STATUTORY RULES OF NORTHERN IRELAND

2009 No. 225

DANGEROUS DRUGS

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Made - - - -	*5th June 2009*
Coming into Operation-	*1st October 2009*

The Department of Health, Social Services and Public Safety(**1**), makes the following Regulations in exercise of the powers conferred on it by sections 17, 18, 20(3) and (7) and 79(3) of the Health Act 2006(**2**).

PART 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 and shall come into operation on 1st October 2009.

Interpretation

2.—(1) The Interpretation Act (Northern Ireland) 1954(**3**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

(2) In these Regulations—

"the 2003 Order" means the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(**4**);

"the 2006 Act" means the Health Act 2006;

"the 2009 Act" means the Health and Social Care (Reform) Act (Northern Ireland) 2009(**5**);

"accountable officer" means a person nominated or appointed under regulation 4;

(**1**) *See* S.I 1999/283(N.I. 1) Article 3(6)
(**2**) 2006 c.28
(**3**) 1954 c.33 (N.I.)
(**4**) S.I. 2003/431 (N.I. 9)
(**5**) 2009 c.1

"the Department" means the Department of Health, Social Services and Public Safety;

"designated body" shall be construed in accordance with regulation 3;

"general dental services" has the meaning given in Article 2(2) of the Health and Personal Social Services (Northern Ireland) Order 1972(**6**);

"health care" means any services designed to secure improvement in the physical and mental health and prevention, diagnosis and treatment of illness in the people of Northern Ireland;

"HSC Trust" means a Health and Social Care Trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991(**7**);

"Independent hospital" means a hospital which is not vested in the Department or managed by a HSC trust and excludes dental practices;

"Local Intelligence Network" shall be construed in accordance with regulation 18(2);

"misuse of drugs legislation" means the Misuse of Drugs Act 1971(**8**) and any subordinate legislation made under that Act;

"NIAS" means the Northern Ireland Ambulance Service Health and Social Care Trust (**9**);

"nursing home" shall be construed in accordance with Article 11 of the 2003 Order;

"pilot scheme" has the meaning given in Article 3 of the Health Services (Primary Care) (Northern Ireland) Order 1997(**10**);

"piloted services" has the meaning given in Article 3 of the Health Services (Primary Care) (Northern Ireland) Order 1997;

"RBSO" means the Regional Business Services Organisation established under section 14 of the 2009 Act;

"Regional Board" means the Regional Health and Social Care Board established under section 7 of the 2009 Act;

"registered dentist" means a person who is registered in the dentists register kept under section 14 of the Dentists Act 1984(**11**);

"registered medical practitioner" means a person who is registered in the register of medical practitioners under Section 2(2) of the Medical Act 1983(**12**);

"registered pharmacist" means a person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland under Article 6 of the Pharmacy (Northern Ireland) Order 1976(**13**);

"registered pharmacy" means a retail pharmacy business in Northern Ireland that is for the time being entered in the register kept under section 75, (registration of premises), of the Medicines Act 1968(**14**);

"regulatory body" means a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (the Council for the Regulation of Health Care Professionals)(**15**);

"relevant individual" shall be construed in accordance with section 17(8)(b) of the 2006 Act;

(**6**) S.I. 1972/1265 (N.I. 14)
(**7**) S.I 1991/194 (N.I. 1), and renamed by s. 1(3) of 2009 c.1 (N.I.)
(**8**) 1971 c.38
(**9**) S.R. 1995/143
(**10**) S.I. 1997/1177 (N.I. 7)
(**11**) 1984 c.24
(**12**) 1983 c.54. Section 2 was amended by S.I. 1996/1591 and S.I. 2002/3135
(**13**) S.I. 1976/1213 (N.I. 22)
(**14**) 1968 c.67
(**15**) 2002 c.17

"relevant premises" shall be construed in accordance with regulation 20;

"residential care home" shall be construed in accordance with Article 10 of the 2003 Order;

"responsible body" shall be construed in accordance with regulation 22;

"retail pharmacy business" has the meaning given in section 132 of the Medicines Act 1968;

"RQIA" means the Health and Social Care Regulation and Quality Improvement Authority(**16**).

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

(4) Where reference is made in these Regulations to arrangements to provide services, the reference is to be construed as a reference to arrangements to provide services that involve, or may involve, the management or use of controlled drugs.

PART 2

Accountable officers

Designated Bodies

3. The following are prescribed as designated bodies for the purposes of section 17 of the 2006 Act—

(a) the Regional Board;

(b) a HSC Trust;

(c) NIAS;

(d) an Independent Hospital.

Appointment of Accountable Officers

4.—(1) A designated body shall nominate or appoint (or under regulation 5(2), or (4) jointly nominate or appoint with one or more other bodies) a fit, proper and suitably experienced person as its accountable officer.

(2) A designated body must notify the Department in writing of—

(a) any nomination or appointment by it under paragraph (1) as soon as practicable; and

(b) the removal of an accountable officer by it (whether or not under regulation 6) as soon as practicable.

(3) The Department shall publish, from time to time and in such manner as it sees fit, a list of accountable officers of designated bodies in Northern Ireland.

Persons who may be appointed as accountable officers

5.—(1) An independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is—

(i) its registered manager, or

(ii) one of its officers or employees who is answerable to its registered manager,

(**16**) Established by Article 3 of S.I. 2003/431 (N.I. 9) and renamed by s 1(2) of 2009 c.1 (N.I.).

and if the person is its registered manager, he must be answerable to the chief executive, chairman or managing director of the hospital; and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(2) Two or more independent hospitals may jointly nominate or appoint one registered manager to be the accountable officer for both or all of the hospitals if the registered manager —

(a) is registered as manager in relation to both or all of the hospitals; and

(b) does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(3) Subject to paragraph (4), a designated body which is not an independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is an officer or employee of the designated body, and—

(i) a member of the board of directors, or the management or executive committee of the designated body,

(ii) a member of the body (howsoever it may be called) that has the responsibility for the management of the designated body, or

(iii) is answerable to a person referred to in paragraph (i) or (ii); and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(4) Two or more designated bodies which are not independent hospitals but which are of the same type may jointly nominate or appoint one person to be the accountable officer for both or all of the bodies, if—

(a) the person satisfies paragraph (3)(a) in relation to one of the designated bodies;

(b) each designated body is satisfied that the person can properly discharge his responsibilities in relation to it; and

(c) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(5) In this regulation—

"registered manager", in relation to an independent hospital, means the person who is registered under Part III of the 2003 Order as the manager of the hospital.

Removal of accountable officers

6.—(1) A designated body shall, having duly considered the matter, remove its accountable officer from office if—

(a) he no longer satisfies the conditions set out in regulation 5; or

(b) he is unfit to be an accountable officer.

(2) A designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly) shall adopt a procedure (which may be part of an internal disciplinary procedure) for consideration, where it is on notice that its accountable officer has breached his duties under these Regulations, or whether or not it needs to remove him under paragraph (1)(b).

(3) A person shall be presumed (unless the contrary is proved) to be unfit to be an accountable officer if he wilfully, negligently or through lack of competence breaches his duties as an accountable officer under these Regulations.

(4) This regulation is without prejudice to any other arrangements that a designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly)

may have for removal of its accountable officer from office as part of the arrangements under which he is employed or engaged.

Funds and other resources available to accountable officers

7.—(1) A designated body shall provide its accountable officer with the funds and other resources necessary to enable him to carry out his responsibilities as its accountable officer.

(2) Those other resources may include access to and use of information systems, accommodation and staff.

Accountable officers to have regard to best practice

8. In discharging his responsibilities, an accountable officer shall have regard to best practice in relation to the management and use of controlled drugs.

Accountable officers to secure the safe management and use of controlled drugs

9.—(1) An accountable officer shall—

(a) both—

(i) establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for securing the safe management and use of controlled drugs by the designated body, and

(ii) ensure that any person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements for securing the safe management and use of controlled drugs by that body or person; and

(b) both—

(i) review, or ensure that his designated body reviews, arrangements established by him or his designated body in accordance with sub-paragraph (a)(i), and

(ii) ensure that any person acting on behalf of, or providing services under arrangements made with, his designated body reviews arrangements established by it or him in accordance with sub-paragraph (a)(ii).

(2) In particular, an accountable officer shall, as part of these arrangements—

(a) establish or ensure that his designated body (and any person acting on behalf of, or providing services under arrangements made with, his designated body) establishes appropriate arrangements to comply with misuse of drugs legislation; and

(b) ensure that his designated body (and any person acting on behalf of, or providing services under arrangements made with his designated body) has adequate and up-to-date standard operating procedures in place in relation to the management and use of controlled drugs.

(3) The standard operating procedures shall, in particular, cover the following matters—

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including—