
STATUTORY INSTRUMENTS

2013 No. 373

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

PART 1

Introductory

Citation, commencement, application and expiry.

1.—(1) These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and come into force on 1st April 2013.

(2) These Regulations apply in relation to England and Scotland.

(3) These Regulations cease to have effect at the end of 31st March 2020.

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);

(1) 1978 c. 29.

(2) 2006 c. 41.

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

(4) 2010 asp 8.

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

(6) 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,

“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);

“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

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).

(7) 2008 c. 14.

(8) 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).

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

(10) 1947 c. 27.

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

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

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

- 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);
- “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)**;

(14) 1973 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).

(15) S.S.I. 2002/305.

(16) S.I. 2005/2414.

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

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

(19) 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.

(21) 2002 c. 17; section 25(3) has been amended by: the Health and Social Care Act 2008 (c. 14), Schedule 10, paragraph 17; S.I. 2010/231; and the Health and Social Care Act 2012, Schedule 15, paragraph 56(b).

(22) S.I. 1999/686.

“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;

“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).

Meaning of “English independent hospital”

3.—(1) For the purposes of these Regulations, “English independent hospital” means a body that runs a hospital in England at or from which health care is provided to individuals and which is not a “health service hospital” within the meaning given in section 275(1) of the 2006 Act (interpretation), unless—

- (a) fewer than 10 individuals work at the hospital (whether as employees, volunteers or otherwise); or

(23) 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).

(24) S.I. 1995/574.

(b) following a request from that body for a determination under this sub-paragraph, the CQC has determined that requiring that body to appoint or nominate an accountable officer would give rise to difficulties that would be disproportionate to the benefits to be derived from such an appointment or nomination, having regard to—

- (i) the usual number of relevant individuals who work at the hospital,
- (ii) the usual level of relevant activities at or provided from the hospital, and
- (iii) any difficulties there may be in identifying a suitable individual to act as an accountable officer for that hospital, taking into account the size of the business being carried on at or from the hospital and any possibility of a joint appointment or nomination by that hospital together with other hospitals,

and that determination has not been rescinded in accordance with paragraph (3)(b).

(2) For the purposes of paragraph (1), “health care” means any form of health care, whether relating to physical or mental health, and including procedures that are similar to forms of medical or surgical care but are not provided in connection with medical conditions⁽²⁵⁾.

(3) A determination by the CQC under paragraph (1)(b) is to be for such duration as the CQC specifies when it makes the determination, but the determination may thereafter—

- (a) be renewed for such further period as the CQC specifies (if it does renew the determination); or
- (b) be rescinded, after the CQC has given the body that runs the hospital to which the determination relates reasonable notice of the rescission.

Meaning of “Scottish independent hospital”

4.—(1) For the purposes of these Regulations, “Scottish independent hospital” means a body that runs a hospital in Scotland and which is an “independent hospital” or a “private psychiatric hospital” within the meanings given to those expressions in section 10F(2) of the 1978 Act⁽²⁶⁾ (meaning of “independent healthcare services”), unless—

- (a) fewer than 10 individuals work at the hospital (whether as employees, volunteers or otherwise); or
- (b) following a request from that body for a determination under this sub-paragraph, HIS has determined that requiring that body to appoint or nominate an accountable officer would give rise to difficulties that would be disproportionate to the benefits to be derived from such an appointment or nomination, having regard to—
 - (i) the usual number of relevant individuals who work at the hospital,
 - (ii) the usual level of relevant activities at or provided from the hospital, and
 - (iii) any difficulties there may be in identifying a suitable individual to act as an accountable officer for that hospital, taking into account the size of the business being carried on at or from the hospital and any possibility of a joint appointment or nomination by that hospital together with other hospitals,

and that determination has not been rescinded in accordance with paragraph (2)(b).

(2) A determination by HIS under paragraph (1)(b) is to be for such duration as HIS specifies when it makes the determination, but the determination may thereafter—

- (a) be renewed for such further period as HIS specifies (if it does renew the determination); or

⁽²⁵⁾ This definition is based on section 9(2) of the Health and Social Care Act 2008 (c. 14), but in these Regulations, for other purposes, “health care” has the meaning given in section 25(1) of the Health Act 2006 (c. 28).

⁽²⁶⁾ Section 10F was inserted by the Public Services Reform (Scotland) Act 2010 (asp 8), section 108.

- (b) be rescinded, after HIS has given the body that runs the hospital to which the determination relates reasonable notice of the rescission.

Meaning of “relevant persons”

5.—(1) Each of the individuals listed in paragraph (2) is a “relevant person” for the purposes of these Regulations (whether or not that person is also a “relevant person” for the purposes of these Regulations by virtue of them being an individual to whom section 19(3) of the Health Act 2006 applies)—

- (a) in England, as regards the NHSCB; or
- (b) in Scotland, as regards any Health Board in whose area they are engaged in relevant activities.

(2) The individuals are—

- (a) a health care professional who provides health care services (including medical, dental, pharmaceutical, nursing or midwifery services)—
 - (i) to private patients other than at or from an English or Scottish independent hospital, or
 - (ii) on behalf of a local authority in England that is providing services as part of the health service, where doing so involves or may involve that health care professional in relevant activities;
- (b) an individual, not being a health care professional, who is engaged in any activity carried on with or on behalf of a health care professional as mentioned in paragraph (a) that involves or may involve that individual in relevant activities;
- (c) an individual (whether or not paragraph (a) or (b) also applies to that individual) who—
 - (i) is the manager of or is carrying on a care home, where doing so involves or may involve that individual (P1) in relevant activities, or
 - (ii) not being P1, is or may be engaged in relevant activities which are carried on with or on behalf of P1.

Meaning of “responsible bodies”

6. For the purposes of these Regulations, the following are responsible bodies—

- (a) as regards England and Scotland, the regulatory bodies;
- (b) as regards England—
 - (i) designated bodies in England,
 - (ii) CCGs,
 - (iii) NHS Protect,
 - (iv) the Prescription Pricing Division of the NHSBSA,
 - (v) the CQC,
 - (vi) local authorities in England, and
 - (vii) police forces in England; and
- (c) as regards Scotland—
 - (i) designated bodies in Scotland,
 - (ii) the Scottish Counter Fraud Services,
 - (iii) the Information Services Division of the Common Services Agency,

- (iv) the Practitioner Services Division of the Common Services Agency,
- (v) HIS,
- (vi) the Care Inspectorate,
- (vii) local authorities in Scotland, and
- (viii) the police force in Scotland.

Meaning of “designated bodies”

7.—(1) For the purposes of these Regulations in their application to England, the following are designated bodies—

- (a) an NHS foundation trust;
- (b) an NHS trust;
- (c) an English independent hospital;
- (d) the NHSCB; and
- (e) the headquarters in England of regular or reserve forces.

(2) For the purposes of these Regulations in their application to Scotland, the following are designated bodies—

- (a) a Health Board;
- (b) a Scottish independent hospital;
- (c) the following Special Health Boards—
 - (i) the Scottish Ambulance Service Board,
 - (ii) the National Waiting Times Centre Board, and
 - (iii) the State Hospitals Board for Scotland; and
- (d) the headquarters in Scotland of regular or reserve forces.

(3) For the purposes of these Regulations—

- (a) the designated bodies mentioned in paragraph (1)(d) and (e) and (2)(a) and (d) are commissioning bodies;
- (b) the designated bodies mentioned in paragraphs (1)(a) to (c) and (2)(a) to (c) are provider bodies.