

**Guidance to support implementation of the
National Health Service (Complaints)
Regulations 2004**

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1. INTRODUCTION

- 1.1 The [NHS \(Complaints\) Regulations 2004](#), which apply in England alone, came in to force on 30 July 2004. These Regulations:
- move responsibility for the independent review of complaints about the NHS to the Healthcare Commission, a non-Departmental public body. Transferring responsibility for the **Independent Review** of complaints to the new [Healthcare Commission \(Commission for Healthcare Audit and Inspection\)](#) brings true independence to the second stage of the NHS complaints procedure.
 - consolidate the current Directions governing complaints about NHS bodies.
 - introduce some minor changes to the existing Local Resolution procedure in secondary care, such as the requirement to have a senior person in the body responsible for the oversight of complaints.

The separate Directions and Regulations relating to complaints handling by primary care practitioners continue to apply.

Outcome

- 1.2 The most satisfactory outcome to complaints often comes when complaints are dealt with fully and effectively at **Local Resolution**. Local Resolution seeks to provide prompt investigation and resolution of the complaint at local level, aiming to satisfy the complainant whilst being fair to staff.
- 1.3 Effective after-event and after-complaint management will better ensure that each case is fully investigated with clear explanations being given to complainants. It will also assist in identifying lessons to be learned from complaints, and in implementing any remedial action.
- 1.4 The complaints process will be more effective if all NHS staff understand the reformed procedure and the role played by the Healthcare Commission within that procedure. Training will enable all staff and non-executives of NHS trusts, primary care trusts and strategic health authorities to deal with someone wishing to make a complaint.
- 1.5 Information on [training](#) can be found on the NHS complaints pages of the Department of Health's website.
- 1.6 It will be helpful also for staff to know how to deal with concerns informally, for example with the help of the Patient Advice and Liaison Services (PALS). PALS and Modern Matrons can each help to address people's concerns on the spot, avoiding the need for the

formal procedure. The initial response to someone who feels aggrieved is often crucial in establishing the confidence that his or her grievance will be properly treated. By responding quickly and efficiently, there will be a better chance of early resolution.

Purpose of the Guidance

- 1.7 This **Guidance** complements the [National Health Service \(Complaints\) Regulations 2004 No.1768](#) (in this guidance referred to as ‘the Regulations’), which, along with the [Health and Social Care \(Community Health and Standards\) Act 2003](#) provides the statutory framework for the NHS complaints procedure. The Regulations came into force on Friday July 30 2004. The guidance updates ‘Complaints, Listening... Acting... Improving: Guidance on implementation of the NHS Complaints Procedure’, issued in 1996.
- 1.8 In this guidance ‘NHS body’ has the meaning given to it in the regulation 2(1), that is ‘a Strategic Health Authority, an NHS Trust which operates from premises wholly or mainly in England, a Primary Care Trust and a Special Health Authority to which section 2 of the Health Service Commissioners Act 1993 applies’. This excludes NHS foundation trusts and primary care providers.
- 1.9 The **Guidance** expands on the statutory framework set out in the Regulations. It is not meant to be all-embracing or to cover every contingency, but is a guide to the mandatory aspects of the complaints procedure. It should be supported by locally developed guidance, allowing bodies to approach management of the complaints procedure in the way that best meets local circumstances. NHS bodies may find it helpful to share locally developed good practice.
- 1.10 The guidance booklets from 1996 for [Family Health Services Practitioners](#) on practice-based complaints procedures have not been amended. However, those operating practice-based complaints procedures will wish to familiarise themselves with the new arrangements for Independent Review with the Healthcare Commission (see [Handling and Consideration of Complaints by the Healthcare Commission](#)).
- 1.11 In addition to this guidance, those responsible for handling complaints may wish to consult the [Good Practice Toolkit for Local Resolution](#).
- 1.12 Extracts from the Regulations are in bold and italics.

2. FRAMEWORK

Legal Framework

- 2.1 The [National Health Service \(Complaints\) Regulations 2004 No.1768](#) implement the new complaints procedure.
- 2.2 The following Regulations and Directions continue to apply to primary care providers:

[The National Health Service \(General Medical Services Contracts\) Regulations 2004 No.291](#)

[The National Health Service \(Personal Medical Services Agreements\) Regulations 2004 No.627](#)

The National Health Service (Pharmaceutical Services) Regulations 1992 No.662 as amended by [The National Health Service \(Pharmaceutical Services\) Amendment Regulations 1996 No.698](#)

The National Health Service (General Dental Services) Regulations 1992 No.661 as amended by [The National Health Service \(General Dental Services\) Amendment Regulations 1996 No. 704](#)

The National Health Service (General Ophthalmic Services) Regulations 1986 No.975 as amended by [The National Health Service \(General Ophthalmic Services\) Amendment Regulations 1996 No. 705](#)

[The General Medical Services Transitional and Consequential Provisions Order 2004 No.433](#)

[The General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004 No.865](#)

Primary Care Trusts Preparation of Proposals and Implementation of Pilot Schemes (Local Pharmaceutical Services) Directions 2003

The Directions concerning implementation of pilot schemes for personal dental services 10th August 1998

Patient Confidentiality

- 2.3 The requirement to maintain confidentiality is absolute during the complaints procedure. Further information on the law, confidentiality and consent is contained in the [Good Practice Toolkit](#).

Mixed Sector Complaints

- 2.4 Complaints which require Independent Review under the NHS complaints procedure and also involve either social services or fall

within the remit of the Mental Health Act Commission (relating to patients who are or have been detained under the Act), remain subject to both the NHS and the local authority or Mental Health Act Commission procedures. NHS bodies should advise complainants of what matters fall under which procedure.

- 2.5 Where a complaint involves more than one NHS provider, or one or more other bodies such as a local authority or a purchaser, there should be full cooperation in seeking to resolve the complaint through each body's local complaints procedure. NHS bodies and local authorities will need to ensure that, between them, they address all matters of concern to the complainant.
- 2.6 If an NHS body receives a written complaint that is **solely** concerned with areas properly dealt with by another health body or by a body outside the NHS, the complaint should be referred to the complaints manager. The complaints manager should, if the complainant agrees, forward the complaint to the correct body. Any doubts over which body is responsible for handling the complaint should be resolved before the complaint is despatched. This should then be recorded in writing.

Coroner's Cases

- 2.7 The fact that a death has been referred to the Coroner's Office does not mean that all investigations into a complaint need to be suspended. It is important for NHS bodies to consult the Coroner's Office and, where appropriate, initiate proper investigations.

NHS Private Pay Beds

- 2.8 The complaints procedure **does not** cover complaints about private medical treatment provided in an NHS setting but it **does** cover any complaint made about an NHS body's staff or facilities relating to care in their private pay beds.

Role of the Strategic Health Authority (SHA)

- 2.9 SHAs may wish to encourage NHS bodies in sharing of good, local practice by assisting in the development of networking arrangements to develop good practice and to give more general support to complaints managers.
- 2.10 The SHA may also wish to make available more broad-ranging support on the whole complaints process by, for example, providing guidance to enable NHS bodies to develop better systems and processes. The Healthcare Commission will provide SHAs with the investigation reports relating to bodies in their areas. SHAs may therefore wish to work with these bodies to develop strategies for implementing recommendations and disseminating learning. SHAs should monitor the outcomes of complaints investigations.

NHS Foundation Trusts

- 2.11 The regulatory requirements on Local Resolution **do not** apply to NHS foundation trusts. NHS foundation trusts are able to develop their own local systems for handling complaints.
- 2.12 However, where a complainant is unhappy with the outcome of any investigation of their complaint by an NHS foundation trust, or the NHS foundation trust has no local complaints procedure in place, the complainant can ask the Healthcare Commission for an Independent Review of their complaint (see [Remit of Healthcare Commission in relation to complaints about NHS foundation trusts](#)).

3. HANDLING AND CONSIDERATION OF COMPLAINTS BY NHS BODIES

Arrangements for the handling and consideration of complaints

Regulation 3

(1) Each NHS body must make arrangements in accordance with these Regulations for the handling and consideration of complaints.

(2) The arrangements must be accessible and such as to ensure that complaints are dealt with speedily and efficiently, and that complainants are treated courteously and sympathetically and as far as possible involved in decisions about how their complaints are handled and considered.

(3) The arrangements must be in writing and a copy must be given, free of charge, to any person who makes a request for one.

(4) Where an NHS trust or a Primary Care Trust makes arrangements for the provision of services with an independent provider, it must ensure that the independent provider has in place arrangements for the handling and consideration of complaints about any matter connected with its provision of services as if these Regulations applied to it.

- 3.1 NHS bodies must have a well-defined procedure in place for investigating and resolving complaints. The procedure should be open, fair, flexible and conciliatory and should encourage communication on all sides. The primary objective is to resolve the complaint satisfactorily.
- 3.2 Complaints managers should involve the complainant from the outset and seek to determine what they are hoping to achieve from the process. The complainant should be given the opportunity to understand all possible options for pursuing the complaint, and the consequences of following these options. Throughout the process, the complaints manager should assess what further action might best resolve the complaint. The complainant should be kept informed.
- 3.3 Complaints managers will need to keep a complete documentary record of the handling and consideration of each complaint – these records will be particularly important if the complaint is referred to the Healthcare Commission or Ombudsman. Complaints records should be kept separate from health records, subject to the need to record information which is strictly relevant to their health in the patient's health records.
- 3.4 At all times NHS staff should treat patients, carers and visitors politely and with respect. However, violence, racial, sexual or verbal harassment should not be tolerated. Neither will NHS staff be

expected to tolerate language that is of a personal, abusive or threatening nature.

Responsibility for complaints arrangements

Regulation 4

Each NHS body must designate one of its members, or in the case of an NHS trust a member of its board of directors, to take responsibility for ensuring compliance with the arrangements made under these Regulations and that action is taken in the light of the outcome of any investigation.

- 3.5 Involvement in the complaints process at chief executive and senior management level is now a requirement. NHS bodies must have a senior person in the organisation to take responsibility for the local complaints procedure and compliance with the Regulations. It is for the NHS body to decide whether the senior person is an executive or non-executive member of the board.
- 3.6 The complaints process often offers opportunities to improve local processes and the senior person may wish to link the complaints procedure with clinical governance processes, and risk management strategies. It may be appropriate, particularly in more complex cases, for the complaints manager to have direct access to the senior person.

Complaints manager

Regulation 5

- (1) Each NHS body must designate a person, in these Regulations referred to as a complaints manager, to manage the procedures for handling and considering complaints and in particular –***
- (a) to perform the functions of the complaints manager under this Part; and***
 - (b) to perform such other functions in relation to complaints as the NHS body may require.***
- (2) The functions of the complaints manager may be performed by him or by any person authorised by the NHS body to act on his behalf.***

- 3.7 NHS bodies must have a designated complaints manager who is readily accessible to both the public and members of staff. Whilst it is not essential for the title 'complaints manager' to be used, it is important that the individual with this role is easily identifiable, particularly to patients and their visitors.
- 3.8 The NHS body decides the precise role and job description of its complaints manager. For example, the complaints manager may not necessarily carry out the day-to-day administration of the complaints procedure or investigation of complaints, but may take responsibility for

overall management of a complaints team, providing guidance and support. Further information on handling complaints is contained in the [Good Practice Toolkit](#).

- 3.9 Where appropriate, NHS bodies can designate a different person to undertake the functions of the complaints manager. This will enable the complaints functions to continue during, for example, the complaints manager's sickness or annual leave.
- 3.10 The complaints manager should be available to complainants who do not wish to raise their concerns with those directly involved with their care, or where front-line staff are unable to deal with the complaint. Complaints managers will need to have access to all relevant records.

Complaints to NHS bodies

Regulation 6

Subject to regulation 7, a complaint to an NHS body may be about any matter reasonably connected with the exercise of its functions including in particular, in the case of an NHS trust or Primary Care Trust, any matter reasonably connected with-

- (a) its provision of health care or any other services, including in the case of a Primary Care Trust, its provision of primary medical services under section 16CC of the 1977 Act; and***
- (b) the function of commissioning health care or other services under an NHS contract or making arrangements for the provision of such care or other services with an independent provider or with an NHS foundation trust.***

Matters excluded from consideration under the arrangements

Regulation 7

The following complaints are excluded from the scope of the arrangements required under this Part –

- (a) a complaint made by an NHS body which relates to the exercise of its functions by another NHS body;***
- (b) a complaint made by a primary care provider which relates either to the exercise of its functions by an NHS body or to the contract or arrangements under which it provides primary care services;***
- (c) a complaint made by an employee of an NHS body about any matter relating to his contract of employment;***

- (d) a complaint made by an independent provider or an NHS foundation trust about any matter relating to arrangements made by an NHS body with that independent provider or NHS foundation trust;**
- (e) a complaint which relates to the provision of primary medical services in accordance with arrangements made by a Primary Care Trust with a Strategic Health Authority under section 28C of the 1977 Act or under a transitional agreement;**
- (f) a complaint which is being or has been investigated by the Health Service Commissioner;**
- (g) a complaint arising out of an NHS body's alleged failure to comply with a data subject request under the Data Protection Act 1998 or a request for information under the Freedom of Information Act 2000;**

3.11 NHS bodies may wish to consult the Information Commissioner about complaints arising out of an NHS body's alleged failure to comply with a data subject request under the Data Protection Act 1998. Information is available on the Information Commissioner's website:
<http://www.informationcommissioner.gov.uk>

3.12 The Freedom of Information access regime does not come in to force until January 2005. Until that time, the Code of Practice on Openness in the NHS continues to apply. The Health Service Ombudsman may consider complaints made under this Code until then.

- (h) a complaint about which the complainant has stated in writing that he intends to take legal proceedings; and**

3.13 If a complaint reveals a *prima facie* case of negligence, or the likelihood of legal action, the complaints manager should inform, and seek advice from, those responsible for dealing with risk management and claims management. Complaints managers should not infer that the complainant has decided to take formal legal action, even if a complainant's initial communication is via a solicitor's letter. Reacting to a complaint in a hostile or defensive manner is more likely to encourage the complainant to seek a remedy through the courts.

3.14 In the early part of the process, it may not be clear whether the complainant simply wants an explanation and apology, with assurances that any failures in service will be rectified for the future, or whether the complainant is in fact seeking information with formal litigation in mind. An open and sympathetic approach and response may satisfy the complainant.

- 3.15 *Prima facie* evidence of negligence should not delay a full explanation of events and, if appropriate, an apology: an apology is not an admission of liability.
- 3.16 However, if the complainant has either instigated formal legal action, or notified in writing that he or she intends to do so, the complaints procedure should be stopped, with the complainant and person identified in the complaint being advised appropriately in writing.
- (i) ***a complaint about which an NHS body is taking or is proposing to take disciplinary proceedings in relation to the substance of the complaint against a person who is the subject of the complaint.***
- 3.17 The complaints procedure is concerned **only** with resolving complaints and **not** with investigating disciplinary matters. The purpose of the complaints procedure is **not** to apportion blame amongst staff, but to investigate complaints with the aim of satisfying complainants whilst being fair to staff. It also offers an opportunity to improve service delivery.
- 3.18 NHS staff may complain about the way they have been dealt with under the complaints procedure and may take such a complaint to the Ombudsman. The Ombudsman would normally expect NHS staff first to have followed local procedures for resolving their complaint. However, the Ombudsman has the power to consider complaints that have not been put to the relevant NHS body and/or where the internal procedure has not been exhausted where she considers that, in the circumstances of the particular case, it is not reasonable to expect this.
- 3.19 Some complaints will identify information about serious matters and NHS bodies may feel it appropriate to consider disciplinary investigation at any point during the complaints procedure. Consideration as to whether or not disciplinary action is warranted is a separate matter for management. It falls outside the complaints procedure and is subject to a separate process of investigation. Nonetheless, information gathered during the complaints procedure may be made available for a disciplinary investigation.
- 3.20 For primary care providers, local disciplinary procedures cannot be considered until investigation by the Healthcare Commission has been completed. Only if action is necessary to protect patients, for example such as the need to involve the police or a professional registration body, would disciplinary investigation interrupt the handling of a primary care provider complaint.
- 3.21 If any complaint received by a member or employee of an NHS body indicates a need for referral to any of the following:
- i) An investigation under the disciplinary procedure;

- ii) One of the professional regulatory bodies;
- iii) An independent inquiry into a serious incident under Section 84 of the National Health Service Act 1977; or
- iv) An investigation of a criminal offence

the person in receipt of the complaint should at once pass the complaint to the complaints manager, who will ensure that it is passed on to a suitable person who can make a decision as to whether to initiate such action; the complaints manager may be designated such a suitable person by the NHS body. This reference may be made at any point during any stage of the complaints procedure. However, investigation of other aspects of the complaint will only be taken forward if they do not, or will not, compromise or prejudice the concurrent investigation.

- 3.22 Where it is decided to take action under any of i-iv above before a complaint investigation has been completed, a full report of the investigation thus far should be made available to the complainant. The complainant should be informed of the expected timeframe of the other investigative process and kept informed of progress. When that process is complete a further response should be sent to the complainant, outlining the outcome and any actions to be taken, being mindful of patient and staff confidentiality at all times.
- 3.23 When any action under i-iv has been concluded, that part of the original complaint which had been referred to a different procedure should only recommence through the NHS complaints procedure where there are outstanding matters in the complaint that have not been resolved.
- 3.24 Staff grievances will continue to be handled separately. All NHS bodies should have local procedures for handling staff concerns about health care issues, in addition to the NHS complaints procedure and established grievance procedures.

Persons who may make complaints

Regulation 8

- (1) ***A complaint may be made by-***
 - (a) ***a patient; or***
 - (b) ***any person who is affected by or likely to be affected by the action, omission or decision of the NHS body which is the subject of the complaint.***
- 3.25 The potential subject of a complaint is wide and not just related to medical care. A complaint may be made about a decision taken by an NHS body that is likely to affect the complainant. Each complaint must be taken on its own merit and responded to appropriately.

(2) A complaint may be made by a person (in these Regulations referred to as a representative) acting on behalf of a person mentioned in paragraph (1) in any case where that person-

- (a) has died**
- (b) is a child:**
- (c) is unable by reason of physical or mental incapacity to make the complaint himself: or**
- (d) has requested the representative to act on his behalf.**

3.26 Where a complaint is being made by a representative under 2(d) above, the complaints manager must first establish that the representative is acting with consent.

3.27 For elected representatives please see [The Data Protection \(Processing of Sensitive Personal Data\) \(Elected Representatives\) Order 2002 No.2905](#)

(3) In the case of a patient or person affected who has died or who is incapable, the representative must be a relative or other person who, in the opinion of the complaints manager, had or has a sufficient interest in his welfare and is a suitable person to act as representative.

(4) If in any case the complaints manager is of the opinion that a representative does or did not have a sufficient interest in the person's welfare or is unsuitable to act as a representative, he must notify that person in writing, stating his reasons.

3.28 It is for the complaints manager, possibly in discussion with the senior person or chief executive, to determine whether the complainant has 'sufficient interest' in the deceased or incapable person's welfare to be suitable to act as a representative. The question of whether a complainant is suitable to represent a patient depends, in particular, on the need to respect the confidentiality of the patient. For example, the patient may earlier have made it known that information should not be disclosed to third parties.

3.29 If the complaints manager determines that a person is not suitable to act as representative, they must provide full information outlining the reasons the decision has been taken.

(5) In the case of a child, the representative must be a parent, guardian or other adult person who has care of the child and where the child is in the care of a local authority or a voluntary organisation, the representative must be a person authorised by the local authority or the voluntary organisation.

(6) In these Regulations any reference to a complainant includes a reference to his representative.

Making a complaint

Regulation 9

(1) Where a person wishes to make a complaint under these Regulations, he may make the complaint to the complaints manager or any other member of the NHS body which is the subject of the complaint.

(2) A complaint may be made orally or in writing (including electronically) and-

(a) where it is made orally the complaints manager must make a written record of the complaint which includes the name of the complainant, the subject matter of the complaint and the date on which it was made; and

(b) where it is made in writing the complaints manager must make a written record of the date on which it was received.

(3) For the purposes of these Regulations where the complaint is made in writing it is treated as being made on the date on which it is received by the complaints manager or as the case may be, other member of the staff of the NHS body.

3.30 With the rapid development of technology, electronically received complaints are becoming more commonplace. Trusts should be mindful of this and consider local procedures to ensure there is no breach of patient confidentiality. Good practice would be to ensure that if any patient's personal information is to be disclosed it is done so only after the complaints manager has received the patient's consent in writing.

3.31 All written complaints, however addressed, should be passed immediately to the complaints manager. The complaints manager or agreed delegate should acknowledge it within 2 days of the date it was received by the trust (see [Regulation 11](#)).

3.32 Complaints are most likely to be initiated through front-line staff or with departmental managers. Front-line staff can deal with complaints, either by resolving the concern on the spot or by passing them to a relevant colleague. Clear local guidance and training will assist front-line staff in distinguishing those issues which would be better referred elsewhere. Overall, arrangements should ensure complaints are dealt with quickly and effectively. These arrangements should ensure that complainants are made aware of the role of advocacy services, such as the Independent Complaints Advocacy Services (ICAS), and how they may be contacted.

3.33 The first responsibility of a recipient of a complaint is to ensure that the patient's immediate health care needs are being met. This may require

urgent action before any matters relating to the complaint are tackled. Staff should, where possible, deal with the complaint rapidly and in an informal and sensitive manner. Complainants should be encouraged to speak openly and freely about their concerns and should be reassured that whatever they may say will be treated with appropriate confidence and sensitivity.

- 3.34 Some complainants may prefer to make their initial complaint to someone who has not been involved in their care. In these circumstances, they should be advised to address their complaints to the complaints manager, the senior department manager or, if they prefer, in writing to the chief executive. Whilst front-line staff should always encourage complainants to be forthcoming in expressing their concern, apprehension, or anxiety, particularly where they are dissatisfied with the care they have received, this should never be done at the expense of overriding the right of the complainants to make their complaint to the complaints manager or the chief executive.
- 3.35 Front-line staff will often find the information they gain from complaints useful in improving service quality. This is particularly so for oral comments or criticisms, which are not raised as formal complaints, and where people want something put right or improved, rather than investigated. Mechanisms for achieving this are best agreed at team level.

Time limit for making a complaint

Regulation 10

- (1) Subject to paragraph (2) a complaint must be made within –**
- (a) six months of the date on which the matter which is the subject of the complaint occurred; or**
 - (b) six months of the date on which the matter which is the subject of the complaint came to the notice of the complainant.**
- (2) Where a complaint is made after the expiry of the period mentioned in paragraph (1), the complaints manager may investigate it if he is of the opinion that-**
- (a) having regard to all the circumstances, the complainant had good reasons for not making the complaint within that period; and**
 - (b) notwithstanding the time that has elapsed it is still possible to investigate the complaint effectively and efficiently.**
- 3.36 NHS bodies should encourage those who wish to complain to do so as soon as possible after an event. Investigation is likely to be most effective when memories are fresh.

- 3.37 When a complaint is made outside the time limit, it will be for the complaints manager to decide whether or not to waive the time limit. The discretion to vary the time limit should be used flexibly and with sensitivity. An example of where discretion might be exercised would be where the complainant has suffered such distress or trauma as to prevent him/her from making their complaint at an earlier stage.
- 3.38 In any case where a complaints manager has decided not to investigate a complaint on the grounds that it was not made within the time limit, the complainant can request the Healthcare Commission consider it (see [Regulation 14](#)).

Acknowledgement and record of complaint

Regulation 11

(1) The complaints manager must send to the complainant a written acknowledgement of the complaint within 2 working days of the date on which the complaint was made.

(2) Where a complaint was made orally, the acknowledgement must be accompanied by the written record mentioned in regulation 9(2)(a) with an invitation to the complainant to sign and return it.

3.39 Acknowledgements must be in writing and sent within two working days of the date on which the complaint was made (see [Regulation 9\(3\)](#)). It is good practice for the acknowledgement to be conciliatory, and indicate that the response will be provided by the Chief Executive within an agreed timeframe (see [Regulation 13\(2\)](#)).

3.40 Complaints managers may wish to provide the complainant with further information about the complaints process. This may include locally produced information leaflets or leaflets provided by the Healthcare Commission. It is advisable to include information about the disclosure of patient information at this stage. Reassurance should be given that any disclosure will be confined to that which is relevant to the investigation of the complaint and only disclosed to those people who have a demonstrable need to know it for the purpose of investigating the complaint.

(3) The complaints manager must send a copy of the complaint and his acknowledgement to any person identified in it as the subject of the complaint.

(4) The acknowledgement sent to the complainant under paragraph (1) must include information about the right to assistance from independent advocacy services provided under section 19A of the 1977 Act.

- 3.41 ICAS was established to provide complainants with support through the NHS complaints procedure. Contact details for local [ICAS providers](#) are available on the Department of Health's website.

Investigation

Regulation 12

(1) The complaints manager must investigate the complaint to the extent necessary and in the manner which appears to him most appropriate to resolve it speedily and efficiently.

- 3.42 As part of its complaints procedure, the NHS body should establish a clear system to ensure the appropriate level of investigation. Complaints might best be resolved through face-to-face meetings with the complainant and early consideration might be given to this approach. Equally, the complaints manager may decide, on a case by case basis that other action would be more helpful.
- 3.43 Complaints managers should ensure that all information relevant to the investigation of the complaint is recorded and kept in the case file. They should bear in mind that should the complaint progress to Independent Review, the Healthcare Commission will request a copy of the case file and will expect all relevant information to be provided without unnecessary delay (see [Handling and Consideration of Complaints by the Healthcare Commission](#)). If the complaint goes to the Ombudsman, she will also require all relevant papers and other information in good time (see [Role of the Health Service Ombudsman](#)).
- 3.44 NHS bodies will wish to ensure impartiality when undertaking investigations into complaints. It is important that any investigating officer considers the complaint with an open mind, being fair to all parties. Investigation must not be adversarial and must uphold the principles of fairness and consistency.
- 3.45 An investigation into a complaint may be undertaken by the complaints manager or any other suitable person appointed by the NHS body. Whoever undertakes the investigation should seek to understand the nature of the complaint and identify any issues not immediately obvious.
- 3.46 It is essential that all investigations be conducted in a manner that is supportive to those involved and takes place in a blame free atmosphere. The process is best described as listening, learning and improving. This includes providing anyone identified as the subject of a complaint with a full account of the reasons for the investigation, giving them a proper opportunity to talk to the investigating officer and ensuring they are kept informed of progress. All involved should be informed of support services that are available to them. It is considered good practice for staff involved in the complaint to be

interviewed by the investigating officer and a written note made. To ensure that information is relayed correctly, and bearing in mind that evidence may be required at a later stage by the Healthcare Commission or the Ombudsman, a brief account of the questions and answers at these interviews should also be kept.

- 3.47 Where the complaint involves clinical issues, the findings and response must be shared with the relevant clinicians to ensure factual accuracy in respect of those clinical issues.

(2) The complaints manager may, in any case where he thinks it would be appropriate to do so and with the agreement of the complainant, make arrangements for conciliation, mediation or other assistance for the purposes of resolving the complaint, and in any such case the NHS body must ensure that appropriate conciliation or mediation services are available.

- 3.48 Early consideration should be given to appropriate measures that may prove effective for resolving a complaint. For instance, conciliation may prove helpful if complaints are to be resolved satisfactorily at a local level. Conciliation is essentially a process of facilitating agreement between the complainant and complained against, whether it be an organisation or person. It is most effective when used early in the complaints resolution process.

- 3.49 NHS bodies now have a legal obligation to ensure conciliation and mediation services are available. PCTs should continue to make conciliators available to practices where either the practice or the complainant requests a conciliator's assistance. Confidentiality must be strictly observed during the conciliation process. Consequently, conciliators should never be required to report to NHS bodies the details of cases in which they are involved.

(3) The complaints manager must take such steps as are reasonably practicable to keep the complainant informed about the progress of the investigation.

- 3.50 It is important that a timely and effective response is provided in order to resolve the complaint, and to avoid escalation. The complainant should be kept informed of progress and, if appropriate, reasons for any delay and a revised timeframe.

Response

Regulation 13

(1) The complaints manager must prepare a written response to the complaint which summarises the nature and substance of the complaint, describes the investigation under regulation 12 and summarises its conclusions.

(2) The response must be signed by the chief executive of the NHS body except in cases where for good reason the chief executive is not himself able to sign it, in which case it may be signed by a person acting on his behalf.

(3) Subject to paragraph (4), the response must be sent to the complainant within 20 working days beginning on the date on which the complaint was made or, where that is not possible, as soon as reasonably practicable.

(4) The response must notify the complainant of his right to refer the complaint to Healthcare Commission in accordance with regulation 14.

(5) Copies of the response mentioned in paragraph (1) must be sent to any other person to whom the complaint was sent under regulation 11(3).

3.51 As with the investigation, the response can be prepared by the complaints manager or any other suitable person appointed by the NHS body. It may be helpful to provide those drafting the response with appropriate training.

3.52 NHS bodies must seek to resolve all complaints within twenty working days. However, there is likely to be variation in the level and complexity of complaints and some may require a greater length of time to conclude the investigation and provide the response. As soon as it becomes clear that it will not be possible to respond within twenty working days, the complaints manager should discuss this with the complainant and agree a new date for response.

3.53 First class post – or, exceptionally, special delivery mail – should be used in correspondence with complainants and practitioners. All communications should be marked ‘Private and Confidential’ and/or ‘Personal’.

3.54 It should be remembered that the aim of this process is to resolve the complaint, whilst being fair to all parties. The complaints manager should consult those who have been complained against in advance of any formal response to the complainant.

It is good practice for responses to be as conciliatory as possible, including appropriate apologies. The complaints manager must provide details of the investigation and how it was undertaken. It is also often helpful to inform the complainant of who undertook the investigation.

3.55 The response should be clear, accurate, balanced, simple, fair and easy to understand. It should avoid technical terms, but where technical terms are used to describe a situation, events or condition, an explanation of that term should be provided. All the points raised in the

complaint should be addressed. An outcome, or explanation of planned action, should be included where the investigation finds that something could/should have been done differently, or if there is anything to be done as a result of the complaint.

- 3.56 The response must refer to the complainant's right to take the complaint to the Healthcare Commission and advise what they can do if they disagree with the response or would like further explanation (see [Regulation 13\(4\)](#)).
- 3.57 Once the formal response has been sent, it should be shared with those involved in the investigation and named in the complaint (see [Regulation 13\(5\)](#)). In more serious cases the NHS body may wish to consider a formal debrief for the staff involved in the complaint.
- 3.58 Arrangements should be made for any outcomes to be monitored to ensure that they are actioned. It is good practice to keep the complainant and those involved in the complaint informed of progress, with a final outcome when all actions have been taken.

4. HANDLING AND CONSIDERATION OF COMPLAINTS BY THE HEALTHCARE COMMISSION

Guidance for this section is currently being finalised and will be added in the near future

General complaints remit of the Healthcare Commission

Regulation 14

- (1) In any case where-**
- (a) a complainant is not satisfied with the result of an investigation-**
 - (i) by an NHS body under regulation 12. or**
 - (ii) by an independent provider, with whom an NHS trust or Primary Care Trust has made arrangements as mentioned in regulation 6, in accordance with its arrangements for the handling and consideration of complaints;**
 - (b) for any reason an investigation mentioned in paragraph (1)(a) has not been completed within 6 months of the date on which the complaint was made, or**
 - (c) a complaints manager has decided not to investigate a complaint on the grounds that it was not made within the time limit mentioned in regulation 10;**

he may request the Healthcare Commission to consider the complaint in accordance with this Part.

(2) In any case where a person has made a complaint to a primary care provider and is not satisfied with the outcome of an investigation of his complaint by the primary care provider, in accordance with its procedures for the handling and investigation of complaints, he, or a person who acted as his representative in accordance with those procedures, may request the Healthcare Commission to consider the complaint in accordance with this Part.

(3) A request under paragraphs (1) or (2) may be made either orally or in writing (including electronically) and must be made within 2 months of, or where that is not possible, as soon as reasonably practicable after, the date on which the response mentioned in regulation 13, or, as the case may be, under the complaints arrangements of the primary care provider, was sent to the complainant.

Remit of Healthcare Commission in relation to complaints about NHS foundation trusts

Regulation 15

(1) Subject to paragraphs (2) to (7), where a person has made a complaint to an NHS foundation trust and either-

(a) *he is not satisfied with the outcome of any investigation of that complaint by the NHS foundation trust in accordance with any procedures it may have; or*
(b) *the NHS foundation trust has no complaints procedures,*
he may request the Healthcare Commission to consider the complaint in accordance with this Part.

(2) *The Healthcare Commission's remit in relation to NHS foundation trusts is limited to consideration only of a complaint which-*
(a) *is made by a patient; and*
(b) *is reasonably connected with the provision of health care or other services to patients by or for the NHS foundation trust.*

(3) *The Healthcare Commission may not consider a complaint made under this regulation where the complaint-*
(a) *is one about which the complainant has stated in writing that he intends to take legal proceedings;*
(b) *is one about which the NHS foundation trust has stated in writing that it is taking or is proposing to take disciplinary proceedings in relation to the substance of the complaint against a person who is the subject of the complaint;*
(c) *arises out of the NHS foundation trust's alleged failure to comply with a data subject request under the Data Protection Act 1998 or a request for information under the Freedom of Information Act 2000; or*
(d) *which is being or has been investigated by the Health Service Commissioner.*

(4) *Where the Healthcare Commission consider that a complaint or any part of a complaint made under this regulation does not fall within paragraph (2), it must refer that complaint or part of a complaint to the Independent Regulator.*

(5) *The provisions in regulation 8 (2) to (6) (provision about representatives) apply to complaints made to the Healthcare Commission about NHS foundation trusts as if-*
(a) *the reference in paragraph (2) to paragraph (1) of that regulation were a reference to paragraph (2) of this regulation; and*
(b) *the references to the complaints manager in paragraphs (3) and (4) were references to the Healthcare Commission.*

(6) *A request under paragraph (1) must be made within 2 months of, or where that is not possible, as soon as reasonably practicable after, the date on which a response under the NHS foundation trust's complaints arrangements was sent to the complainant or, where there are no such arrangements, as soon as reasonably practicable.*

(7) *On receipt of a complaint about an NHS foundation trust, the Healthcare Commission must, within two working days and provided*

that it has the consent, which may be either express or implied, of the complainant, send a copy of the complaint to the Independent Regulator and invite his views on the complaint.

Decision on handling of complaint

Regulation 16

- (1) On receipt of the complaint the Healthcare Commission must assess the nature and substance of the complaint and decide how it should be handled having regard to-**
- (a) the views of the complainant;**
 - (b) the views of the body complained about;**
 - (c) in the case of a complaint about an NHS foundation trust which falls within regulation 15(2), the views of the Independent Regulator;**
 - (d) any investigation of the complaint, whether under Part II or otherwise, and any action taken as a result of such investigation; and**
 - (e) any other relevant circumstances.**
- (2) As soon as reasonably practicable the Healthcare Commission must notify the complainant as to whether it has decided-**
- (a) to take no further action;**
 - (b) to make recommendations to the body which is the subject of the complaint as to what action might be taken to resolve it;**
 - (c) to investigate the complaint further in accordance with regulation 17, whether by establishing a panel to consider it or otherwise;**
 - (d) to consider the subject matter of the complaint as part of or in conjunction with any other investigation or review which it is conducting or proposes to conduct in the exercise of its functions under the 2003 Act;**
 - (e) to refer the complaint to a health regulatory body;**
 - (f) in the case of a complaint about an NHS foundation trust which falls within regulation 15(2), to refer the complaint to the Independent Regulator; or**
 - (g) to refer the complaint to the Health Service Commissioner in accordance with section 10 of the Health Service Commissioners Act 1993.**
- (3) The notice of decision mentioned in paragraph (2)-**
- (a) must be sent to any person who or body which is the subject of the complaint;**
 - (b) may be sent to any other body which the Healthcare Commission considers has an interest in it;**
 - (c) must include the Healthcare Commission's reasons for its decision; and**

(d) in the case of a notification under paragraph (2)(a), must inform the complainant of his right to refer his complaint to the Health Service Commissioner.

(4) For the purposes of its decision under this regulation, the Healthcare Commission may-

- (a) distinguish one part of a complaint from another and make different proposals in respect of those different parts; and**
- (b) take such advice as appears to it to be required.**

Investigation by the Healthcare Commission

Regulation 17

(1) Where the Healthcare Commission proposes to investigate a complaint itself, it must, within 10 working days of the date on which it sent the notice mentioned in regulation 16(2), or where that is not possible, as soon as reasonably practicable, send to the complainant and any other person to whom the notice was sent its proposed terms of reference for its investigation

(2) The complainant and any person or body to whom the terms of reference are sent as mentioned in paragraph (1) may comment in writing on the proposed terms of reference provided that they do so within 10 working days of the date on which they were sent.

(3) The Healthcare Commission may conduct its investigation in any manner which seems to it appropriate, may take such advice as appears to it to be required and, having regard in particular to the views of the complainant and any person who or body which is the subject of the complaint, may appoint a panel to hear and consider the complaint in accordance with regulation 18.

(4) The Healthcare Commission may request any person or body to produce such information and documents as it considers necessary to enable a complaint to be considered properly.

(5) A request under paragraph (4) must be in writing (which may be electronically), must specify what information is requested and state why it is relevant to the consideration of the complaint.

(6) The Healthcare Commission may not make a request under paragraph (4) for information which is confidential and relates to a living individual unless the individual to whom the information relates has consented, such consent may be either express or implied, to its disclosure and use for the purposes of the investigation of the complaint.

Panels

Regulation 18

- (1) Subject to paragraph (2), the Healthcare Commission must prepare and keep up to date a list of people who, in its opinion, are suitable to be members of an independent lay panel to hear and consider complaints.**
- (2) The following persons are not eligible for membership of an independent lay panel-**
 - (a) a member or employee of an NHS body;**
 - (b) any person who is, or who has at any time been, a health care professional or an employee of a health care professional.**
- (3) Where the Healthcare Commission proposes to refer a complaint to a panel it must make arrangements for the complaint to be considered by a panel of three people selected from the list mentioned in paragraph (1), one of whom must be appointed to be the chairman.**
- (4) Subject to paragraphs (5) to (7), a panel may consider a complaint in any manner and adopt any procedure which appears to it to be appropriate to resolve the complaint, having regard to any representations to it which may be made by the complainant or by the person who is the subject of the complaint (in this regulation referred to as the participants).**
- (5) The panel must ensure that the participants are kept informed generally and in particular about-**
 - (a) the composition of the panel;**
 - (b) the date and time of any hearing; and**
 - (c) the names of any person whom the panel proposes to interview or from whom it proposes to take advice or evidence.**
- (6) A participant before a panel may be accompanied or represented by a friend or advocate but may not be represented by a legal representative acting as such.**
- (7) In the event of disagreement among members of the panel, the view of the majority shall prevail.**

Report of Investigation by the Healthcare Commission

Regulation 19

- (1) Where the Healthcare Commission investigates a complaint it must, as soon as reasonably practicable, prepare a written report of its investigation which-**
 - (a) summarises the nature and substance of the complaint;**

- (b) describes the investigation and summarises its conclusions including any findings of fact, the Healthcare Commission's opinion of those findings and its reasons for its opinions;**
- (c) recommends what action should be taken and by whom to resolve the complaint; and**
- (d) identifies what other action, if any, should be taken and by whom.**

(2) The report may include suggestions which it considers would improve the services of an NHS body, an NHS foundation trust or a primary care provider, or which would otherwise be effective for the purpose of resolving the complaint.

- (3) Subject to paragraph (4), the report must be sent to-**
- (a) the complainant together with a letter explaining to him his right to take his complaint to the Health Service Commissioner;**
 - (b) the body which was the subject of the complaint and, in the case of a complaint arising out of services provided by an independent provider, the body which commissioned those services;**
 - (c) in the case of a complaint involving a primary care provider, to the relevant Primary Care Trust;**
 - (d) any relevant Strategic Health Authority; and**
 - (e) in the case of a complaint involving an NHS foundation trust to the Independent Regulator.**

(4) The Healthcare Commission must adapt the report to ensure that confidential information from which the identity of a living individual can be ascertained is not disclosed without the express consent of the individual to whom it relates.

5. GENERAL

Publicity

Regulation 20

(1) Each NHS body and the Healthcare Commission must ensure that there is effective publicity for its complaints arrangements.

(2) Each NHS body must take all reasonable steps to ensure that the persons listed in paragraph (3) are informed of its arrangements, the name of its complaints manager and the address at which he can be contacted.

(3) The person referred to in paragraph (2) are –

(a) patients and their carers;

(b) visitors to any hospital or other premises for the management of which the NHS body is responsible;

(c) staff of the NHS body;

(d) independent providers with whom arrangements have been made under section 16CC or section 23 of the 1977 Act;

(e) any body with which it has made an NHS contract; and

(f) its relevant patients' forum.

5.1 NHS bodies must ensure that the complaints process is well publicised locally. This means that patients and visitors should be made aware of:

- the right to complain,
- advice about how to access the complaints procedure, and the types of help available:
 - frontline staff,
 - complaints managers,
 - Patient Advice and Liaison Services (PALS),
 - Independent Complaints Advocacy Services (ICAS), and
 - other sources, for example the Citizens Advice Bureau (CAB).

5.2 A [public information leaflet](#) providing details of the NHS complaints procedure is available on the Department of Health website. The leaflet may be amended to include details of the local procedure, such as relevant contact information.

- 5.3 Information on the NHS body's arrangements for handling complaints should be made accessible in a format that is useful to all. For example, different languages, braille and cassette tapes. Information must be provided free of charge to any person who makes a request for it (see [Regulation 3\(3\)](#)).

Monitoring

Regulation 21

- (1) For the purpose of monitoring the arrangements under these Regulations each NHS body must prepare a report for each quarter of the year for consideration by its Board.**
- (2) The reports mentioned in paragraph (1) must-**
- (a) specify the numbers of complaints received;**
 - (b) identify the subject matter of those complaints;**
 - (c) summarise how they were handled including the outcome of the investigation; and**
 - (d) identify any complaints where the recommendations of the Healthcare Commission were not acted upon, giving the reasons why not.**

- 5.4 NHS bodies should regularly monitor their arrangements for handling complaints and use the information collected in the quarterly and annual reports to identify trends and consider any lessons that can feed into service improvement. An increase in the number of complaints is not, in itself, a reason for thinking that a service is deteriorating. It may be a positive indicator the NHS body has effective publicity on complaints and is becoming more responsive. The important point is that complaints are well handled, and that lessons learned feed into quality improvement.

Annual Reports

Regulation 22

Each NHS body must prepare an annual report on its handling and consideration of complaints and send a copy of that report-

(a) in the case of a Strategic Health Authority or Special Health Authority, to the Healthcare Commission.

(b) in the case of an NHS Trust, to its relevant Strategic Health Authority and the Healthcare Commission.

(c) in the case of a Primary Care Trust, to its relevant Strategic Health Authority and the Healthcare Commission.

- 5.5 The information contained in the annual report should summarise information contained in the quarterly reports and identify any progress or areas in need of improvement.
- 5.6 Strategic health authorities may wish to consider inviting complaints managers or chief executives of NHS bodies to present annual reports personally to them.
- 5.7 NHS bodies may wish to include information from annual reports in the service improvement section of their annual report and on Freedom of Information web sites.
- 5.8 All types of complaint report must be anonymous to ensure patient / complainant confidentiality.
- 5.9 Consideration should be given to collection of local data on:
- oral concerns not raised or recorded formally
 - patients' comments and suggestions
 - changes in practices and procedures as a consequence of complaints handling

This information should be supplemented by surveys of patient satisfaction in the way in which complaints are handled. Such information will enable service providers to improve the quality of their service.

6. ROLE OF THE HEALTH SERVICE OMBUDSMAN

The Health Service Ombudsman

- 6.1 The Health Service Ombudsman considers complaints made by or on behalf of people who have suffered an injustice or hardship because of unsatisfactory treatment or service by the NHS or by private health providers who have provided NHS funded treatment to the individual.
- 6.2 The Ombudsman is independent of the NHS and of government and derives her powers from the Health Service Commissioners Act 1993 (the 1993 Act), as subsequently amended.

Who can complain to the Ombudsman?

- 6.3 The Ombudsman can consider complaints made:
- by a patient;
 - by a member of the patient's family or their spouse or partner; or
 - by someone acting on the patient's behalf who is authorised to do so.

What can they complain about?

- 6.4 The Ombudsman **can** consider complaints about:
- unsatisfactory care or treatment, including the exercise of clinical judgment;
 - failure to provide a service that ought to have been provided; and
 - poor administration, which might include poor complaint handling, rudeness, misleading advice, refusal to provide information to which an individual is entitled, or clerical error.
- 6.5 The Ombudsman **cannot** consider complaints about:
- private health care not funded by the NHS;
 - NHS personnel matters such as recruitment, pay or discipline;
 - a refusal of access to medical records, which are for the Information Commissioner;
 - contractual disputes between NHS bodies and their suppliers; or
 - matters about which legal action has already been taken or about which the individual intends to take legal action.

- 6.6 Once a complaint is made, the Ombudsman will consider whether an investigation by her is likely to achieve anything worthwhile for the individual making the complaint.
- 6.7 The Ombudsman will **not usually** investigate complaints where:
- the NHS body or practitioner has done all that could reasonably be expected to put things right;
 - the complaint is about the content or adequacy of legislation;
 - it is made to her more than twelve months after the individual making the complaint became aware of the matters complained about, although delay in resolving a complaint within the internal NHS procedure would not normally mean that such a complaint would be 'time-barred'; and
 - the individual making the complaint disagrees with a decision which was properly made by an NHS body or practitioner and provides no evidence that the decision was taken improperly.

When can they complain?

- 6.8 Anyone wishing to complain to the Ombudsman must normally have put their complaint first to the NHS organisation or practitioner concerned. However, the Ombudsman has the power to consider complaints that have not been put to the relevant NHS body and/or where the first two stages of the complaints procedure have not been exhausted where she considers that, in the circumstances of the particular case, it is not reasonable to expect this.
- 6.9 The main stages at which complaints are likely to be made to the Ombudsman are where:
- the responsible NHS body or practitioner has refused to investigate a complaint for whatever reason and where the Healthcare Commission has upheld that refusal;
 - an individual is dissatisfied with attempts at local resolution of their complaint and where the Healthcare Commission has refused an independent review of their complaint;
 - the individual is dissatisfied with the process or outcome of an independent review of their complaint; or
 - the relevant NHS body or the Healthcare Commission decides to refer a complaint direct to the Ombudsman, using their powers to do so under section 10 of the 1993 Act.

What will happen to a complaint once it is made to the Ombudsman?

- 6.10 Upon receipt of a complaint, the Ombudsman will first check that it is a complaint that she has the legal power to consider. She will then assess whether the complaint should be referred back for further action to the relevant NHS body, NHS practitioner or to the Healthcare Commission.
- 6.11 Where she determines that the complaint is one that she can investigate and where referral for further action by the body complained about or the Healthcare Commission is not appropriate, she will call for all the papers and other relevant information. Bodies or individuals under investigation must in law provide any evidence requested by the Ombudsman and must otherwise assist with her investigation in any way she requests. The appointment of a designated officer within NHS bodies responsible for each complaint is also expected to ensure effective liaison during the investigation.
- 6.12 Upon completion of an investigation, the Ombudsman may uphold the complaint in full or in part or may not uphold the complaint at all. In any case, she will set out her findings and the reasons for those findings in her report. Where the complaint is at least partially upheld, she may make recommendations for appropriate redress, which might include an apology, an explanation, improvements to practices and systems or, where appropriate, financial redress. She also has the power to refer individual clinicians to regulatory bodies in the interests of patient safety where she considers that this is appropriate.
- 6.13 The Ombudsman will expect her recommendations to be implemented and will contact the relevant NHS provider to find out how her recommendations have been implemented.

Preventing the intervention of the Ombudsman

- 6.14 The Ombudsman will expect that:
- individuals making complaints are always treated with respect and are not penalised for making a complaint;
 - NHS bodies and practitioners will explain clearly to the individual making a complaint the way in which their complaint will be handled and will ensure that the individual is aware of the appropriate advice, advocacy and support services available to them;
 - individuals are given clear and specific reasons, which are based on the evidence, for any decision taken on their complaint and that those decisions address all of the concerns raised by the complainant; and
 - NHS bodies and practitioners and the Healthcare Commission will

ensure that individuals making complaints are given accurate information about the role of the Ombudsman and are aware of their right to complain to her should they remain dissatisfied with the outcome of their complaint.

Further information

- 6.15 Further information on the role and work of the Ombudsman is available by calling 0845 015 4033 or at her website:
<http://www.ombudsman.org.uk/>