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WELSH STATUTORY INSTRUMENTS

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**2000 No. 1015 (W. 57)**

**NATIONAL HEALTH SERVICE, WALES**

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

Made - - - - 30 March 2000  
Coming into force - - 1st April 2000

The National Assembly for Wales, in exercise of the powers conferred on the Secretary of State by sections 17 and 126(4) of the National Health Service Act 1977(1) and sections 20(2) and 23(1), (3) and (5) of the Health Act 1999(2) and now vested in the National Assembly(3) hereby makes the following Regulations:

**PART I**  
**GENERAL**

**Citation, commencement, interpretation and application**

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

(2) In these Regulations—

“the Act”(“*y Ddeddf*”) means the Health Act 1999;

“the 1977 Act” (“*Deddf 1977*”) means the National Health Service Act 1977;

“the 1997 Act”(“*Deddf 1997*”) means the National Health Service (Primary Care) Act 1997(4);

“the Audit Commission” (“*y Comisiwn Archwilio*”) means the Audit Commission for Local Authorities and the National Health Service in England and Wales;

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- (1) 1977 c. 49; section 17 was substituted by section 12 of 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), 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”.
- (3) The functions of the Secretary of State under these provisions are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the 1999 Act.
- (4) 1997 c. 46.

“clinical governance arrangements” (“*trefniadau llywodraethu clinigol*”) means arrangements by a National Health Service body or a service provider for monitoring and improving the quality of health care<sup>(5)</sup> for which they have responsibility;

“the Commission” (“*y Comisiwn*”) means the Commission for Health Improvement established by section 19 of the Act;

“financial year” (“*blwyddyn ariannol*”) means the period of 12 months ending with 31st March;

“the Functions Regulations” (“*y Rheoliadau Swyddogaethau*”) means the Commission for Health Improvement (Functions) Regulations 2000<sup>(6)</sup>;

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

“health care professional” (“*proffesiynolyn gofal iechyd*”) means a person who is registered as a member of a health care profession;

“health service inquiry” (“*ymchwiliad gwasanaeth iechyd*”) means an inquiry, held or established by the National Assembly or a National Health Service body, into any matter relating to the management, provision and quality of health care for which National Health Service bodies or service providers have responsibility;

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

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

“the National Assembly” (“*y Cynulliad Cenedlaethol*”) means the National Assembly for Wales;

“national service review” (“*adolygiad gwasanaeth gwladol*”) means a review conducted by the Commission under section 20(1)(d) of the Act;

“Part II services” (“*gwasanaethau Rhan II*”) means general medical services, general dental services, general ophthalmic services or pharmaceutical services under Part II of the 1977 Act;

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

“relevant Health Authority” (“*Awdurdod Iechyd perthnasol*”) means the Health Authority in whose area a service provider provides services;

“service provider” (“*darparydd gwasanaethau*”) means a person, other than a National Health Service body, who —

- (a) provides Part II services; or
- (b) provides services in accordance with a pilot scheme under the 1997 Act<sup>(7)</sup>.
- (c) These regulations apply to Wales only.

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<sup>(5)</sup> See sections 18(3) and 20(7) of the 1999 Act for the definition of “health care”.

<sup>(6)</sup> [S.I. 2000/662](#).

<sup>(7)</sup> See section 1 of the 1997 Act for a definition of “pilot scheme”.

## **PART II**

### **ANNUAL WORK PROGRAMME**

#### **Annual work programme**

2.—(1) Subject to paragraph (2), the Commission shall, before the beginning of each financial year, prepare a work programme setting out the activities the Commission is to undertake in that year in the exercise of its functions.

(2) As soon as is reasonably practicable after 1st April 2000 the Commission shall prepare such a work programme in relation to the remainder of the financial year beginning on that date and references in this regulation to “year” and “work programme” shall be construed accordingly.

(3) 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;
- (b) proposals as to the National Health Service 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.

(4) The work programme shall be subject to approval by the National Assembly.

(5) The work programme may be varied—

- (a) with the agreement of the National Assembly; or
- (b) as the National Assembly may determine.

(6) Subject to the following regulations and to any directions given by the National Assembly, the Commission shall exercise its functions in any particular financial year in accordance with the work programme relating to that year.

## **PART III**

### **ADVICE OR INFORMATION ON CLINICAL GOVERNANCE**

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

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

- (a) the National Assembly;
- (b) National Health Service bodies; and
- (c) service providers.

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

- (a) the National Assembly;
- (b) specified National Health Service 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**

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

- (a) any guidance relating to clinical governance arrangements given by the National Assembly or the National Institute for Clinical Excellence;
- (b) any advice or guidance relating to clinical governance arrangements given by any body responsible for the regulation of a health care profession.

**PART IV**

**LOCAL REVIEWS**

**Effectiveness and adequacy of arrangements**

5. In conducting a local review the Commission shall assess the effectiveness of the arrangements by the National Health Service body concerned and consider whether those arrangements are adequate.

**Local review reports**

6.—(1) Following the conclusion of a local review, the Commission shall make a report to the National Health Service 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**

7.—(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 National Health Service body which is the subject of the local review;
- (b) the National Assembly.

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

- (a) the National Health Service body which is the subject of the local review;
- (b) the National Assembly;

(c) any other national health service 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**

**8.**—(1) Following the conclusion of a local review the National Health Service 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 the National Assembly.

(3) Before deciding whether to approve a statement prepared under paragraph (1) the National Assembly shall consult the Commission.

## **PART V**

### **NATIONAL SERVICE REVIEWS**

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

**9.**—(1) At the conclusion of a national service review the Commission shall make a report to the National Assembly.

(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 VI**

### **INVESTIGATIONS**

#### **Investigations**

**10.**—(1) The Commission shall carry out an investigation when requested to do so by the National Assembly.

(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 National Assembly, it shall investigate such matters falling within section 20(1)(c) of the Act or regulation 2(e) of the Functions Regulations 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) of the Functions Regulations as it considers appropriate.

### **Notice of investigation**

11. 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 National Health Service body or service provider which is to be the subject of an investigation;
- (b) in the case of an investigation under regulation 10(2) concerning a Health Authority, a Special Health Authority or a National Health Service Trust, the National Assembly; and
- (c) in the case of an investigation concerning a service provider, the relevant Health Authority.

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

12.—(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; and
- (b) in a case where the body subject to the local review is a Health Authority, a Special Health Authority or a National Health Service Trust, the National Assembly.

(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**

13.—(1) Following the conclusion of an investigation which has been requested by the National Assembly the Commission shall make a report to the National Assembly 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 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 National Assembly; and
- (c) in the case of an investigation concerning 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 National Assembly; and
- (b) in the case of an investigation concerning 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 a report.

### **Special interest reports**

**14.**—(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 National Health Service body or service provider which is the subject of the investigation;
- (b) the National Assembly;
- (c) in a case where 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 National Health Service body or service provider which is the subject of the investigation;
- (b) the National Assembly;
- (c) in a case to which paragraph (2)(c) applies, the relevant Health Authority;
- (d) any other National Health Service 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**

**15.**—(1) Following the conclusion of an investigation, any National Health Service 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 the National Assembly.

(3) Before deciding whether to approve a statement prepared under paragraph (1) the National Assembly shall consult the Commission.

## **PART VII**

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

#### **Rights of entry**

**16.**—(1) Subject to the following paragraphs of this regulation, persons authorised in writing by the Commission may at any reasonable time enter and inspect National Health Service premises<sup>(8)</sup> for the purposes of conducting local reviews, national service reviews or investigations.

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(8) See section 23(6) of the 1999 Act for the definition of “National Health Service premises”.

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

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

(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 National Health Service body, without first having obtained the consent of the officers residing in such accommodation.

(5) Subject to regulation 19, a person authorised by the Commission under paragraph (1) entering National Health Service premises under this regulation may inspect and take copies of any documents which—

- (a) appear to the person authorised to be necessary for the purposes of the review or investigation in question; and
- (b) are held on the premises by—
  - (i) the National Health Service 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**

17.—(1) Subject to regulation 19, in conducting a local review or investigation the Commission or a person authorised by the Commission under regulation 16(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 19, in conducting a local review or investigation the Commission or a person authorised by the Commission may, if it or that person 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 16(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 16(1) in person to produce the documents or information or give the explanation.

(4) The Commission or a person authorised under regulation 16(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 persons referred to in paragraphs (1) and (2) are —
- (a) a National Health Service body;
  - (b) a chairman, member, director or employee of a National Health Service body, or any other person acting on behalf of such a body;

- (c) a member of a committee or sub-committee of a National Health Service 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 or any 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 a National Health Service body, a service provider or a person to which subparagraph (g) applies;
- (g) a local authority which provides, or a person employed by a 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**

**18.**—(1) In this regulation and in regulations 16 and 17, any reference to documents includes a reference to information held by means of a computer or in any other electronic form.

- (1) Where the Commission or a person authorised under regulation 16(1) is exercising —
  - (a) the right under regulation 16(5) to inspect and take copies of documents; or
  - (b) the right under regulation 17(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**

**19.**—(1) The Commission or a person authorised under regulation 16(1) shall not inspect or take copies of documents under regulation 16(5) to the extent that—

- (a) those documents consist of confidential information<sup>(9)</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 17(1) or give an explanation under regulation 17(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;

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<sup>(9)</sup> See section 23(6) of the 1999 Act for the definition of “confidential information”.

- (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.
- (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 16(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 VIII

### MISCELLANEOUS

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

**20.** The Commission shall not assist the Audit Commission under section 21(2) of the Act without the consent of the National Assembly.

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

**21.—**(1) The Commission shall not exercise its function under regulation 2(f) of the Functions Regulations in relation to a particular health service inquiry or proposed health service inquiry without the consent of the National Assembly.

(2) In exercising its function under regulation 2(f) of the Functions Regulations the Commission shall take into account any advice or guidance relating to health service inquiries given to National Health Service bodies by the National Assembly.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(10). 30th March 2000

*D. Elis Thomas*  
The Presiding Officer of the National Assembly

## EXPLANATORY NOTE

*(This note does not form part of the Regulations.)*

These Regulations make provision in relation to the exercise in Wales of the functions of the Commission for Health Improvement established under section 19 of the Health Act 1999.

The Commission's core functions are conferred on it by section 20 of the Health Act 1999 which provides for the Commission —

- to provide advice and information on arrangements for the monitoring and improvement of health care provided by National Health Service Trusts and Primary Care Trusts (where established), including clinical governance arrangements;
- to conduct reviews of the implementation and adequacy of such arrangements;
- to investigate, advise and report on specific matters relating to the delivery and management of health care provided by National Health Service bodies;
- to conduct national reviews on particular types of health care provided by the National Health Service.

Section 20(1)(e) of the Health Act 1999 provides for additional functions to be conferred by regulations. The power to make such regulations is exercisable by the Secretary of State for Health and has been exercised by the addition of the following extra functions as set out in regulation 2 of the Commission for Health Improvement (Functions) Regulations 2000 which reads as follows —

“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>(11)</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.”

There are cross references to regulation 2 in the Commission for Health Improvement (Functions) (Wales) Regulations 2000.

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<sup>(11)</sup> See section 18(3) of the Health Act 1999 (c. 8) (“the 1999 Act”).

These regulations make provision for the preparation of the Commission's annual work programme (regulation 2), the provision by the Commission of advice or information with respect to clinical governance arrangements to the National Assembly and health service bodies and others (regulations 3 and 4), the conduct of local reviews of such arrangements and the reports and follow up action relating to those reviews (regulations 5 to 8), reports following national service reviews of particular types of health care (regulation 9) and the conduct of investigations into the management, provision or quality of health care for which National Health Service bodies have responsibility and the reports relating to those investigations (regulations 10 to 15).

Regulations 16 to 19 make provision for the Commission and persons authorised by it to enter National Health Service premises and to obtain documents, information and explanations.

Regulation 20 precludes the Commission from providing assistance to the Audit Commission in the exercise of certain of its functions, without the consent of the National Assembly. Regulation 21 makes provision regarding the role of the Commission in providing assistance in relation to health service inquiries.