Date:	12 March 2003
Venue:	Committee Rooms 3 & 4, National Assembly for Wales
Title:	CHI (Amendment) (Wales) Regulations

Purpose

1. This paper provides an opportunity for the Health and Social Services Committee to comment on the draft regulations to be provided to the Commission for Health Improvement ("CHI").

Background

2. The provisions in the draft regulations reflect the amendments made to sections 20 and 23 of the Health Act 1999 by sections 12 and 13 of the National Health Service Reform and Healthcare Professions Act 2002. It is the Secretary of State who is empowered to commence the relevant sections following consultation with the Assembly. Sections 12 and 13 have not yet been commenced. Current indications are that section 12 will be commenced in March and section 13 will be commenced in April. Interim provisions are in force to ensure that CHI is able to carry out its functions for 2003/04 until commencement is in force and the new regulations are approved.

3. The provisions also reflect the amendments made to the National Health Service Act 1977 by section 6 of the National Health Service Reform and Healthcare Professions Act 2002 creating the statutory framework for the establishment of Local Health Boards ("LHBs") in Wales.

Content of the Regulations

4. The draft regulations are intended to replace the Commission for Health Improvement (Functions) (Wales) Regulations 2000. In particular they make provision reflecting the abolition of Health Authorities and establishment of LHBs. The draft regulations are likely to be in force only until 31st March 2004, following which a new framework for reviews and investigations should be introduced by the Health and Social Care Bill.

5. During the course of existence CHI has undertaken local reviews of NHS Trusts within Wales, these reviews are carried out for the purpose of monitoring and improving the quality of health care provided by these bodies. Previously the reviews have been know as "local reviews" although they are more properly and now more generally termed "clinical governance reviews" and the draft regulations encompass this new terminology.

6. Section 20 of the Health Act has been amended and the functions of CHI across England and Wales have been widened. CHI is now empowered to conduct reviews and make reports on the management provision or quality of or access to or availability of health care for which NHS bodies or service providers have responsibility. This function amounts to carrying out "general reviews" of health care, this is a new category within the draft regulations. These general reviews may also be more specifically focused on specific types of health care continue to be known as "national service" reviews.

7. Additionally a new function has been conferred on CHI, that of conducting "validation reviews" under section 20(1)(da) of the Act, this inolves reviewing and reporting on the quality of data relating to the management, provision or quality of, to access to or availability of health care and more particularly examining the validity of conclusions drawn from such data.

8. The power of carrying out inspections on NHS bodies and service providers is also conferred on CHI by section 20(1)(db).

9. The draft regulations are similar in nature to the 2000 Regulations providing that CHI must provide an annual work programme. CHI must also give advice or information on clinical governance arrangements to the Assembly, NHS bodies and service providers.

10. In conducting clinical governance reviews CHI must consider the effectiveness and adequacy of arrangements put in place by NHS Trusts. Following reviews, CHI must report to the Assembly and provide copies to the bodies concerned. CHI may also report on any specific matter of public interest ("special interest report") during the course of a review and must provide copies of this report to the Assembly and the body concerned (or in the case of the service provider to the relevant LHB).

11. In the case of general reviews, CHI may also compile a special interest report, copies of which it must provide to the Assembly, the body concerned and the relevant LHB in the case of a service provider. At the end of a general review CHI must report to the bodies subject to the review, in the case of a national service review CHI must report to the Assembly.

12. Following the conclusion of a review the NHS body must, with CHI's assistance, prepare a written statement of the action it proposes to take in the light of the report. Such a statement shall be subject to approval by the Assembly.

13. Additionally CHI is required to carry out investigations where so requested by the Assembly and may do so where requested by any person or body. CHI is required to give reasonable notice to the body in question (or LHB in the case of a service provider). CHI may also undertake an investigation it if considers this appropriate whilst conducting a clinical governance or general review. Following an investigation CHI is required to report to the Assembly and send copies of the report to the bodies concerned, or any person requesting the investigation. During an investigation CHI may also undertake a special interest report.

14. The draft regulations also set out the rights of CHI to enter "relevant premises". This is different from the 2000 regulations. "Relevant premises" means premises owned or controlled by NHS bodies, including an LHBs, or by service providers, as well as any other premises used for any purpose connected with the provision of health care with the context of the NHS. This provision is considerably wider than that of the 2000 Regulations which allowed CHI simply to enter premises of NHS bodies.

15. The regulations also empower CHI to obtain information and explanations from NHS bodies and service providers, as well as directors and members of the bodies and employees of the bodies and service providers in question. This extends to the provision of information held by a computer. The regulations also set out restrictions on the type of information which may be disclosed to CHI, these provisions tie in with those of the Data Protection Act 1998. Information may be disclosed, however, if there is a serious risk to the health or safety of patients.

Financial Implications

16. There are no financial implications arising from the amendment of the regulations. The costs of sponsoring CHI is met from NHSQ clinical effectiveness budget, £2 million of which has been earmarked for CHI sponsorship. This funding is held within the PHLS/NBSB and Central Initiatives BEL. NHS Finance has been consulted and noted the financial implications of this submission

Timetable

17. The main stages which I propose are:

(a) Draft proposed Regulations to be revised in light of Committee's views.

(b) Following inclusion of any proposed amendments from Committee and subject to commencement orders being made for section 12 and section 13 of the National Health Service Reform and Healthcare Professions Act 2002, the draft Regulations will be submitted to first available Business Committee, Legislation Committee, and plenary following confirmation of commencement

(c) The Committee will be advised when commencement orders have been made and the consequent procedural timetable.

Action

18. I would welcome the views of the Health and Social Services Committee on the proposed draft regulations.

Jane Hutt
Minister for Health and Social Services

Contact : Ken Alexander, Tel 029 2082 3791

NATIONAL ASSEMBLY FOR WALES

S T A T U T O R Y I N S T R U M E N T S

2003 No. (W.)

COMMISSION FOR HEALTH IMPROVEMENT (FUNCTIONS) (WALES) REGULATIONS 2003

NATIONAL HEALTH SERVICE, WALES

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").

Regulations 2 to 19 make provision in relation to the exercise of the Commission's functions in Wales. In particular, they make provision for an annual work programme (regulation 2), 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 (regulations 3 and 4), the conduct of reviews of such arrangements and of reviews of the management, provision or quality of, or access to or availability of health care for which NHS bodies or such providers are responsible (regulations 5 to 9), the conduct of investigations into the management, provision or quality of health care for which NHS bodies have responsibility (regulations 10 to 15).

Regulations 16 to 19 make provision for the Commission and persons authorised by the Commission to enter relevant premises and to obtain documents, information and explanations. Regulations 20 and 21 make provision relating to the provision of assistance to the Audit Commission and to inquiries relating to the health service.

S T A T U T O R Y I N S T R U M E N T S

2003 No. (W.)

COMMISSION FOR HEALTH IMPROVEMENT (FUNCTIONS) (WALES) REGULATIONS 2003

NATIONAL HEALTH SERVICE, WALES

Made	*2003*
Coming into force	*2003*

The National Assembly for Wales, in exercise of the powers conferred on it by sections 17 and 126(4) of the National Health Service Act 1977(**1**) and sections 20(2) and 23 of the Health Act 1999(**2**) and of all other powers enabling him in that behalf, hereby makes the following Regulations:

PART I

GENERAL

Citation, commencement, application and interpretation

1. —(1) These Regulations may be cited as the Commission for Health Improvement (Functions) (Wales) Regulations 2003 and shall come into force on [ ] 2003.

(2) These Regulations apply to Wales only.

(3) 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(**3**);

"the Audit Commission" means the Audit Commission for Local Authorities and the National Health Service in England and Wales(**4**);

"clinical governance review" 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;

"clinical governance arrangements" means —

(a) in the case of an NHS trust, or a service provider, arrangements for monitoring and improving the quality of health care(**5**) for which they have responsibility;

(**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. Section 20(2) was amended by section 12(1) and (4) of the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act") and section 23 was amended by section 13(2) of that Act.

(**3**) 1997 c. 46.

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

(b) in the case of a Local Health Board, arrangements for the purpose of monitoring and improving the quality of health care which is provided to individuals in their area;

"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;

"Functions Regulations" means the Commission for Health Improvement (Functions) Regulations 2000(**6**);

"general review" means a review conducted by the Commission under section 20(1)(d) of the Act(**7**);

"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 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(**8**) or regulation 2(e) of the Functions Regulations;

"national service review" means a general review that relates to particular types of health care for which NHS bodies or service providers have responsibility;

"National Assembly" means the National Assembly for Wales;

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

"relevant Local Health Board" means, in relation to a service provider —

(a) where the service provider provides services in the area of only one Local Health Board, that Local Health Board, or

(b) where the service provider provides services in the area of two or more Local Health Board, each of those Local Health Boards;

"relevant premises" means relevant premises as defined by section 23(6) of the Act;

"service provider" means a person, other than an NHS body(**9**), who —

(a) provides Part II services;

(b) provides services in accordance with a pilot scheme under the 1997 Act; or

(c) provides services in accordance with arrangements under section 28 of the Health and Social Care Act 2001(**10**);

"validation review" means a review under section 20(1)(da)(**11**) of the Act.

(4) 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.

(**5**) *See* sections 18(4) and 20(7) of the 1999 Act for the definition of "health care".
(**6**) S.I. 2000/662 as amended by S.I. 2000/797 and S.I. 2002/2469.
(**7**) Section 20(1)(d) was amended by section 20(1) and (2) of the 2002 Act.
(**8**) Section 20(1)(c) was amended by Schedule 1, paragraph 49, of the 2002 Act.
(**9**) See section 20(7) of the Act for the definition of "NHS body"; the definition was amended by Schedule 1, paragraph 49, to the 2002 Act.
(**10**) c. 15.
(**11**) Section 20(1)(da) was inserted by section 12(2)(c) of the 2002 Act.

PART II

ANNUAL WORK PROGRAMME

Annual work programme

2. —(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;

(b) proposals as to the NHS bodies in relation to which the Commission is to conduct clinical governance reviews;

(c) proposals as to the persons or bodies in relation to which the Commission is to conduct general reviews;

(d) any particular matters which the Commission is to consider or take into account when conducting a clinical governance review or a general review;

(e) the particular types of health care which are to be the subject of any national service reviews; and

(f) any particular matters with respect to which the Commission is to conduct validation reviews.

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

(4) The work programme may be varied —

(a) with the agreement of the National Assembly; or

(b) as the National Assembly may determine.

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

PART III

ADVICE OR INFORMATION ON CLINICAL GOVERNANCE ARRANGEMENTS

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) NHS 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 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

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(**12**);

(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

REVIEWS

Effectiveness and adequacy of arrangements

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

Review reports

6. —(1) Following the conclusion of a clinical governance review, the Commission shall make a report to the NHS body concerned.

(2) Following the conclusion of a general review other than a national service review, the Commission shall make a report to the persons or bodies that were the subject of the review.

(3) At the conclusion of a national service review the Commission shall make a report to the National Assembly.

(4) The reports referred to in paragraph (1) to (3) shall set out —

(a) the findings and conclusions of the Commission; and

(b) any recommendations made by the Commission.

Special interest reports – clinical governance review

7. —(1) If in the course of a clinical governance 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 review;

(b) the National Assembly.

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

(a) the NHS body which is the subject of the review;

(b) the National Assembly;

(c) in a case to which paragraph (2)(c) applies, the relevant Local Health Board

(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.

(**12**) *See* S.I.1999/220 as amended by S.I.1999/2219.

Special interest reports – general review

8. —(1) If in the course of a general 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) a person or body which is the subject of the review;

(b) the National Assembly

(c) in a case where a service provider is the subject of the review, the relevant Local Health Board

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

(a) the person or body who is the subject of the review and to whose attention the Commission considers that the matter should be drawn;

(b) where that person or body is a service provider, the relevant Local Health Board;

(c) the National Assembly;

(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.

Further action following a review

9. —(1) Paragraphs (2) to (4) below apply where an NHS body has been the subject of a clinical governance review or of a general review other than a national review.

(2) Following the conclusion of a 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.

(3) A statement prepared under paragraph (2) shall be subject to approval in the case of a Local Health Board, a Special Health Authority or an NHS trust, by the National Assembly.

(4) Before deciding whether to approve a statement prepared under paragraph (2), the National Assembly shall consult the Commission.

PART V

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) or regulation 2(e) of the Functions Regulations of the Act 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 person or body which is to be the subject of an investigation;

(b) in the case of an investigation under regulation 10(2) concerning a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly;

(c) in the case of an investigation concerning a service provider, the relevant Local Health Board.

Conducting an investigation of a body which is the subject of a review

12. —(1) If in the course of conducting a clinical governance review or a general 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) Where the Commission is conducting a clinical governance review, the Commission 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 person or body which is the subject of the review;

(b) in a case where the body subject to the review is a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly.

(3) Where the Commission is conducting a general review, the Commission 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) any person or body who is the subject of the review and who is also to be the subject of the investigation;

(b) where that person or body is a service provider, the relevant Local Health Board.

(4) Where the Commission commences such an investigation, the Commission may suspend or continue the clinical governance review or the general review and, where the 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;

(b) in the case of an investigation concerning a service provider, the relevant Local Health Board.

(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 Local Health Board.

(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 Local Health Board.

(4) A report made under paragraphs (1) to (3) shall set out —

(a) the findings and conclusions of the Commission;

(b) any recommendations made by the Commission.

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 person or body 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 Local Health Board.

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

(a) any person or body which is the subject of the investigation;

(b) the National Assembly;

(c) in a case to which paragraph (2)(c) applies, the relevant Local Health Board; and

(d) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report shall be copied.

Further action following an investigation

15. —(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 in the case of a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly.

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

PART VI

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 relevant premises for the purposes of conducting clinical governance reviews, general 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 relevant 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 relevant premises as of right unless the person or 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 person or body, without first having obtained the consent of the persons residing in such accommodation.

(5) Subject to regulation 19, a person authorised by the Commission under paragraph (1) to enter relevant 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 person or body which owns or controls the premises;

(ii) a chairman, member, director or employee of that person or body;

(iii) any other person acting on behalf of that person or body; or

(iv) a member of a committee or sub-committee of any body concerned.

Obtaining information and explanations

17. —(1) Subject to regulation 19, in conducting a clinical governance review, a general review or an 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 clinical governance review, a general review or an 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 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 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

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.

(2) 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(**13**) 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;

(d) in a case where the Commission is exercising its functions under section 20(1)(c), (d) or (db) of the Act (**14**) or regulation 2(e) of the Functions Regulations —

(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

---

(**13**) *See* section 23(6) of the 1999 Act for the definition of "confidential information".
(**14**) Section 20(1)(db) was inserted by section 13(1) of the 2002 Act.

(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 VII

MISCELLANEOUS

Assisting the Audit Commission

20. The Commission may 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 functions under regulation 2(1)(f) of the Functions Regulations in relation to a particular inquiry or proposed inquiry without the consent of the National Assembly.

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

Revocation

22. The Commission for Health Improvement (Functions) (Wales) Regulations 2000 (15) are revoked.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**16**)

Date

The Presiding Officer of the National Assembly

(**15**) S.I. 2000/1015.
(**16**) 1998 c.38.