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STATUTORY INSTRUMENTS

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**2000 No. 662**

**NATIONAL HEALTH SERVICE,  
ENGLAND AND WALES**

**The Commission for Health Improvement  
(Functions) Regulations 2000**

<i>Made</i>	- - - -	<i>9th March 2000</i>
<i>Laid before Parliament</i>		<i>10th March 2000</i>
<i>Coming into force</i>	- -	<i>1st April 2000</i>

The Secretary of State for Health, in exercise of the powers conferred on him by sections 17 and 126(4) of the National Health Service Act 1977(1) and sections 20(1)(e), 20(2) and 23 of the Health Act 1999(2) and of all other powers enabling him in that behalf, with the agreement of the National Assembly for Wales in relation to the exercise of the powers under section 20(1)(e) of the Health Act 1999(3), hereby makes the following Regulations:

**PART I  
GENERAL**

**Citation, commencement, extent and interpretation**

1.—(1) These Regulations may be cited as the Commission for Health Improvement (Functions) Regulations 2000 and shall come into force on 1st April 2000.

(2) Subject to paragraph (3), these Regulations extend to England only.

(3) This regulation and regulation 2 extend also to Wales.

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- (1) 1977 c. 49; section 17 was substituted by section 12 of the Health Act 1999 (c. 8) (“the 1999 Act”); section 126(4) applies in relation to any power to make orders or regulations conferred by the 1999 Act (see section 62(4) of the 1999 Act) and was amended by the National Health Service and Community Care Act 1990 (c. 19) (“the 1990 Act”), section 65(2) and the 1999 Act, Schedule 4, paragraph 37(6).
- (2) 1999 c. 8; see sections 20(7) and 23(6) for the definitions of “prescribed”. The functions of the Secretary of State under sections 20(2) and 23 of the 1999 Act and sections 17 and 126(4) of the National Health Service Act 1977 (“the 1977 Act”) are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of, and the entries for the 1977 Act and the 1999 Act in Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the 1999 Act.
- (3) See the entry for the 1999 Act in Schedule 2 to the National Assembly for Wales (Transfer of Functions) Order 1999, as inserted by section 66(6) of that Act.

(4) In these Regulations—

“the Act” means the Health Act 1999;

“the 1977 Act” means the National Health Service Act 1977;

“the 1997 Act” means the National Health Service (Primary Care) Act 1997<sup>(4)</sup>;

“the Audit Commission” means the Audit Commission for Local Authorities and the National Health Service in England and Wales<sup>(5)</sup>;

“clinical governance arrangements” means arrangements by an NHS body or a service provider for monitoring and improving the quality of health care<sup>(6)</sup> for which they have responsibility or, in the case of a Primary Care Trust, which is provided by the trust’s relevant service providers;

“the Commission” means the Commission for Health Improvement established by section 19 of the Act;

“financial year” means the period of 12 months ending with 31st March;

“health care profession” means a profession to which section 60(2) of the Act applies;

“health care professional” means a person who is registered as a member of a health care profession;

“health service inquiry” means an inquiry, held or established by the Secretary of State, the National Assembly for Wales or an NHS body, into any matter relating to the management, provision and quality of health care for which NHS bodies or service providers have responsibility.

“investigation” means an investigation by the Commission pursuant to section 20(1)(c) of the Act or regulation 2(e);

“local review” means a review conducted by the Commission under section 20(1)(b) of the Act or regulation 2(c) or (d);

“national service review” means a review by the Commission pursuant to section 20(1)(d) of the Act;

“Part II services” means general medical services, general dental services, general ophthalmic services or pharmaceutical services under Part II of the 1977 Act;

“personal medical services” has the meaning given in section 1(8) of the 1977 Act;

“relevant Health Authority” means—

(a) in relation to a Primary Care Trust, the Health Authority in whose area the trust is established;

(b) in relation to a service provider, the Health Authority in whose area that person provides services;

“relevant service provider” means, in relation to a Primary Care Trust, a service provider who provides—

(a) general medical services under the 1977 Act; or

(b) personal medical services in accordance with a pilot scheme under the 1997 Act,

under arrangements or an agreement with the Health Authority in whose area the trust is established, where the Authority has directed the trust under section 17A(1) of the 1977 Act<sup>(7)</sup> to exercise any functions in relation to those arrangements or that agreement;

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(4) 1997 c. 46.

(5) The Audit Commission was continued in being by section 1 of the Audit Commission Act 1998 (c. 18).

(6) See sections 18(4) and 20(7) of the 1999 Act for the definition of “health care”.

(7) Section 17A was inserted by section 12 of the 1999 Act.

“service provider” means a person, other than an NHS body, who—

- (a) provides Part II services, or
- (b) provides services in accordance with a pilot scheme under the 1997 Act<sup>(8)</sup>.

(5) In these Regulations, references to health care for which a person has responsibility are to be construed in accordance with section 20(5) of the Act.

## PART II

### ADDITIONAL FUNCTIONS OF THE COMMISSION

#### Additional functions

2. The following functions are prescribed pursuant to section 20(1)(e)—
  - (a) the function of providing advice or information with respect to the arrangements by Health Authorities, Special Health Authorities or service providers for the purpose of monitoring and improving the quality of health care for which they have responsibility;
  - (b) the function of providing advice or information with respect to the arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;
  - (c) the function of conducting reviews of, and making reports on, arrangements by Health Authorities, or Special Health Authorities to which the duty in section 18 of the Act has been extended<sup>(9)</sup>, for the purpose of monitoring and improving the quality of health care for which they have responsibility;
  - (d) the function of conducting reviews of, and making reports on, arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;
  - (e) the function of carrying out investigations into, and making reports on, the management, provision or quality of health care for which Special Health Authorities have responsibility;
  - (f) the function of providing advice with respect to the establishment and conduct of health service inquiries.

## PART III

### ANNUAL WORK PROGRAMME

#### Annual work programme

3.—(1) Before the beginning of each financial year the Commission must prepare a work programme setting out the activities the Commission is to undertake in that year in the exercise of its functions.

- (2) Each work programme shall, in relation to that year, set out—
  - (a) any particular matters with respect to which the Commission is to provide advice or information on clinical governance arrangements;

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<sup>(8)</sup> See section 1 of the Act for a definition of “pilot scheme”.

<sup>(9)</sup> See section 18(3) of the 1999 Act and [S.I. 2000/660](#).

- (b) proposals as to the NHS bodies in relation to which the Commission is to conduct local reviews;
  - (c) any particular matters which the Commission is to consider or take into account when conducting a local review or a national service review; and
  - (d) the particular types of health care which are to be the subject of any national service reviews and reports under section 20(1)(d) of the Act.
- (3) The work programme shall be subject to approval by the Secretary of State.
- (4) The work programme may be varied—
- (a) with the agreement of the Secretary of State; or
  - (b) as the Secretary of State may determine.
- (5) Subject to the following regulations and to any directions given by the Secretary of State, the Commission shall exercise its functions in any financial year in accordance with the work programme relating to that year.

## PART IV

### ADVICE OR INFORMATION ON CLINICAL GOVERNANCE ARRANGEMENTS

#### **Persons to whom advice or information to be given**

4.—(1) The Commission shall provide advice or information on clinical governance arrangements to—

- (a) the Secretary of State;
- (b) NHS bodies; and
- (c) service providers.

(2) The Commission shall comply with any request by the Secretary of State to provide advice or information on specified aspects of clinical governance arrangements to—

- (a) the Secretary of State;
- (b) specified NHS bodies; or
- (c) specified service providers.

(3) The Commission may provide advice or information on clinical governance arrangements to any other person or body requesting such advice or information.

#### **Exercise of the function of providing advice or information on clinical governance arrangements**

5. In exercising its functions under section 20(1)(a) of the Act and regulation 2(a) and (b) the Commission shall take into account—

- (a) any guidance relating to clinical governance arrangements given by the Secretary of State or the National Institute for Clinical Excellence<sup>(10)</sup>;
- (b) any advice or guidance relating to clinical governance arrangements given by any body responsible for the regulation of a health care profession;

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(10) *see* S.I. 1999/220 as amended by S.I. 1999/2219.

## PART V

### LOCAL REVIEWS

#### **Effectiveness and adequacy of arrangements**

6. In conducting a local review the Commission shall assess the effectiveness of the arrangements by the NHS body concerned and consider whether those arrangements are adequate.

#### **Local review reports**

7.—(1) Following the conclusion of a local review, the Commission shall make a report to the NHS body concerned setting out—

- (a) the findings and conclusions of the Commission; and
- (b) any recommendations made by the Commission.

(2) The Commission shall publish a summary of any such report.

#### **Special interest reports**

8.—(1) If in the course of a local review a matter comes to the notice of the Commission which it considers should, in the public interest, be brought to the attention of—

- (a) any of the persons or bodies to which paragraph (2) applies; and
- (b) the public,

the Commission may make the matter the subject of an immediate report in addition to the report to be made at the conclusion of the review.

(2) The persons and bodies referred to in paragraph (1) are—

- (a) the NHS body which is the subject of the local review;
- (b) the Secretary of State;
- (c) in a case where a Primary Care Trust is the subject of a local review, the relevant Health Authority.

(3) Copies of any report under paragraph (1) shall be sent to—

- (a) the NHS body which is the subject of the local review;
- (b) the Secretary of State;
- (c) in a case to which paragraph (2)(c) applies, the relevant Health Authority; and
- (d) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report should be copied.

(4) In addition to sending copies of the report to the persons referred to in paragraph (3), the Commission shall publish a summary of the report.

#### **Further action following a local review**

9.—(1) Following the conclusion of a local review the NHS body concerned shall, with the assistance of the Commission, prepare a written statement of the action which it proposes to take in the light of the report made by the Commission.

(2) A statement prepared under paragraph (1) shall be subject to approval by—

- (a) in the case of a Health Authority, a Special Health Authority or an NHS trust, the Secretary of State; or

(b) in the case of a Primary Care Trust, the relevant Health Authority.

(3) Before deciding whether to approve a statement prepared under paragraph (1), the Secretary of State or, as the case may be, the Health Authority shall consult the Commission.

## PART VI

### NATIONAL SERVICE REVIEWS

#### **National service review reports**

**10.**—(1) At the conclusion of a national service review the Commission shall make a report to the Secretary of State.

(2) A report under paragraph (1) shall include the findings and recommendations of the Commission.

(3) The Commission shall publish a summary of any such report.

## PART VII

### INVESTIGATIONS

#### **Investigations**

**11.**—(1) The Commission shall carry out an investigation when requested to do so by the Secretary of State.

(2) The Commission may carry out an investigation where—

- (a) the Commission receives a request to investigate from any person or body; or
- (b) it otherwise appears to the Commission to be appropriate to do so.

(3) Where the Commission is carrying out an investigation at the request of the Secretary of State, it shall investigate such matters falling within section 20(1)(c) of the Act or regulation 2(e) as may be specified in the request.

(4) Where the Commission is carrying out an investigation in any other case, it may investigate such matters falling within section 20(1)(c) of the Act or regulation 2(e) as it considers appropriate.

#### **Notice of investigation**

**12.** Where it is reasonably practicable to do so, the Commission shall provide written notification of its intention to conduct an investigation and the proposed date on which that investigation is to commence to—

- (a) any NHS body or service provider which is to be the subject of an investigation;
- (b) in the case of an investigation under regulation 12(2) concerning a Health Authority, a Special Health Authority or an NHS trust, the Secretary of State; and
- (c) in the case of an investigation concerning a Primary Care Trust or a service provider, the relevant Health Authority.

### **Conducting an investigation of a body which is the subject of a local review**

**13.**—(1) If in the course of conducting a local review a matter comes to the notice of the Commission which it considers should properly be the subject of an investigation, the Commission may commence an investigation into that matter.

(2) If the Commission decides to commence an investigation it shall, where reasonably practicable to do so, provide written notification of the decision and the proposed date on which the investigation is to commence to—

- (a) the body which is the subject of the local review;
- (b) in a case where the body subject to the local review is a Health Authority, a Special Health Authority or an NHS trust, the Secretary of State; and
- (c) in a case where the body subject to the local review is a Primary Care Trust, the relevant Health Authority.

(3) Where the Commission commences such an investigation, the Commission may suspend or continue the local review and, where the local review was suspended, resume the review at any time.

### **Investigation reports**

**14.**—(1) Following the conclusion of an investigation which has been requested by the Secretary of State the Commission shall make a report to the Secretary of State and send a copy of the report to—

- (a) any person or body which has been the subject of the investigation; and
- (b) in the case of an investigation concerning a Primary Care Trust or a service provider, the relevant Health Authority.

(2) Following the conclusion of an investigation which has been requested by any other person or body the Commission shall make a report to that person or body and send a copy of the report to—

- (a) any person or body which has been the subject of the investigation;
- (b) the Secretary of State; and
- (c) in the case of an investigation concerning a Primary Care Trust or a service provider, the relevant Health Authority.

(3) Following the conclusion of an investigation in any other case, the Commission shall make a report to the person or body which has been the subject of the investigation and shall send a copy of the report to—

- (a) the Secretary of State; and
- (b) in the case of an investigation concerning a Primary Care Trust or a service provider, the relevant Health Authority.

(4) A report made under paragraphs (1), (2) or (3) shall set out—

- (a) the findings and conclusions of the Commission;
- (b) any recommendations made by the Commission.

(5) The Commission shall publish a summary of any such report.

### **Special interest reports**

**15.**—(1) If in the course of an investigation a matter comes to the notice of the Commission which it considers should, in the public interest, be brought to the attention of—

- (a) any of the persons or bodies to which paragraph (2) applies; and
- (b) the public,

the Commission may make the matter the subject of an immediate report in addition to the report to be made at the conclusion of the investigation.

- (2) The persons and bodies referred to in paragraph (1) are—
- (a) any NHS body or service provider which is the subject of the investigation;
  - (b) the Secretary of State;
  - (c) in a case where a Primary Care Trust or a service provider is the subject of an investigation, the relevant Health Authority.
- (3) Copies of any report under paragraph (1) shall be sent to—
- (a) any NHS body or service provider which is the subject of the investigation;
  - (b) the Secretary of State;
  - (c) in a case to which paragraph (2)(c) applies, the relevant Health Authority; and
  - (d) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report should be copied.
- (4) In addition to sending copies of the report to the persons referred to in paragraph (3), the Commission shall publish a summary of the report.

#### **Further action following an investigation**

**16.**—(1) Following the conclusion of an investigation any NHS body concerned shall, with the assistance of the Commission, prepare a written statement of the action which it proposes to take in the light of the report made by the Commission.

- (2) A statement prepared under paragraph (1) shall be subject to approval by—
- (a) in the case of a Health Authority, a Special Health Authority or an NHS trust, the Secretary of State; or
  - (b) in the case of a Primary Care Trust, the relevant Health Authority.

(3) Before deciding whether to approve a statement prepared under paragraph (1), the Secretary of State or, as the case may be, the Health Authority shall consult the Commission.

## **PART VIII**

### **RIGHTS OF ENTRY AND OBTAINING INFORMATION**

#### **Rights of entry**

**17.**—(1) Subject to the following paragraphs of this regulation, persons authorised in writing by the Commission may at any reasonable time enter and inspect NHS premises<sup>(11)</sup> for the purposes of conducting local reviews, national service reviews or investigations.

(2) Each person authorised by the Commission under paragraph (1) shall be furnished with written evidence of his authority and on applying for entry to NHS premises for the purposes specified in paragraph (1) shall, if so requested by the occupier of the premises or a person acting on his behalf, produce that evidence.

(3) A person authorised by the Commission under paragraph (1) shall not demand admission to NHS premises as of right unless the NHS body which owns or controls the premises has been given reasonable notice of the intended entry.

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<sup>(11)</sup> See section 23(6) of the 1999 Act for the definition of “NHS premises”.



(4) No person authorised by the Commission under paragraph (1) may enter any premises or part of premises used as residential accommodation for persons employed by any NHS body, without first having obtained the consent of the officers residing in such accommodation.

(5) Subject to regulation 20, a person authorised by the Commission under paragraph (1) entering NHS premises under this regulation may inspect and take copies of any documents which—

- (a) appear to him to be necessary for the purposes of the review or investigation in question; and
- (b) are held on the premises by—
  - (i) the NHS body which owns or controls the premises;
  - (ii) a chairman, member, director or employee of that body;
  - (iii) any other person acting on behalf of that body; or
  - (iv) a member of a committee or sub-committee of that body.

### **Obtaining information and explanations**

**18.**—(1) Subject to regulation 20, in conducting a local review or investigation the Commission or a person authorised by the Commission under regulation 17(1) may require a person to which paragraph (5) applies to produce any documents or information which appear to the Commission, or to the person authorised, to be necessary for the purposes of the review or investigation in question.

(2) Subject to regulation 20, in conducting a local review or investigation the Commission or a person authorised by the Commission may, if it or he thinks it necessary, require a person to which paragraph (5) applies to give the Commission or, as the case may be, the person authorised an explanation of—

- (a) any matters which are the subject of the review or investigation; or
- (b) any documents or information inspected, copied or produced under paragraph (1) or regulation 17(5).

(3) The Commission may, if it considers it necessary require a person required to—

- (a) produce documents or information under paragraph (1); or
- (b) give an explanation under paragraph (2)

to attend before the Commission or a person authorised by the Commission under regulation 17(1) in person to produce the documents or information or give the explanation.

(4) The Commission or a person authorised under regulation 17(1) may not require a person to attend in person in accordance with paragraph (3) unless reasonable notice of the intended date of attendance has been given to that person.

(5) The person referred to in paragraphs (1) and (2) are—

- (a) an NHS body;
- (b) a chairman, member, director or employee of an NHS body, or any other person acting on behalf of such a body;
- (c) a member of a committee or sub-committee of an NHS body;
- (d) a service provider;
- (e) an employee of a service provider, or any other person acting on behalf of such a provider;
- (f) a person who provides or assists in the provision of, or is a member of an employee of a person or body who provides or assists in the provision of, services under the 1977 Act, or in connection with a pilot scheme under the 1997 Act, in accordance with a contract made with an NHS body, a service provider or a person to which sub-paragraph (g) applies;

- (g) a local authority which provides, or a person employed by local authority to provide, services under the 1977 Act, or in connection with a pilot scheme under the 1997 Act, in accordance with arrangements made by virtue of section 31(1) of the Act.

### **Information held by means of a computer or in any other electronic form**

**19.**—(1) In this regulation and in regulations 17 and 18, any reference to documents includes a reference to information held by means of a computer or in any other electronic form.

(2) Where the Commission or a person authorised under regulation 17(1) is exercising—

- (a) the right under regulation 17(5) to inspect and take copies of documents; or
- (b) the right under regulation 18(1) to require any person to produce documents,

and such documents consist of information held by means of a computer or in any other electronic form, the Commission or the person authorised may require any person having charge of, or otherwise concerned with the operation of, the computer or other electronic device holding that information to make that information available, or produce that information, in a visible and legible form.

### **Restrictions on disclosure of information to the Commission**

**20.**—(1) The Commission or a person authorised under regulation 17(1) shall not inspect or take copies of documents under regulation 17(5) to the extent that—

- (a) those documents consist of confidential information<sup>(12)</sup> which relates to and identifies a living individual, unless one or more of the conditions specified in paragraph (3) applies; or
- (b) the inspection or copying of those documents involves the disclosure of information if that disclosure is prohibited by or under any enactment, unless paragraph (4) applies.

(2) A person shall not be required to produce documents or information under regulation 18(1) or give an explanation under regulation 18(2) to the extent that the production of those documents or that information or the giving of that explanation discloses information—

- (a) which is confidential and which relates to and identifies a living individual, unless one or more of the conditions specified in paragraph (3) applies; or
- (b) the disclosure of which is prohibited by or under any enactment, unless paragraph (4) applies.

(3) The conditions referred to in paragraphs (1)(a) and (2)(a) are—

- (a) the information is disclosed in a form in which the identity of the individual cannot be ascertained;
- (b) the individual consents to the information being disclosed;
- (c) the individual cannot be traced despite the taking of all reasonable steps;
- (d) in a case where the Commission is exercising its functions under section 20(1)(c) of the Act—
  - (i) it is not practicable to disclose the information in a form in which the identity of the individual cannot be ascertained;
  - (ii) the Commission considers that there is a serious risk to the health or safety of patients arising out of the matters which are the subject of the investigation; and
  - (iii) having regard to that risk and the urgency of the exercise of those functions, the Commission considers that the information should be disclosed without the consent of the individual.

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(12) See section 23(6) of the 1999 Act for the definition of “confidential information”.

- (4) This paragraph applies where—
- (a) the prohibition on the disclosure of information operates by reason of the fact that the information is capable of identifying an individual; and
  - (b) the information in question is in a form in which the identity of the individual cannot be ascertained.
- (5) In a case where the disclosure of information is prohibited by—
- (a) paragraph (1); or
  - (b) paragraph (2) and the prohibition operates by reason of the fact that the information is capable of identifying an individual,

the Commission or a person authorised by the Commission under regulation 18(1) may require the person holding the information to put the information in a form in which the identity of the individual concerned cannot be identified, in order that the information may be disclosed.

## PART IX

### MISCELLANEOUS

#### **Assisting the Audit Commission**

**21.** The Commission may not assist the Audit Commission under section 21(2) of the Act without the consent of the Secretary of State.

#### **Exercising functions in relation to health service inquiries**

**22.—(1)** The Commission shall not exercise its functions under regulation 2(1)(f) and (g) in relation to a particular inquiry or proposed inquiry without the consent of the Secretary of State.

(2) In exercising its functions under regulation 2(1)(f) and (g) the Commission shall take into account any advice or guidance relating to health service inquiries given to NHS bodies by the Secretary of State.

Signed by Authority of the Secretary of State

9th March 2000

*John Denham*  
Minister of State,  
Department of Health

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision in relation to the functions of the Commission for Health Improvement established under section 19 of the Health Act 1999 (“the Commission”).

Regulation 2 sets out the functions of the Commission to be exercised in addition to those specified in sections 20(1)(a) to (d), 21 and 22 of the Health Act 1999.

Regulations 3 to 22 make provision in relation to the exercise of the Commission’s functions in England. In particular, they make provision for an annual work programme (regulation 3), the provision of advice or information with respect to arrangements for the purpose of monitoring and improving health care for which NHS bodies or providers of family health services have responsibility (“clinical governance arrangements”) (regulations 4 and 5), the conduct of local reviews of such arrangements and the reports relating to those reviews (regulations 6 to 9), reports following national service reviews of particular types of health care (regulation 10) and the conduct of investigations into the management, provision or quality of health care for which NHS bodies have responsibility and the reports relating to those investigations (regulations 11 to 16). Regulations 17 to 20 make provision for the Commission and persons authorised by the Commission to enter NHS premises and to obtain documents, information and explanations. Regulations 21 and 22 make provision relating to the provision of assistance to the Audit Commission and to inquiries relating to the health service.