STATUTORY RULES OF NORTHERN IRELAND

2015 No. 278

DANGEROUS DRUGS

The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015

Made - - - -	*18th June 2015*
Coming into operation	*16th July 2015*

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, 19(1)(a), 20(3) and (7) and 79(3) of the Health Act 2006(**2**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015, and shall come into operation on 16th July 2015.

(2) In these Regulations, "the principal Regulations" means the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009(**3**).

(3) The Interpretation Act (Northern Ireland) 1954(**4**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendment of the principal Regulations

2. The principal Regulations shall be amended as provided by regulations 3 to 22.

Amendment of regulation 2

3. In regulation 2(2) (interpretation)—

(a) after the definition of "designated body" insert the following definition—

> ""domiciliary care agency" has the meaning assigned to it by Article 2(2) of the 2003 Order;";

(b) after the definition of "health care" insert the following definition—

(**1**) See S.I. 1999/283 (N.I. 1) Article 3(6)
(**2**) 2006 c.28
(**3**) S. R. 2009 No. 225
(**4**) 1954 c.33 (N.I.)

""hospital" shall be construed in accordance with Article 2(2) of the 2003 Order;";

(c) omit the definition of "NIAS";

(d) after the definition of "piloted services" insert the following definition—

""Primary medical services performers list" means the list of persons performing primary medical services prepared in accordance with regulations made under Article 57G of the Health and Personal Social Services (Northern Ireland) Order 1972(**5**);";

(e) after the definition of "registered pharmacy" insert the following definition—

""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);";

(f) replace the definition of "regulatory body" with the following definition—

""regulatory body" means—

(i) a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**6**) (the Professional Standards Authority for Health and Social Care(**7**)); and

(ii) the Northern Ireland Social Care Council(**8**);";

(g) after the definition of "regulatory body" insert the following definitions—

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

"relevant independent hospital" shall be construed in accordance with regulation 2A;";

(h) after the definition of "relevant individual" insert the following definition—

""relevant person" shall be construed in accordance with regulation 23;";

(i) after the definition of "relevant premises" insert the following definition—

""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;";

(j) in the definition of "RQIA" replace the full stop with a semi colon; and

(k) after the definition of "RQIA" add the following definitions—

""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;

"statutory provision" has the meaning assigned to it by section 1(f) of the Interpretation Act (Northern Ireland) 1954.".

(**5**) S.I. 1972/1265 (N.I. 14); Article 57G was inserted by Article 8 of the Primary Medical Services (Northern Ireland) Order 2004
(**6**) 2002 c.17
(**7**) Words substituted by the Health and Social Care Act 2012 c. 7 Pt 7 s.222(2)(a)
(**8**) Established by s.1 of the Health and Personal Social Services Act (Northern Ireland) 2001, 2001 c.3 (N.I)

Meaning of "relevant independent hospital"

4. After regulation 2 insert—

"**Meaning of "relevant independent hospital"**

2A.—(1) For the purposes of these Regulations, "relevant independent hospital" means an independent hospital which the Department has determined satisfies the conditions set out in paragraph (2).

(2) The conditions are—

(a) the independent hospital is directly or indirectly concerned with the provision of health care; and

(b) management or use of controlled drugs forms part of the activities of the independent hospital; and

(c) requiring that independent hospital to appoint or nominate an accountable officer would not 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 independent hospital;

(ii) the usual level of relevant activities at or provided from the independent hospital; and

(iii) any difficulties there may be in identifying a suitable individual to act as an accountable officer for that independent hospital, taking into account the size of the business being carried on at or from the independent hospital and any possibility of a joint appointment or nomination by that independent hospital together with other independent hospitals.

(3) A determination under paragraph (1) is to be notified to the independent hospital and is for such duration as the Department specifies, but the determination may thereafter be—

(a) renewed for such further period as the Department specifies; or

(b) rescinded, after the Department has given the independent hospital to which the determination relates reasonable notice of the rescission.

(4) A refusal of a determination under paragraph (1), renewal or refusal to renew under paragraph (3)(a) or rescission under paragraph (3)(b) must be notified to the independent hospital.

(5) Where, in respect of an independent hospital, the Department—

(a) makes a determination, or decides to refuse a determination, under paragraph (1);

(b) renews or refuses to renew a determination under paragraph (3)(a); or

(c) rescinds a determination under paragraph (3)(b),

that independent hospital may request a review of that determination, refusal, renewal or rescission as the case may be.

(6) A request under paragraph (5) must be made in writing within a period of 28 days beginning with the date of the determination, refusal, renewal or rescission as the case may be.

(7) Where an independent hospital has requested such a review under paragraph (5), the Department may ask that independent hospital to furnish such additional information as it thinks fit.

(8) The accountable officer of a relevant independent hospital shall inform the Department of any change in its circumstances which is likely to affect the conditions set out in paragraph (2).".

Amendment of regulation 3

5. In regulation 3 (designated bodies)—

(a) omit paragraph (c);

(b) in paragraph (d), for "an Independent Hospital" substitute "a relevant independent hospital"; and

(c) after paragraph (d) insert—

"(e) the headquarters in Northern Ireland of regular or reserve forces.".

Amendment of regulation 4

6. For regulation 4 (appointment of accountable officers) substitute—

"**Appointment of and support for accountable officers**

4.—(1) Each designated body shall nominate or appoint, or in a group with one or more other designated bodies shall jointly nominate or appoint, a fit, proper and suitably experienced person to be its accountable officer.

(2) Where more than one part of an undertaking is a designated body, an aggregate of parts of that undertaking jointly appointing or nominating an accountable officer is a group of designated bodies for the purposes of this regulation, whether or not the aggregate is, or is part of, a single legal person.

(3) All the designated bodies in a group of designated bodies that are jointly nominating or appointing an accountable officer shall be in Northern Ireland.

(4) A person appointed under paragraph (1) (P) shall satisfy Conditions 1, 2 and 3.

(5) Condition 1 is that P shall be—

(a) in the case of the headquarters of regular or reserve forces, or headquarters of regular or reserve forces acting jointly, a senior officer (that is, a lieutenant colonel or a person of equivalent or superior rank) of the regular or reserve forces (and sub-paragraphs (b) to (d) do not apply in such cases);

(b) a senior manager of P's designated body;

(c) where designated bodies are jointly acting—

(i) unless head (ii) applies, a senior manager of one of the designated bodies jointly acting,

(ii) if the designated bodies jointly acting are part of the same undertaking, a senior manager of that undertaking; or

(d) answerable to a senior manager who satisfies sub-paragraph (b) or (c).

(6) Condition 2 is that P shall be an officer or employee—

(a) of the designated body that nominates or appoints P; or

(b) if P is nominated or appointed by designated bodies jointly acting—

(i) of one of the designated bodies jointly acting, or

(ii) where those bodies are part of the same undertaking, of that undertaking.

(7) Condition 3 is that P does not, or does only exceptionally, prescribe, supply, administer or dispose of controlled drugs as part of P's duties as an employee or officer—

(a) of P's designated body; or

(b) if P is nominated or appointed by designated bodies jointly acting and those bodies are part of the same undertaking, of that undertaking.

(8) Two or more designated bodies may only jointly nominate or appoint a person to be their accountable officer if they are satisfied that P is capable of properly discharging P's functions under these Regulations in relation to each and all of them.

(9) A designated body of a description given in paragraph (b) or (d) of regulation 3 may only jointly nominate or appoint a person to be their accountable officer with another designated body of the same description.

(10) Each designated body that has an accountable officer shall provide P with the funds and other resources necessary for enabling P to discharge P's responsibilities as accountable officer (in the case of joint nominations or appointments, this obligation may be discharged through joint arrangements for provision of funds and other resources).

(11) The other resources may include access to and use of information systems, accommodation and staff.".

Amendment of regulation 6

7. In regulation 6 (removal of accountable officers)—

(a) in paragraph (1)(a) for "the conditions" substitute "condition 1, 2 or 3 and for "5" substitute "4(5) to (7)";

(b) in paragraph (2) after "these Regulations," for "or" substitute "of".

List of accountable officers

8. After regulation 6 insert—

"**List of accountable officers**

6A.—(1) Each designated body shall as soon as is practicable notify the Department in writing of—

(a) any nomination or appointment by it of an accountable officer, or

(b) the removal from office by it of an accountable officer.

(2) Where the nomination or appointment of an accountable officer, or removal from office of an accountable officer, is by a group of designated bodies, notification under paragraph (1) may be undertaken by the designated body or undertaking of which the accountable officer is or was an employee or officer, on behalf of the group.

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

Amendment of regulation 9

9. In regulation 9 (accountable officers to secure the safe management and use of controlled drugs)—

(a) in paragraph (3)—

(i) after the word, "matters" insert the words, "unless not applicable to his designated body";