

**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<sup>(a)</sup>, 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<sup>(b)</sup>.

**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<sup>(c)</sup>.

(3) The Interpretation Act (Northern Ireland) 1954<sup>(d)</sup> 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—  
““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—

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(a) See S.I. 1999/283 (N.I. 1) Article 3(6)  
(b) 2006 c.28  
(c) S. R. 2009 No. 225  
(d) 1954 c.33 (N.I.)

- “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<sup>(a)</sup>”;
- (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<sup>(b)</sup> (the Professional Standards Authority for Health and Social Care<sup>(c)</sup>); and
- (ii) the Northern Ireland Social Care Council<sup>(d)</sup>”;
- (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.”.

### 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—

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(a) S.I. 1972/1265 (N.I. 14); Article 57G was inserted by Article 8 of the Primary Medical Services (Northern Ireland) Order 2004

(b) 2002 c.17

(c) Words substituted by the Health and Social Care Act 2012 c. 7 Pt 7 s.222(2)(a)

(d) Established by s.1 of the Health and Personal Social Services Act (Northern Ireland) 2001, 2001 c.3 (N.I)

- (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”;
  - (ii) in sub-paragraph (f) replace the full stop with a semi colon; and
- (b) after paragraph (3)(f) add—
  - “(g) best practice relating to—
    - (i) the prescribing, supply and administration of controlled drugs, and
    - (ii) clinical monitoring of patients who have been prescribed controlled drugs.”.

### **Amendment of regulation 12**

10. In regulation 12 (powers to require declarations and self-assessments, as part of accountable officers monitoring and auditing arrangements or otherwise) in paragraph (4) for “Article 10 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003” substitute “section 34C of the Medical Act 1983(a)”.

### **Amendment of regulation 17**

11. In regulation 17 (accountable officers to take appropriate action if there are well-founded concerns)—

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(a) 1983 c.54. Section 34C was inserted by the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I. 2010/234)

- (a) in paragraph (2)(g) for “chair of the local intelligence network (LIN), established under regulation 18(2)” substitute “accountable officer nominated or appointed by the Regional Board”;
- (b) in paragraph (3) omit “of regulation 18(3),”.

### **Amendment of regulation 18**

#### **12. In regulation 18 (arrangements for sharing information)—**

- (a) for paragraph (2) substitute—
  - “(2) The accountable officer nominated or appointed by the Regional Board, shall establish and operate a network (a local intelligence network) for the purposes mentioned in paragraph (3).”;
- (b) for paragraph (3) substitute—
  - “(3) Those purposes are facilitating the co-operation of responsible bodies who are members of the local intelligence network in connection with—
    - (a) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by relevant persons;
    - (b) the consideration of issues relating to the taking of action in respect of such matters; and
    - (c) the taking of action in respect of such matters.”; and
- (c) omit paragraph (4).

### **Amendment of regulation 19**

#### **13. In regulation 19 (accountable officers to carry out periodic inspections)—**

- (a) in paragraph (1)(b)(i) omit “, or” and insert a semi colon;
- (b) in paragraph (1)(b)(ii) replace the full stop with a semi colon; and
- (c) after paragraph (1)(b)(ii) add—
  - “(iii) an accountable officer of a regular or reserve force.”.

### **Amendment of Regulation 20**

#### **14. In regulation 20 (relevant premises)—**

- (a) in paragraph (1)(b) after “HSC Trust” insert “or regular or reserve force”;
- (b) in paragraph (2)—
  - (i) omit the words “or the NIAS” where they appear, both times;
  - (ii) in sub paragraph (b)—
    - (aa) after “Board” insert “, regular or reserve force”;
    - (bb) for “an independent” substitute “a relevant independent”;
- (c) in paragraph (3)—
  - (i) for “an independent” substitute “a relevant independent” and for “the independent” substitute “the relevant independent”;
  - (ii) in sub-paragraph (a) before “independent” insert “relevant”;
  - (iii) in sub-paragraph (b)—
    - (aa) before “independent” insert “relevant”;
    - (bb) after “Regional Board” insert “, regular or reserve force”;
- (d) after paragraph (3) insert—

“(3A) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer nominated or appointed by the regular or reserve force or (where appropriate) by a member of the staff of the regular or reserve force —

- (a) the premises of that regular or reserve force in Northern Ireland for which he is the accountable officer or (where appropriate) of which he is a member of staff; and
  - (b) the premises of anyone acting on behalf of, or providing services under arrangements made with that regular or reserve force, unless those arrangements are with the Regional Board, a HSC Trust or a relevant independent hospital.”; and
- (e) in paragraph (4) for “(3)” substitute “(3A)”.

### **Amendment of regulation 23**

15. For regulation 23 (relevant persons) substitute—

“23.—(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 2006 Act applies)—

(2) As regards the Regional Board the individuals are—

- (a) a health care professional who provides health care services to private patients other than at or from a relevant independent hospital, where doing so involves or may involve that health care professional in the supply or administration of controlled drugs;
- (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 the supply or administration of controlled drugs;
- (c) an individual (whether or not paragraph (a) or (b) also applies to that individual) who—
  - (i) is registered under Part III of the 2003 Order as the manager of, or the person who is carrying on, a residential care home, a nursing home or a domiciliary care agency (referred to in this paragraph as “a registered person”) which involves that individual in the supply or administration of controlled drugs, or
  - (ii) not being the registered person, is or may be engaged in the supply or administration of controlled drugs which are carried on with or on behalf of that registered person.”.

### **Amendment of regulation 25**

16. In regulation 25 (duty to co-operate by disclosing information as regards relevant persons) after paragraph (6)(a) insert—

“(aa) a regular or reserve force’s arrangements for service discipline; or”.

### **Amendment of regulation 26**

17. In regulation 26 (responsible bodies requesting additional information be disclosed about relevant persons) after paragraph (5)(b) insert—

“(ba) would prejudice, or would be likely to prejudice, a regular or reserve force’s arrangements for service discipline; or”.

### **Amendment of Regulation 29**

18. In regulation 29 (occurrence reports) for paragraph (1) substitute—

“(1) An accountable officer (P), other than the accountable officer nominated or appointed by the Regional Board, shall give, on a quarterly basis (or more frequently if there have been concerns that warrant it and the accountable officer of the Regional Board has made a request of P), an occurrence report to the accountable officer for the Regional Board.”.

### **Amendment of Regulation 30**

**19.** For regulation 30 (accountable officers’ duties to protect the safety of patients and the general public) substitute—

“**30.**—(1) If information shared under regulation 25 or 26 by a responsible body with another body that is a designated body (DB) shows a concern about the inappropriate or unsafe management or use of controlled drugs by a person who is or who could become as regards DB a relevant individual (RI), paragraph (2) applies.

(2) The accountable officer of the DB may—

- (a) make recommendations to any responsible body (including any DB) as to any action that the accountable officer considers that the responsible body should take in relation to RI to protect the safety of patients and the general public; and
- (b) in connection with doing so, share information about the concern with that responsible body.

(3) If information is shared under regulation 25 or 26 with the accountable officer of the Regional Board about a person (P), who—

- (a) is a relevant person as regards the Regional Board; and
- (b) is not providing services to a designated body as a relevant individual; paragraph 4 applies.

(4) The accountable officer of the Regional Board must take all reasonable steps to protect the safety of patients or the general public in connection with P engaging, or the possibility of P engaging, in relevant activities, including where appropriate—

- (a) referral of the matter to a responsible body (for example a regulatory body); and
- (b) sharing of information about P with any person or a representative of any body (including at a meeting of the local intelligence network of which that person or representative is not a part) who employs or may employ P in relevant activities.”.

**20.** In the following regulations—

- (a) regulation 25, in paragraphs (6)(a) and (7);
- (b) regulation 26, in paragraphs 5(a) and (6); and
- (c) regulation 29, in paragraph (3),

for the word “enactment” in each place that it occurs, substitute “statutory provision”.

### **Amendment of Regulation 31**

**21.** In Regulation 31 (disclosure of information in good faith) for “in good faith under regulation 25, 26, 29 or 30” substitute “under these Regulations if it is done in good faith and there are reasonable grounds for doing it.”.

### **Revocations**

**22.** Regulations 5 (persons who may be appointed as accountable officers) and 7 (funds and other resources available to accountable officers) are revoked.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on  
18th June 2015



*Mark Timoney*  
A senior officer of the  
Department of Health, Social Services and Public Safety

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015, “the Regulations”, amend the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, “the principal Regulations”.

These amendments have been made to make provision for additional safeguards for the safe management and use of controlled drugs introduced in England and Scotland when the Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force on 1 April 2013.

The opportunity has also been taken to align certain arrangements with those in England, Scotland and Wales.

The definition of relevant independent hospital has been inserted to take account of those independent hospitals which are not providing healthcare, have no controlled drug activity, and where a determination would create disproportionate difficulties for the independent hospital in question (regulation 4). These independent hospitals will not be caught by the Regulations.

The armed forces are given the status of a designated body and discrete provision for Northern Ireland Ambulance Services, “NIAS”, has been omitted. NIAS is a Health and Social care trust, the individual NIAS references are therefore unnecessary and superfluous, they have been omitted (regulation 5).

The conditions for appointing an accountable officer have been amended to provide more flexibility for smaller organisations while ensuring that the accountable officer has sufficient seniority to have credibility within their organisation (regulation 6).

The list of standard operating procedures, “SOPs”, which designated bodies shall have has been extended to include a requirement for SOPs covering the prescribing, supply and administration of controlled drugs and the clinical monitoring of patients prescribed controlled drugs (regulation 9).

The accountable officer of the Regional Health and Social Care Board, “the Regional Board”, is responsible for establishing the local intelligence network (regulation 12).

The premises of the armed forces have been added to those which are exempted from inspection by the accountable officer of the Regional Board (regulation 13) and authority provided for the accountable officer of the armed forces to inspect relevant premises (regulation 14).

The definition of a relevant person has been extended and now includes all health care professionals and is not limited to healthcare professionals providing medical, dental, pharmaceutical and nursing or midwifery services to private patients (regulation 15).

Exemption from a requirement to disclose information has been provided for the armed forces where this would prejudice, or would be likely to prejudice, service discipline (regulations 16 and 17).

A provision has been made for occurrence reports to be submitted more frequently than quarterly where there are concerns that warrant it and a request has been made by the accountable officer of the Regional Board (regulation 18).

Regulation 19 substitutes existing regulation 30 of the principal Regulations (regulation 19).

References to “enactment” are substituted with “statutory provision” to ensure that both NI and UK legislation are included within the provision (regulation 20).

Protection from civil proceedings has been extended to include all Regulations (regulation 21).



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STATUTORY RULES OF NORTHERN IRELAND

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