Draft Regulations laid before Parliament under section 64(3) of the Health and Social Care Act 2001, for approval by resolution of each House of Parliament

DRAFT STATUTORY INSTRUMENTS

2002 No.

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

The Health Service (Control of Patient Information) Regulations 2002

Made - - - -	*2002*
Coming into force - -	*1st June 2002*

Whereas a draft of the following Regulations was laid before Parliament in accordance with section 64(3) of the Health and Social Care Act 2001(**1**) and was approved by resolution of each House of Parliament:

Now, therefore, the Secretary of State for Health, in exercise of the powers conferred on him by sections 60(1) and 64(6), (7) and (8) of the Health and Social Care Act 2001 and all other powers enabling him in that behalf, having consulted such bodies as appear to him to represent the interests of those likely to be affected by the Regulations in accordance with section 60(7) of that Act and having sought and had regard to the views of the Patient Information Advisory Group(**2**) on the proposed Regulations in accordance with section 61(2) of that Act, hereby makes the following Regulations—

Citation, commencement, interpretation and extent

1.—(1) These Regulations may be cited as the Health Service (Control of Patient Information) Regulations 2002 and shall come into force on 1st June 2002.

(2) In these Regulations—

"the Act" means the Health and Social Care Act 2001,

"public authority" has the same meaning as in section 3(1) of the Freedom of Information Act 2000(**3**);

(**1**) 2001 c. 15.
(**2**) *See* S.I. 2001/2836.
(**3**) 2000 c. 36.

"public health laboratory service" means the microbiological service provided by the Public Health Laboratory Service Board under section 5(2)(c) and (4) of the National Health Service Act 1977(**4**);

"research ethics committee" means a local research ethics committee established or recognised by a health authority within its area or a multi-centre research ethics committee which is recognised by Secretary of State in respect of research carried out within five or more health authority areas or any other research ethics committee recognised by the Secretary of State.

(3) Any notice given under these Regulations shall be—

(a) in writing; or

(b) transmitted by electronic means in a legible form which is capable of being used for subsequent reference.

(4) Any reference in these Regulations to a numbered regulation is a reference to the regulation which bears that number in these Regulations and any reference to a numbered paragraph in a regulation is a reference to the paragraph which bears that number in that regulation.

(5) These Regulations extend to England and Wales only.

Medical purposes related to the diagnosis or treatment of neoplasia

2.—(1) Subject to paragraphs (2) to (3) and regulation 7, confidential patient information relating to patients referred for the diagnosis or treatment of neoplasia may be processed for medical purposes approved by the Secretary of State which comprise or include—

(a) the surveillance and analysis of health and disease;

(b) the monitoring and audit of health and health related care provision and outcomes where such provision has been made;

(c) the planning and administration of the provision made for health and health related care;

(d) medical research approved by research ethics committees;

(e) the provision of information about individuals who have suffered from a particular disease or condition where—

(i) that information supports an analysis of the risk of developing that disease or condition; and

(ii) it is required for the counseling and support of a person who is concerned about the risk of developing that disease or condition.

(2) For the purposes of this regulation, "processing" includes (in addition to the use, disclosure or obtaining of information) any operations, or set of operations, which are undertaken in order to establish or maintain databases for the purposes set out in paragraph (1), including—

(a) the recording and holding of information;

(b) the retrieval, alignment and combination of information;

(c) the organisation, adaption or alteration of information;

(d) the blocking, erasure and destruction of information.

(3) The processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by bodies or persons who (either individually or as members of a class) are—

(a) approved by the Secretary of State, and

(b) authorized by the person who lawfully holds the information.

(**4**) 1977 c. 49; subsections (2)(c) and (4) of section 5 were amended by the Public Health Laboratory Service Act 1979 (c. 23), section 1.

(4) Where the Secretary of State considers that it is necessary in the public interest that confidential patient information is processed for a purpose specified in paragraph (1), he may give notice to any body or person who is approved and authorized under paragraph (3) to require that body or person to process that information for that purpose and any such notice may require that the information is processed forthwith or within such period as is specified in the notice.

(5) Where confidential information is processed under this regulation, the bodies and persons approved under paragraph (3) shall make available to the Secretary of State such information as he may require to assist him in the investigation and audit of that processing and in his annual consideration of the provisions of these Regulations which is required by section 60(4) of the Act.

Communicable disease and other risks to public health

3.—(1) Subject to paragraphs (2) and (3) and regulation 7, confidential patient information may be processed with a view to—

(a) diagnosing communicable diseases and other risks to public health;

(b) recognising trends in such diseases and risks;

(c) controlling and preventing the spread of such diseases and risks;

(d) monitoring and managing—

(i) outbreaks of communicable disease;

(ii) incidents of exposure to communicable disease;

(iii) the delivery, efficacy and safety of immunisation programmes;

(iv) adverse reactions to vaccines and medicines;

(v) risks of infection acquired from food or the environment (including water supplies);

(vi) the giving of information to persons about the diagnosis of communicable disease and risks of acquiring such disease.

(2) For the purposes of this regulation, "processing" includes any operations, or set of operations set out in regulation 2(2) which are undertaken for the purposes set out in paragraph (1).

(3) The processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by—

(a) the Public Health Laboratory Service;

(b) persons employed or engaged for the purposes of the health service;

(c) other persons employed or engaged by a Government Department or other public authority in communicable disease surveillance.

(4) Where the Secretary of State considers that it is necessary to process patient information for a purpose specified in paragraph (1), he may give notice to any body or person specified in paragraph (3) to require that body or person to process that information for that purpose and any such notice may require that the information is processed forthwith or within such period as is specified in the notice.

(5) Where confidential information is processed under this regulation, the bodies and persons specified in paragraph (3) shall make available to the Secretary of State such information as he may require to assist him in the investigation and audit of that processing and in his annual consideration of the provisions of these Regulations which is required by section 60(4) of the Act.