continue to apply in the new medical examiner system.
- 7.6 The responses were mixed, with some respondents suggesting that the period was irrelevant and the quality of information including medical history and circumstances of the death was far more important. Others felt it was helpful to have a clear cut off point at which deaths should be referred to a coroner. Extensions to 21 or 28 days had been offered in the consultation.
- 7.7 Given that the medical examiner system is to act as a safety net, and the support for an extension to 28 days in the response to the consultation, we propose that a qualified attending practitioner for the purposes of the Death Certification Regulations is a registered medical practitioner who attended the deceased person at any time in the 28 day period ending with the date of the death or, where such a practitioner exists but is not available within a reasonable period, a practitioner who:
- Works as a partner or an employee at the same general practice where the deceased person was a registered patient at the time of death and where the practitioner who had attended the deceased within the 28 day period was also employed or a partner; and
 - Attended the deceased person at any time in the period of 12 months ending with the date of the death.
- 7.8 Although the provisions allow a GP who is a partner or an employee of the practice to certify the cause of death if s/he attended the deceased in the 12 months prior to death, this longer period only applies if the deceased person had been attended in the 28 days by another doctor in the same practice who

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is not available within a reasonable period. We are not proposing a similar provision for hospital doctors because it is very likely that the deceased will have been attended in a hospital by more than one doctor who meets the criteria in the paragraph above.

Role and duties of a qualified attending practitioner at Attending Practitioner Certificate stage (Regulations 4 to 6)

Regulation 4: Duty to prepare an attending practitioner's certificate (APC) and requirements to be met before doing so

7.9 The "Attending Practitioner's Certificate" referred to in the regulations is the equivalent of what is currently referred to as the Medical Certificate of Cause of Death, as completed by the Attending Medical Practitioner. A qualified attending practitioner who is made aware of a death is not required to prepare an attending practitioner's certificate where:

- The practitioner knows that the coroner has decided to conduct an investigation under section 1 of the Act; or
- The practitioner knows that another qualified attending practitioner has prepared (or is preparing) an attending practitioner's certificate.

7.10 In all other cases, a qualified attending practitioner who is made aware of a death must carry out the preparatory work required by regulation 4 and prepare an attending practitioner's certificate to the best of his/her knowledge and belief.

7.11 Before preparing an APC, the qualified attending practitioner must review the deceased person's relevant health records with a view to establishing the cause of death. This should involve a 'conscientious appraisal' of the person's last illness or condition and the circumstances leading to the death. In most cases, the attending doctor will use this review to make (or validate) a written record of clinical information required for regulation 4(1)(c). The practitioner may also choose to carry out an external examination of the deceased person (or arrange for another practitioner to do so on his or her behalf) before completing the APC; however, this is not a requirement.

7.12 Whilst qualified attending practitioners will not be required to seek pre-certification advice from a medical examiner we believe that if it were to become customary, encouraged by good practice guidance, it would help practitioners to provide more relevant information to coroners and would reduce the number of deaths that are notified or referred unnecessarily. The

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need for improvement was highlighted by the Shipman Inquiry which found that in the current process doctors' decisions as to whether or not to report a death to a coroner "are not satisfactory" and that they "fail to do so in an unacceptably high proportion of cases".

- 7.13 Doctors may decide to get pre-certification advice from a medical examiner's officer on how to complete an MCCD and about the death certification process. This advice, together with the education and training that is part of the medical examiner's function, will address some of the shortcomings which the Shipman Inquiry felt might be capable of resolution.
- 7.14 Under regulation 4(1)(c), where a qualified attending practitioner is able to prepare an APC, the practitioner must do so as soon as practicable and arrange for a copy of the certificate to be provided to a medical examiner together with the administrative and clinical information listed in schedule 1 to the Death Certification Regulations, as far as it is practicable to obtain that information. Much of the statutory information will be provided when completing the attending practitioner's certificate. The copy of certificate and the administrative and clinical information may be provided on paper or electronically. The original APC should be retained securely and will not be issued until the medical examiner has confirmed the cause of death and provided notification to this effect.

Administrative and Clinical Information

- 7.15 When complying with regulation 4(1)(c), the qualified attending practitioner may wish to seek the assistance of ward staff or GP practice staff to collate the required administrative information. The clinical information should however be documented personally by the qualified attending practitioner because of the nature of the information required, for example, a written synopsis of the deceased's person's medical history relevant to establishing the cause of death. We intend guidance to make clear the need for attending practitioners to make reasonable enquiries to establish the facts.
- 7.16 The clinical and administrative information provided by a qualified attending practitioner to a medical examiner is largely the same information that must also be provided to the coroner where the death is referred to a coroner under regulation 5(1)(a). As with current practice, the coroner will only need to be sent relevant health records if he or she has requested it – whereas a copy of the relevant health records that the practitioner has used to establish the cause of death must always be provided to the medical examiner. "Relevant health records" are defined in regulation 2 as those that the certifier may reasonably believe to include information about any disease or condition which might have caused, or significantly contributed to the death.

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7.17 In requiring administrative and clinical information to be provided, our intention is to avoid unnecessary work copying information that is already clearly documented in existing records simply to provide it to a medical examiner or coroner on a statutory form. However, in many areas introduction of the new process of death certification will be facilitated by the use of (non-compulsory) standard forms and the Department of Health has therefore provided two national exemplar forms:

- ME-1 (Part A) – Administrative Information; and
- Final Entry in Clinical Record following a Death.

7.18 Medical examiners will also have local discretion about how and where they and their officers make and keep statutory records of their scrutiny, examination, enquiries, discussions and considerations. These records, which are required by regulations 8, 9, 19 and 20, can be made and kept on paper or electronically in any format provided that they are sufficiently clear and complete to enable peer audit and quality review. The National Medical Examiner is expected to provide guidance on the method and quality of record-keeping. These exemplar forms can be accessed from the same site as this consultation document:

- ME-1 (Part B) – Medical Examiner’s Advice and Scrutiny; and
- Queries raised by registrar.

7.19 The list of statutory items contains many fewer items than are currently required on the Cremation Forms 4 and 5, which doctors complete.

Aligning statutory information for all deaths

7.20 For the coroner services, we understand that information about a death is often given by a doctor over the telephone but doctors should comply with any local coroner protocols or MOJ guidance as to the manner in which the information should be provided. See also Chapter 4 on section 18 draft regulations.

7.21 Dame Janet Smith commented in the Shipman Inquiry’s third report that *“The quality of information which comes into the coroner’s office at the time of a death must be greatly improved. Instead of an oral account from the reporting doctor, there should be a short written account of the deceased’s medical history and a written account of the circumstances of death, each to be provided on a prescribed form.”* Although we have not prescribed a form in the death certification regulations for deaths reported to the coroner, we have

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proposed greater consistency in the information that doctors will provide to the medical examiner and to the coroner.

Information relating to implants, medical devices and communicable infection

- 7.22 With the removal of the Cremation Form 4 'Medical Certificate', completed by a doctor, and the examination of the body made by medical referees for Cremation Form 4 'Confirmatory Medical Certificate', it is essential that the medical examiner process has in place new safeguards to ensure that potentially hazardous implants or medical devices in the body are identified for the purposes of the health and safety of people dealing with the cremation of the body.
- 7.23 Where the attending practitioner chooses to neither examine nor arrange for an examination of the body, the source for this health and safety information may come from the health records and sometimes from a conversation with the family.
- 7.24 The clinical and administrative information in Schedule 1 includes potentially hazardous implants, medical devices as well as information on whether the deceased person was suffering from a communicable infection immediately before death, and the transmission route and hazard group of any such infection. The Ministry of Justice intends to amend the Cremation (England and Wales) Regulations 2008 to replace the gap in information left by the expected removal of the Cremation Forms. This may include requiring such health and safety information to be included on a standard form '*Information for funeral directors, cemeteries and crematoria to protect health and safety following a death*' and given to the family to pass on to the relevant service. Further details about the proposed amendments and the requirements for providing health and safety information for cremations will be set out in a separate consultation exercise undertaken by the Ministry of Justice.

Regulation 5: Attending practitioner's referral to a coroner

- 7.25 Where, in the course of carrying out the preparatory work under regulation 4, the practitioner considers that there is a requirement to notify a coroner about the death under the Notification of Deaths Regulations (outlined below and described in Chapter 4), the practitioner must notify the coroner. This could be the case where a qualified attending practitioner is made aware of a death but is subsequently not available (e.g. due to illness or a scheduled leave of absence) to prepare an attending practitioner's certificate in a reasonable period, and another qualified attending practitioner is not immediately available.

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- 7.26 Likewise, where, after carrying out such preparatory work, the practitioner is unable to establish a cause of death to the best of the practitioner's knowledge and belief, the death must be referred to a coroner.
- 7.27 Regulation 5 sets out the steps to be taken for referring a death to the coroner and the requirements where the coroner subsequently determines that the death does not need to be investigated under section 1 of the 2009 Act.

Regulation 6: Duty on the attending practitioner to be available to a relevant medical examiner

- 7.28 It is intended that DH guidance will say that the attending practitioner should make arrangements, for example with the ward staff or bereavement services, to keep the original APC in a secure place pending the medical examiner's confirmation of the cause(s) of death and collection of the certificate by the family. After providing a copy of the APC to a medical examiner, the attending practitioner must take reasonable steps to be available, to respond to any enquiries that a medical examiner may have in relation to the death. We believe that this requirement is necessary to allow a medical examiner to complete scrutiny without creating undue delay or unnecessary distress for the bereaved.

Role and duties of a medical examiner leading to medical examiner confirmation of APC (Regulations 7 to 12)

- 7.29 The Shipman Inquiry's Third Report said that the present system of death certification is open to abuse by a dishonest doctor. The Inquiry concluded that an adequate system of death certification must provide some effective cross-check of events given by the certifying doctor who has treated the deceased and who claims to identify the cause of death. Furthermore, the Inquiry said the account of the same events should be obtained from a family member, or someone with knowledge of the circumstances of the death. These cross-checks will be provided by a medical examiner as part of the scrutiny process not only to deter a doctor such as Shipman, but also to deter any doctor who might be tempted to conceal an error or neglect by him/herself or a colleague. Here we describe some of the cross-checks in the medical examiner's scrutiny.

Overview of scrutiny

- 7.30 The standard approach to scrutiny that we describe here begins on receipt by the medical examiner of an attending practitioner's certificate. However, as long as the requirements set in legislation are met, there may be cases where

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it is appropriate for a medical examiner to commence either 'consented preparatory scrutiny' or 'early scrutiny' in line with the use of local protocols.

- 7.31 Scrutiny includes these six activities in the sequence in which they are expected to occur in most cases:
- Scrutiny of the clinical and administrative information, including relevant health records. *Regulations 8(2)*;
 - External examination of the deceased person's body, if deemed necessary. *Regulations 8(1)*;
 - Scrutiny of a copy of the Attending Practitioner's Certificate (medical certificate of cause of death) prepared by the QAP. *Regulation 8(2)*;
 - Enquiries including discussions, where necessary, with the QAP, other doctors and healthcare staff. *Regulation 8(2)(a)*;
 - Discussion with the relative or other appropriate person about the cause of death. *Regulation 9*; and
 - Consideration of the results of the above activities leading to a record on the conclusions about whether the certified cause of death can be confirmed or the cause of a death referred to the medical examiner by a coroner can be certified. *Regulations 8(3)*.

Consented preparatory scrutiny for organ retrieval and transplants

- 7.32 Our pilot projects show that establishing a local protocol that enables medical examiners to carry out their functions in an effective manner could minimise delays in organ retrieval where wishes of the deceased for donation are known. We propose that general awareness about medical examiners amongst the healthcare team including specialist nurses for organ donations (SNODs), would be beneficial. As detailed below, the proposed section 19 Medical Examiner Regulations – will provide medical examiners with the function of participating in establishing, reviewing and updating local protocols within healthcare organisations to ensure the new death certification process covers all circumstances where speed is of the essence.

Urgent certification requiring 'early scrutiny' by medical examiner

- 7.33 Usually soon after the death, either the certifying doctor or (for example in a hospital) ward staff will be the first people to speak to the bereaved family about the deceased. At this point in time, it is possible that the bereaved from

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particular faith communities might indicate a need for urgent certification and release of the body for burial.

- 7.34 The experience of our pilot sites is that the new process can meet faith communities' requirements as well as the needs of any individual for urgent release of the body, as long as the wishes are made known to appropriate healthcare staff. In practice this means the process can be expedited either by the certifying doctor or the ward staff alerting the medical examiner's office to enable the medical examiner to commence 'early scrutiny' while still complying with the regulations. By this, we mean that the medical examiner will receive the deceased person's health records as soon as death occurs and the need for urgent certification is established. The medical examiner can start reviewing the health records before a doctor provides a copy of an attending practitioner's certificate (MCCD) for scrutiny and confirmation of cause(s) of death.
- 7.35 Medical examiners will be able to delegate an external examination of the body and discussions (subject to certain conditions described later), but will not be allowed to delegate the other prescribed functions, including:
- Scrutiny of the administrative and clinical information, including health records;
 - Scrutiny of a copy of the medical certificate of causes of death prepared by the QAP;
 - Consideration of the results of activities carried out during scrutiny; and
 - Completion of the notification provided to a registrar for all deaths where a cause is confirmed or certified.

Standards and procedures for scrutiny

- 7.36 Medical examiners should ensure that all activities comply with expected standards and procedures set out in guidance that will be published in due course by the National Medical Examiner. The expected standards and procedures are likely to state that:
- Scrutiny will be carried out in a way that is robust, proportionate and independent and avoids undue delay or unnecessary distress for the bereaved;
 - Where steps are taken to meet known individual needs for urgent certification, these will not be allowed to hinder proper scrutiny;

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- All enquiries and discussions carried out as part of scrutiny will be impartial, pragmatic and helpful and not judgemental or unnecessarily pedantic;
- Medical examiners and their officers will provide advice in a way that is valued by QAPs and by the healthcare providers for whom they work;
- All discussions with relatives or other appropriate people will be clear and appropriate; will not create any unnecessary concerns that might otherwise not exist and will be sensitive to cultural and religious requirements;
- Medical examiners and their officers will work closely with hospital bereavement services, mortuary services, coroner's services and registration services to provide a joined-up service; and
- Clear and complete records will be kept to allow medical examiners to identify local patterns and trends, enable local authorities to monitor performance and enable arrangements to be made to carry out quality reviews and peer-audits.

Medical examiner's scrutiny of attending practitioner's certificate

7.37 Regulation 8 relates to all the information that the medical examiner will need for scrutiny, which includes the statutory information provided by the attending practitioner, results of any external examination of the body and information obtained from whatever enquiries the examiner considers reasonable in order to confirm or establish the cause of death. The enquiries must involve looking at local data provided by public health or clinical governance teams about local trends, or unusual patterns to suggest something untoward.

External examination of the body

7.38 Under current arrangements, doctors completing the Cremation 4 and Cremation 5 forms for deaths followed by cremation must examine the deceased externally. Doctors preparing an MCCD should examine the deceased (or rely on an examination carried out by another doctor) in all cases where they have not seen the deceased in the 14 days prior to the death. However, this so-called "either/or" rule can be waived if the death is reported to a coroner who agrees to issue a Form A.

7.39 We recognise that in many cases the external examination carried out by some doctors is little more than cursory and only likely to identify deaths that are unnatural where untoward signs and symptoms are clearly apparent. The new process of death certification will remove the requirement for doctors to

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complete separate cremation forms and with it the examination of the body. Instead, medical examiners (and doctors) will have the discretion to undertake or arrange an external examination of the body, irrespective of whether there is to be a cremation or a burial.

- 7.40 In addition, regulation 8 allows a medical examiner to judge whether or not to rely on the results of any examination carried out personally by someone instructed to do so, on behalf of the examiner or by the certifying doctor. The medical examiner will have discretion under regulation 8 (4) about who may undertake the non-forensic external examination of the body on the examiner's behalf by determining the individual's suitable expertise and whether the person is sufficiently independent as described in regulations 8(5) and (6)). This may be, for example, funeral directors or mortuary technicians.
- 7.41 There has been some debate over who should carry out the external examination of the body, in terms of expertise, appropriate skills and added costs to the new process. Introducing a new duty on doctors to examine a body before preparing a certificate could have resulted in a need to remunerate doctors on a similar basis to fees that the bereaved pay for completion of Cremation Forms 4 and 5. The British Medical Association argued that imposing a new duty would be unduly burdensome, particularly for GPs who would have to make arrangements outside of practice hours to travel to where a body is.
- 7.42 We have agreed that the doctor completing an attending practitioner certificate may choose to carry out an external examination prior to certification if he or she thinks it is necessary or helpful to do so. The practitioner preparing the certificate may ask another registered medical practitioner to examine the body on his or her behalf, but in all cases the results of any examination must be passed to the medical examiner as required by regulation 4(1)(c).
- 7.43 The examination of the body also provides an independent check on standards of care and any issues for clinical governance, which the medical examiner might flag up following any relevant local clinical governance reporting procedures. This additional function for medical examiners is under the Death Certification (Medical Examiners) (England) Regulation 6(1)(e), which only applies in England. Medical examiner's scrutiny of death must also take into consideration any available information in respect of clinical governance as set out in regulation 8(2)(b)(iv) of the Death Certification Regulations.
- 7.44 There has also been debate on the value of an external examination of the body sometime after death unless the person carrying out the examination

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has had specific training in forensic examination of the body. However, it is the view of members of the Death Certification National Steering Group and pilot project medical examiners that individuals who prepare bodies for funerals and who have access to the approach on external examination set out in the e-Learning module for medical examiners, can become proficient in identifying any untoward signs. This might result either in the involvement of a coroner or the need to report indications that might suggest a clinical governance issue.

- 7.45 It is generally accepted that an examination of the body in a hospital mortuary can be carried out satisfactorily by a doctor or a medical examiner. However, in the case of a community death, it is considered impracticable. The body may be some distance from the doctor's surgery and the bodies are often dressed and in a coffin by the time the doctor attends to examine. These observations were also noted by the Shipman Inquiry, which considered examination by the funeral director or mortuary technician. It was Dame Janet's view that funeral directors and mortuary technicians are well placed to observe any signs of violence or neglect while preparing the body for disposition.
- 7.46 Funeral directors already exercise the common law duty to report to the coroner any signs of violence or neglect. With this in mind, our implementation resource site in Sheffield tested an illustrative form and checklist for an examination of the body by anatomical pathology technicians working at the hospital mortuary and funeral directors working in local funeral parlours. Any concerns are notified to the medical examiner for consideration before the case is notified or referred to a coroner. The results from the pilot suggest this approach works. However, we have been made aware of faith and cultural requirements, where an examination of the deceased, who is a woman, must be undertaken by a person of the same gender. Local authorities will need to be sensitive to these requirements.

Regulation 9: Discussion of the death with a relative

- 7.47 Regulation 9 introduces a fundamental change in the death certification process. The medical examiner will have a duty to discuss the circumstances and cause of death with the bereaved family (or a prospective informant where there is no family member) irrespective of whether a death is followed by a cremation or burial. The medical examiner may appoint an officer to do this on the examiner's behalf. This offer of an opportunity to discuss the cause of death with an independent person is different to the current process whereby doctors who complete the Cremation forms may need to speak with the bereaved. Our intention is to make the death certification process open and transparent for the bereaved families. Where no family or friend comes

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forward, the medical examiner may have the discussion about the death with an appropriate person who had known the deceased.

- 7.48 The existing process often leaves families uncertain about what caused the death of their loved one. Sometimes this is due to a lack of a proper explanation, and because the MCCD is often given to the family in a sealed envelope to be delivered on behalf of the doctor to the registrar. This new requirement of a discussion with the bereaved provides an effective cross-check of the account of events given by the doctor who treated the deceased and claims to identify the cause of death. The Shipman Inquiry considered that a cross-check would deter any doctor who might be tempted to conceal activity such as an error or neglect.
- 7.49 Regulation 9 describes arrangements the medical examiner must make, which might involve a conversation in person with the bereaved or over the telephone. Our pilot sites have found that in most cases the bereaved are happy for the conversation to take place over the telephone. For the purposes of these regulations, the bereaved family can be a member of the family who might go to register the death (prospective informant) or a person that a medical examiner considers appropriate to discuss the cause of death, such as where there is no next of kin. The person who has the conversation with the medical examiner's office will be asked to sign a form confirming the discussion. The informant (even where the informant was not party to the discussion) may also sign this form.
- 7.50 Any concerns raised during the conversation may result in the medical examiner or an officer discussing the death with a coroner or the coroner's office, which may then require the medical examiner to refer the death to the coroner.

Regulation 10: Medical examiner's referral to senior coroner

- 7.51 Whilst undertaking a scrutiny of all the information for a death certified by a doctor, a medical examiner might find that he or she is under a duty to notify a senior coroner of a death because there is reason to suspect that the death is unnatural. Regulations made under section 18 of the Act will prescribe the requirements for the medical examiner (as a registered medical practitioner) to notify the senior coroner, including what information is required in doing so. A medical examiner may also need to refer the death to the coroner because she/he is unable to confirm the cause of death. Regulation 10 describes the information that must accompany such referral to the coroner.
- 7.52 Once the medical examiner is made aware by the coroner of his or her decision to investigate a death, the medical examiner will notify the attending

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practitioner to cancel any certificates. Regulation 10(8)(a) requires the word “cancelled” to be written across the face of the cancelled certificate. If the coroner’s decision is not to investigate a death, regulation 10(4)(a) stipulates that the coroner must give reasons for that to the medical examiner who may either advise an attending practitioner to prepare a fresh certificate under regulation 11 or confirm the certificate under regulation 12.

Regulation 11: completion of a fresh attending practitioner’s certificate

- 7.53 Regulation 11 enables the medical examiner to invite the qualified attending practitioner to issue a fresh certificate. This might be where an examiner is unable to confirm the cause of death stated by the certifying doctor or the cause is incorrect. After discussions between the medical examiner and the qualified attending practitioner, the practitioner may feel able to prepare a fresh certificate with a different cause of death. The process for issuing a fresh certificate is set out in regulation 15.
- 7.54 When a disagreement occurs after an MCCD has been prepared and a copy has been provided to a medical examiner, the referral to a coroner would be made by the medical examiner under regulation 10(1)(a). This will only occur when a medical examiner is unable to confirm the cause of death and after discussions with the attending practitioner, where he or she is not willing to prepare a fresh certificate and amend the cause of death.

Regulation 12: medical examiner’s confirmation of APC and notification to the registrar

- 7.55 After the medical examiner has scrutinised a copy of the APC, made all the necessary enquiries and spoken to the family, and confirms the cause of death stated on the APC, the examiner will complete part A of the ME-2(A) form the *statutory notification of a confirmed cause of death* form as in regulation 12(2)(a) and send a copy to the qualified attending practitioner and registrar on the same day, as required by regulation 12(2)(b). We expect that in some instances the form will be handed to the practitioner (for example where the medical examiner’s office is on a hospital site) otherwise it would be sent by e-mail or fax to avoid delays.
- 7.56 The registrar will need to check if Part B of the ME-2(A) form is signed by the bereaved to confirm that the mandatory conversation between a family member and the medical examiner’s office has taken place. At this point the signature will have been taken if the conversation took place face to face. Usually the conversation is over the telephone and the registrar will need to obtain the signature when the informant arrives to register the death. The reforms will introduce a key change to the status of the certificate prepared by

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a doctor - it will no longer be accepted for the purposes of registering a death without a date added on the certificate to show a medical examiner's confirmation and a transmission of the ME-2 (A) notification to the registrar.

Regulation 13(1)(a): Adding medical examiner's confirmation date on APC

- 7.57 Once the medical examiner has completed his scrutiny of the APC, the examiner will notify the attending practitioner by sending a ME-2(A) form. The attending practitioner must ensure that the date of the medical examiner's confirmation is added on the original APC as required by regulation 13(1)(a). The attending practitioner must without delay and no later than two days from the medical examiner providing a notification of the confirmed cause of death take reasonable steps as required by regulation 13(1)(b) to make the prospective informant (usually a member of the bereaved family) aware that the certificate is ready for collection. In practice, the person issuing a confirmed APC (usually a ward nurse in a hospital or a practice manager in a GP surgery) will write the date of confirmation in a box that has been added to the certificate for this purpose.
- 7.58 Guidance on the back of the APC will state the purpose of the date and the requirement to take the APC to register the death within five days of that date. The Coroners and Justice Act 2009 made a consequential amendment to the Births and Deaths Registration Act 1953 so that the informant must provide required information of the death to the registrar within five days start from the date on which the medical examiner notifies the registrar that he or she has confirmed a cause of death certified by an attending practitioner, or certified the cause of death. The intention of the five day requirement in the Death Certificate Regulations is to align with this requirement.

Regulation 13(2): Collection of a confirmed APC

- 7.59 A person who intends to register the death, called the 'prospective informant' or someone who they nominate must collect the confirmed APC, which in a hospital is often from a hospital bereavement service. Regulation 13(1)(d) allows the prospective informant to ask the attending practitioner to send the certificate by registered post or recorded delivery service to an address given at the time such a request is made.
- 7.60 There is a change in current practice, namely for the certificate to be made available in an unsealed envelope. This is intended to make the process more open for the bereaved and reflects the change in legal status of the medical certificate of cause of death. The informant will no longer be required to deliver the certificate to the registrar on behalf of the certifier. Instead the duty will be on the prospective informant to whom the certificate is issued to

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deliver it to the registrar as prescribed in regulation 13(2) within five days of the medical examiner's confirmation date on the attending practitioner's certificate.

Regulation 14 & 15: Invitation by registrar to prepare fresh APC and steps to be taken

- 7.61 There are two occasions when an attending practitioner might be asked to issue a fresh APC - either by a medical examiner under regulation 11 described earlier or by a registrar under regulation 14. In terms of the latter, this is likely to happen when discussions with an informant during registration suggest the cause of death confirmed by a medical examiner is based on incomplete information or where an informant has provided new information which suggests the stated cause of death is incorrect or a death may need to be investigated by a coroner.
- 7.62 At present registrars act as safety net because there is no system for the scrutiny of MCCDs other than where a death has been referred to the coroner. In future, registrars will not be required to fulfil this role. It is the intention of the General Register Office to remove the duty on registrars to refer certain deaths to the coroner contained in regulation 41 of the Births and Deaths Registration Regulations 1987. Instead where an informant raises any concerns about the cause of death at the time of registration, the registrar will discuss the concerns with the medical examiner's office. Similarly, where an informant refuses to sign Part B of the ME-2 form, the registrar should speak with the medical examiner's office. This will help reduce potential delay and inconvenience to informants particularly where this avoids the need for a fresh appointment to be made to complete the registration, which often happens currently when a registrar refers a death to the coroner.
- 7.63 Provisions in regulation 14 require registrars to discuss the case with the medical examiner's office to establish whether a fresh certificate is required or the involvement of a coroner is more appropriate. At this point, the registrar will need to obtain the contact details of the certifier and invite him/her to complete a fresh attending practitioner's certificate.
- 7.64 The attending practitioner who agrees to issue a fresh APC must complete the steps in regulation 15 and take steps to cancel the superseded certificate as required by regulation 15(2)(d). The steps in regulation 15 include preparing a fresh certificate and providing information relevant to establishing the cause of death additional to the information already provided under regulation 4(1)(c) (administrative and clinical information). The original certificate must be marked "cancelled" and returned to the medical examiner's office. In this instance, there is no need for the further discussion about the cause of death

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with the bereaved required by regulation 9. However, there is a requirement for the medical examiner to issue another ME-2(A) statutory confirmation to the practitioner and notification to the registrar.

Regulation 16: QAP - Subsequent unavailability to fulfil duties

- 7.65 We have put a provision in regulation 16 to allow for the eventuality of an attending practitioner who, having prepared a certificate is then not available within a reasonable period of time to complete the further duties (i.e. sending the fresh certificate to medical examiner for scrutiny together with any additional relevant information to establishing the cause of death). The duty to complete the process to accompany the fresh certificate passes to another attending practitioner who meets the criteria of a qualified attending practitioner in regulation 3. We believe such a provision is necessary to minimise delays in the new process.

Part 3: Medical Examiner's Certificate (Regulations 17 to 21)

Regulation 17(1): Senior Coroner's referrals to medical examiner for certification

- 7.66 The only circumstance in which a senior coroner may refer a death to the medical examiner for certification is:
- a) where there is no qualified attending practitioner or none is available in a reasonable period following the death; and
 - b) the coroner has decided that the death is not one which he or she has a duty to investigate under section 1(1) (duty to investigate certain deaths) of the Coroners and Justice Act 2009.
- 7.67 It is our intention to limit the number of deaths that a medical examiner certifies, given that their primary role is to provide independent scrutiny of attending practitioners' certificates. Medical examiners are too far removed to certify deaths, except in the exceptional circumstances described above, as they would have had no involvement in the care of the deceased.

Good practice form from the Coroner to the Medical Examiner (similar to the current Form A (or 100A))

- 7.68 When a coroner refers a death to a medical examiner for certification, the referral must be accompanied by the reasons for deciding not to investigate and a copy of any information the coroner relied on to reach his/her conclusions. We are proposing to develop a good practice form based on information from the coroners' electronic case management system. The proposed good practice coroner form is expected to replace and extend the non-statutory Form A (or 100A) that coroners send to registrars to confirm that the coroner has no further interest in a death that has been reported by a doctor or a registrar. The difference between the Form A and the proposed good practice coroner form is that the former states the decision not to investigate whereas the latter will provide reasons and associated information.
- 7.69 We understand the information which coroners rely on to make their decision, which usually includes a police report and notes of preliminary enquiries, will continue to be assembled by coroners' officers. However, this information may either be provided in a local format, or in the form of a report from the coroner's case management system by a coroner's office to the medical examiner when referring a death for certification.

Regulations 18 - 22: Completion of a medical examiner's certificate, discussion of death and notification to registrar

7.70 The requirements in regulation 19 for the medical examiner's scrutiny of the cause of death before preparing a certificate are almost identical to the requirements of the examiner when scrutinising an attending practitioner's certificate under regulations 8. In addition, the requirements under regulation 20 to offer the family an opportunity to discuss the death with the medical examiner are almost identical to the requirements for such a discussion in regulation 9. There are also similar requirements under regulation 22 to those in regulation 12 in terms of notify the registrar once the cause of death has been established. The reforms do, however, prescribe separate certificates when a medical examiner is the certifier – see below. In this instance the same medical examiner will complete a ME-2(B) form '*Medical Examiner's Notification of certified cause of death*' to notify the registrar that the scrutiny process has been duly completed and the cause of death stated on the Medical Examiner's Certificate is established. We consider the medical examiner to be sufficiently independent to do both unless there is a conflict of interest – see the draft regulations on Medical Examiners.

Regulation 21: Medical examiners notifying or referring a death back to coroner

7.71 In regulation 21 where a medical examiner is unable to establish the cause of death after carrying out the functions in regulations 19 or 20, the medical examiner must refer the death to the coroner. This is in addition to any duty to notify the death to the coroner under regulations made under section 18 of the Act.

Regulation 22: Finalisation and collection of the Medical Examiner's Certificate and Registration

7.72 Following completion of the steps in regulations 19 and 20, the medical examiner will be required to complete the medical examiner's certificate followed by notification to the registrar. The family will be notified that the medical examiner's certificate is available for collection or on request can be sent to them.

7.73 The registrar must, as with all certified deaths, wait to receive the medical examiner's notification, in this instance an ME-2(B) form, before registering a death or, where burial or cremation needs to take place on an urgent basis, before issuing a "Green Form" authorising disposition prior to registration.

Regulation 23: Request for fresh medical examiner's certificate by registrar

- 7.74 Registrars will need to discuss with a medical examiner, or a member of his or her office, any new information provided by the informant or concerns raised about the circumstances surrounding the death, which suggests that the cause of death stated on a medical examiner's certificate is incorrect. If necessary, and after the discussion, the registrar will invite a medical examiner to issue a fresh medical examiner's certificate as prescribed in regulation 23.
- 7.75 The General Register Office guidance to registrars will say that all cancelled certificates, together with paper copies, if any, of the medical examiner confirmation forms ME(2)A and ME(2)B should be returned to the medical examiner's office for archiving.

Requirements and duties on the informant – regulations 13(2) and 22(4)

- 7.76 In the current system, a bereaved member of the family who is qualified and liable to act as informant for the registration of death is given the MCCD in a sealed envelope and asked to deliver it to the registrar on behalf of the doctor.
- 7.77 In the new system, the duty to notify the registrar of a death will continue to be in place but the prospective informant or another nominated person will need to collect the confirmed certificate from the bereavement office in a hospital or from a GP practice, or request that it be sent to them. The informant will need to deliver it to the registrar to register the death under Part 2 of the Births and Deaths Registration Act 1953. An important change is the addition of a date in a box labelled "medical examiner's confirmation date" on the certificate prepared by the attending practitioner, which will indicate the start of the five day period for the purposes of registering a death. This confirmation date will be added to the attending practitioner's certificate once the medical examiner has confirmed to the doctor that there are no concerns and s/he is confirming the cause of death stated on the certificate. For Medical Examiner's Certificates, the five day period will commence from the date that that certificate was completed, as specified in that certificate. These dates will align with the date that the registrar was notified of the confirmation/completion. It is these dates that the bereaved will need to note for registration purposes.
- 7.78 The person with whom the death has been discussed will be made aware of their duty to sign part B of the ME(2)A or part B of the ME(2)B form as described in regulations 9(4) and 20(4). The informant may also agree to sign this form, even if the informant was not a party to the discussion, as the conversation about the death between the medical examiner and the

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bereaved will usually take place over the telephone, it is expected that registrars will need to obtain the signature at registration. However, when the conversation takes place in person it is possible that the medical examiner's office or the bereavement service might obtain the signature from the appropriate person, usually a member of the bereaved family.

Part 4: Miscellaneous Provisions (Regulations 24 to 27)

Manner of providing documents

7.79 Regulation 24 allows for electronic transmission of documents under the regulations (except where originals are required), including copies of MCCDs from the certifier to the medical examiner's office, that are required by these regulations. The new MCCDs will be A4 size to enable faxing, where necessary.

Manner of completing medical examiner's notifications

7.80 We expect medical examiners' offices will use a secure e-mail connection (e.g. NHS.net or Government Connect) to transmit a copy of the appropriate ME-2 form to the register office with an advanced electronic signature added to the form. Where it is not possible to e-mail the ME-2 form, it may be transmitted by fax or delivered by any other means. Regulations 24 and 25 set out the relevant provision for this purpose.

Requirements during a period of emergency

7.81 Regulation 26 relates to a period of emergency when the medical examiner process will be suspended, enabling registrars to accept Attending Practitioner's Certificates (MCCDs) without a medical examiner's scrutiny or confirmation of cause of death. During this period, any attending practitioner will be able to certify a death and where there is no attending practitioner available within a reasonable period of time, the certification functions will be extended to any registered medical practitioner. This special provision will free up all the registered medical practitioners who are working as medical examiners to provide care or certify the dead.

Prescribed Certificates and Forms

7.82 Regulation 27 sets out that the forms and certificates in schedules 2 to 7 will be made available by the Secretary of State. With the introduction of the role of medical examiner and certain statutory functions, the Coroners and Justice Act 2009 refers to the MCCDs (including neonatal MCCD) as either the attending practitioner's certificates (APC) or the medical examiner's

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certificates (MEC) depending on who certifies a death. Introducing separate MCCDs will also help the registrars and others involved in the process to easily identify whether an attending practitioner or a medical examiner had certified the death.

- 7.83 The World Health Organisation Mortality Reference Group has developed a new death certificate template in order to collect data consistently in all countries. We have reflected some of the recommendations, including adding a line 1(d) in Part I of the MCCD 'cause of death box', as recommended by the World Health Assembly in 1990. Line 1(d) allows the cause of death to be recorded more completely. The other significant change is the addition of a box for deaths involving pregnancy of women, again as recommended by the Assembly in 1990. The pregnancy box is intended to improve the identification of maternal deaths. Otherwise, the changes have been kept to a minimum to retain some familiarity for doctors completing the certificates. The changes are briefly explained below.
- 7.84 Doctors will no longer be required to prepare a MCCD for any death that clearly needs to be investigated by a coroner. We have therefore removed Box A on the back of the MCCD which states "I have reported this death to the coroner for further action". Box B - about supplying additional information for statistical purposes - has been moved to the front of the MCCDs as a new option 4.
- 7.85 Employment related deaths will in future be notifiable to a coroner under section 18 regulations without the need for a doctor to prepare a MCCD. The tick box relating to employment and whether the death might have been due to, or contributed to, by the employment followed at some time by the deceased is no longer on the new MCCDs.
- 7.86 Doctors will need to provide some additional information on the certificates including their GMC number and the deceased person's NHS number. NHS numbers are available on the patient's medical records, which doctors must review to complete the MCCD. Over 99 per cent of patients have a NHS number. In the rare occasions that a NHS number is not available, completion of the MCCD must not be delayed. Doctors who have checked the medical records and not found the patient's number can record 'XXX XXX XXXX' on the MCCD.
- 7.87 Once the MCCD has been given to a family member it will be taken to the registrar who will register the death. Currently if the family member or friend provides the NHS number of the deceased person to the registrar, he or she will record it - but this rarely happens. The change to the MCCD will allow the registrar to record the NHS number in almost all cases.

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- 7.88 After the registrar registers the death, the registrar's record is matched against the health records on the Personal Demographics Service (PDS). This often requires the National Back Office to manually review records to identify the correct patient. Inclusion of the NHS number on the MCCD by doctors will reduce the number of records that need to be manually processed allowing the National Back Office to focus on other data quality issues.
- 7.89 Doctors will notice that the new MCCDs no longer require them to add information on qualifications and residence. Instead, they will add their GMC number and print their name.
- 7.90 Other mandatory changes include information about the approximate interval between onset and death. Options (a) to (c) on whether the deceased person had been seen is now more explicit and refers to whether the deceased person had been "externally examined" after death. The body will be externally examined by the certifying doctor if he or she chooses to do so, or the medical examiner or someone on their behalf, if the medical examiner is of the opinion that an examination is necessary. In all cases, the results of the examination must be made available to the medical examiner as an integral part of his or her scrutiny. The information requirements in the separate MCCDs are however, identical or very similar.
- 7.91 The "Notice to Informant" prescribed by the Registration of Births and Deaths Regulation 1987, which is a tear-off form attached to existing MCCDs will no longer be required. Medical practitioners or certifying doctors will not be legally responsible for the delivery of the death certificate to the registrar. Instead a new duty will be placed on the prospective informant or another nominated person to collect the confirmed certificate and deliver it to the registrar. Information for the prospective informant will be provided on the back of the new MCCDs as well as in any literature provided by the local bereavement office.

Attending Practitioner's Certificate(s)

- 7.92 The attending practitioner, as with the current process, will either prepare an Attending Practitioner's Certificate (revised MCCD) in schedule 2 - or a revised MCCD for live-born children dying within the first twenty-eight days of life in schedule 3 - as required by regulation 4. The unique box on MCCDs prepared by an attending practitioner requires a date to be added once the medical examiner has confirmed that he or she has completed the scrutiny process and confirmed the cause of death. The date is expected to be the same as that on the ME-2 form(s) sent by the medical examiner to the registrar confirming the cause of death stated by the doctor on the MCCD.

Medical Examiner's Certificate(s)

- 7.93 A medical examiner may also prepare similar certificates for cause of death under regulation 22 (2)(a), if required to do so by a coroner when there is no qualified attending practitioner to prepare an attending practitioner's certificate within a reasonable period after the death. The certificates prepared by the medical examiner will look similar to those prepared by attending practitioners except for the absence of a box requiring the date of medical examiner's confirmation. The medical examiner certificate for live-born children dying within the first twenty-eight days of life will be in schedule 6 and for other deaths in schedule 5 of the Death Certification Regulations.

ME-2(A) Medical examiner's statutory confirmation of cause of death

- 7.94 The ME-2(A) form '*Medical Examiner's Notification of Confirmed Cause of Death*' (see schedule 4) has two functions. Following the medical examiner's scrutiny of the cause of death, a copy of the ME-2(A) form will be sent by email or fax or handed to the attending practitioner without delay to confirm that the medical examiner is satisfied that the cause of death stated on the copy of the attending practitioner's certificate is correct. The attending practitioner will take the date of the confirmation on the ME-2(A) form and add it to the original attending practitioner's certificate (MCCD) before arrangements are made for this certificate to be given to the bereaved to take to a registrar to register the death. The copy of the ME-2(A) should be placed with the deceased (i.e. patient's) notes. Where the medical examiner's office and bereavement office are in close proximity to each other, the medical examiner's confirmation may be given orally to the attending practitioner and the ME-2(A) form retained by the medical examiner's office for audit purposes.
- 7.95 The medical examiner will transmit the ME-2(A) form to notify the registrar, as prescribed by regulation 12(2)(b), that the cause of death stated on the attending practitioner's certificate is correct. The death can be registered when the person qualified to register the death arrives at the registrar's office with the confirmed attending practitioner's certificate. The certificate is identifiable as 'confirmed' by the date added to the box *Date of Medical Examiner's Confirmation*.

ME-2(B) Medical Examiner's Notification of Certified Cause of Death

- 7.96 The ME-2(B) form is the '*Medical Examiner's Notification of Certified Cause of Death*' (see schedule 7) prescribed in regulation 22(2)(b). It serves a different purpose, although much of the information is similar to that provided on ME-2(A). In this instance, the cause of death will have been certified by a medical

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examiner on the medical examiner's certificate – see above. However, the role of the medical examiner in completing the two ME-2 forms is different. By completing a ME-2(B) form, the medical examiner will declare that he or she has established and certified the cause of death rather than confirmed cause of death as on ME-2(A) form.

- 7.97 For both the ME-2 forms, the registrar must check that Part B on the appropriate form is signed to confirm that the medical examiner or an officer on the medical examiner's behalf had discussed the death, usually with a member of the bereaved family and offered an opportunity to mention any matter which might cause the medical examiner's office to refer the death to a coroner. It is intended that registrars will only be able to proceed with registering a death or issuing a certificate known as the "Green Form" for burial or cremation, once he or she has a fully completed ME-2 form, which includes a signed Part B.
- 7.98 The certificates (MCCDs) and the medical examiner forms (ME-2s) are available separately alongside other related consultation documents. However, the prescribed forms and certificates will be eventually inserted in their respective schedules when the statutory instruments are published.
- 7.99 Regulation 28 confirms that the Chief Medical Officer guidance on completing the new medical certificates of cause of death and medical examiner's forms will be issued. This guidance is under development in consultation with key parties.

The Death Certification (Medical Examiners) (England) Regulations

7.100 The Coroners and Justice Act 2009, as amended by the Health and Social Care Act 2012, put duties on local authorities in England, and local health boards in Wales, to appoint medical examiners for their area, establish a local medical examiners service, and ensure achievement of required standards and levels of performance by medical examiners. Local authorities already have responsibility for coroners and registration services; both these services will need to work with the local medical examiner services and are key to an efficient death certification process.

New statutory role of medical examiner

7.101 In an earlier consultation¹⁶ in 2007, we introduced the role of a medical examiner. It was envisaged that the main responsibilities of a medical examiner might be to speak to the certifying doctor, the deceased's family, or other persons who may have relevant information about the death. We said that medical examiners will need to obtain and consider information from health records and any other source. These responsibilities are part of the medical examiner's scrutiny process, described in regulations made under section 20 of the 2009 Act, leading to confirmation of cause of death stated on a certificate prepared by an attending practitioner.

7.102 We explained how medical examiners might support local clinical governance teams with information from certificates on trends and unusual patterns of deaths. The public health functions of local authorities will also benefit from the surveillance information.

7.103 Since the 2007 consultation, the death certification pilot projects have shown other areas that might benefit from the role of medical examiners as described in regulations made under section 19 of the 2009 Act, in addition to the activities required by section 20 regulations.

7.104 Medical examiners must be registered medical practitioners with at least five years full registration with the General Medical Council and a licence to practise. In this respect, medical examiners and medical referees fulfil similar criteria. However, a key requirement for medical examiners is the specific training that they should complete before they start work. We believe this training requirement for the new medical examiners goes some way to

¹⁶ Consultation on Improving the Process of Death Certification (COI for the Department of Health, July 2007)

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address the Shipman Inquiry's criticism that existing medical referees "receive no training".

- 7.105 In addition to the training requirements, the skills and competencies essential for the role of medical examiners are set out in the person specification drawn up by the National Task Team on Medical Examiners. Both the person specification and a detailed job description, intended to support local authorities and local health boards with the appointment process, will be made available in guidance to local authorities.
- 7.106 The Coroners and Justice Act 2009 requires each local authority and local health board to "appoint enough medical examiners, and make available funds and other resources, to enable those functions to be discharged in its area". The word "appoint" allows medical examiners to be employed, contracted or commissioned on a part-time or full-time basis depending on all service configuration.
- 7.107 As discussed earlier, we expect that many medical examiners will provide two or three sessions or programmed activities a week alongside their existing work in senior medical or general practitioner roles. This means that the configuration of a typical local medical examiner service will require a small team of medical examiners to work on a rotational basis, and who are unlikely to operate in isolation from each other. In fact the service may require medical examiners to be able to pick up and complete a scrutiny process on a death which may have been started off by another medical examiner. It is worth noting that the Shipman Inquiry found the "variability in practice among medical referees" is the result of them "operating in isolation from each other", a weakness in the current system. We believe this is unlikely to happen in the medical examiner system.
- 7.108 Regulation 6(1)(i) provides medical examiners with the function of participating in peer reviews and self-audits.

Regulation 3: Terms of appointment and termination of appointment of medical examiners

- 7.109 The requirements in regulation 3 are supplemented by regulation 4 of the National Medical Examiner (Additional Functions) Regulations, which enables the National Medical Examiner to issue to guidance to local authorities and local health boards regarding the person specification and job description which are to apply in respect of appointments of medical examiners. Such guidance will help ensure that medical examiners will have the expertise, credibility and communications skills to foster both public and other professionals' confidence in the system.

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- 7.110 Appointing authorities must ensure that the terms of appointment of medical examiners includes a provision that the appointment must be terminated immediately in the event that the examiner ceases to be a registered medical practitioner. A further provision on termination of appointment is set out in regulation 3(3) and relates to a medical examiner meeting the standards and levels of performance published by the National Medical Examiner (NME).
- 7.111 In order to maintain their licence, doctors will need to demonstrate to the General Medical Council periodically, that they are up to date and fit to practise in the role they work in. The GMC has published general guidance on what doctors need to do to achieve revalidation. This has been supplemented, at the request of the GMC, with specific guidance from the Royal College of Pathologists as the lead college for medical examiners. This guidance will be updated in the light of experience of running the medical examiner service.
- 7.112 The National Medical Examiner (Additional Functions) Regulations provide for the NME to publish standards on levels of performance that medical examiners are expected to attain. We envisage that most medical examiners will work on a part-time basis. They will come from a range of specialties and expertise which otherwise would not be possible with a single medical examiner working full-time and in isolation.
- 7.113 It is therefore likely that we will need to review regulation 5 following this consultation, as (for example) a requirement for medical examiners to maintain clinical practice may be influenced by GMC's revalidation requirements and any standards that the Royal College of Pathologists introduces for that purpose.

Local authorities and collaborative arrangements

- 7.114 Our costing of local medical examiner services shows that smaller local authorities in England may want to consider collaborating to provide a shared medical examiner service which is more cost efficient. We have placed specific provisions in regulation 3(4) which provides that a term of appointment is for medical examiners appointed by one authority to carry out work in another authority area. This will help enable reciprocal arrangements between local authorities - for example, to cover unforeseen absences or where such an arrangement provides a good 'out-of hours' service to the community where there is known need for urgent certification to enable funerals to take place quickly in accordance with certain faith practices.

Regulation 4: Remuneration of medical examiners

- 7.115 We have not prescribed the level of remuneration for medical examiners (or their support staff) in regulation but provide in regulation for local discretion and agreement between the appointing local authority and the medical examiner. However, guidance will advise that remuneration should be such to recruit the right calibre of medical examiners that fulfil the regulatory requirements and meet the person specification issued by the National Medical Examiner. For the purposes of the impact assessment and in the absence of the ability to test out recruitment at this moment in time, it is assumed that the mid-point range of a consultant salary might be appropriate remuneration.
- 7.116 In all other respects, guidance will say the appointing authority may set the terms and conditions of appointment of a medical examiner bearing in mind that the terms should be such that would attract candidates of a calibre to enable local recruitment and retention and a motivated workforce to provide a good quality local medical examiner service.

Training requirements of medical examiners

- 7.117 The curriculum and training for medical examiners has evolved from early work initiated by a multi-disciplinary group of the Academy of Medical Royal Colleges, which led to the Academy nominating the Royal College of Pathologists as the lead college for medical examiners. The College has established a Medical Examiner Committee to work with e-Learning for Healthcare on developing an e-learning module for medical examiners. The training requirements for medical examiners will be issued by the National Medical Examiner in guidance to local authorities in England and local health boards in Wales.
- 7.118 The different elements of the training are not prescribed but we expect that guidance will describe the training in two parts: an e-learning medical examiner module and a face to face element.
- 7.119 Work on the e-learning module for medical examiners has been underway for some time, led by the Royal College of Pathologists' Medical Examiners Training Committee, in conjunction with e-learning for Healthcare and pilot project medical examiners and coroners. The module is available to staff working in the NHS as well as other related services involved in death certification at:

http://www.e-lfh.org.uk/projects/medical_examiner/index.html

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7.120 For more information about accessing the e-learning module visit the e-Learning for Healthcare website as above.

Regulation 5: Independence of medical examiners

7.121 Our aim as proposed in regulations is for the medical examiner service and the medical examiners that belong to it, to remain independent in their professional role. For this to happen, section 19(5) of the Coroners and Justice Act 2009 clearly states that nothing in the Act or regulations gives a local authority or local health board any role in relation to the way that medical examiners exercise their professional judgement.

7.122 The integrity of the new system relies on regulation 5, which sets out steps that must be taken by a medical examiner if they find themselves insufficiently independent when exercising their functions.

Additional Functions of medical examiners

7.123 Regulation 6 sets out additional medical examiner functions to those in section 20 regulations. These additional functions are described below.

Advisory role

7.124 Regulation 6(1)(a) and (b) relates to the medical examiner's advisory role. We understand the task of preparing an MCCD (to be known as the attending practitioner's certificate) is often delegated to junior doctors in hospitals. Junior doctors do not always have easy access to senior clinicians to discuss their initial conclusions on the cause of death. In future, doctors will be able to access general advice from medical examiners who will be senior doctors with at least five years of experience.

7.125 We envisage that the medical examiner's advisory role will benefit other local services. It is generally recognised that deaths certified incorrectly have an adverse impact on the quality of the mortality statistics which inform public health policy. Coroner services should also see improvements in less inappropriate or over-reporting of deaths. The Ministry of Justice in their 2010 consultation highlighted that some 45 per cent of deaths are reported to coroners each year – this is 15 – 20 per cent higher than in any other country with coroners whose responsibilities are broadly similar.

7.126 The medical examiner's advisory role is extended to providing general medical advice to coroners on a case by case basis, which may mean, for example, that there is no need for coroners to commission post-mortems in respect of some deaths. However, any advice to coroners is expected to be

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general medical advice that can be provided without scrutiny of records or with only the proportionate scrutiny of these usually required to confirm or establish a cause of death or refer the death to a coroner. This limitation is intended to safeguard the resources of medical examiner services for their primary purpose of scrutiny and confirmation of cause of death stated on certificates.

Establishing good working relationships

7.127 It follows that the new medical examiner's office will encounter a range of people and services that play a role in existing death certification process and will continue to do so. In order to ensure the efficient running of the new process, medical examiners may feel the need to either establish or take part in developing local protocols as provided for in regulation 6(c).

7.128 Similarly, there might be other needs for local protocols, for example, to complement local procedures for organ retrieval where a medical examiner may need to undertake scrutiny promptly to avoid any risk of delay with retrieval resulting in an organ becoming unviable for transplant.

Record keeping requirements

7.129 Regulation 6(d) provides medical examiners with the function of maintaining good records of information.

By records, we mean:

- Copies of attending practitioners' and medical examiners' certificates and any associated ME-2 forms used for confirmation of cause of death;
- All information provided by the attending practitioner under section 20 regulation 5 "information to accompany a copy of attending practitioner's certificate given for scrutiny", with the exception of health records;
- Information provided by a coroner for deaths notified to a coroner by a doctor which do not need to be investigated. Most of the information will relate to deaths where the coroner has advised the doctor that he or she can go ahead and prepare a certificate. Some may relate to deaths that a coroner is referring to a medical examiner for certification under section 20, regulation 17 "senior coroners' referrals to medical examiner for certification"; and

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- Records referred to in section 20, regulation 8 (3), 9(c), 19(1)(c) and 20(1)(c)

7.130 In guidance, we intend to ask medical examiners to have due regard to principles in the Data Protection Act (1988), the Caldicott Report (2013), and Records Management: NHS Code of Practice (2006).

Surveillance role

7.131 It is likely that medical examiners will be in a position to observe any trends and report serious concerns about poor care of the deceased person, following local procedures for reporting concerns of a clinical governance nature. Regulation 6(f) gives medical examiners the function to obtain information about the outcome of any such report made.

7.132 Information about the cause of death and any emerging trends or unusual patterns is expected to be readily available to medical examiners from their scrutiny functions under section 20 regulations. It is in this respect of a local medical examiner service that we see benefits emerging for its local public health service, which in time should readily have access to local mortality data. Medical examiners may from time to time be required to provide such reports for example to the director of public health as outlined in regulation 6(g)(ii).

7.133 Similarly, under regulation 6(g)(iii) medical examiners must provide information to support Local Safeguarding Children Boards in their statutory function of collecting and analysing information about the deaths of children in their area. We believe medical examiners should not be required to provide health records, but may need to provide pertinent information such as the cause of death of the child. The information provided should be limited to children's deaths where there is no coroner investigation, to avoid duplication of information that a coroner may decide to release.

Poor quality of certification and identifying training needs of doctors

7.134 The poor quality of certification is something that the Shipman Inquiry identified. Past audits (Swift and West 2002¹⁷) of MCCDs showed that only 55 per cent of certificates were completed to a minimally accepted standard, and many of these failed to provide relevant information to allow adequate coding of cause of death to the International Classification of Diseases 10th revision (ICD-10). Nearly 10 per cent were completed to a poor standard, being illogical or inappropriately completed. Although that audit is over ten

¹⁷ Death certification: an audit of practice entering the 21st century" (Swift and West, 2002, Journal of Clinical Pathology, 2002;55;275-279

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years old, more recent studies have also found shortcomings in the quality of certification, despite its introduction into formal undergraduate training.

- 7.135 The Office for National Statistics carried out a case study¹⁸ analysing just over 5000 records supplied by the pilots, comparing the cause of death proposed by the certifier and the cause confirmed by a medical examiner after scrutiny. Medical examiner scrutiny can change the number, sequence and type of conditions mentioned on the Medical Certificate of Cause of Death. This suggests that medical examiners' analysis of the information relating to the cause of death, obtained both from the medical notes and in discussion with relatives, results in better understanding of the sequence of conditions that led to the death. If the conditions and sequence are recorded more fully, this may lead a change in the underlying cause of death. The results of this case study indicate that the medical examiner scrutiny is likely to affect trends in causes of death reported in mortality statistics.
- 7.136 The pilot projects have also shown that doctors welcomed advice from medical examiners and their officers on how to complete a certificate. As every certificate will need a medical examiner's scrutiny and confirmation before the certificate is accepted for registration purposes, registrars will no longer spend time querying poorly completed certificates or illegible writing. Given the working relationship between doctors and medical examiners, we have conferred an additional function on medical examiners in regulation 6(h) of identifying training needs of doctors who prepare certificates.
- 7.137 Regulation 6(i) requires medical examiners to keep their performance and service under review to help maintain standards.

Medical examiner's officers

- 7.138 The draft NME regulations do refer to the NME issuing guidance to local authorities and local health boards in relation to the specification of qualification of officers appointed or assigned to act on behalf of medical examiners or assist medical examiners in the exercise of their functions and the job description.
- 7.139 In almost all areas, medical examiners will need to be supported by substantive MEOs or by people who provide an MEO function as part of their work for a related service.
- 7.140 The key requirement for a substantive MEO or a person providing the MEO function is that they have suitable expertise and sufficient independence, so

¹⁸ Office for National Statistics (2012) Death Certification Reform: A Case Study on the Potential Impact on Mortality Statistics, England and Wales www.ons.gov.uk/ons/dcp171778_288141.pdf

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that medical examiners can confidently delegate responsibility for use of information documented by the examiner to:

- Make enquiries to obtain additional information;
- Provide advice to, or talk with, qualified attending practitioners about their preliminary view of a cause of death or certified cause of death;
- Discuss a death with relatives or other appropriate people to offer them an opportunity to ask questions about the certified cause of death or to raise concerns that might require a fresh certificate to be prepared or the death notified or referred to a coroner; and
- Provide administrative support to the medical examiner with notifying or referring a death to a coroner.

The National Medical Examiner (Additional Functions) Regulations

7.141 Section 21 of the Coroners and Justice Act 2009 allows the Secretary of State to appoint a National Medical Examiner (NME) for England and Wales (after consulting the Welsh Government). The Act describes the NME's responsibilities as issuing guidance to medical examiners to make sure they carry out their functions in an effective and proportionate manner, and any other functions conferred by regulations.

7.142 The additional functions will encompass a role of providing professional leadership to some 500 registered medical practitioners who will take on the new statutory role of medical examiners alongside their other clinical practice. The Act requires the NME, as with all medical examiners, to be a registered medical practitioner who has been registered throughout the previous five years and practises as such or has done within the previous five years. We expect the post will be part time, enabling the NME to maintain some clinical practice or work as a medical examiner.

7.143 The NME will have the function of, among others matters:

- Advising the Secretary of State on matters relating to the functions of medical examiners and attending practitioners;
- Setting and issuing standards and performance levels that medical examiners are expected to attain in the service they provide, to ensure consistency in quality of delivery across England and Wales;
- Providing guidance to medical examiners to ensure that they carry out their work in an effective, professional and impartial manner; and
- Producing guidance on the curriculum and training for medical examiners.

7.144 We expect the NME to work closely with the Royal College of Pathologists, the lead college for medical examiners.

7.145 An interim appointment has already been made to advise the Secretary of State on implementation of the reforms. The Ministry of Justice has made a corresponding appointment of a Chief Coroner, who from time to time might need medical advice from the NME in relation to the causes of death, including on an individual case. At a national level, the reforms to the coronial and death certification systems will require collaboration on issues that affect

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both services and require a joint resolution. On an operational level, the death certification pilot projects have tested the death certification process in partnership with coroners and registrars to ensure that it delivers improvements for the bereaved. Regulations and standards will extend the need for collaborative working across related services. For example, section 19 regulations require medical examiners to participate in establishing, reviewing and updating local protocols. Service standards are expected to measure the quality of engagement with, among others, related services.

Regulation 2: Advice to the Secretary of State and the Chief Coroner

7.146 In Regulation 2 we propose that the NME has the function of providing advice to the Secretary of State in respect of attending practitioners and medical examiners carrying out functions relating to death certification under section 20 regulations or the section 19(4) regulations.

Regulation 3: Providing advice to the Chief Coroner

7.147 Local medical examiner services are likely to be in regular contact with coroner services in the area and will need to build a good working relationship, offering general medical advice to coroners when required. At a national level we propose that regulations confer on the NME the function to provide advice to the Chief Coroner when required in relation to cause of death in an individual case.

Regulation 4: Guidance to local authorities and local health boards

7.148 Regulation 4 refers to any guidance that the NME will issue to appointing authorities to support them with recruitment and appointment of medical examiners, including officers appointed or assigned to act on behalf of the medical examiners, or assist the examiner with their work. The guidance will include generic person specifications and job descriptions for a medical examiner and medical examiner's officers as well as training requirements.

7.149 The NME will have the function of issuing guidance on training requirements for medical examiners including any training that should be completed before carrying out their functions. As the new medical examiner service will be delivered by approximately 500 medical examiners (working on a sessional basis), the NME will also provide a leadership role. As the head of this new group of professionals, the NME will advise on the training of medical examiners and any specific requirements such as how many of the sessions in the medical examiner module should be completed before taking up the role.

Regulation 5: Standards and levels of performance of medical examiners

7.150 Regulation 5 relates to developing and publishing standards. The Royal College of Pathologists has developed '*Standards for the Delivery of the Medical Examiner Service*', which had been considered by the Death Certification National Steering Group and is a starting point for future work on standards.

7.151 The Steering Group reached a general consensus that standards must be measurable and must not cause undue burden on local authorities in their monitoring role. Furthermore, the group felt that standards should not duplicate any requirements that are already set in regulations, but may identify indicators to help measure the regulatory requirements.

7.152 A common indicator is the number of complaints from the users of a service for example, in this case, if the bereaved feel there is undue delay. These are initial observations on setting standards and wider views are welcome on whether these aspects are appropriate and what might measurable indicators look like:

- A local service that meets local population needs;
- Evidence of reasonable out of hours service provision that complements similar provision by related services and the appropriate provision of procedures that facilitate urgent certification where there is a known individual need for it;
- Information in place (e.g. leaflets or bereavement literature) about the medical examiner service for the bereaved;
- Evidence of local protocols with coroner/bereavement/registrars services;
- Complaints procedure for the bereaved and number of complaints;
- Throughput (i.e. efficient use of resources);
- Timescales (i.e. avoiding undue delay); and
- Quality of engagement with doctors, the bereaved and related services.

7.153 The NME, in conjunction with the lead college, may issue medical examiners' performance standards and procedures. Compliance with these standards and procedures will need to be monitored by a combination of self-audit and peer review. These are expected to cover:

- a) the quality, rigour and proportionality of scrutiny – including:
 - reviewing relevant records in a way that establishes the narrative of the last illness or condition and identifies any anomalies that might require further enquiries;

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- the appropriate use of contextual information on trends, unusual patterns and clinical governance issues; and
 - carrying out or arranging an external examination (unless there is a demonstrable reason that it is not required) and ensuring that this examination is completed in a way that complies with guidance set out in the e-learning materials.
- b) consistency in and rigour of scrutiny for all deaths, irrespective of any known individual need for urgent certification;
- c) maintenance of clear and complete records to enable:
- identification of local trends and patterns relating to deaths for which the medical examiner provides advice and scrutiny;
 - provision of any reports required by local authority / health board to monitor performance; and
 - quality reviews and peer audits.

Reports to the Secretary of State

7.154 Regulation 6 requires the National Medical Examiner to provide reports and information to the Secretary of State about death certification, the medical examiner service including standards or levels of performance attained by medical examiners.

7.155 The National Medical Examiner will require information from medical examiner services to inform these reports.

Annex B

Notification of Deaths to Coroners' Regulations

The draft regulations

8.1 Following the responses to the 2010 consultation paper and further dialogue with interested parties, we have produced draft regulations that require a registered medical practitioner to notify a coroner where a death has occurred in one or more of the following circumstances:

- a) as a result of poisoning, the use of a controlled drug¹⁹, medicinal product²⁰ or toxic chemical;
- b) as a result of trauma, violence or physical injury, whether inflicted intentionally or otherwise;
- c) is related to any treatment or procedure of a medical or similar nature;
- d) as a result of self-harm, (including a failure by the deceased person to preserve their own life) whether intentional or otherwise;
- e) as a result of an injury or disease received during, or attributable to, the course of the deceased person's work;
- f) as a result of a notifiable accident, poisoning or disease²¹;
- g) as a result of neglect or failure of care by another person;
- h) the death was otherwise unnatural;
- i) in prison, police custody or other state detention;
- j) where there is no attending practitioner as prescribed by regulations made under s.20 or no such practitioner is available to certify the cause of death within a reasonable period following the death; or
- k) the identity of the deceased person is unknown.

8.2 The draft regulations also prescribe information that must be provided in the notification. This includes information about the deceased, such as name, address, date of birth as well as the reason for making the notification (i.e. which of the above categories has been satisfied).

¹⁹ "Controlled drug" has the meaning given in section 2(1)(a) of the Misuse of Drugs Act 1971.

²⁰ "Medicinal product" has the meaning given in section 130 of the Medicines Act 1968.

²¹ "Notifiable accident, poisoning or disease" has the meaning given in section 7(4) of the Coroners and Justice Act 2009.

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8.3 We have published the draft regulations for consultation alongside this document. However, we wish to draw particular attention to a number of policy considerations.

“Notifiable” deaths

8.4 It has been suggested previously that the draft regulations should require medical practitioners to notify coroners of “reportable” rather than “notifiable” deaths. However, under the 2009 Act the Lord Chancellor may make regulations requiring a registered medical practitioner in prescribed cases to “notify” a senior coroner of a death of which the practitioner is aware, so “notifiable” is consistent with this. The term “reportable” is in itself rather misleading as deaths can be reportable by a doctor to the public health department but not a coroner, and there is also reference to “reportable deaths” in a different context in section 8(3)(c) of the Coroners Act 1988 (the 1988 Act).

8.5 The draft regulations adopt a format which requires a registered medical practitioner to notify a coroner in prescribed circumstances. The draft regulations then prescribe the format of the notification and the information that must be provided by the registered medical practitioner. Setting it out in this way not only resolves the difficulties of introducing the term “reportable” but also follows a more logical format of “where an event has occurred, a person is required to do the following...”.

8.6 The draft regulations also seek to eliminate the possibility of duplication of notification by disapplying the requirement if a registered medical practitioner believes the coroner has already been notified of a death. A practical concern has been raised whereby a number of medical practitioners have been involved in the care of the deceased prior to death, for example in a surgical environment. In the event of a death during surgery, we expect that an appropriate person will be agreed as being responsible for notifying the coroner, and therefore the remainder of the medical personnel will not be under an obligation to notify under the regulations.

“Unnatural” deaths

8.7 Under section 1 of the 2009 Act, coroners will be under a duty to conduct an investigation where there is reason to suspect the deceased “has died a violent or an unnatural death”. The term “unnatural” is not further defined in that Act or in other legislation, but is a term that is widely understood by those in both the coronial and medical professions to include any deaths that have not resulted from natural causes.

8.8 The majority of the categories prescribed in the draft regulations cover cases in which the death was “unnatural”. There may be exceptions to this, such as

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deaths in custody, deaths where there was no attending practitioner, where the cause of death was originally unknown or where the identity of the deceased is unknown but where the death was due to natural causes (although deaths under these circumstances may also be unnatural).

- 8.9 In response to the 2010 consultation, the Medical Protection Society suggested a category of “unexpected death” as this would allow for deaths that occur without any suspicion of human culpability and help to avoid any suggestion that coroners should be determining matters of civil negligence in the case of individuals.
- 8.10 Given that a coroner is under a duty to carry out an inquest where a death is unnatural, it is sensible to reflect this in the draft regulations. However, concern has been raised by other interested parties who believe that this could be taken by some medical practitioners to include natural deaths that would normally not be referred to a coroner, simply because the death was not expected to occur at the time. We therefore propose that the draft regulations refer only to “otherwise unnatural” which we believe encompasses all eventualities in which a medical practitioner believes a death should be referred.

Cause of death is unknown

- 8.11 Section 20(1)(a)(ii) of the Coroners and Justice Act 2009 allows regulations to be made requiring a registered medical practitioner who attended the deceased before his or her death (an “attending practitioner”) to refer the case to a senior coroner where the practitioner is unable to establish the cause of death. Where such a practitioner exists, but is unavailable to complete the medical certificate, another practitioner from within the same practice may complete the certificate so long as they attended the deceased within a year before the death.
- 8.12 We have considered whether this requirement should be reflected in the draft section 18 regulations as these prescribe all cases in which a death should be referred to a coroner. However, it is important to avoid duplication of statutory duties, so we propose that the duty to refer deaths where the cause of death is unknown to the attending practitioner should be reflected only in the section 20 regulations. This will be made clear in the guidance to the draft section 18 regulations.
- 8.13 Similarly, we envisage that where there is no attending practitioner, or where a practitioner has attended but no person is able to certify the death under the section 20 regulations, the coroner must be notified under regulation 3(4). Regulation 3(4) has been drafted to ensure it corresponds with regulations made under section 20(1).

Other categories of death

- 8.14 Poisoning, controlled drugs, medicinal products and toxic chemicals are covered in a single provision and no distinction is made as to whether the death was a result of deliberate or accidental intake of such substances as both would result in an unnatural death.
- 8.15 Similarly, where a death may have occurred as a result of trauma, violence or physical injury, the provision makes no distinction as to whether this was inflicted intentionally or otherwise as again the result would be unnatural death. The previous distinction as to whether it was inflicted by the deceased person or otherwise has been removed as trauma, violence or physical injury inflicted by the deceased would be covered by the self-harm provision.

Written and oral notifications

- 8.16 The draft regulations establish a principle whereby in order to reduce the burden on the registered medical practitioner, notifications to the coroner may be made orally where appropriate - for example where the medical practitioner does not have immediate access to a means of making a written notification. However we also recognise the need to ensure that information is recorded properly and accurately and that important information is not lost in the process of recording it. We therefore propose that where information is provided orally, a written account must be made by the coroner and in order to ensure its accuracy must be confirmed by the registered medical practitioner.
- 8.17 It has been suggested that the registered medical practitioner's confirmation should also be made in writing for authentication. The difficulty with such an approach is that it would place an additional burden on the coroner to send the recorded information back to the registered medical practitioner and for the registered medical practitioner to send the written confirmation back to the coroner. This would negate any benefit achieved by permitting oral notifications.
- 8.18 Given that the registered medical practitioner and coroner would have discussed the information, we propose that the confirmation itself need not be in writing; accuracy would be confirmed by reading back written information and for the registered medical practitioner to state that he is content. In the event that an oral notification is not appropriate (for example if the death has occurred outside of coroner operating hours), notifications should be made by another format, such as e-mail or faxed notification form. The guidance will provide further information on this issue.

Guidance

- 8.19 As we have set out, the draft regulations have been based broadly on the existing requirement for coroners to investigate where there has been a violent or unnatural death. The draft regulations seek to expand these conditions in order to provide clarity over circumstances under which a registered medical practitioner must notify a coroner of a death. However, we recognise that it is not possible to cover all circumstances.
- 8.20 To assist registered medical practitioners in determining whether a death does fall within one of the categories, we will publish non-statutory guidance that will expand on the categories and give examples of circumstances in which a notification should be made. The proposed guidance is published separately as part of this consultation.
- 8.21 As above, the guidance is clear that notifications can be made orally or in writing. It will be for the registered medical practitioner to determine which, but the guidance will set out examples of what might be appropriate in certain circumstances and that where notifications are made orally, written confirmation must follow. The draft regulations currently do not require confirmation in writing, so the guidance aims to reflect this.

Notification

- 8.22 Draft regulation 4(2) prescribes the information that should, in so far as it is known to the registered medical practitioner, be provided to the coroner when notifying him or her of a death. Again, notifications may be made orally but in such cases the information must also be recorded in writing.
- 8.23 In order to ensure that consistent information is provided in relation to notifiable deaths, the Department of Health has produced an exemplar form that contains all information required by the section 18 regulations. We will recommend registered medical practitioners use this where notifications are made in writing (and submitted by secure post, fax etc.). Where information is provided by other means, such as orally or by e-mail, we will recommend that the exemplar form be used as a template to ensure all the required information is provided to the coroner.

Impact

- 8.24 Other than a cost for training coroners and coroners' staff on the new regulations, we anticipate that the impact of the new regulations would be

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negligible. This part of the reforms is not, therefore, subject to an Impact Assessment.

- 8.25 Registered medical practitioners are under a common law duty to report a death to the coroner where an investigation may be required to establish the full circumstances of the death. Currently under the Coroners Act 1988 a coroner must investigate if the deceased has died a violent or an unnatural death; has died a sudden death of which the cause is unknown; or has died in prison or in such a place or in such circumstances as to require an inquest under any other Act. The 2009 Act amends these circumstances slightly so that a coroner must investigate if he or she has reason to suspect that the deceased died a violent or unnatural death, the cause of death is unknown, or the deceased died while in custody or otherwise in state detention.
- 8.26 The draft regulations made under section 18 of the 2009 Act will make it a statutory duty for registered medical practitioners to notify coroners of certain types of death. These draft regulations will not broaden the scope of deaths beyond those that coroners are currently under a duty to investigate, but will provide greater clarity on what is considered “unnatural” as this is not currently defined. As registered medical practitioners currently notify the coroner of such deaths, there is no additional practical burden brought about by the duty to notify.
- 8.27 The clarification of circumstances under which notifications should be made is anticipated to have a beneficial impact for registered medical practitioners and coroners by reducing the time spent on discussing and determining whether certain deaths should be notified. However, the notification itself is the last stage of the process under which the medical practitioner has determined the cause of death and the notification represents a small proportion of that process so any benefit is likely to be relatively small. We therefore do not anticipate that the impact will exceed the threshold whereby an impact assessment should be made.
- 8.28 In addition, there are no accurate data at present to indicate the proportion of deaths that registered medical practitioners notify under an NHS capacity as compared to private sector healthcare. It is therefore not possible to establish the impact of the statutory requirement on the private sector. However, during the consultation process, coroners are encouraged to consider the draft Regulations to ascertain whether they believe they introduce any positive or negative impact, and to provide as much information possible on the breakdown of notifications that are made during this period.
- 8.29 As stated above, the draft regulations build on the feedback received during the previous consultation exercise which broadly supported the proposed

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categories of death and guidance. Together with feedback from other interested parties, we have now refined policy further in order to reflect all comments received.

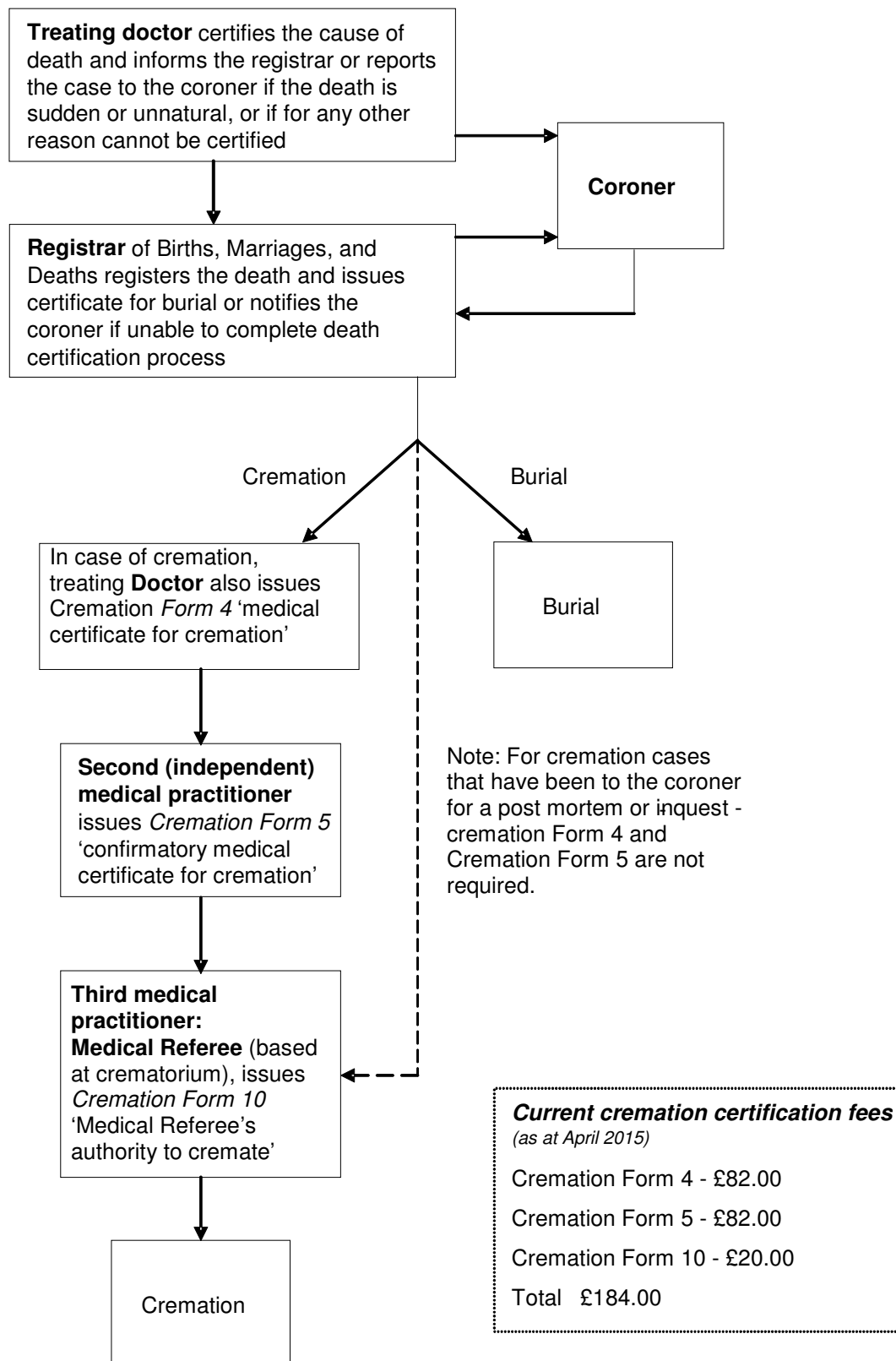
Annex C

Collection of the body

- 9.1 It is the responsibility of hospitals to put in place processes for the safe and correct release of bodies to funeral directors or relatives. We understand that a number of hospitals are requiring sight of the registrar's Certificate for Burial and Cremation (the 'Green Form') prior to agreeing release of a body. There is no legal requirement for this, and imposing such local requirements can lead to significant delays in releasing the body, due to the time it may take for the Green Form to be issued by the registrar, and can cause unnecessary distress to the bereaved.
- 9.2 In light of this, we have developed a suggested good practice form to support a more consistent, quality-controlled, and timely body collection process. We intend that this form will provide a basic template that may be adopted and adapted by hospitals to underpin their body collection process. It may also be suitable for adaptation, in consultation with the local coroner's and medical examiner's offices, for use in other settings (information on processes around collection of the body in other settings can be found in the notes section of the draft form). As is the case now, specific policies are likely to be in place to handle urgent release to meet religious and cultural requirements around care of the body.
- 9.3 Safe handling of the body after collection is important, including the need for infection risks to be safely managed and for implants to be correctly disposed of. We intend to work with the MOJ to ensure key information is captured that funeral directors, cemeteries and crematoria need. The details of which will be included in separate consultation, covering any role that medical examiners are likely to have in the process.

Annex D

Current Death Certification Process



Annex E

Glossary of Terms

Attending doctor: in Chapter 4, the attending doctor is also referred to as an “attending practitioner” (AP).

Attending Practitioner’s Certificate (APC): a medical certificate of cause of death (MCCD) that has been prepared by an AP who is qualified under these regulations to do so. This AP is referred to as a “qualified attending practitioner” (QAP).

Consented preparatory scrutiny: involves the consented scrutiny of records made to date and discussion of an anticipated cause of death prior to an expected natural death in cases where wishes of the deceased for organ donation are known. Medical examiners will need to establish joint local protocols to minimise delays in organ retrieval. Preparatory scrutiny must in all cases be complemented by a final/confirmatory scrutiny after the death occurs – however this will be limited to the review of any new records or unforeseen events and, as such, would usually be able to be carried out remotely, where necessary outside usual working hours, without creating any undue delay in cases where speed is of the essence.

Coroners’ Investigation: a coroner’s investigation is the term introduced by the Coroners and Justice Act 2009 for all cases in which a coroner requests an autopsy and/or holds an inquest.

Coroner Form: the Coroner Form will include more information than the Form A. In most coroner areas it should be possible to extract the “Coroner Form” from the coroner’s case-management system and send it to the medical examiner’s office by secure email.

‘Early scrutiny’: can be provided under a separate local protocol where health records are provided to and reviewed by a medical examiner after the death occurs but before they are reviewed/used by the qualified attending practitioner to decide whether s/he is able to certify the cause of death. In practice this allows doctors and medical examiners to meet the needs of any individual, including faith communities where there is a need for urgent release of the body for funeral preparations.

Medical Examiner’s Certificate (MEC): is a MCCD that has been prepared by a medical examiner for a death referred by a coroner.

Medical Examiners’ Officer: the medical examiner’s officer may be a substantive post or a function provided by a person with suitable expertise and sufficient independence working for a related service.

Natural Death: an apparently natural death is one that is not ‘clearly unnatural’ at the time of death. Clearly unnatural deaths (e.g. those that result from immediately apparent injury, accident, self-harm or violence) are usually reported to the police by a member of the public or to the police or a coroner by the person that verifies the fact of death. The same reporting arrangement applies in relation to any death that occurs whilst a person is in prison, police custody or other state detention.

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Verification of the fact of death: Verification of death is the procedure of determining whether a patient is actually deceased.

'Working-Day': is defined for this purpose as 8.00am and 5.00pm on Monday to Friday (excluding bank holidays) except where the standard working arrangements of people required for completion of the requirement are such that they are available and able to work on a regular basis outside these hours.

Annex F

Membership of the Death Certification Reforms National Steering Group

Organisation
Public Health England
Office for National Statistics
Ministry of Justice
Department of Health, Social Services & Public Safety Northern Ireland
HM Coroner Sheffield (Coroners' Society)
Sheffield Teaching Hospitals NHS Foundation Trust
Department of Health
Royal College of Pathologists
Bereavement Services Association
Gloucestershire Hospitals NHS Foundation Trust
Local Government Association
Coroners' Officers Association
Scottish Government
Cruse Bereavement Care
Coroners' Officers Association
Association of Anatomical Pathology Technologists
National Association of Funeral Directors
Institute of Cemetery & Crematorium Management
Communities and Local Government
HM Coroner South Manchester (Coroners' Society)
General Register Office
The Federation of Burial & Cremation Authorities
Welsh Government
Local Government Group
National Society of Allied & Independent Funeral Directors
Bereavement Advice Centre
Cremation Society of Great Britain
British Medical Association Forensic Medicine Committee

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