## 2013 No. 373

# The Controlled Drugs (Supervision of Management and Use) Regulations 2013

## PART 1

### Introductory

#### Interpretation

**2.**—(1) In these Regulations—

"the 1978 Act" means the National Health Service (Scotland) Act 1978(1);

"the 2006 Act" means the National Health Service Act 2006(2);

"care home", as regards-

- (a) England, has the meaning given in section 3 of the Care Standards Act 2000(3) (care homes); or
- (b) Scotland, has the meaning given in relation to a care home service in paragraph 2 of Schedule 12 to the Public Services Reform (Scotland) Act 2010(4) (care services: definitions care home service);

"the Care Inspectorate" means Social Care and Social Work Improvement Scotland, established by section 44 of the Public Services Reform (Scotland) Act 2010 (Social Care and Social Work Improvement Scotland);

"CCG" means a clinical commissioning group established under section 14D of the 2006 Act(5) (effect of grant of an application);

"commissioning body" is to be construed in accordance with regulation 7(3)(a);

"Common Services Agency" means the body of that name constituted by section 10 of the 1978 Act(6) (Common Services Agency);

"CQC" means the Care Quality Commission established by section 1 of the Health and Social Care Act 2008(7) (the Care Quality Commission);

"designated body", as regards—

- (a) England, is to be construed in accordance with regulation 7(1); or
- (b) Scotland, is to be construed in accordance with regulation 7(2);

<sup>(1) 1978</sup> c. 29.

<sup>(</sup>**2**) 2006 c. 41.

<sup>(3) 2000</sup> c. 14; section 3 has been amended by the Health and Social Care Act 2008 (c. 14), Schedule 5, paragraph 4.

<sup>(4) 2010</sup> asp 8.

<sup>(5)</sup> Inserted by the Health and Social Care Act 2012 (c. 7), section 25(1).

 <sup>(6)</sup> Section 10 has been amended by: the Health Services Act 1980 (c. 53), Schedule 6, paragraph 2; the National Health Service and Community Care Act 1990 (c. 19), Schedule 10; the Health Act 1999 (c. 8), Schedule 4, paragraph 44; the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(4); and the Patient Rights (Scotland) Act 2011 (asp 5), section 17(1).

<sup>(7) 2008</sup> c. 14.

"enactment" includes an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament;

"English independent hospital" is to be construed in accordance with regulation 3;

"Health Board" means, except in the phrase "Special Health Board", a board which is constituted by order under, and called a Health Board by virtue of, section 2(1)(a) of the 1978 Act(8) (Health Boards);

"the health service" means-

- (a) as regards England, the health service continued under section 1(1) of the 2006 Act(9) (Secretary of State's duty to promote comprehensive health service); and
- (b) as regards Scotland, the health service established in pursuance of section 1 of the National Health Service (Scotland) Act 1947(10) (duty of Secretary of State);

"HIS" means Healthcare Improvement Scotland established by section 10A of the 1978 Act(11) (Healthcare Improvement Scotland);

"hospital" means an institution or home which is—

- (a) an institution for the reception and treatment of persons suffering from illness (whether relating to physical or mental health);
- (b) a maternity home;
- (c) an institution for the reception and treatment of persons during convalescence or persons requiring medical rehabilitation (including where such treatment is as a consequence of procedures that are similar to forms of medical or surgical care but are not provided in connection with medical conditions); or
- (d) as regards Scotland, an institution providing dental treatment maintained in connection with a dental school,

and includes clinics, dispensaries and out-patient departments maintained in connection with any such home or institution;

"local authority", as regards-

- (a) England, has the meaning given in section 2B(5) of the 2006 Act(12) (functions of local authorities and Secretary of State as to improvement of public health); and
- (b) Scotland, means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(13) (constitution of councils) and also includes a joint board or joint committee with the meanings given in section 235(1) of the Local Government (Scotland) Act 1973(14) (general provisions as to interpretation);

"local intelligence network" is to be construed in accordance with regulation 14(2);

"local intelligence network area" is to be construed in accordance with regulation 14(1);

"local lead CDAO" is to be construed in accordance with regulation 14(4);

<sup>(8)</sup> Section 2 has been amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c.19), section 28, Schedule 9, paragraph 19(1), and Schedule 10; the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(2); the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(2); and the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5), section 2(1).

<sup>(9)</sup> Section 1 was substituted by the Health and Social Care Act 2012 (c. 7), section 1.

<sup>(10) 1947</sup> c. 27.

<sup>(11)</sup> Section 10A was inserted the Public Services Reform (Scotland) Act 2010 (asp 8), section 108.

<sup>(12)</sup> Section 2B was inserted by the Health and Social Care Act 2012 (c. 7), section 12.

<sup>(13) 1994</sup> c. 39; section 2 has been amended by the Environment Act 1995 (c. 25), Schedule 22, paragraph 232(1).

<sup>(14) 1973</sup> c. 65; section 235(1) has been amended by: the Local Government etc. (Scotland) Act 1994, Schedule 13, paragraph 92(66), and Schedule 14; the Education (Scotland) Act 1980 (c. 44), Schedule 3, paragraph 1; and the Audit (Miscellaneous Provisions) Act 1996 (c. 10), section 4(2).

"National Waiting Times Centre Board" means the Special Health Board of that name constituted by the National Waiting Times Centre Board (Scotland) Order 2002(15);

"NHSBSA" means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(16);

"NHSCB" means the National Health Service Commissioning Board established by section 1H of the 2006 Act(17) (the National Health Service Commissioning Board and its general functions);

"NHS Protect" means the Division of the NHSBSA known as NHS Protect;

"NHS foundation trust" means a corporation of the type referred to in section 30(1) of the 2006 Act(**18**) (NHS foundation trusts);

"NHS trust" means a body that is an NHS Trust for the purposes of the 2006 Act(19) other than an NHS Trust established under the National Health Service (Wales) Act 2006(20);

"provider body" is to be construed in accordance with regulation 7(3)(b);

"regular force" means the Royal Air Force, the Royal Navy, the Royal Marines or the regular army (that is, Her Majesty's military forces other than the Army Reserve, the Territorial Army or the forces raised under the law of a British overseas territory);

"regulatory body" means a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(21) (the Professional Standards Authority for Health and Social Care);

"relevant activities" means activities that involve, or may involve, the management or use of controlled drugs;

"relevant person" is to be construed in accordance with regulation 5;

"relevant services" means services that involve, or may involve, the management or use of controlled drugs;

"reserve force" means the Royal Air Force Reserve, the Royal Auxiliary Air Force, the Royal Fleet Reserve, the Royal Naval Reserve, the Royal Marines Reserve, the Army Reserve or the Territorial Army;

"Scottish Ambulance Service Board" means the Special Health Board of that name constituted by the Scottish Ambulance Service Board Order 1999(22);

"Scottish Counter Fraud Services" means NHSScotland Counter Fraud Services, which is part of the Common Services Agency;

"Scottish independent hospital" is to be construed in accordance with regulation 4;

"senior manager", in relation to a body or undertaking means one of the individuals who play significant roles in—

- (a) the making of decisions about how the whole or a substantial part of its activities are to be managed or organised; or
- (b) the actual managing or organising of the whole or a substantial part of those activities;

<sup>(</sup>**15**) S.S.I. 2002/305.

<sup>(16)</sup> S.I. 2005/2414.

<sup>(17)</sup> Section 1H was inserted by the Health and Social Care Act 2012 (c. 7), section 9(1).

<sup>(18)</sup> Section 30(1) has been amended by the Health and Social Care Act 2012, section 159(1).

 <sup>(19)</sup> See section 275(1) of that Act, which contains a definition of "NHS trust" to which amendments have been made by: the Health Act 2009 (c. 21), section 18(9); and the Health and Social Care Act 2012, 173(7), 178(9), and Schedule 14, paragraph 37.
(20) 2006 c. 42.

<sup>(21) 2002</sup> c. 17; section 25(3) has been amended by: the Health and Social Care Act 2008 (c. 14), Schedule 10, paragraph 17; S.I.

<sup>2010/231;</sup> and the Health and Social Care Act 2012, Schedule 15, paragraph 56(b).

<sup>(22)</sup> S.I. 1999/686.

"Special Health Board" means a board which is constituted by order under, and called a Special Health Board by virtue of, section 2(1)(b) of the 1978 Act(**23**);

"the State Hospitals Board for Scotland" means the Special Health Board of that name constituted by the State Hospitals Board for Scotland Order 1995(24).

(2) Where, by virtue of these Regulations, a person, body or group of bodies is required to ensure a matter, the requirement is to be construed as a requirement to take all reasonable steps to ensure that matter.

(3) For the purposes of these Regulations—

- (a) the following bodies—
  - (i) the Special Health Boards that are designated bodies, and
  - (ii) Scottish independent hospitals that are designated bodies,
  - do not provide Health Boards with relevant services;
- (b) a person included in a pharmaceutical list maintained by the NHSCB provides the NHSCB with relevant services (that is, the services that the person is required to provide as a consequence of the listing are treated as provided to the NHSCB);
- (c) a person included in a list of a Health Board maintained by virtue of the following provisions of the 1978 Act—
  - (i) section 25(2) (arrangements for the provision of general dental services),
  - (ii) section 26(2) (arrangements for the provision of general ophthalmic services, or
  - (iii) section 27(3) (arrangements for the provision of pharmaceutical services),

provides the Health Board with relevant services (that is, the services that the person is required to provide as a consequence of the listing are treated as provided to the Health Board).

<sup>(23)</sup> Section 2 has been amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c.19), section 28, Schedule 9, paragraph 19(1), and Schedule 10; the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(2); the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(2); and the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5), section 2(1).

<sup>(24)</sup> S.I. 1995/574.