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STATUTORY INSTRUMENTS

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**2003 No. 696**

**The Prescription Only Medicines  
(Human Use) Amendment Order 2003**

**Amendment of article 1 of the principal Order**

2.—(1) Article 1 of the principal Order (citation, commencement and interpretation) is amended as follows.

(2) In paragraph (2)—

(a) after the definition of “aerosol”, insert the following definitions—

““clinical management plan” means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

- (a) the patient to whom the plan relates,
- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

“clinical trial exemption” means an exemption conferred by—

- (a) section 31(5) of the Act,
- (b) article 4 of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(1),
- (c) article 2 or 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974(2), or
- (d) article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995(3);”;

(b) in the definition of “extended formulary nurse prescriber”—

(i) for paragraph (a), substitute the following paragraph—

“(a) who is a first level nurse, and”, and

(ii) in paragraph (b), for “that register” substitute “the professional register”;

(c) after the definition of “external use”, insert the following definition—

““first level nurse” means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;”;

(d) after the definition of “Health Authority”(4), insert the following definition—

““health care” means services for or in connection with the prevention, diagnosis or treatment of disease;”;

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(1) S.I.1972/1200.

(2) S.I. 1974/498.

(3) S.I. 1995/2808.

(4) The definition of “Health Authority” was inserted by S.I. 2000/1917.

- (e) in the definition of “health prescription”, after “dentist” insert “, supplementary prescriber”;
- (f) after the definition of “health prescription”, insert the following definition—  
 ““health record” has the meaning given by section 68(2) of the Data Protection Act 1998<sup>(5)</sup>”;
- (g) after the definition of “homoeopathic certificate of registration”<sup>(6)</sup>, insert the following definitions—  
 ““independent clinic”—  
 (a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000<sup>(7)</sup>, and  
 (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001<sup>(8)</sup>;  
 “independent hospital”—  
 (a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and  
 (b) in relation to Scotland, means—  
 (i) an independent hospital, or  
 (ii) a private psychiatric hospital,  
 as defined by section 77(1) of the Regulation of Care (Scotland) Act 2001;  
 “independent medical agency”—  
 (a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and  
 (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001”;
- (h) after the definition of “NHS trust”<sup>(9)</sup>, insert the following definition—  
 ““nursing home” has the meaning given by article 16 of the Registered Homes (Northern Ireland) Order 1992<sup>(10)</sup>”;
- (i) after the definition of “Primary Care Trust”<sup>(11)</sup>, insert the following definition—  
 ““prison service” means—  
 (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952<sup>(12)</sup>),  
 (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989<sup>(13)</sup>), and  
 (c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953<sup>(14)</sup>);”;

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(5) 1998 c. 29.

(6) The definition of “homoeopathic certificate of registration” was inserted by S.I. 2000/1917.

(7) 2000 c. 14.

(8) 2001 asp 8.

(9) The definition of “NHS trust” was inserted by S.I. 2000/1917.

(10) S.I. 1992/3204 (N.I. 20).

(11) The definition of “Primary Care Trust” was inserted by S.I. 2000/1917.

(12) 1952 c. 52.

(13) 1989 c. 45.

(14) 1953 (c. 18 (N.I.)).

- (j) after the definition of “registered ophthalmic optician”, insert the following definition—
- ““registered provider” means—
- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
    - (i) in relation to England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency,
    - (ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and
  - (b) in relation to a nursing home, the person registered under Part III of the Registered Homes (Northern Ireland) Order 1992 as the person carrying on the nursing home, other than a manager who is to be treated as carrying on the home by virtue of article 17(2) of that order;
- “relevant manager” means—
- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
    - (i) in relation to England and Wales—
      - (aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
      - (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,
    - (ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of Regulation of Care (Scotland) Act 2001, and
  - (b) in relation to a nursing home, the manager of the nursing home, unless they are the registered provider for that home;
- “relevant register” means—
- (a) in relation to a first level nurse, the professional register, and
  - (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954<sup>(15)</sup> or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976<sup>(16)</sup>;
- (k) after the definition of “Strategic Health Authority”<sup>(17)</sup>, insert the following definition—
- ““supplementary prescriber” means—
- (a) a first level nurse, or
  - (b) a pharmacist,
- against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;”.

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<sup>(15)</sup> 1954 c. 61.

<sup>(16)</sup> S.I. 1976/1213 (N.I.22).

<sup>(17)</sup> The definition of “Strategic Health Authority” was inserted by regulation 7 of, and Schedule 4 to, S.I. 2002/2469.

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**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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(3) In paragraph (7)(**18**), for “12C” substitute “12E”.